

#	Title	Review Period	Summary of Changes
1	109.061 Patient Accounting Billing for Self-Administered Drugs	Triennial	New Policy
2	HEM 3.5.1 Clinitek Status UA Dipstick Procedures: Quality Control, Patient Testing, and Preventive Maintenance	Biennial	New Policy
3	L.61 iSCREEN™ Urine DX Drug Screen Tox Cup	Biennial	New Policy
4	L.BB.110 Blood Bank Compliance with Documentation of EMS Blood Product Handlers	Biennial	New Policy



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Owner Kimberly Dillard:  
Director, Revenue Cycle  
Policy Area Administrative - Compliance

## 109.061 Patient Accounting Billing for Self-Administered Drugs

### POLICY:

It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) to ensure that outpatient self-administered drugs are properly billed to patients, guarantors or third-party payors.

Most outpatient self-administered drugs are statutorily excluded from the Medicare program and must not be billed as covered services. Hospitals may discount or waive amounts that Medicare beneficiaries owe for non-covered self-administered drugs (including non-covered self-administered drugs that may be covered under Medicare Part D) and any associated administration services charges when certain conditions are met as outlined below.

### DEFINITION:

**Self-Administered Drug (SAD):** A self-administered drug is a drug or biological furnished to a hospital patient in an outpatient setting for therapeutic purposes which is usually self-administered and is not an integral component of a procedure or directly related to it, i.e., when it facilitates the performance of or recovery from a particular procedure. When it is an integral component of a procedure or directly related to it, the drug or biological is considered to be a packaged supply and may be covered by Medicare. In addition, some drugs and biologicals commonly used in outpatient hospital settings are statutorily covered under Part B and are therefore not considered "self-administered" such as:

- Immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.
- Oral anti-cancer drugs (and pro-drugs) taken during cancer chemotherapy which have the same active ingredient and are used for the same indications as covered chemotherapy drugs.
- Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full

therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration, and erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis.

## PROCEDURE:

- A. Facility personnel must determine if drugs provided to a patient in an outpatient setting which are in a self-administrable form (e.g., pills, syrups, suppositories) are "self-administered" according to the definition in this policy.

Examples of situations where drugs provided in an outpatient setting would be "self-administered" include, but are not limited to:

1. Drugs given to a patient for their continued use at home after leaving the hospital.
2. Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.
3. Daily routine insulin or hypertension medication given pre-operatively to a patient.
4. A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
5. A laxative suppository for constipation while the patient waits to receive an unrelated X ray.

*Note: In addition to the above situations, Medicare contractors may include on their website a listing of drugs which they have deemed to be self-administered.*

- B. If a drug provided to a patient in an outpatient setting is determined to be "self-administered," facility personnel will then determine if the drug or biological is an integral component of a Medicare-covered procedure or is directly related to it. In this case, it is considered to be a packaged supply and will be billed as a covered service to Medicare. Examples of situations where "self-administered" drugs provided in an outpatient setting would be considered "packaged" as an integral component of, or directly related to a procedure, include, but are not limited to:

1. Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
2. Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre- and post-operatively.
3. Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
4. Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
5. Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of the procedure.

- C. Facilities will review their charge masters and billing procedures to confirm that SADs, and SADs that are packaged as integral to a procedure, are appropriately identified.
  - D. Drugs determined to be "self-administered," but not packaged as integral to a Medicare covered procedure, and any associated drug administration charges will not be billed as covered services to Medicare.
  - E. SADs not considered packaged as integral to a procedure may be billed to the patient or other third-party payer. However, hospitals may discount or waive amounts that Medicare beneficiaries owe for non-covered SADs (including non-covered SADs that may be covered under Medicare Part D) and the associated administration services that the beneficiary receives in outpatient settings, providing the following conditions are met:
    - 1. Beneficiary receives the drug for ingestion or administration in outpatient settings;
    - 2. Hospitals must uniformly apply their policies regarding discounts or waivers on non-covered SADs (e.g., without regard to a beneficiary's diagnosis or type of treatment;
    - 3. Hospitals must not market or advertise the discounts or waivers; AND
    - 4. Hospitals must not claim the discounted or waived amounts as bad debt or otherwise shift the burden of these costs to the Medicare or Medicaid programs, other payers, or individuals.
- Note: Drugs given to a patient for their continued use at home after leaving the hospital do not meet these conditions, are not eligible for discounts or waivers, and must be billed to the beneficiary unless CMS provides additional guidance.*
- F. Drugs determined **not** to be "self-administered," or determined to be "self-administered" **but** considered packaged as integral to a procedure, will be billed to Medicare as covered services with the appropriate revenue code, provided all other Medicare coverage requirements have been met. Drugs determined to be covered by the Medicare program (including statutorily covered Part B drugs and Medicare-covered drugs as provided in National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs)) will be billed to Medicare as covered services and not to the beneficiary.
  - G. Patient Accounting and Revenue Integrity personnel will educate all staff associates responsible for billing pharmacy services on the contents of this policy. Facility personnel will educate pharmacy staff responsible for requesting or adding procedure charge codes to the charge master on the contents of this policy.
  - H. Patient Accounting/Revenue Integrity personnel will stay current with Medicare Contractor interpretations through regular review of Self-administered Drug Exclusion Lists published on Medicare Contractor websites.

## REFERENCE(S):

- 1. Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 50.2.
- 2. CMS Medicare Prescription Drug Benefit Manual (Pub. 100-18), Chapter 6, Appendix C.
- 3. [OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings, October 29, 2015.](#)



## All Revision Dates

10/14/2025

## Approval Signatures

Step Description	Approver	Date
Chief Financial Officer	Michael Taylor: Chief Financial Officer, Health Care Agency	10/14/2025
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	4/1/2025
Hospital Finance	Jill Ward: Chief Financial Officer, VCMC & SPH	1/22/2025
Compliance Officer	Melissa Guevarra: Acting Compliance Officer	1/22/2025
Revenue Cycle	Kimberly Dillard: Director, Revenue Cycle	12/30/2024





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Owner	Christian Press: Supervisor-LIS, Laboratory Services
Policy Area	Laboratory Services

## HEM 3.5.1 Clinitek Status UA Dipstick Procedures: Quality Control, Patient Testing, and Preventive Maintenance

### PURPOSE:

The **Siemens Clinitek Status Analyzer** is a portable, benchtop instrument powered by an electrical outlet, designed for in-vitro diagnostic use. It enables the semi-quantitative or qualitative detection of multiple analytes in urine samples, including protein, blood, leukocytes, nitrite, glucose, ketone, pH, specific gravity, bilirubin, and urobilinogen.

### System Functionality

The system uses **reflection from six LEDs** to quantify urine constituents. This reflected light is converted into electrical impulses, processed by the analyzer's microprocessor, and translated into clinically meaningful results.

### Siemens Multistix Reagent Strips

- **Purpose:** Multistix reagent strips aid in diagnosing kidney function, urinary tract infections, carbohydrate metabolism (e.g., diabetes mellitus), and liver function.
- **Physical Characteristics:** The strips also evaluate acid-base balance and specific gravity of urine.
- **Clinical Application:** Results may be used alongside other diagnostic information to rule out certain disease states and to determine the need for microscopic evaluation.

Multistix reagent strips are ready to use upon removal from the bottle and are fully disposable after use. These reagent strips are intended for in vitro diagnostic use only and have been classified as nonhazardous under OSHA guidelines in 29 CFR 1910.1200(d).

# POLICY:

To establish a policy for the Siemens Clinitek Status Analyzer regarding:

- **Performance of Urinalysis**
- **Quality Control (QC)**
- **Proficiency Testing**
- **Instrument Maintenance**
- **Infection Control Measures**
- **Training of Personnel**
- **Competency Validation**

The following policy adheres to guidelines from the laboratory accrediting agency, **The College of American Pathologists (CAP)**, and **Clinical Laboratory Improvement Amendments (CLIA)** standards for point-of-care testing.

- The Clinitek Status Analyzer (FDA approved waived test) shall be used to screen patient urine for Glucose, Ketone, Specific Gravity, Blood, pH, Protein, Nitrite, Bilirubin, Uro-Bilinogen, and Leukocytes. Results obtained shall not be used for definitive diagnostic and further testing from the main lab shall be up to the discretion of the attending physician.
- Daily QC of the reagent test strip shall be performed by testing known negative and positive controls.
- Proficiency testing will be completed as required by the laboratory department's accrediting agency, CAP.
- The maintenance of the instrument shall be performed to provide accurate test results and operate correctly. (Procedure in the "Preventative Maintenance" section) This includes periodic checking of the white calibration bar in the test table for dirt or discoloration, especially after a strip jam. Adherence will enhance the instrument's ability to provide reliable results.
- To ensure safety and compliance with infection control guidelines, gloves must be always worn during testing. After testing, store specimens appropriately, clean any spills in the work area, remove gloves and clean hands immediately.
- Training and signing off initial and recurring competency evaluations of personnel must occur prior to live patient testing before testing privileges are granted.
- Urinalysis by Clinitek Status shall be performed by trained personnel, their skills must be validated annually per CAP guidelines

# STORAGE:

- Store Multistix 10 reagent strips at room temperature (15°-30°C), away from direct sunlight.
- Keep all unused strips in the original bottle; transferring strips to another container may cause deterioration.
- Do not use strips past their expiration date or remove the desiccant from the bottle.
- Protect strips from light, heat, and moisture to maintain reagent activity.

- Avoid touching the test areas of the strips. Discard any strips showing discoloration or darkening of reagent areas, as this indicates deterioration.

## EQUIPMENT AND MATERIALS

- Siemens Clinitek Status Analyzer
- Siemens Multistix 10SG Reagent Test Strip
- CLINIQA Level 1 and 2 QC Material
- CLINIQA Urinalysis Control Assigned Value Chart package insert
- Personal Protective Equipment (PPE): Gloves, lab coat, safety glasses
- Biohazard waste container
- Quality Control Test Result Log Sheet
- Clean-catch Midstream, random urine sample from the patient
- Paper Towels
- Sani-Cloth Disinfectant Wipes

## SPECIMEN COLLECTION:

- Obtain 10 mL (optimal) freshly voided, well mixed urine.
- Do not centrifuge urine. Minimum volume = 1mL.
- Specimen must be labeled with patient identification.
- If using an addressograph label, affix label to urine cup not on the lid.
- Collect the urine in an approved sterile urine collection container.
- Work areas and specimen containers should always be free of detergents and other contaminating substances
- Specimen should be at room temperature for less than 2 hours.
- If the test cannot be performed within 30 minutes, the urine sample should be refrigerated.
- Refrigerated specimens must be analyzed within 24 hours.
- Refrigerated urines must be brought to room temperature before analysis.

## SPECIMEN REJECTION:

If an unacceptable specimen is received, document the issue in the Electronic Medical Record and promptly notify the patient's care team. A new sample should be recollected if necessary.

### **The following conditions warrant specimen rejection:**

- **Improperly Labeled Specimen**
  - Any specimen not correctly labeled with the patient's identification details must be

rejected, and a new sample requested.

- **Specimen Left at Room Temperature for More Than 2 Hours**

- Urine samples kept at room temperature for over 2 hours are unsuitable for testing and must be discarded.

- **Refrigerated Specimens Older Than 24 Hours**

- Urine samples stored in the refrigerator for more than 24 hours may have deteriorated and should not be used for testing.

- **Grossly Bloody Specimens**

- Visibly bloody urine samples should be sent to the main laboratory for further analysis, as blood could interfere with hCG test results.

- **Specimens Containing Urine Preservatives**

- **Samples containing preservatives are unsuitable for hCG testing, as these chemicals can affect test accuracy.**

- **Grossly Bloody or Pus-Filled Specimens with Visible Clots**

- Any grossly bloody or pus-filled sample, especially with visible clots, should be sent to the main laboratory for analysis. (Refer to the manufacturer's insert for additional details.)

## **HANDLING THE MULTISTIX REAGENT TEST STRIP**

- Store at room temperature between 15 to 30 degrees C.
- Initial and date the reagent bottle after opening.
- Do not use beyond the expiration date indicated on the bottle.
- Do not store the bottle in direct sunlight.
- Do not remove the reagent strip from its bottle until immediately before use.
- Store the bottle tightly always capped.
- Do not touch the test areas of the reagent strip.
- Do not use reagent test strips that showed discoloration and darkening of the reagent areas which may indicate deterioration.

## HANDLING OF CONTROL SOLUTIONS

- A. Stable until expiration date when stored unopened at 2-8° C.
- B. Once control is opened, it is stable for 31 days when stored tightly capped at 2-25° C.
- C. Write the opening date, new expiration date, and user's initials after opening control vials.
- D. After each use, promptly recap vial and store at 2-8° C
- E. Controls should never be frozen.
- F. Never use past the expiration date.

## DEFINITION(S):

Chemical Principles of the Reagent Strips	
Test Name	Chemical Principle
Glucose	Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide That couples 4-aminoantipyrine and 4-methylcatechol to create an orange to dark red color reaction.
Bilirubin	Bilirubin couples with diazotized dichloroaniline in a strongly acid medium. Colors range through various shades of tan.
Protein	At a constant pH, the development of any green color is due to the presence of protein (Protein error-of-indicators principle). Colors range from yellow for negative through yellow-green and green to green-blue for positive reactions.
pH	The double indicator principle gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
Blood	Hemoglobin catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. Colors range from orange through green; very high levels of blood may cause the color development to continue to blue.
Ketone	Acetoacetic acid reacts with nitroprusside. Colors range from pink, for a negative reading, to maroon for a positive reading.
Urobilinogen	In a modified Ehrlich reaction, p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.
Nitrite	Nitrate (derived from the diet) is converted to nitrite by the action of Gram-negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts

	with p-arsanilic acid to form a diazonium compound. This diazonium compound couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.
<b>Leukocyte</b>	Esterases in granulocytic leukocytes catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.
<b>Specific Gravity</b>	pKa changes occur for certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration

## VCMC/SPH Urine Dipstick Point of Care Normal Values

Assay	Normal Value	Units of Measurement	Range of Results
<b>pH</b>	4.6-8.0	pH	5.0 - 8.5
<b>Specific Gravity</b>	1.001-1.035	SG	1.000 – 1.030
<b>Leukocytes</b>	Negative	Grading	Trace, Small, Moderate, Large
<b>Protein</b>	Negative	mg/dL	Negative, Trace, 30 - 2000
<b>Glucose</b>	Negative	mg/dL	Negative, 100 - 2000
<b>Ketones</b>	Negative	mg/dL	Negative, 5 - 160
<b>Blood</b>	Negative	Grading	<b>Non-Hemolyzed:</b> <ul style="list-style-type: none"> <li>• Trace</li> <li>• Moderate</li> </ul> <b>Hemolyzed:</b> <ul style="list-style-type: none"> <li>• Trace</li> <li>• Small</li> <li>• Moderate</li> <li>• Large</li> </ul>
<b>Bilirubin</b>	Negative	Grading	Small, Moderate, Large
<b>Nitrite</b>	Negative	Grading	Negative, Positive
<b>Urobilinogen</b>	0.2	mg/dL	0.2 – 8.0

***Urine samples with test results indicating the need for microscopic examination and/or Culture & Susceptibility (C&S) testing will have lab orders automatically generated via reflex rules in the electronic medical record (EMR) if the initial dipstick test results warrant further workup. The rules for dipstick order***



reflexing are outlined in the following table.

## **VCMC/SPH Urine Dipstick Point of Care Reflex Rules**

Test	Reflex	Analytes	Criteria
Urinalysis Dipstick w/Reflex	UA microscopy	PRO: Protein	≥ 70 mg/dL
		NIT: Nitrates	≥ 1+
		LEU: Leukocytes	Trace - Large
		BLO: Blood	Trace - Large
	Urine culture	NIT: Nitrates	≥ 1+
		LEU: Leukocytes	Trace - Large
		WBC: White blood cells	≥ 6 cells/HPF
		WBCC: White blood cells	≥ 1 cells/HPF
		BACT: Bacteria	≥ 3+/HPF

## **PROCEDURE(S):**

### **CALIBRATION PROCEDURE**

The Clinitek Status Analyzer performs a “self-test” and calibration each time it is turned on. In addition, the analyzer performs an automatic calibration each time a test is run. The white calibration bar (on the test Table) provides traceable calibration approved by the National Institute of Standards and Technology.

### **QUALITY CONTROL TESTING PROCEDURE**

1. **At the main Select screen, touch “QC Test/Due”.**
2. This will appear after 24 hours since the last QC analysis.
3. **Select “QC Strip Test Required”. “Required” appears on screen after 24 hours since the last Quality Control analysis.**
4. **Screen then prompts for Operator ID. This should be the user’s Ventura County Employee ID as specified in Telcor QML Point of Care database. Press Enter.**
  - The employee number can also be entered via custom barcoded provided by nursing

management.

- This screen will prevent non-certified staff from using the device.
5. **The next screen requires the operator to enter their name. Use the alpha keyboard and enter your name. Press Enter. (? Not sure if this happens, check after setup)**
  6. **Select QC 1 Level 1 appears on the Screen.**
    - Scan the QC Level 1 **Lot Number**. Press **Enter**. You must scan the barcode to proceed.
    - Enter the QC Level 1 **Expiration Date**. Press **Enter**.
  7. **Select “Enter new Lot and Expiration date” for the Multistix reagent strips.**
  8. **Scan the barcode on the side of the round Siemens Multistix 10SG container.**
  9. **BEFORE you press START, take one Multistix out of the vial and have the Level 1 QC ready to dose the reagent strip.**
    - Once you press START you have 8 seconds to apply QC 1 drop to each pad, starting at the bottom of the strip.

Follow the steps in this order:

1. Prepare QC material
  2. Prepare reagent strip
  3. Press “START”. Table may retract quickly and come back out for the strip. Ignore this, it is pretty quick.
  4. Dip strip into QC
  5. Remove excess urine from strip. Blot strip gently by turning on edge against a paper towel.
  6. Place strip on Clinitek Status strip table.
  7. *WARNING: Do not push or pull the test table. This will cause damage*
10. After the 8-second countdown, the test table will retract, pulling the placed strip into the instrument.
  11. The analyzer will perform an automatic calibration and then analyze the QC.
  12. Once the analysis is complete the Results screen will be displayed as “**PASS**” or “**FAIL**” the quality control. If the QC passed, select the PRINT button and results will be printed.
    - **If QC results are stored in an interfaced database they don’t need to be printed.**
    - **If there’s network downtime, QC results must be printed.**
  13. A summary of the QC performed will be displayed on the next screen.
  14. Store paper QC results in the “Quality Control Log” section the POCT binder.
  15. Results are entered manually after network downtime.
  16. The Clinitek Status knows the QC status whether it is pass or fail and will not allow patient testing until QC Levels 1 & 2 have “**PASSED**”.
  17. Select Done. Clinitek then prompts for QC Level 2. **Repeat steps 6-15.**
    - Note: QC **Level 2 Strip Lot** is the same lot number of Multistix used for running **QC Level**

18. When one or both levels of the QC **"FAIL"** the instrument will prompt you to repeat the failed QC test.
19. Follow these steps when a QC run fails.
20. After the **1<sup>st</sup> QC Failure**, Inspect the calibration bar. Ensure it is clean. Then, Rerun QC with newly opened QC Material.
21. **After the 2<sup>nd</sup> QC Failure, contact the laboratory for assistance.**

## Quality Control (QC) Testing

### A. QC Frequency:

1. Perform QC testing:
  - a. When opening a new lot or shipment of test cassettes.
  - b. At the start of each day before patient testing.
  - c. If the analyzer has been moved or serviced.

### B. Running QC Tests:

1. Use both positive and negative control solutions.
2. Follow the same steps as patient testing, substituting control solution for the urine sample.

### C. Acceptance Criteria:

1. QC results must fall within the manufacturer's acceptable range.
2. If QC results fail, troubleshooting must be done, and the analyzer should not be used for patient testing until resolved.

## PATIENT UA DIPSTICK POC TEST PROCEDURE:

-Run the test using full test mode-

1. **At the main screen, touch Strip Test.**
2. **Enter your Operator ID as defined in the QML Database.**
3. **Select Enter New Patient.**
4. **Use patient's financial number (FIN) as patient's ID.**
5. **Enter Strip Lot by scanning the barcode on the side of the Multistix 10 SG container.**
6. **After you press START you have 8 seconds to dip the test strip into urine specimen and place it on the test table. Ensure the strip is placed all the way back on the table or you will get an error right away and have to repeat the testing.**
7. **BEFORE you press START, take one Multistix out of the container and have the sample ready to dose the reagent strip.**

-Follow these steps exactly-

8. Prepare urine specimen for dipping.
9. Prepare reagent strip.
10. Press "START" (Table may retract briefly and come back out. Ignore this, it is quick.)
11. Dip strip into urine
12. Remove excess urine from strip by blotting strip edge gently against a paper towel.
13. Place strip on Clinitek Status strip table.
  - **WARNING: Do not push or pull the test table. This will cause damage**
14. After the 8-second countdown, the test table will retract, pulling the placed strip inside the instrument.
15. The analyzer will perform an automatic calibration and analyze the urine.
16. Once analysis is complete the Results screen will display, and results are printed. Record results in the electronic record if there is no interface or you are experiencing downtime. Interfaced analyzers should send results to Cerner and post in the patient's chart after 3-5 minute
17. Results are taped onto a designated page in the POCT binder.
18. Remove the test strip and dispose of it in biohazard container.
19. Touch Done to complete the test and return to the main Select screen.
20. Wipe any urine left on the table with a paper towel.
  - If a urine dipstick result indicates a microscopic analysis or culture order is required, an order will generate automatically, and a label should print out at the label printer next to the Clinitek Status. Rules for reflex testing are described in the next section.
  - If a label does not print out or the reflex testing, but should, contact the laboratory for assistance in getting the reflex texting completed.

## TEST REPORTS:

1. Attach the instrument printout to the patient result log.
2. Record results in Cerner.
3. During Computer Downtime
4. Affix the patient's label that contains the patient's name and medical record number, account number as well as ordering provider's name and location in the space provided in the upper right hand corner during computer downtime.
5. Attach or transcribe the printed test results from the instrument tape to the form.
6. Enter the date and time of testing and initials or signature.
7. All patients' test results printouts shall be retained for three years together with the QC records.

# PREVENTIVE MAINTENANCE:

## CLINITEK Status®+ Analyzer Maintenance Procedure

### Daily Maintenance

- Wipe down the external surfaces of the analyzer with a disinfectant wipe, ensuring the test table and cassette insert are clean.
- Clean the screen with a mild glass cleaner and a lint-free cloth.

### Weekly Maintenance: Cleaning the Test Table and Insert

- Moisten a cotton-tipped swab with distilled water and gently clean the test table and insert.
  - **Caution:** Avoid touching the white calibration bar during cleaning.
- Wear appropriate personal protective equipment (PPE) throughout this process.
- Follow your facility's standard operating procedure for cleaning frequency.

### As-Needed Maintenance: Cleaning the Calibration Bar

- Inspect the white calibration bar regularly, particularly after a strip jam.
- If dirty or discolored, gently wipe it clean with a cotton-tipped swab or lint-free cloth moistened with distilled water.
  - **Caution:** Do not scratch or use any solvent on the calibration bar.

### Decommission Maintenance: Disinfecting Test Table and Insert (For removal from service)

- Disinfection is necessary if the test table or insert is relocated, especially if moved through non-biohazardous areas.
- Use deionized water mixed with 5% sodium hypochlorite (bleach) as a disinfectant.
- Soak the test table and insert in the disinfecting solution for 2–10 minutes.

**Caution:** Ensure the white calibration bar is not exposed to any disinfectant.

## REFERENCE(S):

- Siemens Multistix Reagent Strips Product Insert, AN30516C, Rev. 4/99.
- Freeman, J.A. and M.F. Beeler: *Laboratory Medicine - Clinical Microbiology*, Lea and Febiger, Philadelphia, PA, 1974.
- Graff, S.L., *A Handbook of Routine Urinalysis*, J.B. Lippincott
- Henry, John, *Clinical Diagnosis and Management by Laboratory Methods*, W.B. Saunders Co., 16th ed., 1979.
- Race, G.L. and M.G. White: *Basic Urinalysis*, Harper and Row, Hagerstown, MD, 1979.
- Siemens Medical Solutions Diagnostics Clinitek Status Analyzer Operator's Manual 13287. rev. T, 2008-05.

## All Revision Dates

10/3/2025

## Attachments

- [Clinitek QC Log Sheet UA + hCG.docx](#)
- [Clinitek Status A Maintenance Log.docx](#)
- [Clinitek Status B Maintenance Log.docx](#)
- [HEM 3.5.1 Clinitek Status UA SOP.docx](#)

## Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	10/3/2025
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
Laboratory Services Department	Christian Press: Supervisor-LIS, Laboratory Services	8/15/2025
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	7/29/2025



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

## L.61 iSCREEN™ Urine DX Drug Screen Tox Cup

### INTENDED USE:

The iSCREEN™ Urine Test DX Drug Screen Tox Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off Level (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500
Secobarbital (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzylecgonine	150
Fentanyl (FTY)	Fentanyl	1
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Methamphetamine (MET)	d- Methamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1,000



Marijuana (THC)	1-nor- $\Delta^9$ -THC-9 COOH	50
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## TEST PRINCIPLE:

- A. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.
- B. During testing, a urine specimen migrates upward by capillary action.
- C. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip.
- D. The presence of a drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.
- E. A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.
- F. To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## DEFINITION(S):

- A. **Adulteration**- the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroy the drugs present in the urine. Dilution may also be used to produce false negative drug test results.

## SPECIMEN COLLECTION:

- A. The urine specimen should be collected directly into the provided test cup.
- B. Urine from any time of day can be used.
- C. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
- D. Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing.
- E. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed well before testing.
- F. Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain a fresh specimen.

## TEST MATERIALS:

- A. Materials Provided:
  1. Test Cups

2. Package Insert
  3. Procedure Card
  4. Adulteration Color Chart
- B. Materials Required but not Provided:
1. Timer
  2. iSCREEN™ Cup Urine Controls (Positive & Negative)

## STORAGE & STABILITY:

### A. Test Cups

1. Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). DO NOT FREEZE.
2. The test is stable through the expiration date printed on the sealed pouch.
3. The test cup must remain in the sealed pouch until use.
4. Do not use beyond the expiration date.

### B. Controls

#### 1. Unopened

- a. The controls are stable until the expiration date when stored at 2°C to 8°C (Oxazepam is stable for only 6 months).
- b. Store at -20°C to -10°C to extend the Oxazepam stability, up to 3 years or until expiration date, whichever comes first.

#### 2. After Opening

- a. The controls are stable for 31 days after being opened or until the expiration date, whichever comes first, when stored tightly capped at 2°C and 8°C.

## PRECAUTIONS:

- A. For medical and other professional in vitro diagnostic use only.
- B. Do not use after the expiration date.
- C. The test cup should remain in the sealed pouch until use.
- D. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. It is recommended to wear gloves when handling the test cup with urine specimen.
- E. The used test cup should be discarded according to federal, state, and local regulations.

## TEST PROCEDURES:

- A. Allow the test, urine specimen, and/or controls to reach room temperature 59-86°F (15-30°C) prior to testing.

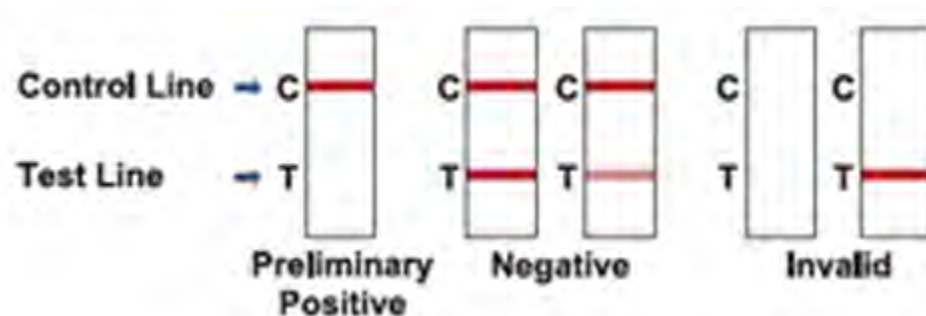
- B. Once at room temperature, remove the cup from the sealed pouch.
- C. Instruct donor to provide specimen.
- D. Ensure specimen volume exceeds the minimum line and set timer.
- E. Replace and secure the cap while test cup is on a flat surface.
- F. Check the temperature label up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
- G. Peel off label to reveal adulteration strips and view results.
- H. Peel off label on the multi-drug test cup to view test results.
  - I. The adulteration strip(s), if applicable, should be read between 3-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results. Retest the urine with a new cup or collect another specimen in case of any positive result for any adulteration test.
  - J. If results do not indicate adulteration, read the drug test result at 5 minutes. Do not interpret the result after 10 minutes.
  - K. If preliminary positive results are observed, send the cup to the laboratory for confirmation when required.
    - 1. Ambulatory Care Clinics: Confirmation of positive urine drug screen results will be routinely performed on every specimen.
    - 2. Ventura County Medical Center/Santa Paula Hospital: Confirmation of positive urine drug screen results will be routinely performed on medicolegal specimens only.

## RESULTS INTERPRETATION:

### A. Test Results

- 1. Negative(-): A colored line appears in both the Control region (C) and Test region (T). A negative result means that the drug concentration in the urine sample is below the designated cut-off level for that specific drug . NOTE: The shade of the colored line in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.
- 2. Positive(+): A colored line appears in the Control region (C) and NO line appears in the Test region (T). A positive result means that the drug concentration in the urine sample is above the designated cut-off level for that specific drug.
- 3. Invalid: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for an invalid result. If this happens, read the instructions again and repeat the test with a new test cup. If the result is still invalid, contact the manufacturer.

Note: Each test strip needs to be looked at individually. Each line may vary in color and darkness or the rate at which the line appears. (DO NOT compare lines within the same test strip or between different test strips).



#### B. Adulterant Results

1. No instrumentation is required. Refer to the color chart card included in the test kit.
2. Results are obtained by visually comparing the reacted color blocks on the strip to the printed color indicator on the color chart.

## TEST LIMITATIONS:

- A. The test provides only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography-mass spectrometry (GC-MS) or Liquid Chromatography-mass spectrometry (LC-MS) is the recommended confirmatory method.
- B. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
- C. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results. If adulteration is suspected, the test should be repeated with another urine specimen or another cup.
- D. A positive result does not indicate intoxication, the concentration of drug in the urine, or the route of drug administration.
- E. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- F. This test is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result..
- G. A positive test result may be obtained from certain foods or food supplements.

## EXTERNAL QUALITY CONTROL (QC):

#### A. QC Test Requirements

1. An external quality control test is required with each new shipment and each new lot of test cups, as well as every thirty days to verify test performance, including storage conditions.

#### B. QC Test Procedures

1. Allow controls to come to room temperature followed by gentle swirling or inversion

before use. DO NOT SHAKE.

2. Remove two test cups from the sealed foil pouch. Peel back and remove the labels from the test cups to show the drug test strips.
3. Label one cup "Positive" and the other cup "Negative".
4. Remove the cap from the test cup labeled "Positive" and fill with the full 10 ml vial of the Positive control.
5. Recap the test cup and place on a flat surface. Be sure NOT to tilt or flip it over.
6. Wait for 5 minutes and read the results. DO NOT read results after 5 minutes.
7. Repeat steps 1-5 with the Negative Control.

C. Interpretation of QC Test Results

1. Positive controls must test positive on the iSCREEN™ test cup.
2. Negative controls must test negative on the iSCREEN™ test cup.

## REFERENCE(S):

- A. Abbott Laboratories. iSCREEN™ Urine Test DX Drug Screen Tox Cup CLSI + More Packet. Document version 2/28/25. Abbott Laboratories, 2025.
- B. Abbott Laboratories. *iSCREEN™ Urine Test DX Drug Screen Tox Cup Package Insert*. Revision 7/24/2024. Abbott Laboratories, 2025.
- C. Abbott Laboratories. iSCREEN™ Cup Urine Drug Screen Control LC, Negative & Positive Package Insert. Revision 8/2024. Abbott Laboratories, 2024.

## All Revision Dates

10/23/2025

## Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	10/23/2025
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/14/2025
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	10/14/2025



Origination 10/30/2025  
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Next Review 10/30/2027

Owner Christian Press:  
Supervisor-LIS,  
Laboratory  
Services  
Policy Area Laboratory  
Services

## L.BB.110 Blood Bank Compliance with Documentation of EMS Blood Product Handlers

### PURPOSE:

To establish a documented procedure for **Ventura County Medical Center's Blood Bank (VCMCBB)** to ensure compliance with **AABB Standard 6.2.4** and **FDA 21 CFR 606.160(b)(3)** by correctly documenting when **Ventura County Fire Department (VCFD)** and **Emergency Medical Services (EMS)** personnel are involved in the handling of blood products for the pre-hospital transfusion program.

### Scope

This policy applies to VCFD and EMS personnel operating under VCMCBB who are authorized to handle and administer blood products in pre-hospital settings.

### POLICY:

Ventura County Fire EMS shall be granted access to Cerner PathNet via a **dedicated generic login**:

- **Username:** vcfireems
- **User Role:** Medical Technologist (read-only functions applicable to release process)
- **Purpose:** To allow EMS staff to acknowledge pickup and field use of blood components via secure electronic documentation in the hospital LIS.

The account is strictly limited to:

- Viewing and documenting the **receipt of blood products** for EMS transport.
- Documenting **return or disposition** of unused units.
- Providing **electronic signature** of blood product hand-off when picked up from VCMC.

All activity using the `vcfireems` account will be **logged and auditable** in compliance with **AABB Standard 6.2.4** and **FDA 21 CFR 606.160(b)(3)** regarding component traceability.

## DEFINITION(S):

## PROCEDURE:

1. EMS arrives at the Blood Bank to pick up assigned blood units for prehospital use.
2. Blood Bank staff verifies EMS badge and documents identity on log sheet.
3. If VCFD or EMS performs an emergency pre-hospital transfusion with the dispensed blood product, the VCMC Blood Bank will reconcile the unit to the patient chart after the trauma patient has been registered at VCMC ED.
4. Blood Bank staff uses the **vcfireems** ID when reconciling the transfused units in Cerner as a placeholder for the EMS staff member who originally picked up the blood product from the VCMC Blood Bank.

## REFERENCE(S):

FDA 21 CFR 606.160(b)(3)

AABB 34th Edition 5.1.8.1

AABB 33rd Edition 6.2.4

### All Revision Dates

10/30/2025

### Approval Signatures

Step Description

Approver

Date



Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	10/30/2025
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	9/6/2025
Laboratory Services Department	Christian Press: Supervisor-LIS, Laboratory Services	5/7/2025

COPY



# VENTURA COUNTY MEDICAL CENTER

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## Medical Executive Committee Document Approvals

October and November 2025

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 Owner: Danielle Gabele: Chief Nursing Executive, VCMC & SPH  
 Policy Area: Administrative - Patient Care  
 References:

## 100.075 Restraint and Seclusion

### PURPOSE:

To provide a policy for the use of violent and non-violent restraints and death in restraints.

### ~~POLICY:~~ POLICY:

All patients have the right to be free from ~~physical or mental abuse, and corporal punishment. All patients have the right to be free from~~ unnecessary restraint or seclusion, of any form, imposed by staff as a means of coercion, discipline, convenience, or retaliation ~~by staff~~. Restraint ~~and~~ or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued as soon as possible. When the use of restraint is necessary, and the least restrictive method must be ~~discontinued at the earliest possible time~~ used to ensure a patient's safety.

### ~~PHILOSOPHY:~~

~~Ventura County Medical Center and Santa Paula Hospital are committed to preventing, reducing, and working to eliminate the use of restraints and seclusion. Hospital leadership supports the philosophy to use non-physical interventions and to use guidelines to promote safety, dignity and wellbeing when physically restrictive measures become necessary to promote healing. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm. These requirements are specific to the patient behavior that the restraint or seclusion intervention is being used to address.~~

### ~~PROCEDURE:~~ PROCEDURE:

#### ~~4. DEFINITIONS~~

- ~~A. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely and cannot be easily removed by the patient.~~
- ~~B. Restraints for Non-Violent/Non-Self-Destructive Behaviors may be considered appropriate when the patient displays potentially harmful behaviors toward self or jeopardizes their health and safety, interfering with required treatment/life support measures, and when alternatives / other methods are ineffective to protect the patient from harm. Examples of appropriate uses of non-violent/ non-self-destructive restraints would include pulling IV lines and tubes or attempts to compromise airways~~

~~G. **Restraints used for Violent/Self-Destructive Behaviors** are used to protect the patient against injury to self or others. These types of restraint or seclusion are used when the patient's violent or self-destructive behavior jeopardizes the immediate physical safety of the patient, staff, or others and when other methods are ineffective to protect the patient, staff or others from injury or harm.~~

~~i. Violent/self-destructive restraints are intended to be a brief intervention to allow time for calming the patient and advancing them toward less restrictive alternatives and preventive strategies.~~

~~D. **A chemical restraint** is a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. [Excludes Hillmont Psychiatric Center (HPC)]~~

~~E. **Seclusion** is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.~~

~~i. Seclusion is used only in the behavioral health units.~~

~~ii. Restraints and seclusion are used only when less restrictive interventions are ineffective.~~

~~iii. If a patient becomes violent and is an immediate danger to self and staff, the risk of the restraint or seclusion is outweighed by the risk of not using the restraint or seclusion.~~

~~iv. Less restrictive interventions shall first be determined by staff to be ineffective to protect the patient or others from harm prior to the introduction of more restrictive measures.~~

## ~~2. **ALTERNATIVES AND PREVENTIVE STRATEGIES TO USE OF RESTRAINT:**~~

~~A. NOTE: The use of handcuffs, manacles, shackles, other chain-type restraint devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this policy.~~

~~B. Alternatives are considered before using restraint on any patient and particularly on potentially vulnerable patients, such as emergency, pediatric or cognitively and/or physically limited patients.~~

~~C. Alternatives may include but are not limited to the following methods:~~

~~i. Moving the patient closer to the nursing station~~

~~ii. Using bed device alarms~~

~~iii. Toileting more frequently~~

~~iv. Encouraging family/visitor visits and/or participation~~

~~v. Engaging the patient in diversion activities~~

~~vi. Using pharmacologic interventions as appropriate~~

~~vii. Evaluating for potential medication interactions~~

~~viii. Evaluating current lab values~~

~~ix. Assessing sleep deprivation~~

~~x. Repositioning the patient for comfort~~

~~xi. Assessing for substance abuse~~

~~xii. Assessing for dementia~~

## ~~3. **TYPES OF RESTRAINTS**~~

~~Ventura County Medical Center and Santa Paula Hospital has approved the use of the following~~

restraints in accordance with manufacturer instructions:

- A. ~~Side rails up X 4~~
- B. ~~Mitts~~
- C. ~~Joint immobilizer~~
- D. ~~Soft Limb~~
- E. ~~Ankle restraints (locked, use for behavioral health, Emergency Department, and transport)~~
- F. ~~Physical hold during forced administration of psychotropic medication (violent)~~
- G. ~~Chemical restraint~~
- H. ~~5-point (locked, BH only)~~
- I. ~~Violent Restraints (ED and ICU only)~~

#### 4. ~~CRITERIA FOR USE OF RESTRAINT:~~

- A. ~~A restraint is used only if needed to improve the patient's well-being and less restrictive interventions have been found to be ineffective to protect the patient or others from harm.~~
- B. ~~Restraints are implemented in the least restrictive manner possible and are ended at the earliest possible time.~~
- C. ~~When practical, restraint use is discussed with the patient and, when appropriate, with the patient's family around the time of restraint application.~~
- D. ~~A restraint does not include orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physically holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).~~
- E. ~~A restraint does not include methods that promote and/or protect the patient from harm.~~  
~~Examples:~~
  - 1. ~~The use of side rails on therapeutic beds to improve circulation or prevent skin breakdown.~~
  - 2. ~~The use of padded side rails for seizure precautions.~~
  - 3. ~~The use of raised side rails for a patient on a stretcher.~~
  - 4. ~~Use of restraints during recovery from anesthesia that occurs when the patient is in critical care or PACU. However, if restraints continue after transfer to another unit or after the patient recovers from the effects of anesthesia, a restraint order is necessary.~~
- F. ~~The use of handcuffs, manacles, shackles or other chain type restraint devices applied by non-hospital employed or contracted law enforcement officials for custody, detention and public safety reasons are not governed by this policy.~~
- G. ~~Restraints may be used if indicated for patients with nasal Bi-Pap; restraints are not used on patients with Bi-Pap where a full face mask is indicated.~~
- H. ~~Physically holding a patient during forced psychotropic medication procedures is considered a restraint, and requires an order and documentation consistent with violent/self-destructive restraints.~~
- I. ~~Restraints are not a routine part of a fall prevention program.~~
- J. ~~Restraints Used for Non-Violent/Non-Self-Destructive Behaviors~~
  - i. ~~Restraints for non-violent/non-self-destructive behavior are used when the patient is unable to~~

~~follow directions and is exhibiting unsafe behaviors such as: pulling IV lines, tubes, or airways or displaying potentially harmful behaviors toward self.~~

- ~~ii. In all cases, the least restrictive form of restraint that protects the physical safety of the patient, staff or others is used.~~
- ~~iii. Restraints are discontinued at the earliest possible time, regardless of the scheduled expiration of the order.~~

**K. ~~Restraints or Seclusion Used for Violent/Self-Destructive Behaviors~~**

- ~~i. Restraints or seclusion for violent or self-destructive behavior are used to protect the patient against injury to self or others. These types of restraints are used when the patient's violent or self-destructive behavior jeopardizes the immediate physical safety of the patient, staff, or others, and when other methods are ineffective to protect the patient or others from injury or harm.~~
- ~~ii. Restraints and/or seclusion are discontinued at the earliest possible time, regardless of the scheduled expiration of the order.~~
- ~~iii. In all cases, the least restrictive form of restraint or seclusion that protects the physical safety of the patient, staff or others is used.~~
- ~~iv. Seclusion may only be used for the management violent/self-destructive behavior that jeopardize the immediate physical safety of the patient, the staff member or others on the Behavioral Health Units.~~

**5. ~~ORDERS:~~**

- ~~A. A physician or Inpatient Psychiatric Unit (IPU) RN who is responsible for the care of the patient and authorized to order the application of restraints, must order the use of restraints or seclusion.~~
- ~~B. Each order must include the justification for the use of restraint and/or seclusion and type of restraint.~~
- ~~C. The expectation is that a physician or IPU RN responsible for the care of the patient, places the order for the restraint or seclusion immediately prior to the application of the device.~~
- ~~D. In some situations, however, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion. In these emergency situations, the RN may make the decision to utilize the restraints, but the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (not to exceed 30 minutes) after the restraint or seclusion has been applied. The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order.~~
- ~~E. If the attending physician did not order the restraint, he or she must be consulted as soon as possible but not to exceed two hours. If the attending physician is unavailable, responsibility for the patient must be delegated to another physician, who is then considered to be the covering physician.~~
- ~~F. If more than one intervention or multiple types of restraints are needed all must be included in the order (example: soft limbs and mitts).~~
- ~~G. Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).~~
- ~~H. A "Trial Release" constitutes a PRN use of restraints or seclusion and therefore is not permitted. A~~



~~temporary, directly supervised release that occurs for the purpose of providing care for a patient's needs or to observe for early release, is not considered a discontinuation of restraints or seclusion intervention.~~

- ~~I. If a patient was recently released from restraint or seclusion, and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order is required.~~
- ~~J. If continued use of the restraint is indicated, each order for restraint used to ensure the physical safety of the non-violent/ non-self-destructive patient is renewed each calendar day.~~
- ~~K. Within one hour of initiating violent/self-destructive restraint/seclusion, a face-to-face physical and behavioral assessment is completed by a physician or qualified Inpatient Psychiatric Unit RN. If the restraint or seclusion is discontinued before the face-to-face assessment is conducted, the one-hour face-to-face evaluation is still required to be completed.~~
- ~~L. Orders for violent/self-destructive restraints may be renewed according to the times limits listed below for a maximum of 24 consecutive hours. A face to face evaluation must be conducted every 24 hours. Restraints and/or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the restraint or seclusion is discontinued.~~
- ~~M. Orders for violent/self-destructive restraints are time-limited not to exceed four (4) hours for patients 18 years of age or older, two (2) hours for children 9 — 17 years of age, one (1) hour for children younger than nine years old. If the need for restraints continues beyond the above time frames, a new order is required. The need for continued use of restraints or discontinuation is determined by the assessment of the RN.~~
- ~~N. All orders will be acknowledged by the RN responsible for the care of the patient. Acknowledgment of an order consists of the following:
  - ~~i. The order was obtained at the correct time, immediately (not to exceed 30 minutes) of application.~~
  - ~~ii. The device(s) and location of device(s) were ordered correctly.~~
  - ~~iii. Any modification of the order must occur at the time of acknowledgment.~~~~
- ~~O. Chemical Restraint Initiation – Initial assessment and ordering parameters are the same as for violent/self-destructive restraint/seclusion. It is not the intent of this standard to interfere with the clinical treatment of patients who are suffering from serious mental illness who need therapeutic doses to improve their ability to function in the world around them.
  - ~~i. A chemical restraint is a medication or a dose of a medication that is NOT a standard treatment or dose for the patient's condition.~~
  - ~~ii. If the medications used are a standard part of treatment for the patient's medical or psychiatric condition, they are not considered a chemical restraint.
    - ~~a. For example, if the patient is admitted with a history of outbursts, agitation, and/or assaultive behaviors and this is incorporated in his or her plan of care, and is a focus of the treatment, then the medication the patient is receiving, even on an "as needed" basis, is not considered a chemical restraint.~~~~~~
- ~~P. Chemical Restraint Continuation – If the patient needs additional medication and the patient has been assessed by a physician and the behavior has been addressed on the care plan, it is no longer a chemical restraint.~~

## **6. ASSESSMENT-MONITORING-DOCUMENTATION:**

**A. Non-Violent/Non-Self-Destructive Restraints:**

- ~~i. The presence of a restraint order is verified on the restraint flowsheet every shift.~~
- ~~ii. Verify that the attending physician was notified with the initial order.~~
- ~~iii. Monitor with documentation every two (2) hours.~~
- ~~iv. Perform range of motion exercises every two (2) hours while patient is awake.~~
- ~~v. Perform circulation and skin assessments of restrained extremities every two (2) hours.~~
- ~~vi. Vital Signs (BP, P and R) every four (4) hours.~~
- ~~vii. Offer fluids/bathroom/bedpan every two (2) hours while patient is awake.~~
- ~~viii. Assess if a less restrictive intervention may be appropriate.~~
- ~~ix. Provide documentation for justification of continued use every two (2) hours.~~
- ~~x. Provide personal hygiene needs as patient requires but not less than every 24 hours.~~
- ~~xi. Provide patient and family (if present) education indicating the reason for restraints and the type of restraint used as appropriate initially and as needed.~~

**B. Violent/Self-Destructive Restraints:**

- ~~i. The Restraint Order for violent /self-destructive restraints should be renewed every four hours for patients 18 years of age and older, every two (2) hours for 9-17 years old, and every one (1) hour for children younger than nine years of age.~~
- ~~ii. Document that the attending physician was notified with the initial order.~~
- ~~iii. Continuous monitoring with documentation every 15 minutes. Patients in seclusion can be monitored via video in the Inpatient Psychiatric Unit. Restrained patients will have continuous 1:1 face-to-face monitoring.~~
- ~~iv. For patients in simultaneous restraints and seclusion, direct visual observation is continual in 1:1 patient care, and is recorded every 15 minutes.~~
- ~~v. Assess if a least restrictive intervention may be appropriate.~~
- ~~vi. Reassessment for the continued use of restraints or seclusion (IPU only) occurs in person every two (2) hours or more frequently if indicated. Reassessment for the continued use of simultaneous restraints and seclusion (IPU only) is done in person and at a minimum every one (1) hour.~~
- ~~vii. Use of restraints and/or seclusion (IPU only) is only employed while the unsafe situation continues.~~
- ~~viii. Perform circulation and skin assessments of restrained extremities every two (2) hours.~~
- ~~ix. Vital signs: (BP, P and R) every four (4) hours at a minimum, preferably every two (2) hours, or as soon as patient is safe from self-harm, and staff can safely assess vitals.~~
- ~~x. Perform range of motion exercises every two (2) hours while patient is awake. It may be necessary to remove each restraint one at a time and re-apply before removing the next.~~
- ~~xi. Offer fluids/bathroom/bedpan every two (2) hours while patient is awake.~~
- ~~xii. Provide personal hygiene needs as patient requires but not less than every 24 hours.~~
- ~~xiii. Provide patient and family (if present) education indicating the reason for restraints and the~~

~~type of restraint used as appropriate, initially, and as needed.~~

~~xiv. Use of chemical restraints requires:~~

- ~~a. Documentation of the specific behaviors necessitating chemical restraint.~~
- ~~b. Monitoring of vital signs, sedation and behavior each time a chemical restraint is administered.~~

**7. TRAINING/EDUCATION:**

**A. Physicians/Registered Nurses (RNs)**

- ~~i. Physicians and IPU RNs authorized to order restraint or seclusion must have a working knowledge of hospital policy regarding the use of restraints or seclusion.~~
- ~~ii. Education regarding use of restraints is documented in their initial and re-appointment applications to the medical staff.~~

**B. Staff (i.e., nursing, Security, and patient care providers)**

- ~~i. Staff members receive training for their assigned duties performed under this policy.~~
- ~~ii. Training on restraint use occurs while in orientation and periodically thereafter. If a staff member has not received the restraint education, that staff member does not care for a patient independently until the training is completed. RNs are provided education on determining the initial and continued need for restraint or seclusion.~~

**C. Training requirements include the following components:**

- ~~i. Patient behaviors, events and environmental factors that may trigger behaviors that require the use of restraints and/or seclusion;~~
- ~~ii. Appropriate alternative and preventive interventions to restraints;~~
- ~~iii. The use of nonphysical intervention skills;~~
- ~~iv. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;~~
- ~~v. The safe application and use of restraints, including training on how to recognize and respond to signs of physical and psychological distress;~~
- ~~vi. Clinical identification of specific behavioral changes that indicate that restraint is no longer necessary;~~
- ~~vii. Monitoring the physical and psychological well-being of the patient who is restrained, including respiratory, circulatory status, skin integrity and vital signs.~~
- ~~viii. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation.~~

**8. CRITERIA FOR THE DISCONTINUATION OF RESTRAINTS:**

- ~~A. Restraints for non-violent/non-self-destructive behaviors are discontinued when the patient's behavior ceases and he/she no longer displays potentially harmful behaviors towards self which jeopardizes their health and safety, interfering with required treatment/life support measures.~~
- ~~B. Restraints used for violent/self-destructive behaviors are discontinued when the patient's behavior ceases and he/she no longer exhibit violent/self-destructive behavior which jeopardizes the immediate physical safety of the patient, staff, or others.~~

**9. PLAN OF CARE:**

- ~~A. The treatment plan is reflective of an assessment and evaluation of the patient indicating an identified problem, the need for a restraint or seclusion, and what restraints are implemented.~~
- ~~B. The patient's plan of care is based upon the patient's individual condition and needs.~~
- ~~C. The plan of care is reviewed and updated by the RN every shift and more often as needed.~~
- ~~D. The patient and the family is updated of changes in the plan of care when appropriate.~~

**10. DEATH REPORTING:**

~~Administration and/or the regulatory designee is responsible for reports of deaths associated with restraint and/or seclusion use according to CMS requirements.~~

**11. PERFORMANCE IMPROVEMENT:**

~~Performance improvement processes are used to appropriately evaluate the use of restraint and/or seclusion (IPU only) with a focus on prevention, reduction and improved patient outcomes.~~

## REFERENCES:

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- ~~▪ United States Department of Veterans Affairs (2008, August 25). Patient restraint use drops dramatically at DeBakey VA [Press release]. Retrieved from [http://www.houston.va.gov/pressreleases/News\\_20080825.asp](http://www.houston.va.gov/pressreleases/News_20080825.asp)~~
- ~~▪ Wolf, T. P. (2006, December 1). *Fit to be tied RNs use alternatives to restraints*. Retrieved from <http://news.nurse.com/pbcs.dll/article?AID=200661222027>~~

**ATTACHMENTS:**

### Summary of Restraint Requirements

<u>Intervention</u>	<u>Non-violent/behavioral</u>	<u>Violent/Behavioral</u>
<u>Initial Order</u>	<u>Used for patients who present with changes that are primarily related to their medical surgical health condition(s).</u>	<u>Behavior that jeopardizes the immediate physical safety of the patient, staff member(s), or others. These are patients who present symptoms for which a medical etiology is ruled out and have been identified as requiring behavioral health services.</u>
<u>Personnel who prescribe restraint(s)</u>	<u>Obtain within 1 hour of application</u>	<u>Obtain immediately after the application of the restraint without compromising patient safety</u>
<u>Licensed Provider (LP) reassessment</u>	<u>Every day</u>	<u>Every day</u>
<u>LP face to face evaluation</u>	<u>N/A</u>	<u>Within one hour of application and every 24 hours</u>
<u>Order Renewal</u>	<u>Calendar day</u>	<u>Every 4 hours (age 18 or older) Every 2 hours (age 9 – 17) Every 1 hour (age under 9)</u>
<u>Nursing assessment/ reassessment documentation</u>	<u>Assessment/Reassessment every 2 hours</u>	<u>See the violent/behavioral restraint section</u>
<u>Discontinuation</u>	<u>Based on the assessment, as soon as restraint is no longer needed</u>	<u>Based on the assessment, as soon as restraint is no longer needed</u>

## A. Definitions

1. **Restraint:** Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely and cannot be easily removed by the patient.

**\*Note: Non-restraint:**

- a. Forensic restraints such as handcuffs, shackles, or other restrictive devices by law enforcement
  - b. Prescribed orthopedic devices, surgical dressings or bandages, protective helmets
2. **Restraint for *Non-violent/Non-Self-Destructive Behaviors*:** Non-violent/non-self-destructive restraints are considered appropriate when the patient displays potentially harmful behaviors toward themselves or jeopardizes their health and safety, interferes with required treatment/life support measures, or when alternatives / other methods are ineffective to protect the patient from harm. Examples of appropriate uses of non-violent/ non-self-destructive restraints would include pulling IV lines and tubes or attempts to

compromise airways.

3. Restraints used for **Violent/Self-Destructive Behaviors**: Used to protect the patient against injury to self or others. These types of restraint or seclusion are used when the patient's violent or self-destructive behavior jeopardizes the immediate physical safety of the patient, safety, or others and when other methods are ineffective to protect the patient, staff or others from injury or harm.
  - a. Violent/self-destructive – restraints are intended to be a brief intervention to allow time for calming the patient and advancing them toward less restrictive alternatives and preventative strategies.
4. A **Chemical Restraint**: A drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.
5. **Seclusion**: Involuntary confinement of a patient alone in a room or area where the patient is physically prevented from leaving.
  - a. Seclusion is used only in the behavioral health units (Inpatient Psychiatric Unit (IPU)).

## **B. Alternatives and Preventative Strategies to Restraint Use**

1. Alternatives are considered before using restraint on any patient particularly on potentially vulnerable patients, such as emergency, pediatric, or cognitively and/or physically limited patients.
2. **\*Note:** This policy does not govern the use of handcuffs, manacles, shackles, or other chain-type restraint devices by non-hospital-employed or contracted law enforcement officials for custody, detention, or public safety reasons.

## **C.Types of Restraints**

1. Ventura County Medical Center and Santa Paula Hospital have approved the use of the following restraints in accordance with manufacturer instructions:
  1. Side rails up X 4  
**\*Note:** all 4 siderails are NOT considered a restraint if:
    - a. Padded side rails were placed in an up position as a seizure precaution
    - b. Special air mattress (e.g., beds with movement) to prevent pressure ulcers
    - c. Unsteady or potential for fall
    - d. Cognitively impaired or agitated
    - e. Unable to get out of bed
  2. Mittens
  3. Joint immobilizer
  4. Soft limb
  5. Ankle restraints
  6. Physical hold during forced administration of psychotropic medication (violent)
  7. Velcro (tough) restraints (Emergency Department (ED))

## D. Non-violent/Non-behavioral:

### 1. Orders:

- a. A provider orders the restraint(s). In an emergent situation, an RN can apply the restraint(s), and an order must be obtained within one hour
- b. Restraints are not ordered on a "prn" or "trial" basis
- c. If restraints have been discontinued and are required again, a new order is obtained
- d. If additional restraints are required, a new order needs to be obtained
- e. Renewed by the end of each calendar day

### 2. Assessment/Reassessment:

- a. Ongoing restraint assessments are documented in the electronic health record (EHR) every 2 hours  
\*Note: BiPAP: restraints may be used for nasal BiPAP, **NOT** face-mask BiPAP

### 3. Discontinuation:

- a. If a restraint is no longer needed per the patient's assessed behavior, the order and the intervention must be discontinued

### 4. Training/education:

- a. Licensed providers (LPs) authorized to write orders must have knowledge of the hospital's restraint policy
- b. Registered nurse (RN) restraint application competency is demonstrated upon hire and annual

## E. Violent/Behavioral

### 1. Orders:

- a. A Licensed Provider (LP) is authorized to order the application of restraints and/or seclusion and include the justification.
- b. A restraint or seclusion order is placed before application; however, an IPU/ED RN may apply the restraints in an emergent situation in the IPU or ED setting. An LP order needs to be placed within 30 minutes.
- c. Violent/self-destructive restraints should be renewed every 4 hours for patients 18 years of age and older, every 2 hours for 9 – 17 years of age, and every one hour for children younger than 9 years of age (ED/IPU only).
- d. Violent/self-destructive restraints may be renewed according to the time limits listed above for a maximum of 24 consecutive hours. A face-to-face evaluation must be conducted every 24 hours.
- e. Restraints are not ordered on a "prn" or "trial" basis.
- f. Restraints may be discontinued by the RN or LP as soon as possible when the patient is deemed safe.
- g. If restraints are required again, a new order is obtained.

### 2. Assessment/Reassessment:

- a. A face-to-face physical and behavioral assessment is completed by a physician or an IPU RN within one hour of restraint and/or seclusion.

- b. For patients in restraints: continuous 1:1 face-to-face monitoring: document on patient observation record (POR)—see attachment----- Face to Face sets the distance. In IPU Dr orders distance. Continuous 1:1 Observation is consistent to other policies.
- c. For patients with restraints **and** seclusion: direct visual observation is continual in 1:1 patient care and is documented every 15 minutes. We do not use restraints and seclusion together.
- d. Reassessment for the continued use of restraints **or** seclusion (IPU only) occurs in person every two hours or more frequently if indicated.
- e. Reassessment of the continued use of restraints **and** seclusion (IPU only) is done in person and at least every one hour. We do not use restraints and seclusion together.

### **3. Discontinuation:**

- a. If a restraint **or** seclusion is no longer needed per the patient's assessed behavior, the order and the intervention must be discontinued.
- b. If restraint **and** seclusion are no longer needed per the patient's assessed behavior, the order and the interventions must be discontinued.

### **4. Training/Education:**

- a. Physicians/Registered Nurses (RNs)
  - i. Physicians and IPU RNs authorized to order restraint, or seclusion must have a working knowledge of hospital policy.
  - ii. Restraint education is documented in their initial and re-appointment applications to the medical staff.
- b. Registered nurse (RN) restraint application competency is demonstrated upon hire and annually.

## **F. Plan of Care**

- 1. The treatment plan is reflective of an assessment and evaluation of the patient indicating an identified problem, the need for restraint or seclusion, and what restraints are implemented.

## **G. Death Reporting:**

- 1. Administration and/or regulatory designee is responsible for reports of deaths associated with restraints and/or seclusion use according to CMS requirements.
  - a. RN staff will immediately complete the restraint/seclusion status on the report of death worksheet (see attachment).
  - b. RN staff will notify the Chief Nursing Executive (CNE) or their designee.

## **H. Performance Improvement**

- 1. Performance improvement processes are used to appropriately evaluate the use of restraint and/or seclusion (IPU/ED), focusing on prevention, reduction, and improved patient outcomes. All hospital areas that use restraints should be all the hospital areas.





## References

- [CMS Regulation: Restraints & Seclusion \(2021-2022\). 482.13](#)
- [de Bruijn W, Daams JG, van Hunnik FJG, et al. \(2020\). Physical and Pharmacological Restraints in Hospital Care: Protocol for a Systematic Review. \*Front Psychiatry\*.10:921. doi:10.3389/fpsyt.2019.00921](#)
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- [Kisacik, OG, Sonmez, M., Cosgun, T. \(2020\). Use of physical restraints in critical care units: Nurses' knowledge, attitudes, and practices. \*Critical Care Nurse\*. 40\(3\): 37-48](#)
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- [The Joint Commission: new and revised restraint and/or seclusion requirements \(2024\).](#)

All revision dates:

9/17/2025, 10/14/2024, 7/20/2020, 7/9/2018, 7/5/2018, 6/22/2018, 11/1/2016, 8/1/2015, 10/1/2011, 12/1/2010, 2/1/2008, 5/1/2006, 1/1/2005, 2/1/2004, 11/1/2001, 4/1/2001, 1/1/2001, 2/1/1999, 12/1/1998, 10/1/1998, 6/1/1998, 9/1/1995

## Attachments

-  [Attachment A - Restraint Required Documentation.pdf](#)
-  [Attachment B - Face-To-Face Evaluation Form.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Department Review	Erin Olivera: Clinical Nurse Manager, IPU/CSU	pending
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/17/2025



**Origination:** 2/11/2019  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** 10/11/2022  
**Next Review:** 3 years after approval  
**Owner:** Minako Watabe: Chief Medical Officer, VCMC & SPH  
**Policy Area:** Administrative - Patient Care  
**References:**

## 100.233 Informed Consent and Blood Transfusion

### POLICY:

California State Law requires that physicians provide all patients who may require transfusion(s) of blood and/or blood products specific information about the transfusion. This policy outlines the physician's role and responsibilities for obtaining informed consent prior to the administration of blood or blood products.

### PROCEDURE:

Obtaining informed consent for the transfusion of blood or blood products is the responsibility of the physician and is a requirement of multiple regulatory bodies. The essential components of informed consent include: the risks, expected benefits, and available alternatives to transfusion, including non-treatment. The patient shall receive written information ("A Patient's Guide to Blood Transfusion") regarding options pursuant to the Paul Gann act.

Physicians are responsible and accountable for:

- Obtaining informed consent (risks, benefits and alternatives) from the patient or legal designee for the transfusion of blood or blood products.
- Documenting consent or refusal to consent on the *Consent/Declination for Transfusion of Blood or Blood Products form (VCMC-365-004)*.
- Providing the patient with the brochure, "A Patient's Guide to Blood Transfusion" whenever there is a reasonable possibility of a transfusion.
- Providing information about autologous blood use (defined to include pre-donation, intraoperative autologous transfusion, plasmapheresis and hemodilution).
- Documenting any refusal by the patient to consent to the administration of blood or blood products.

When possible, the discussion about receiving blood and/or blood products shall occur prior to admission and prior to ordering the transfusion. If the ordering physician is not available, another physician responsible for the patient's care shall facilitate the discussion with the patient. Nurses shall not provide or obtain informed consent for the transfusion of blood or blood products from the patient. Discussion points shall include the risks, benefits, and alternatives to blood transfusions including the use of directed donation (donor specific), autologous blood and the availability of intraoperative or postoperative blood salvage except in a life threatening emergency. If eligible, the patient shall be given the option to pre-donate blood prior to elective surgery.

In emergency situations where an immediate blood transfusion is necessary to prevent a patient's death or

permanent harm, and the patient is physically or mentally unable to give or refuse informed consent, blood or blood products may be administered at the discretion of the treating physician. The physician shall document the medical necessity in the medical record.

When consent for the transfusion of blood or blood products is denied by the patient, the physician and the patient shall initial, sign and date the appropriate lines on the Consent/Declination for Transfusion of Blood or Blood Products form. Physicians are encouraged to provide additional documentation in the patient's medical record about the refusal.

Denial of permission to administer any blood products by competent adult patients should be honored; however, in cases of incompetent adult patients, the consent to administer blood or blood products shall be addressed with decision-makers as for any other medical procedure. In the event a physician has medical/legal concerns, the on call hospital administrator shall be contacted. If the physician has determined that the transfusion is necessary to sustain life or prevent lifelong disability of a minor patient and the parents or legal guardians have refused to provide consent, the physician, in consultation with case management and the risk department, shall contact Child Protective Services (CPS).

For hospitalized patients with a recurring need for blood or blood products during a single hospital admission, only one consent form needs to be signed unless the physician or patient indicates there has been a change in the information upon which the consent was based. For patients in the outpatient setting, informed consent is valid for 30 days as long as the reason for the transfusion remains unchanged.

All revision dates:

10/11/2022, 7/23/2019, 2/11/2019

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	9/5/2025
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	8/25/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/21/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/21/2025
Policy Owner	Minako Watabe: Chief Medical Officer, VCMC & SPH	8/21/2025



**Origination:** N/A  
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**Last Approved:** N/A  
**Last Revised:** N/A  
**Next Review:** 3 years after approval  
**Owner:** Imelda Reyes-Jay: Clinical Reg.  
 Compliance & Patient Safety Mgr  
**Policy Area:** Administrative - Employee  
**References:**

## 101.032 Care for the Caregiver (Peer Support) Program - Helping Healers Heal

### PURPOSE:

To provide guidelines and structure for offering emotional first aid and support to staff and physicians after a harmful /adverse or traumatic event.

### POLICY:

Ventura County Medical Hospital (VCMC) and Santa Paula Hospital (SPH) recognize the potential emotional and psychological impact that adverse, harmful and emotionally traumatic events can have on employees and physicians. To that end, VCMC and SPH are committed to providing support and care for our caregivers impacted by emotionally traumatic events.

The Peer Support process is part of the Patient Safety and Risk Management Program. As such, all program related referrals and encounters are maintained in a confidential manner. The effectiveness and evaluation of the Peer Support program are reported to the Quality Assessment and Performance Improvement / Patient Safety Committee (QAPI/PS) and Medical Executive Committee (MEC). The Program Steering Committee shall reconvene quarterly to review progress and guide ongoing enhancements.

### DEFINITION(S):

**Adverse/Harm event:** An unanticipated event that may have or did result in harm.

**Peer support:** Emotional first aid provided to a person who is involved in unexpected health care or other emotionally traumatic event.

**Debriefing:** The process of holding a post-event discussion about what happened during the event. The discussion may include input from participants regarding what occurred, what worked well, what could be improved upon, or personal feelings associated with the event. The scope and purpose of the debriefing should be established in the opening comments. A debriefing is not an investigation and is separate and apart from a peer supporter interaction.

**Harm:** Any measurable amount of physical, psychological, or emotional distress.

**Peer Supporter:** A trained member of the Peer Support Team who is available to respond to physicians or personnel to offer and provide emotional first aid following a harmful, an adverse or emotionally traumatic event.

**Traumatic Event:** An experience in the workplace that causes emotional upheaval or has the potential to impact the well-being of staff/employee(s) in the work environment. Examples of a traumatic event include but are not limited to the following:

- Workplace violence event
- Severe injury or death to a patient, employee, or visitor
- Medical error
- Unanticipated patient harm or death (especially when the age or other characteristics remind the individual of a family member or loved one)
- Sudden loss of a co-worker
- Collective, significant personal loss
- Multiple deaths in a clinical area
- Seriously troubled employee creating havoc with multiple staff members
- Actual suicidal or homicidal attempts by a patient, employee, or visitor

## PROCEDURE(S):

The Peer Support program can be activated by any staff member in response to a harmful or emotionally traumatic event that triggers the need for emotional support of employees or physicians.

Activation of the program may be accomplished automatically or through communication with the program coordinator.

The Quality Assessment and Performance Improvement (QAPI) team functions as Peer Support Intake Coordinators and can be reached via **the event notification system, email, designated phone number or Tiger Text**.

Once activated, the Intake coordinator may contact the individual or their supervisor/manager to determine the level of support and resources needed. Resources and referrals may include but are not limited to a trained Peer Support Team member, Employee Assistance Program, Chaplain/Pastoral Services, or external psychological support services.

### A. **ACTIVATION TIERS:**

1. **Tier One Activation:** Department/Unit level support will be provided by the unit manager, fellow team member/colleague, supervisor, or department chair. Support may be provided at any time peers appear to be experiencing levels of stress that exceed their ability to cope whether it is due to a patient harm event, emotionally traumatizing experience, or cumulative stress. Support includes:
  - a. Connecting with affected individual(s)
  - b. Providing one-on-one reassurance and/or professional support.
  - c. Reaffirming confidence in the individual.
  - d. Assisting by contacting the Peer Support Intake coordinator, to determine if additional resources are needed
  - e. Assisting the individual to temporarily leave the unit and go to the designated 'Safe Space' to emotionally process the event.
  - f. Considering relieving involved individuals of duties for the balance of the shift or longer, if necessary, through collaboration with the Human Resources or staffing office; (call in flex staff if

available and/or request oncoming employees to come in early, etc.)

- g. Checking in on staff member regularly after initial interaction
  - h. Notifying individual of next steps if any
2. **Tier Two Activation:** Upon receipt of notification, the intake person will gather initial information, triage the call, and provide a hand-off report to a trained peer supporter or resource as needed.
- a. Intake information includes: Date and time of request, name of involved staff member, unit, type of event, effectiveness of tier one support, any special concerns, etc.
  - b. Trained peer supporters may receive a request for peer support from anyone; however, the peer supporter should notify the intake coordinator if the request is made outside of the formal activation process.
  - c. The peer supporter will respond to **M-F business hours (8:00am -4:00pm)** by phone or in person to provide support to the involved employee(s)
  - d. The Administrator On Duty (AOD) will be notified of requests for peer support during the off-shift and weekend hours and provide resources (Employee Assistance Program (EAP) Hotline, chaplain on duty, or peer supporter).
3. **Tier Three Support:** may be triggered by the peer supporter, supervisor, a colleague or the individual when needed. Additional resources include but are not limited to:
- a. Employee Assistance Program
  - b. Social Work
  - c. Chaplain
  - d. Clinical Psychologist
  - e. Other - as designated by the organization

**B. Peer supporter will** (in addition to support provided in Tier One):

- 1. Provide one-on-one crisis intervention
- 2. Maintain confidentiality
- 3. Avoid writing or keeping any notes regarding the encounter other than name, contact information and date/time of any agreed upon follow-up contact
- 4. Demonstrate active listening techniques
- 5. Offer support
- 6. Redirect conversation as needed to focus on the individual rather than the event
- 7. Be attentive and “in the moment” with the staff member
- 8. Evaluate and determine the need for referral to Tier 3 support for additional assistance as needed
- 9. Document in the Peer Support Log
- 10. Participate in ongoing team meetings and education

Expedited access to external resources will be provided when needs arise. (Inform the AOD for facilitation of access to resources).

Individuals manifesting signs consistent with impairment will be managed according to the organization's process for evaluating potentially impaired physicians/employees. The peer supporter shall notify the AOD

immediately when it is believed the individual may be affected to the point of impairment regardless of when there is concern in the recovery process.

**Non-emergencies** will be addressed the next business day during business hours.

**Contact Information / Resources:**

- Direct Line (M-F 8:00 am - 4:30 pm) and unmonitored outside of these hours - (805) 652-6621
- [Tiger Text \(TT\): Helping Healers Heal \(H3\)](#)
- eMail: H3@~~ventura~~venturacounty.orggov
- Employee Assistance Program: (805) 654-4327
- For emergent issues: Notify immediate supervisor and AOD
- Crisis Intervention: call or text 988 or visit the 988 Lifeline website at <https://988lifeline.org>

## PROGRAM EVALUATION:

Peer supporters will complete a confidential Peer Support Log within 72 hours of interaction.

- A. Invitations to provide feedback will be sent out electronically to all providers and staff requesting participants in the Peer Support program provide feedback regarding their experience and include any recommendations for improvement.
- B. Evaluation of the program will be achieved through volume statistics (number and frequency of deployments over the number of patient harm events) as well as qualitative analysis through post-encounter surveys.
  1. Program statistics will be reported through the QAPI/PS and MEC.
  2. Data detailing the effectiveness of the Peer Support program will be shared via a dashboard.

## REFERENCE(S):

1. AHRQ Primer: Support for Clinicians Involved in Errors and Adverse Events (Second Victims)
2. Davidson, Judy; Proudfoot, James; Lee, Kelly; Zisook, Sidney; "Nurse Suicide in the United States: Analysis of the CDC 2014 National Violent Death Reporting System Dataset", Archives of Psychiatric Nursing, 33(Oct 2019),16-21.
3. Duarte, D.; El-Hagrassy, M.M.; Castro e Couto, T.; Gurgel, W.; Fregni, F.; Correa, H. Male and Female Physician Suicidality – A Systemic Review and Meta-Analysis, JAMA Psychiatry, June 2020; 77(6)
4. Internet Citation: Communication and Optimal Resolution (CANDOR) Toolkit. Content last reviewed May 2016. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/quality-patientsafety/patient-safety-resources/resources/candor/introduction.html>
5. Shapiro, Jo and McDonald, Timothy Supporting Clinicians during Covid-19 and Beyond – Learning from Past Failures and Envisioning New Strategies The New England Journal of Medicine, October 14, 2020 <https://www.nejm.org/doi/full/10.1056/NEJMp2024834?query=TOC>

All revision dates:

### Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
MEC	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	9/5/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/13/2025
Peer Support	Jordana Kaban: Physician	8/13/2025
Peer Support	Imelda Reyes-Jay: Clinical Reg. Compliance & Patient Safety Mgr	7/29/2025





**Origination:** 5/1/1983  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** 9/24/2025  
**Next Review:** 3 years after approval  
**Owner:** Magdy Asaad: Infection Prevention Manager  
**Policy Area:** Administrative - Environment of Care  
**References:**

## 106.005 Diseases and Conditions Reportable to the Ventura County Public Health Department

### POLICY:

To comply with the California Code of Regulations, Title 17 Section 2500 and The Joint Commission Hospital Accreditation Standards regarding reporting diseases and conditions to the Ventura County Public Health Department.

### PROCEDURE:

**RESPONSIBILITY** for reporting includes, but is not limited to:

Physicians  
 Infection Control Practitioners  
 Physician's Assistants  
 Nurse Practitioners  
 Nurses  
 Laboratory Staff

Anyone having knowledge of a reportable condition

There are two methods of reporting to the Ventura County Public Health Department. The first is the Confidential Morbidity Report (Attachment A), Communicable Diseases other than Tuberculosis and AIDS. The preferred method of reporting is by using the CalRedie electronic reporting program. A login can be obtained by contacting the Communicable Disease office of the Ventura County Public Health Department.

The list of diseases, conditions and the required form for reporting is attached to this policy. A diagnosis or a suspected case of any of the diseases or conditions listed on Attachment B must be reported to the Ventura County Public Health Department within the designated time frame.

Tuberculosis reporting requires a separate form (Attachment C). "The Legal Aspects of TB Reporting" information is included as Attachment D. These forms can also be found on the Ventura County Public Health Department website at: [www.vchca.org/ph](http://www.vchca.org/ph). Click on Communicable Disease Reporting and select the appropriate form.

**Severe Reportable** Influenza Case History form must be completed for any patient with influenza who is in the Ventura County Medical Center/Santa Paula Hospital ~~ICU or any patient aged 0 to 64 who has succumbed to~~

~~the disease:~~

- [Influenza-associate deaths in laboratory-confirmed cases less than 18 years of age. reported vis CalRedie.](#)
- [Influenza due to novel strains \(humans\) reported by phone as well.](#)

~~The Severe Influenza Case History and the~~ Tuberculosis Report are faxed to the respective numbers at the Ventura County Public Health Department. The fax numbers are on the forms.

The regular CMR's should be entered into CalRedie. In lieu of this, the form may be faxed to Ventura County Public Health at the number on the form.

AIDS cases are telephoned to the AIDS office. The telephone number is located on the front of the CMR

**All reports faxed/sent to the Ventura County Public Health Department must also be faxed to the Infection Control Office at (805) 652-3273.**

## Reference:

California Code of Regulations Title 17 Section 2500  
The Joint Commission Hospital Accreditation Standards





## Attachments:

- A. Confidential Morbidity Report Fax form
- B. Confidential Morbidity Report Instructions
- C. TB Suspect/Case Report and Plan Form
- D. Legal Aspects of TB Reporting information

All revision dates:

9/24/2025, 5/1/2016, 11/1/2013, 9/1/2006, 3/1/2004

## Attachments

-  [A: Confidential Morbidity Report Form](#)
-  [B: Confidential Morbidity Report Instructions](#)
-  [C: TB Suspect/Case Report and Plan Form](#)
-  [D: Legal Aspects of TB Reporting Information](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	9/24/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	9/24/2025



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Last Revised: 10/8/2025  
Next Review: 3 years after approval  
Owner: Kristina Swaim: Nurse Director,  
Maternal Child Health  
Policy Area: Administrative - Nursing  
References:

## 108.056 Nursing Procedure for Fever in the Pediatric Cancer Patient

### POLICY:

To provide guidelines for the care of pediatric cancer patient with fever or suspected infectious process.

- A. There are several primary and secondary causes for immune deficiency in children. Patients who are being treated for cancer may have multiple defects in the immune defenses (Baggott, ~~2002~~2011). Neutropenia is a well described immune defect. (CPG.32 Fever in Pediatric Cancer Patients)
- B. Neutropenia may be defined as Absolute Neutrophil Count (ANC) of  $\leq 1000/\text{mm}^3$
- C. All fevers combined with neutropenia are considered life-threatening until proven otherwise.
- D. Pediatric patients with fever and known potential for immune deficiency should be presumed neutropenic until proven otherwise.
- E. Fever may be defined by two readings above  $100.0^{\circ}\text{F}$  in a 1 hour period or a single reading of  $100.4^{\circ}\text{F}$  or higher. ~~(Rectal temperatures and procedures are contraindicated in patients with immune deficiencies.)~~  
~~Pediatric patients with fever and known potential for immune deficiency should be presumed neutropenic until proven otherwise.~~  
~~All fevers combined with neutropenia are considered life threatening until proven otherwise.~~
- F. Acetaminophen PO is preferred antipyretic. IV acetaminophen may be used, with care to not delay antibiotics or fluid resuscitation. Ibuprofen and other NSAIDs are generally contraindicated due to anti-platelet effects. Thrombocytopenia often occurs with neutropenia.
- G. Per rectum medications, procedures, and temperatures are contraindicated in patients with immune deficiencies, as may cause bacteremia.
- H. Establishing vascular access, initiating IV antibiotics and fluid resuscitation are immediate priorities (Weiss, et al 2020).

### PROCEDURE:

- A. Rapidly identify febrile pediatric patients with a potential immune deficiency.
- B. Perform a complete assessment, including vital signs, mental status, peripheral perfusion and airway status within first ~~0-55~~ minutes.
- C. Notify responsible ~~resident~~ physician regarding patient status to obtain new orders (refer to Peds Onc

Fever power-plan). If no response within 5 minutes, proceed to notify attending pediatrician or oncology physician.

- D. Draw all STAT lab tests as ordered. If the patient has a Central Venous Catheter (CVC) including peripherally inserted central venous catheter (PICC), ~~aerobic and anaerobic~~ draw blood cultures per order. Blood cultures MUST be drawn from the CVC. If there is more than one CVC lumen, cultures are drawn from each lumen separately and labeled as such. Peripheral blood cultures are generally not required unless there is no CVC present.
- E. Obtain vascular access if none available.
- F. After all appropriate cultures have been obtained, IV antibiotics should be initiated within 1 hour.
- G. The first antibiotic dose may be divided among all CVC lumens if there is more than one. Use alternating CVC lumens for all subsequent IV antibiotic doses.
- H. Monitor and report signs of hypoperfusion both initially and during evaluation.
  - 1. Hypotension
  - 2. Altered mental status
  - 3. Capillary refill > 2 seconds
  - 4. Thready peripheral pulses or differential between peripheral and central pulses
  - 5. Cool extremities
  - 6. Low urine output
  - 7. Mixed venous oxygen saturation <70%
  - 8. Serum lactate > 2
- I. For patients with hypoperfusion, initiate fluid resuscitation per orders. Typically, this will consist of a rapid infusion of Normal Saline 20ml/kg to start. For patients with hypoperfusion, volume may be given in 5-10 minutes via hand syringe push. Bolus volume may be repeated until adequately perfused.
- J. Initiate transfusion of irradiated blood products as ordered, per policy.
- K. Administer Acetaminophen per order and consider cooling measures if unable to reduce temperature.

## References:

Baggott, C.R., Kelly, K.P., Fochtman, D. & Foley, G.V., ~~Patterson, K., (2002)2011~~). ~~Nursing care of children and adolescents with cancer (3<sup>rd</sup> Ed.)~~. Nursing care of Children and Adolescents with Cancer and Blood Disorders (4th ed.). Association of Pediatric Hematology & Oncology Nurses (APHON). Philadelphia: Sanders.

Weiss, Scott L. MD, eMSCE, FCCM (Co-Vice Chair) et al; Executive Summary: Surviving Sepsis Campaign International Guidelines for the Management of Septic Shock and ~~Sepsis~~Sepsis-Associated Organ Dysfunction in Children<sup>7</sup>. Pediatric Critical Care Medicine: February 2020 - Volume 21 - Issue 2 - ~~p~~P 186-195  
doi, doi: 10.1097/PCC.0000000000002197

All revision dates:

10/8/2025, 1/13/2021

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Interdisciplinary Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Medical Staff Committees: ED & Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/6/2025
P&T Committee	Sul Jung: Associate Director of Pharmacy Services	8/8/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/29/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/29/2025
Director of Nursing, Ambulatory Care	Cynthia Fenton: AC Director of Nursing	5/29/2025
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	5/28/2025



Origination: 12/6/2001  
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 Last Approved: N/A  
 Last Revised: N/A  
 Next Review: 2 years after approval  
 Owner: Gayle Haider: Supervisor-Quality Assurance, Laboratory Services  
 Policy Area: Laboratory Services  
 References:

## L.01 Laboratory Services Accountability and Responsibility to the Medical Staff and Administration

**PROCEDURE: General Laboratory**

**SUBJECT: ACCOUNTABILITY AND RESPONSIBILITY TO THE MEDICAL STAFF AND ADMINISTRATION**

**POLICY NO:**

Admin 1.1

**DEPARTMENT: Laboratory**  
**AFFECTS: LABORATORY**

**EFFECTIVE DATE: 12/06/2001**

**REVIEW DATES:**  
2/06,3/07,8/08,8/09,11/10,11/12  
6/15, 1/22, 12/23

**PREPARED BY:**

**Nancy Koenker**

**(Reviewed by Gayle Haider)**

**REVISION DATES:**

11/16

The Pathology Department at Ventura County Medical Center includes the Clinical Laboratory and Anatomic Pathology. The services provided are Anatomic Pathology, Cytology, Blood Bank, Chemistry, Hematology, Coagulation, Urinalysis, Serology, Microbiology, Parasitology, and Molecular. The Pathology Department, under the direction of the Pathologist, shall be responsible for the daily operations of the department and shall report directly to administration and be accountable to the medical staff for meeting their needs and the needs of their patients. The functions performed, in order, to meet these needs shall include proper identification, collection, transportation, storage, processing and examination of clinical specimens and reporting of results. Pathology services shall also include consultation and active participation in prevention, diagnosis and management of patients. The service shall provide educational opportunities for medical and technical staff.

## POLICY

The Laboratory Services Department at Ventura County Medical Center includes the Clinical Laboratory and Anatomic Pathology. The services provided are Anatomic Pathology, Cytology, Blood Bank, Chemistry, Hematology, Coagulation, Urinalysis, Serology, Microbiology, Parasitology, and Molecular.

The Laboratory Services Department, under the direction of the Pathologist, shall be responsible for the daily operations of the department and shall report directly to administration and be accountable to the medical

staff for meeting their needs and the needs of their patients.

## **PROCEDURE**

- A. The functions performed, in order, to meet these needs shall include proper identification, collection, transportation, storage, processing and examination of clinical specimens and reporting of results.
- B. Pathology services shall also include consultation and active participation in prevention, diagnosis and management of patients.
- C. The service shall provide educational opportunities for medical and technical staff.

All revision dates:

### **Attachments**

No Attachments

### **Approval Signatures**

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	9/6/2025
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	12/27/2024





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**Next Review:** 3 years after approval  
**Owner:** Erlinda Roxas: Director,  
Laboratory Services  
**Policy Area:** Ambulatory Care- Point of Care  
Testing  
**References:**

## L.62- Hemocult II® SENSE® Elite Fecal Occult Blood Test

### Intended Use:

- A. The Hemocult II® SENSE® elite test is a rapid, qualitative method for detecting fecal occult blood which may be indicative of gastrointestinal disease. It is not a test for colorectal cancer or any other specific diseases.
- B. The Hemocult II® SENSE® elite test is recommended for professional use as a diagnostic aid during routine physical examinations, for hospital patients to monitor for gastrointestinal bleeding in patients with iron deficiency anemia or recuperating from surgery, peptic ulcer, ulcerative colitis and other conditions, and in screening programs for colorectal cancer when the Patient Instructions are closely followed.
- C. Serial fecal specimen analysis is recommended when screening asymptomatic patients.
- D. The Hemocult II® SENSE® elite test and other unmodified guaiac tests are not recommended for use with gastric specimens.

### Summary & Explanation of Test:

- A. Van Deen is generally credited with the discovery that gum guaiac, a natural resin extracted from the wood of *Guaiaecum officinale*, is useful in detecting occult blood.
- B. The Hemocult II® SENSE® elite test more reliably detects abnormal bleeding associated with gastrointestinal disorders than standard guaiac tests. As a result, it will have a higher sensitivity for disease but also a higher false-positive rate among non-diet compliant patients. Hemocult II® SENSE® elite positive test results appear as more stable, intense blue color reactions than the results of other guaiac tests, improving overall readability and precision. As with other guaiac tests, accuracy depends upon the status of the patient at the time the specimen is taken and may be affected by interfering substances.
- C. The Hemocult II® SENSE® elite test, like the Hemocult® test, is a simplified and standardized variation of the laboratory guaiac procedure for detection of occult blood. The Hemocult II® SENSE® elite test formulation includes an enhancer which makes the test more sensitive and more readable than other guaiac-based tests. Because the Hemocult II® SENSE® elite test requires only a small fecal specimen, offensive odors are minimized and storage or transport of large fecal specimens is unnecessary.
- D. Hemocult II® SENSE® elite is the same format and chemistry as Hemocult® SENSE®, therefore it provides the same performance. The elite version provides clarified diet instructions, easier patient



sampling, and easier processing.

## Principles of Test:

The Hemoccult II® SENSE® elite test is based on the oxidation of guaiac by hydrogen peroxide to a blue-colored compound. The heme portion of hemoglobin, if present in the fecal specimen, has peroxidase activity which catalyzes the oxidation of alpha-guaiaconic acid (active component of the guaiac paper) by hydrogen peroxide (active component of the developer) to form a highly conjugated blue quinone compound.

## Performed By:

Fecal occult blood testing may be performed by Ambulatory Care Clinic staff who have successfully completed the OSOM® Ultra Strep A Test competency training activities and evaluations, including Registered Nurses, Licensed Vocational Nurses, and Medical Assistants.

## Required Materials:

- A. Hemoccult II® SENSE® elite Slides (Test Cards) containing guaiac paper
- B. Hemoccult® SENSE® Developer– a developing solution containing a stabilized mixture of less than 4.2% hydrogen peroxide, 80% denatured ethyl alcohol and enhancer in an aqueous solution
- C. Applicator Sticks
- D. Patient Screening Kit Dispensing Envelopes with Patient Instructions
- E. Flushable Collection Tissues
- F. Mailing Pouches (for returning completed Test Cards)
- G. Hemoccult II® SENSE® elite Product Instructions

The Hemoccult II® SENSE® elite Test Card is designed so patients can collect serial specimens at home from bowel movements on three different days. After the patient prepares the Hemoccult II® SENSE® elite test, it may be returned in person or by mail (use Hemoccult® Mailing Pouch) to the laboratory, hospital or medical office for developing and interpretation.

## Storage & Handling:

- A. Store Test Cards and Developer at controlled room temperature (15 to 30°C) in original packaging. Do not refrigerate or freeze.
- B. Protect from heat and light. Do not store with volatile chemicals (e.g., ammonia, bleach, bromine, iodine, and household cleaners).
- C. The Hemoccult II® SENSE® elite Slides and Hemoccult® SENSE® Developer will remain stable until the expiration dates which appear on each slide and developer bottle when stored as recommended.

## Precautions:

- A. For in vitro diagnostic use.
- B. Do not use after expiration date which appears on each test component.
- C. Because this test is visually read and requires color differentiation, it should not be interpreted by

individuals with blue color deficiency (blindness).

- D. Patient specimens, and all materials that come in contact with them, should be handled as potentially infectious and disposed of using proper precautions.
- E. Slides (blue and green striped)- Keep cover flap of slide sealed until ready to use. Protect slides from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, and household cleaners). Hemoccult II® SENSE® elite Slides present no hazard to the user.
- F. Developer (blue and green striped label with blue bottle cap)- Hemoccult® SENSE® Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.
- G. Hemoccult® SENSE® Developer is an irritant. DO NOT USE IN EYES. AVOID CONTACT WITH SKIN. Should contact occur, rinse promptly with water and consult a physician.
- H. Use Hemoccult® SENSE® Developer (blue and green striped label with blue bottle cap) only with Hemoccult® SENSE® and Hemoccult II® SENSE® elite Slides (Test Cards). Do not interchange Hemoccult® SENSE® with Hemoccult® test reagents, which are identified by yellow and green striped packaging, or with components from any other manufacturer.

## Patient Preparation & Instructions:

- A. Preparation before taking the test.
  - 1. Okay to eat:
    - a. Pork, chicken, turkey and fish
    - b. Fruits and vegetables
    - c. High-fiber foods (e.g., whole wheat bread, bran cereal, popcorn)
    - d. Acetaminophen (Tylenol\*)
    - e. Up to one adult aspirin (325 mg) a day
  - 2. Avoid 7 days prior to and during testing:
    - a. No more than one adult aspirin (325 mg) a day
    - b. No other non-steroidal anti-inflammatory drugs such as ibuprofen (Motrin\*, Advil\*\*) . NOTE: Please talk to your physician or pharmacist if you have any questions about medications you take regularly.
  - 3. Avoid 3 days prior to and during testing:
    - a. No red meat (beef, lamb, or liver)
    - b. No more than 250 mg vitamin C a day from supplements, and citrus fruits and juices. An average orange contains approximately 70-75 mg vitamin C. One hundred percent of the recommended daily allowance of vitamin C is 60 mg.
    - c. NOTE: Some iron supplements contain vitamin C in excess of 250 mg.
- B. Taking the test on 3 different days.
  - 1. Precautions:
    - a. Do not take test if blood is visible in your stool or urine (e.g., menstruation, active hemorrhoids, urinary tract infection).

- b. Remove toilet bowl cleaners from toilet tank and flush twice before collecting stool.
- c. For best results, prevent stool from contacting toilet water. Other clean, dry containers may be used if desired.
- d. Protect Test Card from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, and household cleaners).

2. Test Steps:

- a. **STEP 1:** Write your name, ID# (if known), and physician's name on front of Test Card.
- b. **STEP 2:** Fill in Day 1 Collection Date. Open Day 1 flap.
- c. **STEP 3:** Urinate before bowel movement, if possible. Collect stool using one of the following options:
  - i. Tissue + Plastic Wrap (preferred)
    - Flush toilet.
    - Obtain 2 foot piece of plastic wrap (not included).
    - Lift lid and seat of toilet.
    - Secure plastic wrap across back half of bowl, allowing middle to hang down just above water.
    - Unfold tissue (provided) halfway. Place on top of plastic wrap.
    - Lower seat.
    - Have a bowel movement.
  - ii. Tissue Alone
    - Flush toilet.
    - Unfold tissue (provided) completely.
    - Float tissue on surface of water.
    - Allow edges to stick to sides of bowl.
    - Have a bowel movement.
- d. **STEP 4:** Obtain a small stool sample with provided Applicator Stick. Apply thin smear in box A.
- e. **STEP 5:** Reuse Applicator Stick to obtain a 2nd sample from a different part of stool. Apply thin smear in box B. Flush tissue and stool ONLY. Discard stick and plastic wrap (if used) in waste container.
- f. **STEP 6:** Close flap. Store Test Card in the patient kit envelope. Let dry. Do not store smeared Test Card in any moisture-proof material (e.g., plastic bag).
- g. **STEP 7:** Repeat steps through for Day 2 and Day 3.

C. Returning the test.

**Note: Current U.S Postal Regulations prohibit mailing completed Test Cards in any standard paper envelope. Use the Mailing Pouch provided in Patient Screening Kit.**

- 1. Insert completed and overnight air-dried Test Card into enclosed U.S. Postal Service approved mailing pouch.

2. Peel tape from flap. Fold flap over. Press firmly to seal.
3. Deliver or mail sealed Mailing Pouch to your physician or laboratory within 10 days of Day 1 Collection Date.

## Specimen Collection & Preparation:

- A. The Hemoccult II® SENSE® elite test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemoccult II® SENSE® elite Test Card as a THIN SMEAR using the Applicator Stick provided.
- B. Slides containing samples may be stored for up to 14 days at room temperature (15 to 30°C) before developing.
- C. Patients should be instructed to return completed Slides (Test Cards) to the physician or laboratory after preparing the last test and according to the patient instructions.
- D. IMPORTANT NOTE: Current U.S. Postal Regulations prohibit mailing completed slides in standard paper envelopes. Physicians who wish their patients to return Slides by mail must instruct them to use only the U.S. Postal Service approved Mailing Pouch provided in the patient kit.
- E. Fecal specimens should be collected from bowel movements on three (3) different days. To further increase the probability of detecting occult blood, separate samples should be taken from two (2) different areas of each fecal specimen.

## Interfering Substances:

In general, patients should be carefully instructed to not ingest foods, vitamins or medications which can cause false-positive or false-negative test results.

- A. Substances which can cause false-positive test results:
  1. Red meat (beef, lamb and liver)
  2. Aspirin (gr eater than 325 mg/day) and other non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin and naproxen
  3. Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, and cancer chemotherapeutic drugs
  4. Alcohol in excess
  5. The application of antiseptic preparations containing iodine (povidone/iodine mixture)
  6. Dietary iron supplements will NOT produce false-positive test results with Hemoccult II® SENSE® elite tests
  7. Acetaminophen is NOT expected to affect test results
- B. Substances which can cause false-negative test results:
  1. Ascorbic acid (vitamin C) in excess of 250 mg per day
  2. Excessive amounts of vitamin C enriched foods, citrus fruits and juices
  3. Iron supplements which contain quantities of vitamin C in excess of 250 mg per day

# Patient Test Development Procedure:

## A. Precautions:

1. Slides are best developed no sooner than three days after sample application to allow for degradation of fruit and vegetable peroxidases that may be present in the fecal sample.
2. If immediate developing is required, wait 3-5 minutes to allow the sample to penetrate the guaiac paper.
3. **Always develop the test, read the results, interpret them, and decide whether the fecal specimen is positive or negative for occult blood BEFORE developing the Performance Monitor®.**
4. Any blue originating from the positive Performance Monitor® should be ignored when reading the sample test results.

## B. Developing the Test

1. Open large back flap of Test Card to expose all six fecal smears.
2. Apply **two drops** of Hemocult® SENSE® Developer to guaiac paper directly over each smear.
3. **Read and interpret results within 60 seconds.**
4. Any trace of blue on or at the edge of any smear is positive for occult blood.

## C. Developing the Performance Monitor (Internal Quality Control):

1. The Performance Monitor® provides an internal control for the entire Slide and must be developed on every Test Card.
2. Apply **one drop** of Hemocult® SENSE® Developer between the positive and negative Performance Monitor.
3. **Read results within 10 seconds.** If the Test Card and Developer are functional, a blue color will appear in the positive Performance Monitor and no blue will appear in the negative Performance Monitor.
4. Neither the intensity nor the shade of the blue from the positive Performance Monitor should be used as a reference for the appearance of positive test results. Any blue originating from the positive Performance Monitor should be ignored when reading the sample test results.

## D. Reporting Test Results:

1. Document patient test results in the Electronic Medical Record.
2. Document results of the Performance Monitor in the Electronic Medical Record.

# Interpretation of Patient Test Results

- A. **Positive Result-** Any trace of blue or blue/green on or at the edge of the smear should be interpreted as positive for occult blood.
- B. **Negative Result-** A distinct brown or green color (no blue) on or at the edge of the smear should be interpreted as negative for occult blood.
- C. **Invalid Result-** If a blue color fails to appear in the positive Performance Monitor and/or a blue color does appear in the negative Performance Monitor, test results should be considered invalid. Do NOT proceed to patient testing if the Performance Monitor results are unacceptable.

# Quality Control (QC) Test Procedures:

A. **Quality Control Test Frequency:** An external quality control test will be run when opening a new box of test cards or new bottle of developer and every thirty days on open boxes/bottles to verify test performance.

B. **Quality Control Test Procedure:**

1. **STEP 1:** Remove a slide from the box and open the back of the card.
2. **STEP 2:** Apply one drop of developer between the positive and negative Performance Monitor areas.
3. **STEP 3:** Interpret results within 10 seconds.
  - a. A blue color should appear in the positive location of the Performance Monitor.
  - b. No color should appear in the negative location of the Performance Monitor.

C. **Quality Control Test Results:**

1. **Positive-** A Blue color should appear in the positive location of the Performance Monitor.
2. **Negative-** No color should appear in the negative location of the Performance Monitor.

DO NOT proceed to patient testing if the Performance Monitor results are unacceptable.

## Limitations:

- A. Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. Also, blood, if present, may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.
- B. Conversely, a Hemoccult II® SENSE® elite test result may be positive on specimens from healthy patients. This may be due to interfering substances in the diet or to medications. It may also be due to low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease.
- C. Therefore, as with any occult blood test, results with the Hemoccult II® SENSE® elite test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult II® SENSE® elite tests are designed for preliminary screening as an aid to diagnosis. They are not intended to replace other diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema, or other x-ray studies.
- D. The Hemoccult II® SENSE® elite test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. Interfering factors, such as low pH, high drug concentrations, metal ions or plant peroxidase in food, may affect the function of guaiac-based occult blood tests.
- E. Addition of a drop of water (rehydration) to the guaiac test card prior to the addition of the developer increases the sensitivity of the test, but also increases the number of false-positive test results. For this reason, rehydration is not a recommended procedure for the Hemoccult II® SENSE® elite test.

# Performance Characteristics:

Refer to Manufacturer's Instructions for Use (Attachment).

## Reference(s):

Hemoccult II® SENSEA® Instructions for Use, November 2009.

All revision dates:

### Attachments

 [Hemoccult II SENSEA\\_Instructions for Use.pdf](#)

### Approval Signatures

Step Description	Approver	Date
MEC/Oversight	Stephanie Denson: Manager, Medical Staff Office	pending
Associate Hospital Administrator- Ancillary Services	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	10/3/2025
Medical Director Laboratory Services	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
AC Chief Medical Officer	Allison Blaze: Chief Medical Officer, Ambulatory Care	11/19/2024
AC Director of Nursing	Cynthia Fenton: AC Director of Nursing	8/30/2024
Director Laboratory Services	Erlinda Roxas: Director, Laboratory Services	8/8/2024



Origination: N/A  
Effective: Upon Approval  
Last Approved: N/A  
Last Revised: N/A  
Next Review: 3 years after approval  
Owner: Erlinda Roxas: Director,  
Laboratory Services  
Policy Area: Ambulatory Care- Point of Care  
Testing  
References:

## L.63- OSOM® Ultra Strep A Test

### Intended Use:

The OSOM® Ultra Strep A Test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens.

### Summary & Explanation of Test:

Group A Streptococcus is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis. Conventional identification procedures for Group A Streptococcus from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 18 to 24 hours or longer. The OSOM® Ultra Strep A Test detects either viable or nonviable organisms directly from a throat swab, providing results within 7 minutes.

### Principles of Test:

The OSOM® Ultra Strep A Test is a color immunochromatographic assay using Dual Label Technology (DLT). DLT uses antibody labeled color particles coated at two separate locations in the test device. DLT allows greater sensitivity than the conventional single label technology without sacrificing specificity. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result. A red Control Line will also appear to indicate the test is valid.

### Performed By:

Rapid strep testing may be performed by Ambulatory Care Clinic staff who have successfully completed the OSOM® Ultra Strep A Test competency training activities and evaluations, including Registered Nurses, Licensed Vocational Nurses, and Medical Assistants.

### Required Materials:

- A. Included in Test Kit



1. Test Stick
2. Extraction Reagent Bottles
3. Test Tubes
4. Positive/Negatives Control
5. Throat Swabs

B. Not Included in Test Kit

1. Disposable Gloves (optional mask and face shield)
2. Quality Control (QC) log
3. Timer or Watch
4. Tongue Depressor

## Storage & Handling:

- A. Store test sticks, reagents and controls tightly capped at 15° – 30°C (59° – 86°F).
- B. Do not use test kit materials after listed expiration date.

## Precautions:

- A. For in vitro diagnostic use only.
- B. Follow standard precautions during the collection, handling, storage and disposal of controls, patient specimens and all items exposed to patient specimens.
- C. Caution: The Reagent A contains Sodium Nitrite and may be harmful if swallowed. Do not taste or swallow. Wash thoroughly after handling.
- D. The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control material down a sink.
- E. Do not interchange or mix components from different kit lots.

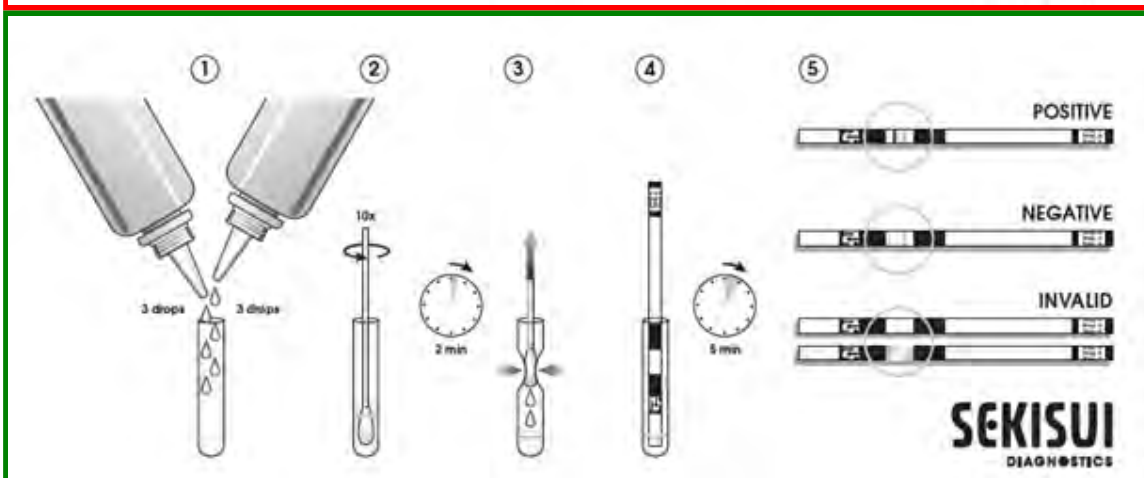
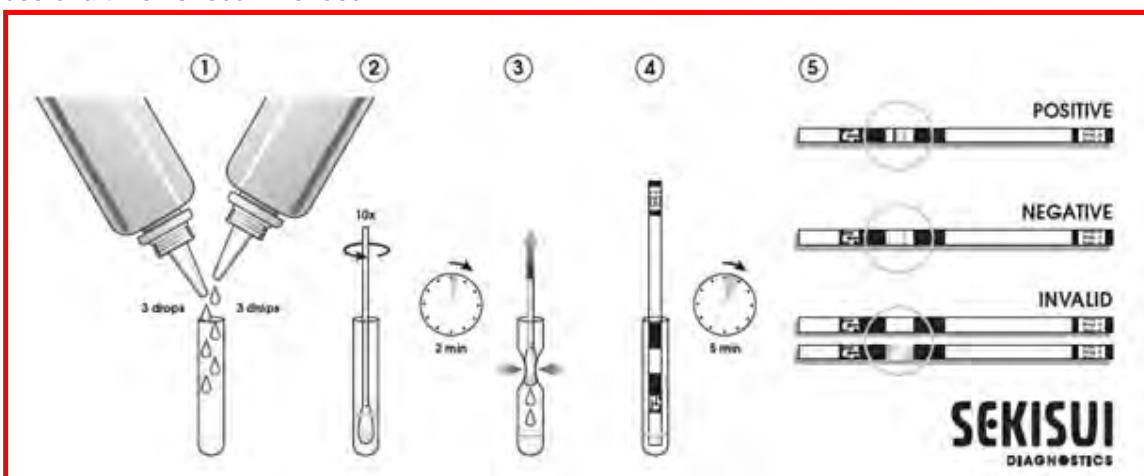
## Specimen Collection & Preparation:

- A. Collect specimens with a sterile swab from the tonsils and/or the back of the throat taking care to avoid the teeth, gums, tongue or cheek surfaces.
  1. Do not use swabs with cotton tips, wooden shafts or calcium alginate swabs.
  2. Do not use a collection system that contains charcoal or semisolid transport media.
- B. For pediatric patients (age 17 and below) requiring a culture result as well as the OSOM® Ultra Strep A Test result, streak the culture plate with the swab before starting the OSOM® Ultra Strep A Test procedure as the extraction reagents will cause the specimen to become nonviable.
- C. Process the swab as soon as possible after collecting the specimen. If you do not perform the OSOM® Ultra Strep A Test immediately, store the swabs either at room temperature or refrigerated for up to 48 hours. The swabs and the test kit must be at room temperature prior to running the test.
- D. Because the performance characteristics of this product were established with the sterile rayon swabs supplied with the kit, use of these swabs is recommend to assure optimal performance. Because the test

does not require live organisms for processing, a rayon transport swab containing Stuart's or Amies media may also be used; however, swabs from other suppliers have not been validated.

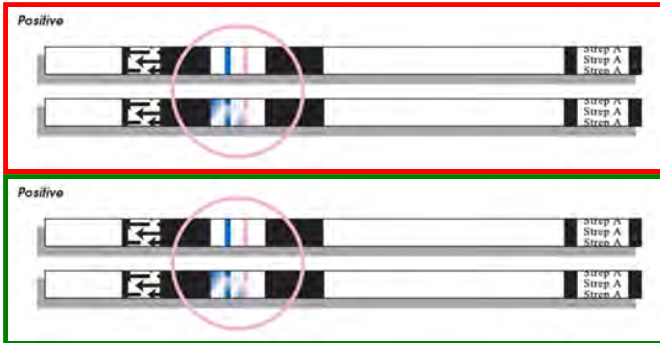
## Test Procedure:

- A. **STEP 1:** Just before testing, add **3 drops** Reagent A (pink) and **3 drops** Reagent B to the Test Tube (the solution should turn light yellow).
- B. **STEP 2:** Immediately put the swab into the Tube. Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten **(10) times**. Best results are obtained when the specimen is vigorously extracted in the solution.  
**Let stand for 2 minutes.**
- C. **STEP 3:** Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.  
Discard the swab.
- D. **STEP 4:** Remove the Test Stick(s) from the container; re-cap the container immediately. Place the Absorbent End of the Test Stick into the extracted sample.
- E. **STEP 5:** Read results at **5 minutes**. Positive results may be read as soon as the red Control Line appears. Negative results must be confirmed at 5 minutes. Results are invalid after the read time. The use of a timer is recommended.



# Interpretation of Test Results:

- A. **POSITIVE**- A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen. Note that the blue line can be any shade of blue and can be lighter or darker than the line in the picture.



- B. **NEGATIVE**- A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.



- C. **INVALID**- If after 5 minutes, no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test using a new sample or contact Sekisui Diagnostics Technical Service.



Note: A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; as long as the Test Line and Control Line are visible, the results are valid.

## Reporting Test Results:

- A. **Positive Group A Strep Test:** A positive result will be reported as 'Positive for Group A Strep' for pediatric and adult patients.
- B. **Negative Group A Strep Test:**
1. Adult Patients (age 18 and older): A negative result will be reported for adults as 'Negative for Group A Strep' and testing is complete.

2. Pediatric Patients (age 17 and below): A negative result will be reported as 'Negative by screening method with culture to follow'. A negative pediatric direct antigen test must have a confirmatory throat culture done by the laboratory.

C. Document patient test results in the Electronic Medical Record.

- D. Do not report test results if the test strip has an invalid result or if the test stick read time has exceeded 5 minutes.

## Quality Control (QC) Test Procedures:

A. **Internal Procedural Controls-** The OSOM Ultra Strep A Test provides three levels of procedural controls with each test run:

1. The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
2. The red Control Line is an internal positive procedural control. For the Test Stick to be working properly, capillary flow must occur. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear.
3. A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background will clear. A discernible result will be seen. If the red Control Line does not appear the test is invalid. If the background does not clear and interferes with the test result, the test is invalid. Call Sekisui Diagnostics Technical Service if you experience either of these problems.

B. **External Quality Control Testing**

1. Quality Control Test Frequency: Positive and Negative controls will be run when opening a new box of test kits and every thirty days on open boxes to verify test performance.
2. Quality Control Test Procedure:
  - a. Follow Step 1 in the TEST PROCEDURE section to dispense Reagent A and B into the Test Tube.
  - b. Vigorously mix the Positive Control material. Add **1 drop** of the Positive Control from the dropper bottle into the Test Tube.
  - c. Place a clean swab into the Test Tube.
  - d. Follow the Steps 3 – 5 in the TEST PROCEDURE section to test the swab.
  - e. Repeat with Negative Control.
3. Quality Control Test Results:
  - a. Positive controls must test positive on the OSOM® Ultra Strep A Test.
  - b. Negative controls must test negative on the OSOM® Ultra Strep A Test.
  - c. Record quality control test results on the OSOM® Ultra Strep Monthly Quality Control Test Log.

## Limitations:

As with all diagnostic assays, the results obtained by this test yield data that must be used only as an adjunct

to other information available to the physician. The following factors must be considered to obtain reliable results:

- A. The OSOM® Ultra Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test detects both viable and non-viable Group A Streptococci, and may yield a positive result in the absence of living organisms.
- B. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained. Negative results can occur from inadequate specimen collection or antigen level which is below the detection limit of the test.
- C. The OSOM® Ultra Strep A Test should be used only with throat swab specimens. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established.
- D. This test does not differentiate between carriers and acute infection.
- E. Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.(1,2)
- F. If the test result is inconsistent with the clinical symptoms, a second throat swab should be collected for repeat testing.

Note: The *American Academy of Pediatrics* states: "Several rapid diagnostic tests for GAS pharyngitis are available. The specificities of these tests generally are very high, but the reported sensitivities vary considerably. As with throat cultures, the accuracy of these tests is most dependent on the quality of the throat swab specimen, which must contain pharyngeal and tonsillar secretions, and on the experience of the person who is performing the test. Therefore, when a patient suspected of having GAS pharyngitis has a negative rapid streptococcal test, a throat culture should be obtained to ensure that the patient does not have GAS infection." It also states: "Cultures that are negative for GAS infection after 24 hours should be incubated for a second day to optimize isolation of GAS."

## Performance Characteristics:

Refer to Manufacturer's Instruction for Use (Attachment).

## Reference(s):

OSOM® Ultra Strep A Package Insert 3101-1, December 2012

All revision dates:

### Attachments

 [OSOM Ultra Strep A\\_Instructions for Use.pdf](#)

### Approval Signatures

Step Description	Approver	Date
MEC/Oversight	Stephanie Denson: Manager, Medical Staff Office	pending
Associate Hospital	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	10/3/2025

Step Description	Approver	Date
Administrator- Ancillary Services		
Medical Director Laboratory Services	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
AC Chief Medical Officer	Allison Blaze: Chief Medical Officer, Ambulatory Care	11/19/2024
AC Director of Nursing	Cynthia Fenton: AC Director of Nursing	8/30/2024
Director Laboratory Services	Erlinda Roxas: Director, Laboratory Services	8/8/2024



**Origination:** N/A  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** N/A  
**Next Review:** 2 years after approval  
**Owner:** Erlinda Roxas: Director,  
Laboratory Services  
**Policy Area:** Laboratory Services  
**References:**

## L.POC.55 Hemoccult Fecal Occult Blood Test

### PURPOSE

- A. To establish guidelines for Hemoccult test as a rapid, convenient and virtually odorless qualitative method for detecting fecal occult blood, this may be indicative of gastrointestinal disease. It is not a test for colorectal cancer or any other specific disease.
  1. To define the nature of laboratory testing that may be personally performed by physicians within their scope of clinical practice. Patient management is often facilitated by immediate and direct physician performance of certain laboratory tests at the time of a patient encounter.
  2. Physicians are authorized to perform both waived tests under CLIA'88, Provider Performed Tests (PPT), and Provider Performed Microscopy (PPM) procedures.
    - a. Physician Performed Testing (PPT) is defined as testing that is personally performed by a physician in conjunction with the physical examination or treatment of a patient.
- B. To define an effective quality management program to include:
  1. Quality control reagents/materials
  2. Review and corrective action of quality control and/or reagent failure
  3. Inventory management
    - a. Quality control is performed on each new lot or shipment of Hemoccult kits.
    - b. Quality control is performed according to manufacturer's instructions.
    - c. Quality control records are retained in the Point-of-Care Testing in the Laboratory for 3 years.

### POLICIES

- A. Hemoccult test shall be used by physicians as a preliminary screening as an aid to diagnosis.
- B. Testing shall be performed by the physician, mid-level ~~healthcare~~ health care providers (physician assistants and nurse practitioners) with documented initial training, ~~6-month~~, and annual competency assessments.
  1. Validation of competency among physicians is the responsibility of Medical Staff Credentialing Office.
  2. Competency to the specific tests performed by the physicians will be assessed using external proficiency testing samples or blind testing samples and direct observation of occult blood testing.

- C. It is the physician's responsibility to provide proof of competency to the Medical Staff Credentialing Office.
- D. Proficiency testing and skills assessment is required of all testing personnel.
- E. Test results on specific test performed by the physicians are documented in the Fecal Occult Blood Test Workflow in the Hospital Information System.
- F. This test should not be interpreted by individual with blue color blindness because it is visually read and requires color differentiation.

## EQUIPMENT/MATERIALS NEEDED

- A. Hemocult® Card - Store at room temperature and under low light conditions.
  - 1. DO NOT REFRIGERATE.
- B. Hemocult® developer- Store at room temperature and under low light conditions
- C. Applicator sticks
- D. Biohazard container
- E. Disposable gloves
- F. Stool sample from the patient

## PROCEDURE

- A. Quality Control Test
  - 1. Run controls with each batch of patient tests (as in procedure below).
  - 2. Gather patient's sample, reagent and kit.
  - 3. Identify patient sample to be tested. Label test kit with patient's name and medical record number.
  - 4. Apply this smear of fecal sample on Box A + B.
  - 5. Wait 3-5 minutes before developing.
  - 6. Apply 2 drops of Hemocult developer to guiac paper directly over each smear.
  - 7. Read results within 60 seconds.
  - 8. Apply one drop of Hemocult developer between the positive and negative performance uniform areas.
  - 9. Read results within 10 seconds. If the slide and developer are functional:
    - a. Blue color will appear in the positive Performance Monitor area
    - b. No blue color will appear in the negative Performance Monitor area

## INTERPRETATION OF RESULTS

- A. **Negative:** No blue color develops (green is negative)
- B. **Positive:** Any amount of blue diffusing into the paper around the patient sample within 60 seconds.

## REPORTING

Copy the following to a drago auto-text or include the information in notes section:



- Patient Result []
- Hemocult Card QC Result []
- Test Slide Lot Number []
- Test Slide Exp Date []
- Developer Lot Number []
- Developer Expiration Date []

All revision dates:

## Attachments

-  [FECAL OCCULT BLOOD COMPETENCY CHECKLIST.docx](#)
-  [Hemocult.pptx](#)
-  [Hemoocult-1\\_2-product-instructions.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	9/6/2025



**Origination:** 6/1/1986  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** 10/6/2025  
**Next Review:** 3 years after approval  
**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** OB Nursing  
**References:**

## MCH.43 Hepatitis B Prevention in Newborns

### POLICY:

To prevent chronic hepatitis B in all infants born to mother acutely or chronically infected with hepatitis B virus.

To reduce the incidence of perinatal hepatitis B transmission, all newborn infants with a birth weight of greater than or equal to 2000 grams shall receive hepatitis B vaccine by 24 hours of age. To further reduce Hepatitis B transmission, Hepatitis B vaccine and hepatitis B Immune Globulin (HBIG) will be given per ~~Centers for Disease Control and Prevention~~ California Department of Public Health (CDC CDPH) protocol to all infants whose mothers are known to be hepatitis B surface antigen (HB<sub>s</sub>Ag) positive, HB<sub>s</sub>Ag status unknown, or if the mother is known to be at high risk, which may include those who are victims of sexual assault, current history of drug use, history of multiple sex partners, liver disease, deferred blood donor.

### PROCEDURE:

#### A. Identify maternal hepatitis B status:

1. Look up hepatitis B surface antigen (HBsAg) on prenatal records or under current lab results in Electronic Health Record (EHR) system.
2. Mothers identified as HBsAg positive have babies that require prompt treatment.
3. Mothers whose status is unknown should have HBsAg testing immediately on admission.
4. Mothers with no prenatal care shall have HBsAg drawn and shall be identified as HBsAg unknown until lab results are determined.

#### B. Treat baby according to maternal HBsAg status and weight in grams:

1. For all infants born to HBsAg positive mothers:
  - a. Administer hepatitis B vaccine and HBIG within 12 hours of birth. These should be administered in opposite legs.
  - b. Request HBIG from pharmacy
  - c. Administer HBIG in the opposite leg from the hepatitis B vaccine
2. For all infants born to HBsAg-unknown mothers:
  - a. Administer hepatitis B vaccine within 12 hours of birth and:
  - b. For infants with a birth weight greater than or equal to 2000 grams, administer HBIG by 7 days of age or by hospital discharge (whichever occurs first) if maternal HBsAg status is confirmed

positive or remains unknown.

- c. For infants with a birth weight less than 2000 grams, administer HBIG by 12 hours of birth unless maternal HBsAg status is confirmed negative by that time.
3. For all infants with a birth weight greater than or equal to 2000 grams born to HBsAg-negative mothers:
  - a. Administer hepatitis B vaccine as a universal routine prophylaxis within 24 hours of birth, or when medically stable as determined by LIP.-
  - b. For all infants with birth weight less than 2000 grams born to HBsAg-negative mothers, administer hepatitis B vaccine as a universal prophylaxis at one month of age or at hospital discharge (whichever occurs first).

## VACCINATION ADMINISTRATION

Standards of administration of hepatitis B vaccine and HBIG vaccine.

- A. Obtain physician's order.
- B. Obtain signed consent from mother to permit infant to be vaccinated.
- C. Identify maternal HBsAg status and infant's weight and gestational age.
- D. Determine priority of when to give vaccinations according to this policy and procedure (identified above).
  1. Collect needed materials:
    - a. Hepatitis B vaccine
    - b. HBIG is obtained from the Pharmacy
    - c. Syringe and needle.
    - d. Current vaccination sheets (VIS).

## DOCUMENTATION

- A. The most current Vaccine information sheet (VIS) sheets are given to the mother when consents are needed for optional vaccinations. One VIS sheet is given to the mother and a copy is scanned into the newborns EHR. **Positive maternal HBsAg mandates immediate administration of the hepatitis B vaccine and the HBIG vaccine and does not require written consent.**
- B. Document in Cerner EHR
  1. Fill out requested information completely with baby's identification data.  
Note date, manufacturer and lot #, signature of administrator, site and VIS I.D. under appropriate headings.
  2. HBIG must be documented, if given.
- C. Initiate a Public Health referral using the Hospital Reporting Form for Perinatal Hepatitis B for positive or unknown HBsAg mothers, see attachment. (PHBPP). Ventura County Public Health Immunization program 805-981-5211 for questions.
- D. A copy of the lab result should be kept in both the mother's and infant's EHR.

## REFERENCES:

"Elimination of Perinatal Hepatitis B: Providing the First Vaccine Dose within 24 hours of Birth" Pediatrics (2017); Volume 140, Number 3

Management of Infants Born to Women with Hepatitis B Virus Infection for Pediatricians; Centers for Disease Control and Prevention; September 29,2021

Ventura County Public Health Perinatal Hepatitis B Prevention Program

All revision dates:

10/6/2025, 5/15/2024, 9/18/2020, 3/27/2018, 2/15/2018, 7/1/2016, 11/1/2013, 12/1/2010, 3/1/2009, 8/1/2004

## Attachments

-  [Hep B Screening and Referral Algorithm.pdf](#)
-  [PHBPP Newborn Report.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/8/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/4/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/4/2025
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	6/4/2025



Origination: 7/1/1999  
 Effective: Upon Approval  
 Last Approved: N/A  
 Last Revised: 7/8/2025  
 Next Review: 3 years after approval  
 Owner: Kristina Swaim: Nurse Director,  
 Maternal Child Health  
 Policy Area: NICU  
 References:

## N.67 Double-Volume and Partial-Volume Exchange Transfusion

### PURPOSE:

To guide nurses in the Neonatal Intensive Care Unit (NICU) at Ventura County Medical Center (VCMC) when assisting in the process of double-volume and partial-volume exchange transfusions.

### ~~POLICY:~~ POLICY:

~~To describe Neonatal Intensive Care Unit (NICU), Obstetrics (OB) and Pediatrics (PEDI) nursing responsibilities for the care of the newborn with hyperbilirubinemia at Ventura County Medical Center (VCMC).~~

### ~~PROCEDURE:~~

~~The nurse will evaluate and identify those newborns/neonates at high risk for hyperbilirubinemia and acute bilirubin encephalopathy.~~

~~Patients with hyperbilirubinemia may be a "direct" admit to PEDS or NICU once initial communication has occurred between the Primary Care Provider and the Pediatric hospitalist or Neonatologist at Ventura County Medical Center.~~

~~The nurse will document findings on the shift assessment and/or patient care flow sheet and report any abnormal findings to the physician.~~

~~A physician order is required to obtain serum bilirubin level, initiate phototherapy, and for exchange transfusion. Parental consent is required for exchange transfusion.~~

### ~~Risk Factors for Hyperbilirubinemia~~

- ~~A. Jaundice\* observed in the first 24 hours.~~
- ~~B. Previous jaundiced sibling who received phototherapy.~~
- ~~C. Gestation <37 weeks.~~
- ~~D. Exclusive breastfeeding with excessive weight loss.~~
- ~~E. Mediterranean or Asian descent.~~

~~F. Significant bruising and/or cephalohematoma~~

~~G. Maternal/fetal blood incompatibility~~

~~\* Jaundice is a yellowing of the skin and subcutaneous tissue that progresses in a cephalocaudal direction (from head to the trunk).~~

## **GUIDELINES:**

~~A. Assess the infant every four (4) hours for the following:~~

- ~~1. Color of skin, sclera, or mucosa for degree of jaundice~~
- ~~2. Weigh diapers and check for urine color/concentration~~
- ~~3. Feeding pattern/volume~~
- ~~4. Apnea~~
- ~~5. Temperature instability~~
- ~~6. Muscle tone~~
- ~~7. Amount, color, and consistency of stool~~

~~B. Assessment for signs and symptoms of Acute Bilirubin encephalopathy~~

- ~~1. Vomiting~~
- ~~2. Lethargy~~
- ~~3. High-pitched cry~~
- ~~4. Hypotonia/hypertonia~~
- ~~5. Opisthotonos~~
- ~~6. Apnea~~
- ~~7. Seizures~~
- ~~8. Deafness~~

~~C. Measure TCB every 12 hours in infants greater than 35 weeks gestation for jaundice by using the Transcutaneous Bili Meter (TCB) (JM-103 or JM-105). This is to be done at 0800 and 2000 in the couplet care units.~~

~~D. Validate cord blood work up for type/RH if mother's blood type is O, RH negative, or unknown.~~

~~E. **Cord Bilirubin Management**~~

- ~~1. <1.5 mg/dL= Check serum bilirubin at twelve (12) hours of life notify primary physician~~
- ~~2. 1.5-2.4 mg/dL=Check serum bilirubin at eight (8) hours of life notify primary physician~~
- ~~3. 2.5-3.4 mg/dL=Check serum bilirubin at six (6) hours of life notify primary physician~~
- ~~4. >3.5 mg/dL=Check serum bilirubin immediately, notify primary physician and consult with NICU~~

~~F. Draw blood sample for serum bilirubin as ordered by physician.~~

~~G. Managing Bilirubin on the Bhutani Curve (nomogram)~~

- ~~1. Each TCB measurment is to be plotted on the nomogram according to the age of the infant (in hours)~~

2. If at any time the TCB measurement falls into the high intermediate or high risk zone, consult with physician to have a total bilirubin level drawn.
  3. Plot the serum total bilirubin level on the nomogram according to the age of the infant (in hours).
  4. ~~When the risk level falls in the high intermediate or high risk zone. Serum total bilirubin levels plotted in the high risk zone are considered a "critical value".~~
- H. If serum total bilirubin risk level is in the high intermediate zone, consider an order for phototherapy and/or neonatal consult for potential NICU transfer.
- I. Collaborate with physician regarding:
1. Increasing frequency and/or amount of feeding
  2. Request Lactation Consultation
  3. Breast feeding with supplementation as needed
- J. Report to physician when jaundice is noted, especially in conjunction with:
1. Dark colored, concentrated urine
  2. Poor oral feedings
  3. Lethargy, hypotonia
  4. Delay in meconium passage or infrequent stools
  5. Positive Coombs' tests on cord blood (with or without a blood total bilirubin)
  6. Elevated and/or rising Total Serum Bilirubin results

## ~~Use of the transcutaneous bilimeter (JM-105 Jaundice Meter)~~

### ~~A. Indications for Use~~

1. ~~Jaundice meter is to be used on infants >35 weeks gestation pre phototherapy.~~
2. ~~Jaundice meter is **not** to be used on infants for whom phototherapy treatments have been initiated or that have undergone an exchange transfusion.~~

### **Note**

~~The JM-103 and the JM-105 are intended to be a "sequential use" screening device seeking to offer measurement of TCB changes occurring to the infant as hyperbilirubinemia progresses. Documentation of these consecutive readings provides a trend of what is happening with the infant.~~

### ~~B. Procedure~~

1. ~~See manufacturer's instructions on the use and calibration checker of the transcutaneous bilimeter.~~

### ~~C. Set-Up~~

1. ~~The JM-105 allows the Clinician to perform either a single measurement or to take an average reading from 1-5 samples (meter is set for 3 consecutive readings).~~
2. ~~For a single measurement, no setup is required and upon power up the screen will read N-1. VCMC/SPH will do a measurement every 12 hours.~~

### ~~D. Operation~~

1. A TCB measurement will be done at 0800 and 2000 on all newborns over the age of 12 hours.
2. The sternum is the preferred site used for obtaining all measurements.

#### Note

The JM-105 measurement displayed is a "calculated" bilirubin concentration. It may be different from a total serum lab analysis (TSB). Statistical data has shown that the JM-105 is usually within  $\pm 1$  standard deviation (1.5 mg/dl) and 80-90% of the time within 2 standard deviations of the TSB value.

#### E. Cleaning

1. Between each infant, wipe down the measuring probe with Sani-wipes.
2. The calibration checker should also be cleaned with Sani-wipes.

## PHOTOTHERAPY:

- A. Collaborate with physician regarding the need for phototherapy if Total Bill is  $>6$  mg/dL in the first 12-24 hours or  $>12-15$  mg/dL any time after 24-48 hours. Physician order required for phototherapy.
- B. Four types of phototherapy are currently available: overhead bank lights, the spotlight, the bili-blanket and the bili-bed. The type of light to be chosen is dependent on the needs of the infant and the availability of the unit. The nurse may consult with the physician or use the following general guidelines to determine the type of light:
  1. **Bili-bed** to be used only in an open crib with infants over 1800 grams. May be used in mother's room. Eye protection is provided via special bunting.
  2. **Bili-blanket** may be used in any type bed. Often chosen as the second light when increased phototherapy intensity is needed. May be used in mother's room. Must be used with eye protectors unless swaddled within infant's blankets.
  3. **Spotlight** (portable or attached to radiant warmer) used with isolette or warmer isolation or in combination with other modalities of phototherapy. Must be used with eye protection.
  4. **Overhead bank bili-lights** may be used in any bed. If used in open crib, infant must weigh over 3 kgs and be able to maintain stable temperature. Must be used with eye protection. Position lights 12-18 inches above infant. Use all lights as outlined in the manufacturer's equipment manual.
- C. Prepare infant as follows:
  1. **Undress** and position infant with maximum light exposure to trunk. Diapers/bikini (paper masks with nose guards removed) are optional but should be removed if serum bilirubin near exchange level. Place diaper or chux under buttocks.
  2. **Cover** eyes with bili mask/shield; close eyelids prior to applying mask and ensure proper fit to prevent occlusion of nares.
  3. **Place** in isolette or open crib under bili light.
  4. **Validate** that at least 12-18 inches is between infant and either bank light or spotlight. Ensure that all phototherapy lights are present and working.
  5. If using an incubator, there should be a minimum space of 2 inches between the incubator and the lamp to minimize overheating of the incubator.
  6. **Apply** skin temperature probe to infant as needed to regulate isolette temperature while under



~~phototherapy.~~

~~D. Assess axillary temperature every 2–3 hours.~~

~~E. Assess the following every 3–4 hours while phototherapy is in progress:~~

- ~~1. Pulse, respiration~~
- ~~2. Input/output~~
- ~~3. Stool color/consistency~~
- ~~4. Skin/pressure points for presence of rash, lesions, or redness~~
- ~~5. Eye irritation, inflammation, discharge, excessive pressure on lids, or corneal irritation.~~

~~F. Assess bili light irradiance intensity every shift as follows:~~

- ~~1. Intensive phototherapy should have irradiance  $\geq 30 \mu\text{w}/\text{cm}^2$  per nm (per AAP guidelines)~~

~~G. Monitor serum Total Bilirubin as ordered by physician. Turn bili lights off when obtaining blood specimen.~~

~~H. Collaborate with the physician regarding lab results and continued phototherapy.~~

~~I. Turn and reposition every 2–3 hours.~~

~~J. Change linen promptly if soiled.~~

~~K. Wash peri-anal area as needed and pat dry to prevent skin irritation. Do not use oils or creams on the infant's skin while under phototherapy lights.~~

~~L. Rinse eyes as needed every 8 hours with normal saline soaked cotton balls.~~

~~M. Remove infant from phototherapy for feedings, unless otherwise indicated by physician. Turn off phototherapy lights and remove eye patches for 20 minutes.~~

~~N. Maintain infant's skin/axillary temperature between 96.8° F and 98.6° F.~~

~~O. Explain procedure and equipment to parents. Assist parents to identify and express concerns and questions about hyperbilirubinemia and phototherapy.~~

~~P. Encourage parents to visit and care for infant as much as possible, including:~~

- ~~A. Feeding the infant~~
- ~~B. Holding, touching and cuddling the infant~~
- ~~C. Diapering, bathing and applying eye protection.~~

~~Q. Report the following promptly to the physician:~~

- ~~1. Total bilirubin level results~~
- ~~2. Poor feeding, vomiting/regurgitation~~
- ~~3. Excessively loose stools or absence of bowel movements~~
- ~~4. Eye irritation/inflammation (redness, swelling, discharge)~~
- ~~5. Signs of dehydration (poor skin turgor, depressed fontanels, dark concentrated urine)~~
- ~~6. Lethargy, irritability, or high pitched cry~~

## **~~EXCHANGE TRANSFUSION:~~**

~~Exchange~~ Double-volume exchange transfusion is indicated when bilirubin levels are approaching levels ~~commonly~~ associated with ~~Bilirubin~~ acute bilirubin encephalopathy. Typically in the setting of severe isoimmune hyperbilirubinemia despite phototherapy or when there is evidence of Hemolytic Disease of the Newborn (HDN) (i.e. positive direct antiglobulin test). Coordinate with physician and blood bank for exchange transfusion. Red cells and ~~plasm~~ plasma are combined to make "reconstituted whole blood." Blood products for neonates are group O Rh negative washed packed red blood cells that ~~is~~ are cytomegalovirus (CMV) negative and irradiated ~~and~~ mixed with AB plasma without any requirements. These ~~blood types avoid~~ special requirements limit any additional hemolysis.

Partial-volume exchange transfusions are performed to decrease the hematocrit and whole blood viscosity in polycythemic neonates with hyperviscosity or to increase the hematocrit in severe anemia from acute blood loss while avoiding or exacerbating Congestive Heart Failure . Infants with a venous hematocrit higher than 65% may need a partial exchange to reduce the hematocrit. An infant with a high hematocrit should be assessed for the following symptoms: lethargy and irritability; hypotonia; tremors; poor sucking ability; tachypnea; tachycardia; respiratory distress; abdominal distension; decreased bowel sounds, and poor feeding.

During hematocrit lowering partial-volume exchange, Fresh Frozen plasma (FFP) and isotonic saline have been used as replacement fluids for whole blood withdrawn. However, it has been shown that crystalloid solution is just as effective in decreasing the hematocrit of neonate with polycythemia. The volume for the partial-volume exchange transfusion should be divided into 3 or 4 equal aliquots of 5-10 ml/kg, not to exceed 20 ml.

During Partial volume exchange to treat anemia: packed (high hematocrit) Red Blood Cells (RBC) are the replacement product. The volume for the treatment for anemia would be the volumes calculated to correct the anemia.

The following criteria are used to help determine the need and timing of double volume exchange transfusion:

- A. Cord blood indirect bilirubin level > 4mg/dL.
- B. Hgb < 8 g/dL and bilirubin > 6 mg/dL within one hour of delivery of a term infant.
- C. Hgb < 11.5 g/dL and bilirubin > 3.5 mg/dL within one hour of delivery of a preterm infant.
- D. Increase of bilirubin levels by 0.5 mg/dL per hour despite phototherapy.
- E. Bilirubin levels > 20 mg/dL by 24-48 hours of age in a term infant and 17-18 mg/dL in a compromised or high risk preterm infant.
- F. Total serum bilirubin levels as designated by the 2022 American Academy of Pediatrics (AAP) Hyperbilirubinemia Guidelines.
- G. Any evidence of acute bilirubin encephalopathy, per the Neonatologist evaluation.

## **PROCEDURE:**

### **PRE-TRANSFUSION PREPARATION/ASSESSMENT:**

- A. ~~Coordinate with the physician and blood bank with total volume of reconstituted product and hematocrit~~
  - 1. ~~Verify physician order for the exchange transfusion~~
  - 2. ~~Obtain blood bank and other lab samples as ordered~~
  - 3. ~~Specific blood product desired (i.e., PRBC, FFP).~~

- ~~4. Single exchange volume calculated as follows: 70-90 mL/kg for term infants and 85-110 mL/kg for preterm infants~~
- ~~5. Verify parental consent for procedure and transfusion~~
- ~~6. Verify that the "A patient's guide to blood transfusions" (Paul Gann) brochure, has been received by family. Answer any questions.~~
- ~~7. Notify blood bank technician of the procedure being done. Communicate with the technician that the series of labs that will be sent, need to be resulted in the EMR, at the time that is printed on the lab tube.~~
- ~~8. Perform Time Out procedure.~~
- ~~9. Request physician to order Calcium Gluconate 10% to be prepared, and available at bedside.~~

Coordinate with the physician and blood bank with total volume of reconstituted product and hematocrit.

1. Verify physician order for the exchange transfusion.
2. Verify patient identification.
3. Verify weight to be used for procedure.
4. Verify parental consent for procedure and transfusion.
5. Verify the "A patient's guide to blood transfusions" (Paul Gann) brochure, has been received by family. Answer any questions.
6. Ensure a minimum of one RN bedside assisting.
7. Obtain type and cross and Pre-exchange transfusion lab work per physician order. Confirm the Newborn screen has been drawn.
8. The exchange transfusion procedure will include central access typically an umbilical venous line. Infants having an exchange transfusion will also require peripheral intravenous (IV) access for maintenance fluid during and after the procedure. It is necessary to have intravenous access for medication infusion during the procedure.
9. The volume of donor blood required for the total procedure is equal to twice the calculated circulating blood volume plus volume for tubing dead space and blood warmer (approximately 50 mL). Circulating blood volume is approximately 80-100 mL/kg in full-term and 100-120 mL/kg in preterm infants.
10. To minimize blood pressure changes, blood should be withdrawn and re infused in small aliquots. Withdrawal and infusion volumes are dependent on the infant's weight
  - a. Less than 1000 grams = 3-5 mL
  - b. 1000 - 2000 grams = 5-10 mL
  - c. 2001 - 3000 grams = 15 mL
  - d. Greater than 3000 gram = 20 mL every 3 minutes.
  - e. Notify blood bank of Neonatal exchange transfusion. Review specific blood product desired (i.e. combined pRBC and FFP). Blood used in an exchange transfusion should be as fresh as possible; preferably less than 5 days old. Review the volume required for the procedure.
    - i. Provide blood bank infant's and Mother's information (Names, MRNs, date of births)
    - ii. pRBC will be mixed with FFP by Blood Bank to desired hematocrit concentration typical

goal of 40% for double volume exchange transfusion. Severe anemia would target a much higher hematocrit, typically 55%.

iii. Release prepare order of RBC's; FFP's in electronic health record (EHR).

11. Request physician to order Calcium Gluconate to be prepared by Pharmacy in syringes, and available at bedside due to hypocalcemia. Signs and symptoms of hypocalcemia is neuromuscular hyperactivity, muscle twitching and convulsions may prompt a higher dose of Calcium Gluconate. Monitor for cardiac dysrhythmias particularly in QRS complex.

**B. Prepare the infant**

1. Ensure infant is NPO 4 hours before exchange, during exchange and for 4 hours after exchange.
  - ~~a. If the infant has been fed in the last 2 hours (review with provider) insert a nasogastric tube to empty stomach.~~
  - a. If the infant has been fed in the last 2 hours (review with provider) insert a nasogastric tube and empty stomach. Obtain a glucose level prior to, during as needed, and after the procedure. Both Hypoglycemia and hyperglycemia are a complication of a double -volume exchange transfusion. Monitor the infant for signs and symptoms of feeding intolerance or gastrointestinal bleeding after the exchange transfusion to reduce the risk of necrotizing enterocolitis.
2. Place the infant on a radiant warmer with temperature probe in place; appropriate cardiorespiratory monitor and a pulse oximeter with the alarms set appropriately for continuous monitoring during the exchange procedure.
3. Place a blood pressure cuff on the infant's upper extremity and connect to the monitor for repeated blood pressure assessments at set time intervals (e.g. every 5 minutes).
4. ~~Restrain the infant for the procedure with~~ Apply soft four limb restraints, as needed. Attempt to maintain a position of physiological flexion, if possible, and monitor the infant's extremities.
5. Labs will usually be collected either before the exchange transfusion begins or on the sample obtained from the first draw of the exchange. Labs may be ordered according to the infant's condition by Medical Provider which may be considered but not limited to the following: complete blood count with platelets (central source); electrolytes, calcium, glucose; blood gas; bilirubin; and coagulation panel.
6. Review results of pre-procedure lab tests.

**C. ~~Gather equipment:~~**

- ~~1. Exchange Transfusion Tray~~
- ~~2. Umbilical Catheterization Tray~~
- ~~3. Umbilical Catheters (per Physician's request)~~
- ~~4. Blood Warmer and blood warming coil~~
- ~~5. Sterile gown, gloves, cap and mask~~
- ~~6. Four limb restraints~~
- ~~7. Additional syringes (for Lab work or arterial blood gases)~~
- ~~8. Exchange transfusion log~~

**EQUIPMENT:**

1. Sterile disposable Exchange Transfusion Tray

2. Sterile drapes
3. Signed consent for blood transfusion and exchange transfusion
4. Order for type and screen and blood products
5. Blood administration tubing with filter (in exchange transfusion tray) and IV pole
6. Blood Warmer and designated tubing (See attachment HOT LINE BLOOD WARMER -Set up)
7. Ordered blood product and blood bank documentation
8. Radiant warmer bed
9. Cardiopulmonary and pulse oximetry monitor with cables and attachments
10. Emergency equipment with medications: oxygen source with suction equipment
11. Umbilical Catheterization Tray with sterile drapes
12. Umbilical Catheters (per Physician's request)
13. Hospital approved disinfectant with sterile water or normal saline to remove disinfectant
14. Sterile gown, gloves, cap and mask
15. Four limb soft restraints with soft Posey immobilizer
16. Additional syringes (for Lab work or arterial blood gases)
17. NICU Exchange transfusion Record and log Form
18. Point of care glucose meter and supplies
19. Informed consent form
20. Lab tubes

#### D. Prepare for Emergency

1. Validate that the resuscitation equipment is at the bedside and function properly including bag/mask, suction equipment, and an oxygen source.
2. Have resuscitation fluids as ordered by ~~practitioner~~neonatologist available (for example ~~Albumin 5% and Normal Saline~~ 0.9% Sodium Chloride).
3. ~~Have prepared syringes or 2 vials of Calcium Gluconate 10% at bedside. Dilute Calcium Gluconate 10% to 50mg/ml. Have physician ordered and pharmacy prepared Calcium gluconate syringes at bedside.~~

#### E. Double check the blood product with another registered nurse (RN) or physician as outlined in the Blood transfusions and Blood Bank regulations Administrative policy. If blood cannot be hung within 30 minutes, it needs to be returned to Blood Bank. Blood is not to be stored in the NICU.

1. Utilize the blood warmer per the equipment product manual. The RN must ensure that the temperature on the blood warmer is according to manufacturer instructions. Attach blood to blood filter and warming cassette, hang from blood warmer. Ensure discard tubing is secured in discard bag.

## DURING THE EXCHANGE TRANSFUSION:

#### A. ~~Monitor the infant's vital signs as follows:~~

1. ~~Prior to transfusion~~

- ~~2. Every 5-10 minutes or as designated on the Exchange Transfusion Log Sheet or ordered by the physician~~
- ~~3. Notify the physician immediately if signs and symptoms of hypocalcemia are present such as: change in the QT interval, agitation, tachycardia, or muscle twitching.~~
- ~~B. Gently agitate the blood bag every 15 minutes to prevent red blood cell sedimentation.~~
- ~~C. Record the blood volume in and out, the vital signs, the SpO<sub>2</sub>, and any lab work done on the Exchange Transfusion Log during procedure.~~
  - ~~1. The blood volume infused and phlebotomized~~
  - ~~2. The vital signs and SpO<sub>2</sub>~~
  - ~~3. Lab work sent~~
  - ~~4. Lab results~~
  - ~~5. Medications given~~
- ~~D. Collaborate with the physician every 30 minutes during the exchange regarding the need for blood glucose, electrolytes or arterial blood gas (ABG) sampling.~~
- ~~E. Provide pacifier and oral sucrose for comfort and pain management.~~
- A. Perform Time-Out procedure. Assist physician in placing umbilical venous and arterial catheters.
- B. Monitor the infant's vital signs as follows:
  1. Prior to transfusion.
  2. Every 5-10 minutes or as designated on the Exchange Transfusion Log Sheet or ordered by the physician.
  3. Notify the physician immediately if signs and symptoms of hypocalcemia are present such as: change in the QT interval, agitation, tachycardia, or muscle twitching.
- C. For hyperbilirubinemia or anemia treatment: Using the blood administration set provided in the blood exchange tray; spike the unit of blood while ensuring the roller clamp remains closed. Hang blood bag. Gently agitate the blood bag every 15 minutes to prevent red blood cell sedimentation. (See attachment Hot line blood warmer set up).
- D. Set up fluid warmer according to directions. Attach end of blood administration set to the fluid warmer tubing, being mindful to maintain the sterility of the end of the fluid warmer tubing that connects to the patient so it can be passed to the physician.
- E. Prime blood administration set and fluid warmer tubing with blood. Insert attachment on the fluid warmer tubing into the fluid warmer's machine. Turn on Blood warmer.
- F. The physician will connect the 4-way stopcock to the umbilical or other central line. Physician will connect blood administration set syringe and blood waste bag to the stopcock.
- G. Secure the connection where the tubing enters the waste bag with tape to prevent dislodgement.
- H. The physician will pull desired volume of donor blood into syringe, then slowly administer donor blood, next slowly aspirate infant's blood, and lastly push the infant's blood into the waste collection bag. Physician will state blood volume withdrawn from the donor unit and volume infused; Physician will state donor blood volume infused and infant blood volume wasted. RN will read back to the physician the volume infused/wasted and running total, to ensure accuracy of communication.

1. Many cycles will be repeated until goal volume.
  2. The RN should gently agitate the blood bag every 15 minutes to prevent red blood cell sedimentation.
- I. Partial volume exchange with central venous access for treatment of polycythemia consist of a pre calculated volume of blood withdrawn with each aliquot. The Medical Provider will draw and waste infant's blood then administer crystalloid volume replacement: using a replacement volume of crystalloid (0.9% NS or Lactate Ringer's) to the pre calculated volume of blood withdrawn with each aliquot. No blood products are administered to the infant.
  - J. Partial volume exchange transfusion for treatment of severe anemia. In a high risk setting of congestive heart failure or volume overload, donor packed RBC is transfused to the infant using a pre calculated volume of the transfusion. Infant's blood is withdrawn and wasted to avoid volume overload.
  - K. Record the blood volume in and out, the vital signs, the SpO<sub>2</sub>, and any lab work done on the Exchange Transfusion Log during procedure.
    1. Record exchange start time.
    2. Record volume of each withdrawal and infusion
    3. The vital signs and SpO<sub>2</sub> at a minimum of every 15 minutes
    4. Lab work sent
    5. Lab results
    6. Medications given
  - L. Collaborate with the physician at least every 30 minutes during the exchange regarding the need for blood glucose, electrolytes or arterial blood gas (ABG) sampling.
  - M. Provide pacifier and oral sucrose for comfort and pain management.
  - N. Occasionally, more than one unit of reconstituted blood is required to achieve the volume required for the exchange transfusion. Ensure that you release and obtain the second unit from the blood bank prior to completing the first unit to ensure that there is no delay during the exchange transfusion period.
  - O. When preparing to exchange with a second unit of reconstituted blood, perform the stopped action on the first unit including documentation of the volume infused and patient tolerance of transfusion.
  - P. Spike the second unit using the primed blood tubing that infused the first unit.
  - Q. Do not record the exchange transfusion end time until the entire procedure is over.
  - R. Have physician ordered and pharmacy prepared Calcium gluconate syringes at bedside.
  - S. Repeat blood glucose checks hourly during the procedure and upon completion.

## EMERGENCY MANAGEMENT:

- A. ~~Administer~~ Administer Calcium Gluconate ~~10%-100~~ 100-200 mg/kg ~~diluted to 50mg/ml, slow IVP~~ infusing slowly over 10 minutes IV as ordered for hypocalcemia prevention or treatment while monitoring the infant's heart rate and ECG.
- B. Calcium may coagulate donor blood, so give through separate access, or flush in between.
- C. Calcium replacement is often needed for double volume exchange and partial exchanges that treat anemia. Calcium is not needed for partial exchange that treat polycythemia.



- D. In the event of respiratory arrest or severe bradycardia, implement neonatal resuscitation measures as outlined by the American Heart Association and American Academy of Pediatrics.

## POST-TRANSFUSION:

- A. Complete transfuse order of Reconstituted RBC's and FFP's in the EHR. May need to ensure a release and to obtain the second unit of Reconstituted RBC's and FFP's leading to no gap during Double volume exchange transfusion.
- B. At the end of the entire procedure:  
Record the exchange end time  
Document a stopped action for the blood transfusion and enter the total exchange volume.  
Document patient tolerance and suspected reaction.
- C. Maintain the infant NPO for 4 hours minimum and as ordered by physician.
- D. Remove restraints, reposition and comfort infant.
- E. **Monitor** the vital signs every 15 minutes x4; then every 30 minutes x2; then every hour x1, SpO<sub>2</sub>, ECG, blood glucose, and urine output every hour for a minimum of four hours post Exchange Transfusion then return to usual monitoring per physician order.
- F. **Monitor** the blood gases, Hgb, Total and Direct Bilirubin as ordered by the physician including a blood glucose. Hemocrit should be drawn after the transfusion has been completed and repeated 4 hours later.
- G. **Document** all patient changes/status, vital signs, oxygen saturation, blood glucose, and urine output pre and post transfusion in the EMR, and on the Exchange Transfusion Log sheet during the procedure as mentioned above.
- H. **Document** all response to care delivered as mentioned previously.
- I. **Place** discard blood bag in a red biohazard bag and discard in appropriate waste receptacle.
- J. **Complete** Crossmatch ~~Tranfusion~~ Transfusion Tag form, and make a copy. Return original form to the Blood Bank with signatures.
- K. Observe for feeding intolerance and monitor abdominal girth and bowel sounds every 4 hours x24 hrs.

## Documentation

- A. Record all assessment data: date and time the procedure began and ended.
- B. Results noted and steps taken during the procedure:
1. Vital signs from the monitors at least every 15 minutes during the procedure and record in EMR.
  2. Glucose checks hourly during and at the end of the procedure
  3. The infant's activity and any adverse reactions.
  4. The amount of blood in and blood out with each cycle.
  5. Lab specimen sent.
  6. Medications administered.
- C. Record all implementation of phototherapy.
- D. Record evaluation of effectiveness of care in relation to:
1. Stability/instability of infant undergoing phototherapy (thermoregulation, GI function etc.).



2. Improvement/worsening of hyperbilirubinemia.
3. Presence/absence of complications from condition or treatments.
4. If exchange transfusion was done document all the above mentioned in post transfusion, as well as Time-Out, and CLIP form if applicable, total intake and output of blood in EMR and procedure note.
5. Maternal/family coping of mechanisms/participation in care, education/understanding of therapy.

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All revision dates:

7/8/2025, 9/13/2023, 2/22/2023, 8/11/2020, 6/1/2011, 3/1/2010, 1/1/2008, 4/1/2007, 12/1/2003, 3/1/2003, 1/1/2002, 11/1/2001

## Attachments

-  [Attachment A: Bhutani Curve](#)
-  [HOTLINE BLOOD WARMER -Set up.docx](#)

## Approval Signatures

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

Step Description	Approver	Date
Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Blood Usage Committee	Erlinda Roxas: Director, Laboratory Services	7/28/2025
Blood Usage Committee	Francisco Bracho: MD	7/24/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/24/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/22/2025
NICU	Kristina Swaim: Clinical Nurse Manager, OB	7/22/2025
NICU	Robert Posen: NICU Medical Director	7/14/2025



Origination: 5/30/2024  
Effective: Upon Approval  
Last Approved: N/A  
Last Revised: 8/6/2025  
Next Review: 3 years after approval  
Owner: Tess Slazinski: Clinical Nurse  
Specialist, Critical Care  
Policy Area: Nursing Practice Protocols  
References:

## NPP.04 Small Bore Tube Feeding Tube Insertion And Management

### POLICY:

To provide a guideline for the Registered Nurse (RN) superusers for placement of an IRIS post pyloric small bore feeding tube. Appropriate placements are gastric, duodenal, or jejunal. The feeding tubes are placed in the Intensive Care Unit (ICU) per a licensed practitioner (LP) order.

### Indications for Use:

Patients who are unable to take nutrition by mouth and at risk for aspiration pneumonia.

### Contraindications for Use:

DO NOT use this system in patients who are post transsphenoidal hypophysectomy (TPH) surgery, basilar skull fracture, suspected basilar skull fracture, and/or facial fracture(s). These small bore tubes with a camera at the base are not to be utilized for gastric decompression, it will fracture the distal aspect of the tube.

### Functions to be Performed and Competency:

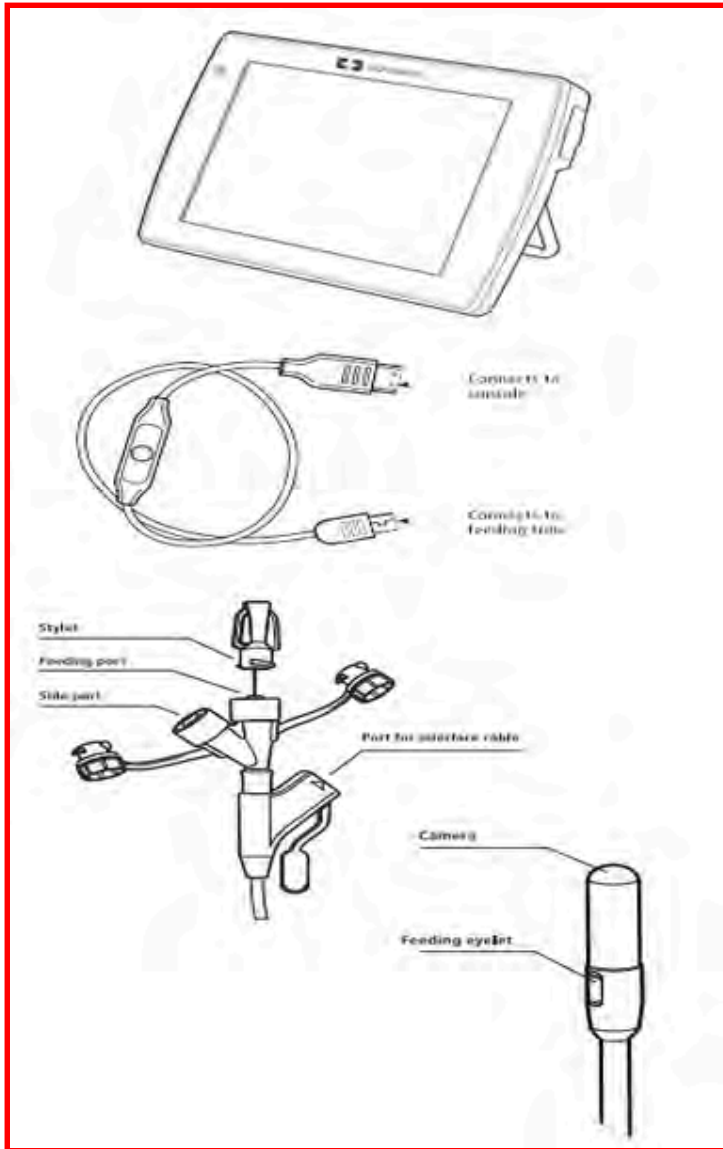
Advanced practice nurses and registered nurse superusers who have received didactic training from the device company and performed **three** successful placements are permitted to place these feeding tubes. A confirmatory x-ray is obtained to ensure proper placement per a LP order.

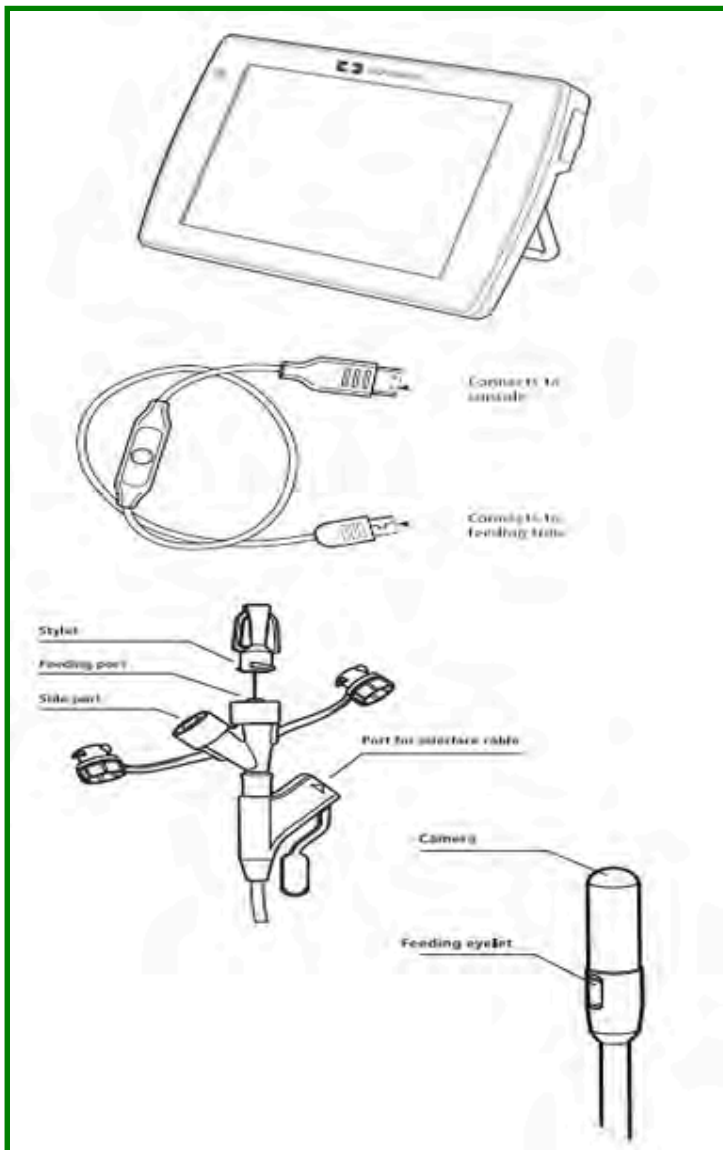
### Procedure:

- A. **Pre-insertion:** Explain the procedure to the patient and/or family.
- B. **Equipment preparation (see photo A):**
  - a. Position the console in direct line of sight.
  - b. Plug in the power cable if necessary.
  - c. Power on the console using the power button.
  - d. Enter login and password
  - e. Connect the interface cable to the console, then connect the interface cable to the feeding tube.
  - f. Start procedure on console and input patient information.

- g. Activate the Hydromer™ coating on the tip of the tube by submerging it in water for a least 5 seconds.

**Photo A:**

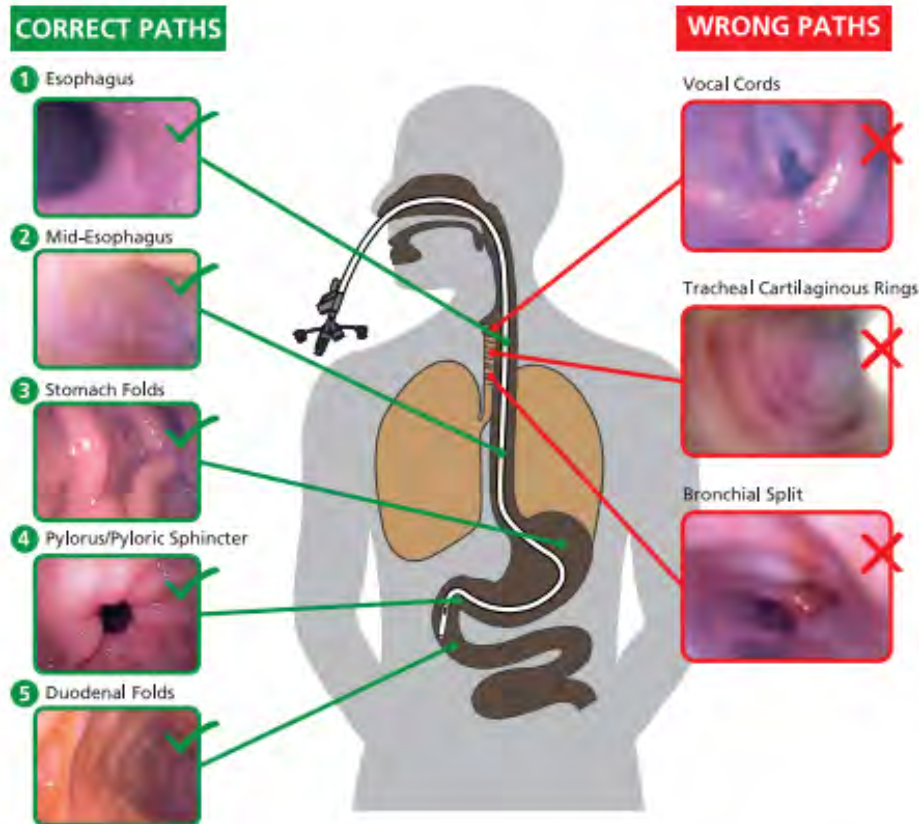




### C. Insertion:

- a. Position the patient for feeding tube placement and estimate feeding tube length.
- b. Chose the most patent nare (oral placement is also acceptable) and insert the feeding tube with the stylet.
- c. Using the console for placement
  - i. Utilize the console screen to correctly identify markers during placement (see photo B)

#### **Photo B:**



#### D. Capture an Image

- If an image needs to be captured, it can be obtained by using the interface cable or the console.

#### E. Ending the procedure

- When the procedure is complete and the feeding tube has been placed properly, tap the green check mark.
  - Tap the green check mark again to complete the procedure.
- Disconnect the interface cable from the feeding tube.

#### F. Confirm Placement

- Obtain confirmatory x-ray per LP order.
- Remove stylet prior to enteral nutrition delivery.
  - The stylet is reusable (e.g., can be used to retrace the feeding tube in case it gets pulled back or out). **Do not discard.** Place in a Biohazard bag at the patient's bedside.

#### G. Reconnecting

- The console to place the feeding tube will retain the memory of which patient is associated to that tube.
- Reconnecting the console to the same feeding tube will allow the console to recognize the tube and provide a patient data confirmation prompt.

# DOCUMENTATION

Document in patient chart the following:

- A. Tube site and assessment
- B. Patient's tolerance
- C. Other details as appropriate.

## References

Cardona, E., et al. (2021). Bedside postpyloric enteral tube placement using Kangaroo IRIS technology: A single-center case series. *Nutrition*, 86: 111195.

Covidien User Manual (2012). Kangaroo Feeding Tube with IRIS Technology console and accessories. Covidien LLC, Maine.

Taylor, S., et al. (2021). Tube placement using "IRIS": A pilot assessment of its utility and safety. *Intensive and Critical Care Nursing*, 66.

Taylor, S., et al. (2021). Integrated real-time imaging system, "IRIS" Kangaroo feeding tube: A guide to placement and image interpretation. *BMJ Open Gastroenterology*, 8(1): e000768.

All revision dates:

8/6/2025, 1/14/2025, 5/30/2024

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Interdisciplinary Practices Committee	Stephanie Denson: Manager, Medical Staff Office	10/6/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/22/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/22/2025
Nursing Education	Sharon Waechter: Clinical Nurse Manager, Nursing Education	8/22/2025
Protocol Author	Tess Slazinski: Clinical Nurse Specialist, Critical Care	8/6/2025



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**Next Review:** 3 years after approval  
**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** OB Nursing  
**References:**

## OB.09 Code Maternity

### POLICY:

To provide a rapid, coordinated response to maternal hemorrhage in order to prevent cardiovascular collapse and arrest in any in-patient unit or Emergency Department.

### PROCEDURE:

#### STAGE-BASED APPROACH TO OBSTETRIC HEMORRHAGE

- A. Stage 0: Focus is on risk management and active management of the third stage of labor.
  1. Assess every patient for risk factors for hemorrhage (Attachment B).
  2. ~~Measured~~Measure cumulative quantitative blood loss on every birth.
  3. Provide active management of Stage Three Labor, per physician's order.
  4. Blood product readiness:
    - a. Perform type and screen on all laboring patients.
    - b. Perform type and cross on all patients at high risk for hemorrhage (Attachment A&B).
    - c. For patient with positive antibody screen and all high risk for hemorrhage, perform type and cross.
    - d. Obstetric (OB) hemorrhage cart will be made available in the Labor and Delivery and Post Partum units. (OB hemorrhage cart locked at all times, and checked daily)
    - e. At Ventura County Medical Center (VCMC) OB hemorrhage cart is available in the main ~~OR~~operating room (OR) with medications available.
    - f. At SPH the OB hemorrhage cart is located in the Emergency Department
- B. Stage 1: Blood loss greater than 500 mL at vaginal delivery **OR** greater than 1000 mL at cesarean delivery with continued bleeding **OR** signs of concealed hemorrhage. vital sign abnormal **OR** trending (HR  $\geq$ 110, BP < 85/45, O<sub>2</sub> sat <95%, shock index 0.9) **OR** Confusion.
  1. Activate OB Hemorrhage Emergency Management Plan (Attachment B).
  2. Establish IV access if not present, at least 18-gauge.
  3. Increase IV oxytocin rate to 500-1000 mL per hour of 30uunits/500 mL solution.



4. Fundal/bimanual massage.
5. Administer another uterotonic medication. If no response, consider second uterotonic (Attachment B &C).
6. Empty ~~Bladder~~bladder with straight foley or place foley with urimeter if not already done.
7. When using second uterotonic strongly consider inserting ~~JADA~~Jada or uterine balloon tamponade
  - a. Contraindications to ~~JADA~~Jada or Uterine Tamponade use include
    - i. ~~engoing~~Ongoing intrauterine pregnancy
    - ii. Untreated uterine rupture
    - iii. Unresolved uterine inversion
    - iv. Current cervical cancer
    - v. Known ~~Uterine~~uterine anomaly
    - vi. Current purulent infection of vagina, cervix or uterus
    - vii. For ~~Cesarean Sections~~cesarean sections: ~~Cervix~~cervix <3cm dilated before use of ~~JADA~~Jada
    - viii. ~~JADA~~Jada system or ~~Uterine~~uterine balloon tamponade should not be left within the uterus for more than 24 hours.
    - ix. If Jada or balloon in place follow procedure for labeling patient i.e. should have wrist band
8. Blood Product readiness:
  - a. Modify Hemorrhage Risk to "High" if not already classified as High Risk, and take appropriate precautions
  - b. Consider ~~T&C~~type and cross 2 Units ~~units packed red blood cells (PRBCs)~~ where clinically appropriate if not already done

C. Stage 2: Continued bleeding despite stage 1 interventions and less than 1500 mL cumulative blood loss **OR** VS remain abnormal

An OB or ED staff member will activate a "Code Maternity." A physician or ~~OB~~ staff member will call the paging operator and activate a "Code Maternity" including location (e.g., labor and delivery, operating room, postpartum room, ED, etc.).

**At VCMC** the paging operator will call "Code Maternity" overhead and will page or call the following individuals:

- Obstetrician on call
- Back-up on call Obstetrician
- Nursing Supervisor
- Anesthesiologist on call
- Rapid Response Nurse
- Laboratory technician

**At Santa Paula Hospital** the Paging operator will call "Code Maternity" overhead and then page the Nursing Supervisor. The Paging operator will then page or call the following individuals to the Nursing Supervisor phone at 218-1712:

~~SPH physician on call~~

- VCMC Obstetrician on call
  - Rapid Response Nurse
  - Anesthesiologist on call
  - Hospitalist ~~or ED physician~~
  - Laboratory technician
1. The Obstetrician/physician will respond by coming directly to the location. If the Obstetrician on call cannot respond rapidly, the Charge Nurse or designee will begin calling Obstetricians on the emergency call back list.
  2. The Nursing Supervisor will call the OR (operating room) team.
  3. The Anesthesiologist will come to the location. If unable to respond rapidly, the Charge Nurse or designee will call the second call Anesthesiologist.
  4. Complete evaluation of vaginal wall, cervix, placenta, uterine cavity
  5. AT VCMC: The Rapid Response Nurse and ICU charge nurse will respond to the location. Level One blood transfuser will be located in OB PACU for use.  
AT SPH: The ~~ED charge~~rapid response nurse/nursing supervisor will respond to the location with Level One blood transfuser.
  6. The Laboratory will respond immediately, delivering an iced cooler containing two (2) units of O Negative Blood, and (2) units of thawed AB plasma, within five (5) minutes. If the physician determines that the patient can wait for the completion of compatibility testing of type specific/type compatible red blood cells, the blood will be returned to the Blood Bank.
  7. At SPH the charge nurse will send an available staff member to lab immediately to retrieve and deliver an iced cooler containing two (2) units of O Negative Blood, within five (5) minutes. If the physician determines that the patient can wait for the completion of compatibility testing of type specific/type compatible red blood cells, the blood will be returned to the Blood Bank.
  8. Send Labs, including disseminated intravascular coagulation (DIC) panel. Plus or minus ~~ABG~~arterial blood gas will be drawn.
  9. Consider additional uterotonics, or uterine tamponade device.
  10. The decision to use tranexamic acid with the Code Maternity protocol shall be made within three (3) hours of incident. The loading dose is available in the OB Pyxis machine. The loading dose of 1 gram (100 mg/mL) of tranexamic acid is given intravenously at an approximate rate of 1 mL per minute. If bleeding continues after 30 minutes or stops and restarts within 24 hours of the first dose, a second dose of 1 g of tranexamic acid is again administered.
  11. Establish second large bore IV at least 18-gauge, if not done in Stage 1.
  12. Place intrauterine balloon.
  13. At VCMC, if it is anticipated that greater than 4 units of blood will be required, the physician or Anesthesiologist may activate the Massive Transfusion Protocol.
  14. At SPH, the Blood Bank will contact blood supplier.
  15. Move to Operating Room, if indicated.
- D. Stage 3: Cumulative blood loss greater than 1500 mL, continued bleeding, greater than two (2) units given, vital signs unstable or suspicious for DIC: Activate Code Maternity, if not yet done.
- a. Activate Massive Transfusion Protocol (as above) at VCMC. Refer to Policy ***T.02 Adult Mass***





### ***Transfusion Protocol***

1. Activate Massive Transfusion Protocol, transfuse aggressively.
  2. ~~Give~~Give 1:1 ratio of PRBC to ~~FFP~~fresh frozen plasma
  3. 1 PLT apheresis pack per 6 units PRBC
- b. At SPH, the Lab will contact blood supplier.
- c. Move to Operating Room.

All revision dates:

5/5/2025, 10/9/2024, 5/1/2023, 2/17/2023, 10/9/  
2019, 12/20/2017, 12/20/2017, 11/1/2016

## **Attachments**

-  [Attachment A Obstetric Hemorrhage Care Guidelines Table Format.pdf](#)
-  [Attachment B Obstetric Hemorrhage Risk Factor Assessment Screen.pdf](#)
-  [Attachment C Medications for Postpartum Hemorrhage.pdf](#)
-  [Quick Start Guide.pdf](#)

## **Approval Signatures**

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine & OB	Stephanie Denson: Manager, Medical Staff Office	9/5/2025
Blood Usage Committee	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	7/1/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	6/11/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	5/5/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	5/5/2025
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	5/5/2025



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 Next Review: 3 years after approval  
 Owner: Sharon Waechter: Clinical Nurse Manager, Nursing Education  
 Policy Area: Administrative - Nursing  
 References:

## NPP.08 Clinical Implementation Guide for Electrocardiogram Guided Tip Confirmation System During Peripherally Inserted Central Catheter Placement

### ~~POLICY:~~

~~To provide guidelines to facilitate standardization of practice for insertion by Registered Nurses (RN) of Peripherally Inserted Central Catheter (PICC) using Electrocardiogram (ECG) Guided catheter tip confirmation.~~

### ~~SCOPE:~~

### Policy

To provide guidelines to facilitate standardization of practice for insertion by Registered Nurses (RN) of Peripherally Inserted Central Catheter (PICC) using Electrocardiogram (ECG) Guided catheter tip confirmation.

It is the policy of Ventura County Medical Center and Santa Paula Hospital that all standardized procedures are developed collaboratively and approved by the Interprofessional Practice Committee (IPC), whose membership consists of Physicians, Registered Nurses (RN), Pharmacists, Advanced Practice Nurses and Administrators. Standardized procedures are reviewed every three years.

To outline and define responsibility in performing interventions requiring a physician order in accordance with the California Board of Registered Nursing and the Nursing Practice Act, all approved standardized procedures will be kept in Policy Stat. The Registered Nurse, as outlined in the Nurse Practice Act, Business and Professions Code Section 2725, is authorized to implement appropriate standardized procedures or changes in treatment regimen after observing signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determining that these exhibit abnormal characteristics.

### Function to Be Performed

1. This applies to RNs at Ventura County Medical Center who have successfully completed population appropriate training and demonstrated competency in Vascular Access device insertion, care and

maintenance, patient/caregiver education across the care continuum.

2. RNs must also have completed the online education course on the ECG guided tip confirmation system (TCS) and yearly ECG PICC competency checkoff.

## **~~DEFINITION(S):~~**

### **Definitions**

The ECG guided TCS is indicated for guidance and positioning of the PICC. The ECG TCS provides real-time catheter tip location information by using the patient's cardiac electrical activity. ECG TCS is indicated for use as an alternative method to chest x-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in the patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythms. In such patients, who are easily identifiable prior to PICC insertion, the use of an additional method is required to confirm catheter tip location.

## **~~EQUIPMENT:~~**

### **Equipment**

1. Sherlock 3CG Tip Confirmation System
2. Site Right Portable Ultrasound Machine
3. PICC Catheter with Sherlock 3CG Tip Positioning System (TPS) Stylet

## **~~PROCEDURE(S):~~**

### **Roles and Responsibilities**

The steps for this procedure will be completed by the RN. RNs will review and implement these functions whenever this task is performed.

#### A. Scope of supervision required

1. The RN is responsible and accountable to the nursing director over vascular access.
2. Overlapping functions are to be performed in areas which allow for a consulting provider to be available to the RN by phone or in person.
3. Provider consultation is to be obtained under the following circumstances
  - a. Emergency conditions requiring prompt medical intervention
  - b. Upon the request of the patient, RN or physician
  - c. Anytime any deviation from this protocol is necessary

#### B. Requirements for the RN

1. Active California RN license
2. BLS or ACLS if indication
3. Special training: formal orientation to specific procedure referenced in this policy with demonstrated competency validation

### C. Evaluation of the RN competence

1. Initial upon hire to department: the Nurse director/delegate will assess the RN's ability to perform the procedure
2. Annually: the Nurse director/delegate will evaluate the RN's ability to perform this procedure during performance review cycle

### D. A list of RNs who demonstrate competency to perform this procedure is held by the nursing education department

## **Procedure**

### **1. Prepare ECG Sensor:**

- a. Enter patient identification information (name, medical record number, date of birth).
- b. Slide the fin assembly onto the sensor until fully seated and place the sensor in protective cover. Do not use excessive force when connecting or disconnecting the fin assembly to or from the sensor or equipment damage may occur.
- c. Position sensor on patient's chest with the top of sensor above the sternal notch and centered on the sternum. Place sensor as flat as possible for best result.
- d. Prepare and attach the external ECG electrodes to the lead wires. Ensure electrode locations are oil-free, completely dry, and on intact skin (e.g., not over open wounds, lesions, infected, or inflamed areas. Discontinue electrode use immediately if skin irritation occurs.
- e. Attach electrodes to all the lead wires. Remove backing and press firmly onto skin at the specified locations:
  - Place BLACK electrode lead wire on patient's lower right shoulder
  - Place RED electrode lead wire on lower left side, inferior to the umbilicus and laterally along the mid-axillary line. CAUTION: Placement of the red lead wire outside of this region may result in reduced ECG performance.

### **2. Evaluate baseline ECGs:**

- a. Turn on TCS and note external waveform.
- b. Verify that P-wave is present and identifiable and consistent on the main screen.
- c. If no persistent or regular P-wave is identified, continue with procedure utilizing magnetic tracking and external measurements followed by tip confirmation via alternative method (i.e., x-ray or fluoroscopy).
- d. Adjust ECG scale as needed to ~~endure~~ensure that entire ECG waveforms are visible in the ECG window throughout the insertion procedure.

### **3. Catheter Tip Guidance and Positioning**

- a. Follow Tip Locating System (TLS) "Instructions for Use" for magnetic navigation.
- b. Insert catheter until the magnetic navigation shows stylet icon (Sherlock Spyglass) moving consistently downward.
- c. Continue to slowly advance the catheter until the catheter is inserted to the external measurement determined prior to insertion and/or negative P-wave deflection is noted. Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the intravascular P-

- wave. In this case, rely on magnetic tracking and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location as per policy and clinical judgement.
- d. Activate FREEZE function on TCS. This will save the current waveform on the right-side reference screen for later comparison. Repeat as needed.
  - e. SLOWLY adjust catheter tip position until the maximum P-wave amplitude is reached. Compare main screen waveform to reference screen waveform while closely monitoring for negative P-wave deflection.
  - f. If negative deflection prior to P wave present, adjust catheter tip position to maximum P-wave amplitude with no negative deflection
  - g. Advance or retract catheter from maximum P-wave to place tip in desired location (the cavoatrial junction of the superior vena cava).
  - h. Note catheter exit site marking (centimeters from exit site to hub) and document on TCS screen.
  - i. To record waveforms at the final catheter tip position, activate FREEZE function on TCS. Activate "PRINT" function to save image
4. PICC RN/ Vascular Access Specialist inserting the catheter will notify the RN/ provider for authorization of line use. The PICC RN/ Vascular Access Specialist may order radiograph at his or her discretion when clinically indicated. PICC RN/Vascular Access Specialist will place an order to use the vascular access device.
- ~~TCS Documentation: Upon successful insertion and TCS confirmation, the PICC RN/ Vascular Access Specialist will follow Ventura County Medical Center process to ensure the ECG waveform determining optimal tip position will be entered into the medical record.~~
5. When ECG TCS is used to determine optimal PICC tip placement in the SVC, no radiographic confirmation is required. ECG technology has been proven to be a more accurate determination of tip placement than radiographs (per INS Standards). If there is a discrepancy between tip confirmation with ECG TCS and chest X-ray (CXR) read, ECG TCS is considered to be the more accurate of the two technologies. The Vascular Access Specialist inserting the catheter may approve use of the line per policy when the appropriate change in the P wave is noted. At the time of placement, the external catheter measurement will be documented.

## ~~REFERENCES:~~

## Documentation

- A. The RN will document the following in the electronic health record (EHR)
  1. Patient tolerance
  2. Upon successful insertion and TCS confirmation, the PICC RN/ Vascular Access Specialist will follow Ventura County Medical Center process to ensure the ECG waveform determining optimal tip position will be entered into the medical record.

## References

- a. Infusion Nurses Society (2016). Policies and Procedures for Infusion Nursing, (4<sup>th</sup> Ed.) Norwood, MA: Author
- b. BARD Access Systems (2013). Sherlock 3CG Tip Confirmation System, [www.bardaccess.com](http://www.bardaccess.com)

- c. Appl Health Econ Health Policy (2016). Sherlock 3CG Tip Confirmation System for Placement of Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance, Megan D. [www.springerlink.com](http://www.springerlink.com)

All revision dates:

8/28/2025, 4/15/2025, 3/14/2023

## Attachments

 [Sherlock PICC Tip Confirmation Sheet.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine & Medicine	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Interdisciplinary Practices Committee	Stephanie Denson: Manager, Medical Staff Office	7/15/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/13/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/13/2025
Nursing Education	Sharon Waechter: Clinical Nurse Manager, Nursing Education	6/13/2025
Protocol Author	Sharon Waechter: Clinical Nurse Manager, Nursing Education	5/21/2025





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**Last Revised:** 4/3/2025  
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**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** OB Nursing  
**References:**

## OB.17 OB Breastfeeding Support

### POLICY:

Staff at Ventura County Medical Center/~~Santa Paula Hospital (VCMC/SPH)~~ shall provide all pregnant women information on breastfeeding as well as an educational plan for families on the advantages of breastfeeding to mothers and newborns. The staff caring for pregnant women, newborns and new mothers shall facilitate informed health care decisions on the part of mother and family, support education to assist with the successful establishment and maintenance of breastfeeding, and encourage the core components of the Baby Friendly Hospital Initiative (BFHI) and UNICEF/World Health Organization (WHO's) "Ten Steps to Successful Breastfeeding."

### PROCEDURE:

#### Step 1: Have a written policy that is routinely communicated to all health care staff

- A. New staff orientation including time frame.
- B. It is the responsibility of the staff who care for pregnant women, newborns and new mothers, to support both mother and infant during the pregnancy, birthing and lactation process.
- C. The nurse will assess family's knowledge of breastfeeding; and facilitate their feeding choice in accordance with the Ten Steps to Successful Breastfeeding.
- D. The nurse will implement the Golden Hour: during the first hour of the newborn's life, when the family and newborn are together uninterrupted for the first time, to enhance skin-to-skin contact immediately after birth and until the completion of the first feeding, unless there are medically justifiable reasons for delayed contact. Skin-to-skin contact is defined as the placing of the naked newborn prone on the mother's bare chest. Skin-to-skin contact is a critical component for successful breastfeeding. Skin-to-skin will be documented in the newborn's Electronic Health Record (EHR).
- E. After cesarean birth, mothers and their infants should be placed in continuous, uninterrupted skin-to-skin contact as soon as the mother is responsive and alert, unless there is a medically justifiable reason that prohibits skin-to-skin.
- F. The philosophy of VCMC/SPH supports the WHO International Code of Marketing of Breast Milk Substitutes, by offering education and materials that promote human milk rather than other infant food or drinks and by refusing to accept or distribute free or subsidized supplies of breast milk substitutes, nipples and other feeding devices (Baby-Friendly Initiative, 2009).

## **Step 2: Train all health care staff in the skills necessary to implement this policy**

- A. OB Provider Training Plan (See Provider Training Binder).
- B. Staff Education Requirements: All staff who provide clinical care and have direct contact with breastfeeding mothers and babies will receive basic training in the benefits, management and practical aspects of breastfeeding. Other members of staff who have contact with pregnant women and/or breastfeeding mothers and babies will have sufficient understanding of why breastfeeding is important and how it works to enable them to fulfill their role within the policy.
- C. The teaching program will include 15 hours of instruction and 5 hours of competency covering the 15 sessions identified by UNICEF/WHO. The staff will be educated through:
  - a. Workshop: Birth and Beyond training class
  - b. In service at staff meetings
  - c. Facility Designed Self-contained Learning Modules
  - d. Hands on instruction with preceptor. Each staff member will be evaluated with competency validation tool to assess proficiency in assisting a mother with:
    - i. Proper latch
    - ii. Positioning
    - iii. Hand expression
- D. Continuing Education:
  - a. Providing baby friendly visual aids throughout unit
  - b. Maintaining performance improvement project
    - i. Golden hour
    - ii. Increase breastfeeding rates
  - c. Staff opportunity to become lactation certified
  - d. Certification pay for lactation certification
  - e. Education leave with pay for continuing education
  - f. Communication board providing continuing education opportunity.
- E. Staff that attended the Train the Trainer program through Birth and Beyond California received specifically designed training to address the learning and competency verification requirements of the BFHI. The educated staff will take on the responsibility for in-house training.
- F. All members of staff will be oriented to the policy in the first week of their employment. This will take place on a one to one basis, with a mentor or senior member of staff going through the policy with the new employee. Both will sign a confirmation that the orientation has taken place. Training will be mandatory and all members of staff will receive all elements of training within six month of the employee's commencement and be completed by that time.
- G. Institutional policy regarding the acceptance of previous education from new staff members: Previous training and documentation from new employees will be accepted if the required topics identified in the BFUSA guidelines and Evaluation Criteria are up to date with current literature/evidence.
- H. Documentation of staff education: Documentation and curriculum (certificates of attendance, certificate of

completion) containing the 15 sessions including employees name, training course name and date of completion will be kept on file.

- I. The Clinical Nurse Manager for the Mother/Baby unit will ensure that all staff in the Mother/Baby unit will receive the required number of hours training on the topics that are specified by the Baby-Friendly Hospital Initiative. This training will be completed within 6 months of hire. Details for the execution of the training are specific in a separate training plan. Upon completion of training the supervising nurse will supervise and verify the clinical competency of each staff member.
- J. Documentation of all training and competency verification will be maintained by the Nursing Manager for the Mother/Baby Unit. Such documentation shall consist of topics, date of training, and date of competency verified. Sign in sheets and certificates of attendance will be maintained on file in the Clinical Nurse Manager's office.
- K. New employees who have received training prior to employment will be exempt from the training after they provide sufficient documentation of training in all the required topics, participate in the required number of hours of clinical supervision and have had their competencies verified by the supervising nurse.

### **Step 3: Inform all pregnant women about the benefits and management of breastfeeding**

- A. Patient Education Plan (See patient education binder)
- B. All OB providers and hospital-based clinic personnel will provide prenatal education to all patients on the following topics and document such in their prenatal records:
  - a. Benefits of Breastfeeding
  - b. The importance of exclusive breastfeeding
  - c. Non-pharmacological pain relief methods for labor
  - d. Early initiation of skin-to-skin contact
  - e. Early initiation to breastfeeding
  - f. Rooming-in on a 24 hour basis
  - g. Baby led feeding
  - h. Frequency of feeding in relation to establishing a milk supply
  - i. Effective positioning and latch techniques
  - j. Exclusivity of breastfeeding for the first 6 months
  - k. Continuation of breastfeeding after introduction of appropriate complimentary foods
- C. Educational material will not contain formula company logos of infant formula companies, bottles, or other related items.
- D. Teaching the use of infant feeding bottles, or how to prepare formula will only be given in a one-on-one setting (group teaching is to be avoided).
- E. All pregnant patients will be given breastfeeding education and written material about breastfeeding within the first trimester, whenever possible.
- F. OB providers and hospital-based clinic personnel will be responsible to distribute education packets and avail themselves to patient questions, concerns, and resources.

- G. Delivery of the patient education packet will be documented on the prenatal record.
- H. VCMC/SPH fosters the development of community-based programs that make available individual counseling or group education on breastfeeding. Our facility collaborates with the Breastfeeding Coalition of Ventura County; a directory of breastfeeding support including; prenatal services, on-line breastfeeding resources, meetings, and contacts.
- I. The nurse will provide The Breastfeeding Resource Guide to community-based programs to all families upon admission and messages.

## **Step 4: Help mothers initiate breastfeeding within one hour of birth**

### **Vaginal Delivery/Cesarean Section**

- A. Ensure best practices for breastfeeding support and safely transition the newborn from intrauterine life to extra-uterine life. All mothers and infants at VCMC/SPH are encouraged to participate in uninterrupted and continuous skin-to-skin contact immediately after birth and until the completion of the first feeding, unless medically contraindicated. Skin-to-skin contact during the first hours and days of life promote the process of attachment and bonding between mother and newborn.
- B. Routine newborn procedures, ID bands, physical assessment, vital signs, measurements, administration of Vitamin K and Erythromycin Ophthalmic ointment will be postponed until after the initial period of skin-to-skin contact.
- C. Procedures requiring separation of the mother and baby (bathing) will be delayed until after this initial period of skin-to-skin contact.
- D. The nurse will offer assistance, and encourage mothers to recognize when their newborns are ready to breastfeed, unless medically contraindicated.
- E. Benefits for newborns that remain skin-to-skin with their mothers include rapid thermoregulation and less risk of dehydration than newborns placed under radiant warmers.
- F. After Cesarean birth, babies will be placed in continuous, uninterrupted skin-to-skin contact with mother as soon as the mother was responsive and alert unless separation was medically indicated. The nurse will offer assistance and encourage mothers to recognize when their newborns are ready to feed and offer help unless medically contraindicated.
- G. In the event that mother and newborn are separated for medical reasons, skin-to-skin contact will be initiated as soon as mother and newborn are reunited in couplet care, and medically stable enough for this care.
- H. Skin-to-skin contact will be encouraged throughout the hospital stay.
- I. Skin-to-skin care will be documented in the patient EHR.
- J. When it is necessary for an infant to be admitted to the Transitional Care Nursery, the nursing staff will educate the mother regarding the importance of skin-to-skin for her infant and support the implementation of skin-to-skin care as soon as is medically possible.

## **Step 5: Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants**

### **Step 6: Encourage breastfeeding on demand**

- A. The nurse caring for the couplet (mother/newborn) on the postpartum unit is responsible for observing and assessing as many **breastfeedings**breastfeeding opportunities as possible, at least two (2)

~~breastfeedings~~[breastfeeding sessions](#) per 12 hour shift.

- B. The nurse will document all breastfeeding support as stated above, in the patient EHR.
- C. The nurse will make use of the assessment and observation time to teach mother correct positioning and latch and the signs of an effective feeding.
- D. The nurse will educate the mother and family regarding newborn feeding cues and frequency of feedings. Encourage the mother to nurse on cue, at least 8 to 12 times in 24 hours, regardless of feeding method. There are no limits on how often or how long infants should be fed. Support breastfeeding with information regarding length of sleep for newborns and cluster feeding (a process of prioritization of activities of individual). Reinforce newborn led feeding. Encourage postpartum breastfeeding women to attend breastfeeding education classes and support groups.
- E. When the newborn displays feeding cues (licking of lips, rooting, sucking on hands), help the mother with latching the baby to the breast.
- F. The nurse will assess the mother's breastfeeding techniques and if necessary, demonstrate appropriate breastfeeding positioning and attachment with mother and newborn, optimally within three hours, and not later than six hours after birth, or upon any change in patient condition (Baby Friendly Initiative, 2010).
- G. Prior to discharge, breastfeeding mothers should be educated on basic breastfeeding practices, including:
  - a. The importance of exclusive breastfeeding
  - b. How to maintain lactation for exclusive breastfeeding for about 6 months
  - c. Criteria to assess if the baby is getting enough breast milk
  - d. How to express, handle, and store breast milk, including manual expression
  - e. How to sustain lactation if the mother is separated from her infant or will not be exclusively breastfeeding after discharge
  - f. The recommendation for a routine follow-up with infant's healthcare provider in 48 to 72 hours after hospital discharge
  - g. [Resources to access lactation support services.](#)
- H. The breastfeeding session will be assessed at the breast with a LATCH Score (Breastfeeding Promotion – Implementing Model Hospitals, 2007). (See Attachment A.)
- I. The nurse will instruct the mother to wash her hands before breastfeeding.

#### Breastfeeding Positions

##### 1. **Cradle Position**

Mother holds infant across abdomen with the baby's head in the crook of the arm. The infant's back is supported by the mother's forearm, and cups the baby's buttocks or thigh with her hand. The baby's bottom arm can be tucked under the mother's breast. Infant should be on his side, tummy-to-tummy, facing the mothers breast with the nose in front of the mother's nipple. The infant's ear, shoulder, and hip should be in a straight line. Use pillows to support the baby at the breast.

##### 2. **Transitional/Cross Cradle**

Mother holds infant using arm/hand opposite the side of the breast to be used during the feeding. The forearm supports the baby's back and the hand forms a "C" to hold/ support the head at the base of the skull. Infant should be on his side, tummy-to-tummy, facing the mothers breast with the nose in front of the mother's nipple. The infant's ear, shoulder and hip should be in a straight line.

Use pillows to support the baby at the breast..

**3. Lying Down Cradle/Side Lying**

Mother should lie on her side with her back at a 45 degree angle to the bed. Use pillows to support the mother's back and head, and between the knees. Place baby in crook of mother's arm. Infant should be on his side, with a rolled blanket or pillow behind the baby's back for support, to prevent him from rolling away from mother. Infant should be facing the mother's breast with the nose in front of the mother's nipple. The infant's ear, shoulder and hip should be in a straight line.

**4. Clutch**

Mother sits up or reclines backwards, supported by the bed and/or pillows. Place support pillows under the mother's arm, along her side. Place baby on pillows with head towards breast and legs tucked under mother's arm. Mother supports baby's back with her forearm and her hand forms a "C" to hold/support the head at the base of the skull.

**5. Latch for all positions**

The hand that supports the breast should be in the "C" hold (four fingers on one side, thumb on the other.) Fingers should not touch the areola. Match the breast to the shape of the baby's mouth. Tickle baby's lips with the nipple and wait for the mouth to open wide and quickly bring baby, chin first, to the breast. Make sure baby is taking in 1-1½ inches of nipple and areola and that the head is slightly tilted back, you do not want baby breastfeeding chin to chest. Lips should flange outward. The mother may feel a gentle tugging or pulling sensation, but should not experience any pinching pain. Mother should support the breast as necessary throughout the feeding.

- J. To protect milk supply, if a maternal or newborn medical condition necessitates interruption of breastfeeding or if newborn exhibits difficulty with latch-on, the nurse will encourage the mother to consider pumping every three (3) hours until breastfeeding can resume (see policy N.04, *Breast Milk Storage and Collection*).
- K. The nurse will educate mother's regarding signs and symptoms of infant feeding issues requiring referral to lactation counselor or physician. Some common concerns include sore, inverted or flat nipples, thrush, Reynard's, engorgement, plugged ducts, mastitis, or abscess (Baker, G., 2011). Breast creams, ointments, shells, shields, or lanolin are not routinely given to any mother without a physician order.
- L. The nurse will provide additional individualized assistance to those high risk and special needs mothers and infants, and to mothers who have breastfeeding problems, and/or who must be separated from their infants. In these situations, the physician may offer and consent the mother for use of Human Donor Breast Milk.
- M. Milk expression will begin within six (6) hours of birth. Expressed milk is given to the baby as soon as the baby is medically ready. The mother's expressed milk is used before any supplementation with breast milk substitutes, when medically appropriate.
- N. The nurse will review neonatal and maternal effectiveness of feeding. Signs in the baby indicate sufficient milk intake (urine output, stooling, acting content after feedings, waking to request feedings 8 to 12 times in 24 hours, weight gain, and general condition of the newborn). Signs in the mother that indicate effective feeding (comfortable breasts, no evidence of nipple pain or damage (Baby Friendly Initiative, 2010)).
- O. Mothers who have chosen to feed formula to their newborn will receive verbal and written instruction. Information will be given on an individual basis to women who have chosen to formula feed or mix feed their infants. Infant feedings as well as completion of the education given to the mother will be documented in the patient EHR.
  - a. Appropriate hygiene

- b. Cleaning of utensils and equipment
- c. Appropriate reconstitution
- d. Accuracy of measurement of ingredients
- e. Handling
- f. Storage
- g. Appropriate feeding methods.

## **Step 7: Give infants no food or drink other than breast milk unless medically indicated**

- A. VCMC/~~SPH~~ promotes exclusive breastfeeding of breast milk only from birth to discharge, unless medically contraindicated.
- B. The nurse will document, "that the newborn was exclusively fed breast milk during the entire hospitalization." "Exclusive breast milk feeding is defined as a newborn receiving only breast milk, including Human Donor Breast Milk (HDBM) and no other liquid or solids except for drops or syrups consisting of vitamins, minerals, or medications." Sweet-Ease or a similar 24% sucrose and water solution given to the newborn for the purpose of reducing pain is classified as a medication and is not considered a supplemental feeding (The Joint Commission, 2010).
- C. The Joint Commission's Perinatal Care Core Measure Set #PC-05 includes all live born newborns discharged from the hospital, with the exception of those who:
  - Were discharged from the Neonatal Intensive Care Unit (NICU)
  - Were diagnosed with galactosemia during the hospital stay
  - Were fed parenterally while in the hospital
  - Experienced death
  - Had length of stay > 120 days
  - Were enrolled in clinical trials
- D. Documented reason for not exclusively feeding breast milk

### **Infant**

- 1. Classic galactosemia
- 2. Maple syrup urine disease
- 3. Phenylketonuria

**Breastfeeding infants should not be supplemented with infant formula without a medical indication.**

This facility follows the recommendations of the authorities listed below to determine whether supplementing a healthy term neonate with formula is medically indicated:

- Indications for supplementation: Academy of Breastfeeding Medicine (ABM) Clinical Protocol #3: Guidelines for the use of Supplementary Feedings in the Healthy Term Breastfed Neonate  
<http://www.bfmed.org/Media/Files/Protocols/Protocol%203%20Supplementation%20English%20Version.pdf>



- Contraindications for breastfeeding: ABM Protocol #17: Model Breastfeeding Policy <http://www.bfmed.org/Media/Files/Protocols/English%20Protocol%207%20Model%20Hospital%20Policy.pdf>
- Maternal Medications during Breastfeeding: LactMed <https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm>
- Academy of Breastfeeding Medicine Clinical Protocols 1-27 <http://www.bfmed.org/Resources/Protocols.aspx>

If, after consulting the Academy of Breastfeeding (ABM) Protocols and LactMed, it is determined that an infant should be supplemented, there must be a written medical order for the supplementation. The order must include the medical indication found in one of the ABM Protocols or LactMed. The amount of each formula supplementation will be charted in the infant's medical record in addition to the type of supplemental feeding device used and the reason for the supplementation (i.e., list the medical indication for the feeding or that it was given for a mother's informed request).

### **Maternal**

1. HIV infection
2. Illegal substance use
3. Active tuberculosis; untreated
4. HTLV I or II
5. Infected breast abscess; untreated

### **Women under the following circumstances should be discouraged from breastfeeding:**

1. Women who have a history of drug abuse and that did not receive any prenatal care;
2. Women who relapsed into drug use or licit substance misuse in the 30-day period prior to delivery;
3. Women that have demonstrated a positive maternal drug screen or documentation of misuse of licit drugs in the last 30 days prior to delivery;
4. Women who are not willing to engage in substance abuse treatment or are in treatment but not willing to provide consent for contact with counselor;
5. Women who do not have confirmed plans for postpartum substance abuse treatment or pediatric care;
6. Women who are taking a psychiatric medication that is contraindicated or has unknown effects during lactation.

### **Mother who may need to avoid breastfeeding temporarily**

1. Severe illness that prevents mother from caring for her infant.
2. Herpes Simplex virus with vesicular lesions on breast.
3. Maternal use of some medications, i.e., radioactive substances, chemotherapy, etc., that may cause side effects such as drowsiness and/or respiratory depression or result in thyroid suppression and/or electrolyte abnormalities.

### **E. Conditions that are not contraindications to breastfeeding**

1. Positive HBsAg; if the infant receives both hepatitis B vaccine and hepatitis B immune globulin, breastfeeding need not be delayed while waiting for administration.
2. Positive Hepatitis C. There are no reported cases of transmission via breast milk (AAP/ACOG 2007, Guidelines for perinatal care. 6<sup>th</sup> ed.).



**F. The nurse will explore reasons when a mother states that she has no plans to breastfeed, or requests formula.**

G. When a mother requests her breastfeeding infant be supplemented with a breast milk substitute, the staff will explore and address the mother's concerns. The mother will be taught the possible negative consequences of feeding an infant breast milk substitutes without a medical indication. If the mother decides to feed her infant breast milk substitutes after receiving education, her choice will be supported by the staff. The education will be documented. The amount of each formula supplementation will be charted in the infant's medical record in addition to the type of supplemental feeding device used and the reason for the supplementation (i.e., for a mother's informed request). A physician order is required when an infant is supplemented as a result of an informed maternal request.

H. Staff will avoid the use of artificial nipples and infant feeding bottles when any healthy term breastfeeding infant receives a breast milk substitute (whether the breast milk substitute is given per mother's informed request or for a medical indication). The nurse will educate the mother on the possible negative effects the use of an artificial nipple can have on her breastfeeding success. The mother will be encouraged to utilize an alternative supplemental feeding device. Alternative supplemental feeding devices used at VCMC/SPH are syringes or supplemental nursing systems (SNS). The nurse will discuss with the patient the different options available in order to avoid an artificial nipple (either a syringe or an SNS). The nurse will teach the mother how to use the alternative feeding device she chooses. If, after the education, the mother continues to request an artificial nipple, the nurse will honor her request. The education and the mother's informed decision to use an artificial nipple will be documented in the infant's medical record.

I. VCMC/SPH continuously purchases infant formula, bottles, and nipples at a fair market value as required by Baby Friendly Guidelines and Evaluation Criteria since our Baby Friendly designation was conferred. Our methodology for determining fair market value is determined by our Central Supply department and through our buying group PHS.

**Step 8: Practice rooming in-allow mothers and infants to remain together twenty-four hours a day.**

- A. All mother-newborn couplets practice rooming-in. Rooming-in is defined as mother and newborn couplet room together on a 24 hour basis. Rooming-in begins immediately after birth for vaginally born babies, and as soon as mother joins newborn in postpartum for Cesarean births.
- B. Newborn assessments and vital signs are performed at the bedside.
- C. Newborns are not separated from their mothers unless the newborn requires medical care in the Neonatal Intensive Care, Pediatric Intensive Care or Pediatric unit, or for blood draws and hearing screens. If mother's condition is unstable and necessitates transfer to an alternate unit, the newborn is housed in the Transitional Care Nursery until discharge, or until mother's condition improves and rooming-in can resume. This separation will not last more than one (1) hour. Reason for separation, location of the newborn, and the time parameter will be documented in the newborn's medical record.
- D. Mothers of breastfeeding newborns admitted to the Pediatrics unit are encouraged to stay with their newborn to prevent interruption of breastfeeding. Mothers of breastfeeding newborns admitted to the NICU or PICU are encouraged to pump their breasts every 2 to 3 hours to maintain lactation.
- E. When a mother requests transfer of her newborn to the nursery, it is the nurse's responsibility to explore the basis for this request. The nurse will educate mother on the importance of rooming-in, so that she can practice infant led feeding. The nurse will document this education in the newborns chart. The nurse will continue to support exclusivity of breastfeeding with the couplet.

- F. Transitional Care Nursery (see policy OB.65, *Admission of a Well Newborn to the Transitional Care Nursery*).

### **Step 9: Give no pacifiers or artificial nipples to breastfeeding infants.**

- A. Pacifiers and/or artificial nipples should not be given to any breastfeeding newborn unless specifically ordered by a physician, nurse practitioner, or requests by the mother.
- B. Considering the importance of pacifier use in the risk reduction of SIDS, mothers should also be informed on the appropriate time to introduce a pacifier with the breast feeding infant. This can generally be done around 3-4 weeks of age, once breastfeeding is well established.
- C. The nurse will explore the reasons for mother's request. Mother should be informed that pacifiers and/or artificial nipples are negatively associated with both duration and exclusivity of breastfeeding especially during the establishment of breastfeeding. The mother's informed choice will be documented in the newborn chart.
- D. In the event a newborn must undergo a painful medical procedure (i.e. circumcision), the newborn will be allowed to utilize the pacifier for pain control; the pacifier will be disposed of following the procedure.

### **Step 10: Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.**

- A. Discharge information offered to mothers will include:
  - a. Written education and discharge plan for routine follow up visits.
  - b. Ventura County Breastfeeding Coalition Resource Guide and Referral; a directory of breastfeeding support resources in Ventura County. The Breastfeeding Coalition of Ventura County is a county-wide resource for education, advocacy, and referral to ensure that breastfeeding becomes the cultural norm, while promoting maternal and infant health through exclusive breastfeeding for at least the first six months of life (The Breastfeeding Coalition, 2012).
  - c. Employees of manufacturers or distributors of breast milk substitutes, bottles, nipples, and pacifiers have no direct communication with pregnant women and mothers.
  - d. The facility does not receive free gifts, non-scientific literature, materials, equipment, money, or support for breastfeeding education or events from manufacturers of breast milk substitutes, bottles, nipples, and pacifiers.
  - e. No pregnant women, mothers, or families are given marketing materials or samples or gift packs by the facility that consists of breast milk substitutes, bottles, nipples, pacifiers, or other infant feeding equipment or coupons for the above items.
  - f. Any educational materials distributed to breastfeeding mothers are free from messages that promote or advertise infant food or drinks other than breast milk.
  - g. Policies and procedures impacting maternity care and infant feeding practices support breastfeeding according to current evidence based guidelines.

### **Documentation**

- A. LATCH Score in EHR
- B. Feeding flow sheets
- C. Individual care plan
- D. Nursing notes

#### E. Physician progress notes

- Lactation Specialist consultation
- Education record
- Hospital infant feeding postnatal checklist
- Intake and Output record
- Discharge summary

## REFERENCES:

- Academy of Breastfeeding Medicine Protocols
- Baby Friendly USA: Policy Development Tool & Guidelines and Criteria for Evaluation
- Hale, Thomas & Rowe, Hilary, "Medications and Mother's Milk"
- LactMed, <https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm>
- Mohrbacher, Nancy, "Breastfeeding Answers Made Simple: A Guide for Helping Mothers"

## ATTACHMENTS:

Attachment A – LATCH Breastfeeding Assessment

All revision dates:

4/3/2025, 8/19/2021, 11/20/2017, 4/1/2016, 4/1/  
2014, 10/1/2013, 6/1/2013, 12/1/2012, 6/1/2012, 5/1/  
2010, 3/1/2009, 1/1/2005

## Attachments

 [Attachment A - LATCH Breastfeeding Assessment](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	9/5/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/4/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/4/2025
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	6/4/2025



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**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** OB Nursing  
**References:**

## OB.28 Elective Termination of Pregnancy

### POLICY:

To provide Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) Obstetrics (OB) Departments staff with guidelines regarding their responsibilities in caring for patients for induction of fetal demise related to pregnancy termination.

### PURPOSE:

~~To induce fetal death prior to a procedure such as dilation and evacuation (D&E) or induction of labor for termination prior to 22+6/7 weeks gestation by last menstrual period and/or early ultrasound dating. The purpose of this procedure is to aid in a D&E procedure or to ensure fetal demise prior to delivery for induction.~~

In cases of termination of pregnancy prior to fetal viability, it may be necessary to induce fetal demise prior to surgical termination (D&E) or induction of labor. Fetal viability is defined by gestational age parameters and/or fetal well being. A fetus may be deemed non-viable past 23-24 weeks gestation due to severe medical conditions in the fetus that are not compatible with life.

In some cases, clinicians or patient's may express a preference to proceed with induction of labor or D&E after fetal demise has been insured. This document aims to support the procedural steps to insure fetal demise prior to induction of labor or surgical D&E.

1. Induction of fetal death is indicated for patients undergoing:
  - a. Induction of labor for termination of pregnancy if greater than or equal to ~~22~~23+0/76/7 weeks gestation by best dating on the day of induction. **OR**
  - b. Dilation and evacuation for termination of pregnancy if requested by surgical provider.

### PROCEDURE:

- A. Staff members have the responsibility to provide care to women undergoing elective termination of pregnancy. Care focuses on bio-psychosocial health promotion, maintenance, and/or restoration by attending to the woman's need for information to promote informed decision making, physiologic stability, personal hygiene, comfort, safety, and emotional support.
- B. Right of staff members to participate or object to participating in an abortion:
  1. Staff members may decline to participate in an elective termination. No staff member may impose their personal beliefs onto the said patient or care provider. For the purpose of this policy staff

- member includes all licensed and support staff.
2. Obligation to the patient does not stop when the patient's values conflict with those of the practitioner. While the staff member has the right to conscientiously object to participating in an abortion, the staff member is obligated to abide by the patient's values, even temporarily, until care is transferred to another staff member.
  3. A staff member shall not be penalized, harassed, embarrassed or disciplined for participating or refusing to participate in the performance of an abortion in keeping with the staff member's moral, ethical or religious beliefs.

## GUIDELINES

- A. Preparation of patient
  1. Reassure patient.
  2. Informed consent provided by physician team
  3. Nursing staff to obtain signed consent forms
  4. Explain the procedure to patient. Use of digoxin by physician. Insertion of lamenaria or cytotec by physician or registered nurse using sterile gloves and lubricant.
- B. [Mifepristone 200 mg as ordered](#)
- C. Digoxin 1.5-2mg/ml as ordered
- D. Laminaria or Cytotec as ordered ( *see Policy **OB. 24**, Use of intrauterine Cervical Ripening Agent with Fetal Demise*)
- E. Preparation of equipment and supplies at bedside.
- F. Assist physician as indicated.
- G. Check blood pressure prior to procedure, immediately after and as ordered, more frequently if indicated. Check temperature every four (4) hours, every 2 hours if ruptured.
- H. Observe carefully for excessive blood post-delivery. Dilation and curettage (D&C) may be required to completely empty uterus.

## EQUIPMENT

- A. IV Pitocin per protocol
- B. Blood pressure cuff, stethoscope, thermometer
- C. Amniocentesis Tray when administering Digoxin
- D. [Mifepristone](#)
- E. Digoxin
- F. Lamenaria or cytotec
- G. Gloves (sterile)
- H. Lubricant
- I. Born out of asepsis (BOA) pack
- J. Container or crib for fetus.

K. IV Infusion pump

## DOCUMENTATION

- A. Document all medication on the medication administration record (MAR). Document in electronic health record (EHR).
- B. Indicate time of delivery, sex, weight, and length of fetus. Record disposition of fetus. See OB policy OB.29, *Management of Antepartum Fetal Death*.
- C. In preparing fetus for Morgue, place identification bands on infant, wrap in baby blanket and chux. Place identification card with infant's name, weight, length and place on outside of chux.
- D. If sent to the Laboratory, properly label container with name and hospital number of mother.
- E. Place pathology order in Cerner EHR
- F. Place order for Autopsy if requested by family or provider.

## KEY POINTS

- A. Observe Standard Precautions
- B. Obtain consents; include consent for possible Dilatation and ~~Curetage~~Curettage, and blood administration.
- C. Psychological support of the patient is of extreme importance. Notify social worker. See OB policy OB.29, *Management of Antepartum Fetal Death*.
- D. Explore patient's wishes to see or to hold fetus after birth.
- E. Offer palliative care consultation. Observe patient for pain, start Patient Controlled Analgesia or regional anesthesia as ordered and assess effectiveness. Confirm with clinician if genetic testing or autopsy are requested.
- F. Products of Conception (See OB policy OB.29, *Management of Antepartum Fetal Death*):
  - 1. Are to be examined by the physician prior to being placed in formalin solution and sent to the Laboratory. If fetus is past 20 weeks gestation, over 500 grams in weight or over 25 cm in length, a stillborn certificate and disposition of remains are required.
  - 2. Nursing staff will record delivery information in the delivery logbook as follows:
    - a. Use green ink for **all** fetal demises. Record demises less than 20 weeks in the back of the book marked "Fetal Demise, Less Than 20 Weeks." Record demises greater than 20 weeks or greater than 500 grams if dates are unknown in regular section of delivery book.
    - b. Live births over 20 weeks with heartbeat, respirations or other signs of life are recorded in regular section of book in black ink.
  - 3. Upon request of burial by parents, arrangements with mortuary to be made by parents with social services.
  - 4. Fetus weighed and measured in OB if indicated.
  - 5. If patient cannot afford burial, consent form for VCMC to handle disposition of the fetus will be signed ("Authorization to Retain and Dispose of Body Form") See OB policy OB.29, *Management of Antepartum Fetal Death*.
  - 6. Honor patient's wishes as to hold the fetus, take 2 pictures, a lock of hair if applicable, and footprints

to give to family.

7. Check OB policy OB.29, *Management of Antepartum Fetal Death*, to see that all paperwork is completed by Social Services or nursing.

## REFERENCES:

[www.rn.ca.gov](http://www.rn.ca.gov) - Board of Registered Nurses, Reproductive Privacy Act

AWHONN: Perinatal Nursing, 4<sup>th</sup> Edition, 2013

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## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine & OB	Stephanie Denson: Manager, Medical Staff Office	1/9/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/15/2024
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	11/30/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	11/30/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	11/30/2023





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Owner: Kristina Swaim: Nurse Director,  
Maternal Child Health  
Policy Area: OB Nursing  
References:

## OB.31 Cervical Ripening

### POLICY:

To ripen the cervix of patients who are candidates for induction of labor.

### PROCEDURE:

**Candidates for Misoprostol, Dinoprostone Vaginal or Cervical Ripening Balloon include:**

- A. Fetal demise
- B. Gestational hypertension
- C. Preeclampsia, eclampsia
- D. Premature rupture of membranes (except cervical ripening balloon)
- E. Post-term pregnancy
- F. Maternal medical conditions (e.g., severe fetal growth restriction, isoimmunization, oligohydramnios)
- G. May be used with multiple gestation pregnancy
- H. Elective induction greater than 39 weeks gestational age

### Contraindications:

- A. Patient refusal
- B. Known hypersensitivity to prostaglandins
- C. Patients already receiving oxytocin (except cervical ripening balloon)
- D. Placenta previa
- E. When vaginal delivery is contraindicated
- F. Active genital herpes
- G. Category III fetal heart rate (FHR) tracing
- H. Patients with prior cesarean delivery (except cervical ripening balloon)

### Essential Steps:

- A. Determine vertex presentation with ultrasound.



- B. Perform sterile vaginal exam to determine Bishop score. In case of a low ( $\leq 6$ ) Bishop score, a cervical ripening agent may be considered.
- C. Place patient on an external fetal monitor (EFM). A 20 minute recording of the fetal heart rate and uterine contraction pattern shall be obtained with a Category I fetal strip.
- D. Obtain admission orders from licensed ~~independent~~ practitioner (~~LPLP~~). Carry out orders before administering ripening agent.
- E. Have patient void.
- F. Continue to monitor patient with the fetal monitor; refer to policy [OB.45 OB Management of Fetal Heart Rate Tracing](#).
- G. Re-dosing is withheld if:
  - 1. Tachysystole (5 or more contractions in a 10 minute period, averaged over 30 minutes) or hypertonus (contraction lasting greater than 120 seconds). The restrictions may be overridden at the discretion of the ~~LPLP~~ after clinical evaluation of the patient.
  - 2. Adequate cervical ripening is achieved.
  - 3. The patient enters active labor.
  - 4. Category II tracing must be reviewed by ~~LPLP~~ and approved prior to re-dosing.
  - 5. Category III tracing.

### Misoprostol:

- A. Equipment: 25 or 50 mcg misoprostol tablet, sterile gloves. Dosing can include the following.
  - 1. 25 mcg inserted intravaginally every four (4) hours by ~~LPLP~~ or registered nurse
  - 2. 25 mcg orally every two (2) hours
  - 3. 50 mcg orally every four (4) to six (6) hours
- B. Keep patient supine for one (1) hour following vaginal insertion.
- C. Intermittent Fetal Monitoring may be used according to policy [OB.45 OB Management of Fetal Heart Rate Tracing](#) as directed by ~~LPLP~~ and risk factors.
- D. ~~Oxytocin may be started 2-6 hours after last dose of misoprostol~~ Oxytocin may be started 2-6 hours after last dose of misoprostol based on frequency of dosing ordered.
  - 1. Misoprostol ordered q 4 hours, oxytocin may be started 4 hours after last dose.
  - 2. Misoprostol ordered q 2 hours, oxytocin may be started 2 hours after last dose.
  - 3. Misoprostol ordered q 6 hours, oxytocin may be started 6 hours after last dose.
- E. Maximum number of doses is six (6). If a patient has been administered a 6 doses a safety huddle will be initiated by the Healthcare team.

### Dinoprostone Vaginal:

- A. Equipment: dinoprostone, sterile gloves.
- B. Dose is 10 mg in a vaginal insert.
- C. Unstable at room temperature, must be refrigerated until use.
- D. Inserted by ~~LPLP~~ or registered nurse.

- E. Keep patient supine for two (2) hours following insertion.
- F. Remove after onset of labor or after 12 hours.
- G. Assess for removal if tachysystole (5 or more contractions in a 10 minute period) or hypertonus (contraction lasting greater than 120 seconds).
- H. Delay oxytocin for 30 minutes after removal of insert, follow approved policy [OB.30 Oxytocin use for Labor Induction/Augmentation](#).
- I. Monitor for 30 minutes after removal.

### Cervical Ripening Balloon In-Patient:

- A. ~~Equipment: 18F foley catheter, large luer lock syringe, stylet, speculum, long forceps (provider preference).~~ Equipment: Cervical Ripening balloon per provider preference.
- B. Pass catheter through cervix.
- C. Inflate with ~~30-60 mL of~~ sterile saline as ordered.
- D. Secure to inner aspect of patient's thigh.
- E. Ambulation is appropriate with intermittent EFM per policy [OB.45 OB Management of Fetal Heart Rate Tracing](#) and LPLP's orders.
- F. Continuous traction may be applied to the catheter. Patient may experience a vasovagal response; discontinue traction if this occurs.
- G. Notify LPLP to deflate or remove balloon, rupture of membranes, fever, bleeding, or uterine tachysystole.
- H. May use cervical ripening balloon in conjunction with oxytocin or cervical ripening agent per LPLP's orders.

### Cervical Ripening Balloon Out-Patient:

Procedure is to be performed by a LPLP after review of chart, review of exclusion criteria, obtaining a reactive fetal non-stress test (NST) , after obtaining informed consent from the patient. (Attachment A).

- A. LPLP should call Labor and Delivery (L&D) Unit to assure appointment can be scheduled for induction of labor the following day, no more than 24 hours after placement of cervical ripening ballon.
- B. LPLP should review patient's clinical chart and determine that the patient is an appropriate candidate.
  - 1. **Eligibility:** If there are any questions about the patient's candidacy, please call the on-call LPLP on L&D.
    - a. 39 weeks gestational age or greater at the time of Foley balloon placement by good prenatal dating
    - b. Bishop Score less than 6
    - c. Intact membranes
    - d. Vertex presentation
  - 2. **Exclusions:**
    - a. Any contraindications to a vaginal delivery/induction of labor
    - b. Severe maternal hypertension (stable chronic and gestational hypertension are okay)
    - c. Previous uterine incision

d. Multiple gestation

- C. **LPLP** should review the procedure with the patient and obtain informed consent.
- D. Assess vital signs, NST and Deepest Vertical Pocket (DVP) prior to placement of Foley balloon. Patient must have a reactive NST and adequate DVP.
- E. Place Foley and inflate with 30 mL to 60 mL of normal saline.
- F. Notify **LPLP** of suspected rupture of membranes, fever, abnormal bleeding, non-reassuring fetal heart tones (FHT) or tachysystole.
- G. Provide and review the post procedure instructions with the patient.

## BISHOP'S SCALE:

SCORE				
CERVICAL STATE:	0	1	2	3
Dilation (cm)	Closed	1-2	3-4	5-6
Effacement %	0-30	40-50	60-70	≥80
Station of Head	-3	-2	-1/0	+1/+2
Consistency of Cervix	Firm	Medium	Soft	---
Position of Cervix	Posterior	Midposition	Anterior	---

## EQUIPMENT

- A. Sterile gloves.
- B. Fetal heart monitor.
- C. Written order
- D. Intravenous infusion pump (with IV use only).
- E. Agents used in this facility are misoprostol and dinoprostone vaginal, cervical ripening balloon. The recommended dose for misoprostol is 25 mcg in pill form for intravaginal use or 50 mcg for oral use. The time-release formulation of dinoprostone contains 10 mg of PGE<sub>2</sub>.

## DOCUMENTATION

- A. Document the administration of cervical ripening medication in the Electronic Health Record (EHR) for antepartum care. Include how the patient tolerated the procedure.
- B. Assessment of fetal size should be documented prior to the start of cervical ripening or induction of labor
- C. Document FHR and contraction pattern. Follow policy [OB.45 OB Management of Fetal Heart Rate Tracing](#).

## KEY POINTS

- A. Observe standard precautions.
- B. Apply the external fetal monitor and monitor both FHT and uterine contractions while medication in place.
- C. Place the patient in the lithotomy position for the insertion of the cervical ripening medication.

- D. Dinoprostone vaginal is to be inserted by the **LPLP** or registered nurse. Misoprostol may be inserted by **LPLP** or registered nurse.
- E. Patient may progress to active labor status.
- F. The vaginal insert dinoprostone can be easily removed in the event of tachysystole or Category II or Category III FHR tracing.
- G. Exercise caution when using in patients with:
1. Asthma or history of asthma
  2. Glaucoma
- H. Oxytocin may be started 2-6 hours after last dose of misoprostol and 30 minutes after removal of dinoprostone vaginal insert.

## REFERENCES:

- ACOG Bulletin #143, March 2014
- Rice-Simpson, Kathleen. AWHONN Cervical Ripening and Induction and Augmentation of Labor 2nd Edition
- ACOG Bulletin #107, March 2015
- AAP/ACOG Guidelines for Perinatal Care 6th Ed., p. 150
- ACOG Practice Bulletin Number 107
- AWHONN: Perinatal Nursing, 4<sup>TH</sup> edition, 2013

All revision dates:

9/15/2025, 11/19/2024, 10/11/2023, 10/14/2020, 4/29/2020, 5/15/2019, 5/15/2019, 1/1/2015, 11/1/2013, 5/1/2011, 7/1/2010, 1/1/2005, 12/1/1992

## Attachments

-  [Cervical Ripening Consent2020.pdf](#)
-  [Cervical Ripening Patient Educaiton .PDF](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine & OB	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/23/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/31/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/31/2025
Policy Owner	Kristina Swaim: Nurse Director, Maternal Child Health	7/31/2025



**Origination:** 2/11/2019  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** 2/15/2025  
**Next Review:** 3 years after approval  
**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** PEDS/PICU  
**References:**

## P.43 Prevention of Ventilator-Associated Events in the PICU

### POLICY:

To provide PICU-specific guidelines for the prevention and surveillance of ventilator associated events (VAE).

### PROCEDURE:

1. All hospital-wide policies and procedures shall be observed in addition to PICU-specific policies regarding the prevention of VAE.
2. Hand hygiene, use of personal protective equipment (PPE) and equipment decontamination and handling will be performed according to Infection Prevention policies and procedures.
3. Oral care is to be provided to intubated patients every 4 hours and as needed using the oral care kit appropriate for the patient's age.
  - All oral care kits are for single patient oral use.
  - In patients under 2 years or in children with small oral cavities, oral care is to be provided using oral care kits containing Biotene®.
  - In patients over 2 years of age oral care is to be provided using kits containing the following: Cetylpyridinium.05% and hydrogen peroxide 1.5% swabs, covered yankauer, suction handle and Y-connector.
4. The head of the bed will be elevated 15-30 degrees on all intubated patients unless contraindicated (spinal cord injury).
5. All patients over 8 years of age or with risk factors (including but not limited to: central venous catheter placement, craniotomy, laparotomy, trauma, cardiac diagnosis, obesity) will be placed on sequential compression stockings to assist in the prevention of deep venous thrombosis. Use of enoxaparin should be considered in patients with two (2) or more risk factors.
6. All intubated patients shall be considered for stress gastric ulcer prevention for the length of intubation.
7. Assessment of readiness to wean from the ventilator will occur once a day.
  - RN and RCP will discuss recommendations for weaning of ventilator settings, nebulizer treatments or extubation during shift assessment.
  - RN and RCP will discuss any significant factors influencing readiness to wean with the pediatric

intensivist.

## General VAE Prevention Care Guidelines:

1. Hand hygiene with either antimicrobial soap and water or alcohol gel will be performed prior to any patient contact and after contact with patient or their environment per Administrative policy [106.055 Hand Hygiene](#).
2. Elevate head of bed 15 - 30 degrees unless contraindicated (e.g. spinal cord injury) or a physician order is present stating otherwise. In patients where elevation of the head of the bed is not possible, evaluate for the use of rotational bed with pediatric intensivist.
3. Patients will be turned a minimum of every 2 hours to increase pulmonary drainage and decrease the risk for VAP.
4. All patients over 8 years of age or with risk factors will be placed on sequential compression stockings to assist in the prevention of deep venous thrombosis unless contraindicated. In patients under 8 years of age, evaluation for use of sequential compression stockings will occur on a case by case basis.
5. In patients with cuffed tubes, endotracheal tube cuff pressure should be maintained at minimal occluding volume (MOV).

## Oral Care Guidelines:

1. Prior to the provision of oral care, the nurse will verify the security of the endotracheal tube by ensuring the tape/tube holder is secure. If the endotracheal tube is not secure, the nurse will notify the respiratory therapist immediately.
2. Oral care is to be provided to intubated patients every 4 hours and as needed using the oral care kit appropriate for the patients age.
3. Prior to provision of oral care, the oral cavity will be suctioned to remove excess secretions.
  - **Biotene®** - In patients under 2 years or in children with small oral cavities, oral care is to be provided using oral care kits containing Biotene®.
    - a. Apply Biotene® gel to swab and then to lips to soften dried saliva.
    - b. Apply Biotene® gel with foam swab to gums (inside and outside) and tongue (do not force swab).
    - c. Gently swab oral cavity while exerting gentle pressure using short horizontal and/or circular strokes.
    - d. Swab exterior surface of endotracheal tube (ETT) residing in oral cavity.
    - e. Residual gel remains in mouth to act as moisturizer and will dissolve over one hour or so.
    - f. Reapply thin coating of Biotene® gel to lips to act as moisturizer.
    - g. **Dispose of excess gel and swabs – these are single use items.**
  - **Hydrogen Peroxide** - In patients over 2 years of age, oral care is to be provided using kits containing the following: Cetylpyridinium .05% and hydrogen peroxide 1.5% swabs, suction handle, covered yankauer, oropharyngeal suction tool, toothbrush, oral foam swab, and Y-connector.
    - **General Information**
      1. The provided suction handle connects to the standard suction tubing. It allows for variable suction control and facilitates changing of provided oral suctioning tools.

- When not in use, make sure the ON/OFF switch is in the OFF position to prevent the loss of suction power.
2. The soft tipped covered yankauer helps remove debris and oral secretions.
    - To use the covered yankauer, retract the sleeve and slide cap down until it locks into place.
    - Close the sleeve when not in use to help contain oral secretions and protect the yankauer from collecting environmental debris.
    - Rinse after use with sterile saline until tubing is clear.
    - The covered yankauer should remain in place when toothbrush/suction swab is not in use.
  3. The suction toothbrush is to be used for the removal of dental plaque, debris, and oral secretions. It has two sides, a green foam side and a brush side. The foam side can be used for gentle cleaning of the gums and tongue. The brush side is for the removal of dental plaque and difficult to remove debris.
    - The suction toothbrush is for single patient oral use.
  4. The suction swab is to be used between brushings to remove debris and oral secretions.
  5. The soft, flexible oropharyngeal suction catheter is used to remove secretions from the oropharyngeal area above the vocal cords.
  6. Use the hydrogen peroxide solution as an oral debriding agent to remove phlegm, mucus or other secretions.
  7. Use the antiplaque solution to remove plaque that leads to gingivitis. This solution also acts as an oral antiseptic reducing the chance of oral infection or minor irritations.
  8. Use the mouth moisturizer to soothe and moisturize lips and oral tissue after providing oral care and as needed.
    - **Directions for Use**
1. Before opening toothbrush/suction swab package: turn package over, burst oral care solution packet with thumbs.
  2. Peel lid to open.
  3. Remove Mouth Moisturizer package and applicator swab.
  4. Attach toothbrush/suction swab to suction handle.
  5. Clean teeth and oral cavity for approximately one minute.
  6. To suction, slide switch on suction handle to ON position. When finished return switch on suction handle to OFF position.
  7. To clear suction tubing, rinse with sterile saline or sterile water.
  8. Ensure foam is intact after use. If not, remove any particles from oral cavity
  9. Discard toothbrush/suction swab. Reattach covered yankauer to suction handle.

## Suctioning Guidelines:

1. **Use separate suction setup for ETT and oral suction systems.** This includes canisters/tubing, etc. (The risk of cross-contamination between oral and ETT is high.) Change canisters and tubing every 24 hours and/or as needed. Date the canister when changed. Label one canister "oral suction," and the other

“ETT suction.”

2. Change Ballard In-line suction catheters every 24 hours and as needed.
3. The RN will change oral suctioning devices (yankauer, little sucker, bulb syringes) every 24 hours and as needed. Covered yankauer suction devices should be used whenever the VAP kits for patients over 2 years of age are utilized.
4. Use in-line suction catheter to suction ETT.
5. Suction only as clinically indicated. Clinical conditions include but are not limited to:
  - ☐ Visible secretions.
  - Unexplained drop in SaO<sub>2</sub> and/or evidence of secretions per airway graphics auscultation.
6. Suction mouth prior to ETT or nasal suctioning.
7. Oral suctioning should occur before ETT suctioning, before repositioning ETT, prior to extubation or significant patient repositioning.
8. The tip of the suction tubing is to be stored in a non-sealed plastic bag when not using a covered yankauer.
9. Avoid lavage with normal saline when suctioning. If saline is necessary, wear clean gloves and use an alcohol pad to open the ampule to decrease risk of contamination.
10. Rinse in-line catheter with a saline ampule using the opening technique described above.

### **Ventilator Management:**

1. Ventilator circuits will be changed and dated every 7 days by Respiratory Therapy.
2. The nurse/RCP will monitor and drain condensate (every 2 hours) from the ventilator circuit away from the patient into the collection cup as it accumulates.
3. Always drain the ventilator circuit prior to repositioning the patient.

### **Gastric Guidelines:**

1. Placement of patients on peptic ulcer disease prophylaxis is recommended.
2. Gastric overdistention should be avoided in an attempt to prevent aspiration.
3. Gastric residual volumes may be checked every four (4) hours and prior to bolus feeds in patients with enteral feeding tubes.

### **Documentation:**

1. Document oral/airway care outcomes in the patient's electronic health record (EHR).

## **SURVEILLANCE:**

~~VAE is defined as nosocomial pneumonia diagnosed in patients mechanically ventilated for at least 48 hours with signs of a new lower respiratory tract infection.~~

~~VAE should be suspected when a mechanically ventilated patient develops a new or progressive and persistent infiltrate on 2 or more serial chest radiographs.~~

~~Clinical criteria for the suspicion of VAE include:~~

- ~~▪ In children <1 year of age:~~



- ~~• A new or progressive and persistent radiographic infiltrate, plus worsening gas exchange (eg, O<sub>2</sub> desaturation, increased O<sub>2</sub> requirement, or increased ventilatory support) and three of the following:~~
      - ~~1. Temperature instability.~~
      - ~~2. Blood leukocyte count of > 15,000 cells/ml or < 4,000 cells/ml.~~
      - ~~3. New onset of purulent tracheobronchial secretions, increase secretions, or increased suctioning requirements.~~
      - ~~4. New onset of tachypnea, and nasal flaring with retraction of chest wall. New onset of wheezing, rales, or rhonchi.~~
      - ~~5. New onset of cough.~~
      - ~~6. Bradycardia (<100 bpm) or tachycardia (>170 bpm).~~
  - ~~• In children > 1 year of age:~~
    - ~~• A new or progressive and persistent radiographic infiltrate, plus three of the following:~~
      - ~~1. Temperature of > 38.4 °C or < 36.5 °C.~~
      - ~~2. Blood leukocyte count of > 15,000 cells/ml or < 4,000 cells/ml.~~
      - ~~3. New onset of purulent tracheobronchial secretions, increased secretions, or increased suctioning requirements.~~
      - ~~4. New onset of dyspnea, apnea, or tachypnea.~~
      - ~~5. New onset of rales or rhonchi.~~
      - ~~6. Worsening gas exchange (eg, O<sub>2</sub> desaturation, increased O<sub>2</sub> requirement, or increased ventilatory support).~~

~~Laboratory studies are not required for the clinical diagnosis of pneumonia.~~

- ~~• Acceptable confirmatory laboratory studies include:~~
    - ~~• Deep tracheal lavage (e.g., Blind Bronchial Sampling).~~
    - ~~• Bronchoalveolar lavage.~~
    - ~~• Pleural fluid culture.~~
    - ~~• Positive culture of virus from respiratory secretions.~~
    - ~~• Positive detection of viral antigen or antibody from respiratory secretions (e.g., PCR, EIA, DFA).~~
  - ~~• Routine tracheal aspirates are not conclusive, as positive results may reflect colonization and not true infection. Clinical correlation is necessary.~~

## • Settings

- Neonatal and Pediatric locations in acute care hospitals where denominator data (ventilator and patient days) can be collected for patients.

## • Inclusion Criteria

- All patients in the neonatal and pediatric inpatient locations regardless of patient's age
- Patient on a ventilator who are receiving
  - A conventional mode or mechanical ventilation
  - High-frequency oscillatory or jet ventilation
- Patients on a ventilator who are receiving a conventional mode of mechanical ventilation or high frequency oscillatory or jet ventilation
  - While in prone position
  - While receiving surfactant, corticosteroids, nitric oxide therapy, helium-oxygen mixtures (heliox)

or epoprostenol therapy

• Exclusion Criteria

- All patients in the adult inpatient locations regardless of patient's age
- Patients on extracorporeal life support or paracorporeal membrane oxygenation are excluded from PedVAE surveillance during periods of time when the support is in place for the entire calendar day

• Definitions

- PedVAE: are identified by deterioration in respiratory status after a period of stability or improvement on the ventilator. Patients must be mechanically ventilated for at least 4 calendar days to fulfill PedVAE criteria (the day of intubation and initiation of mechanical ventilation is day 1).
- Ventilator: Any device used to support, assist, or control respiration (inclusive of weaning period) through the application of positive pressure to the airway when delivered via an artificial airway, specifically an oral/nasal endotracheal or tracheostomy tube.
- Mean Airway Pressure (MAP): The average pressure exerted on the airway and lungs from the beginning of inspiration until the beginning of the next inspiration. In patients on mechanical ventilation, MAP is the most powerful influence on oxygenation and is determined by positive end-expiratory pressure (PEEP), peak inspiratory pressure (PIP), inspiratory time, and frequency. A sustained increase in the daily minimum MAP of > 4cmH<sub>2</sub>O following a period of stability or improvement on the ventilator is one of the two criteria that can be used in meeting the PedVAE definition.
- Fraction of Inspired Oxygen (FiO<sub>2</sub>): The fraction of oxygen in inspired gas. A sustained increase in the daily minimum FiO<sub>2</sub> of > 0.25 (25 points) following a period of stability or improvement on the ventilator is one of the two criteria that can be used in meeting the PedVAE definition.
- Daily Minimum MAP: The lowest value of MAP during a calendar day (see attachment).

• Algorithm

Patient has a baseline period of stability or improvement on the ventilator, defined by > 2 calendar days of stable or decreasing daily minimum \*FiO<sub>2</sub> or MAP values. The baseline period is defined as the 2 calendar days immediately preceding the first day of increased daily minimum FiO<sub>2</sub> or MAP.

- Daily minimum FiO<sub>2</sub> is defined as the lowest value of FiO<sub>2</sub> documented during a calendar day that is maintained for > 1 hour.
- Daily minimum MAP is the lowest value documented during the calendar day.
- For patients < 30 days old, daily minimum MAP values 0-8 cmH<sub>2</sub>O are considered equal to 8 cmH<sub>2</sub>O for the purpose of surveillance.
- For patients > 30 days old, daily minimum MAP values 0-10 cmH<sub>2</sub>O are considered equal to 10cmH<sub>2</sub>O for the purposes of surveillance.



After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

- A. Increase in daily minimum FiO<sub>2</sub> of > 0.25 (25 points) over the daily minimum FiO<sub>2</sub> of the first day in the baseline period, sustained for > 2 calendar days.
- B. Increase in daily minimum MAP values of > 4 cmH<sub>2</sub>O over the daily minimum MAP of the first day in the baseline period, sustained for > 2 calendar days.



### Pediatric Ventilator-Associated Event (PedVAE)

The determination of VAE shall be made by the pediatric intensivist upon review of relevant historical factors, clinical findings, and laboratory results.

## REFERENCES:

~~Guidelines for Preventing Healthcare-Associated Pneumonia, Centers for Disease Control and Prevention, 2003.~~

~~Getting Started Kit: Prevent Ventilator-Associated Pneumonia (How-to Guide), Institute for Healthcare Improvement, 2005.~~

~~Ventilator-Associated Pneumonia, Pediatric Supplement, Pediatric Affinity Group.~~

1. [National Healthcare Safety Network \(NHSN\), Pediatric Ventilator-Associated Event \(PedVAE\) For use in neonatal and pediatric location only. January 2024. CDC](#)
2. [Mahmoud, N., Hammad, A., Okaily N., & Afify, M. \(2024\). Value of implementing a care bundle approach to improve outcome of pediatric ventilator – associated events \(PedVAE\) in pediatric intensive care unit \(PICU\). International Journal of Pediatrics and Adolescent Medicine 11\(3\):p 70-82, September 2024. | DOI: 10.4103/ijpam.ijpam\\_61\\_24](#)
3. Oral Health and Care in the Intensive Care Unit: State of the Science, American Journal of Critical Care, January 2004, Volume 13, No. 1, 25-33.
4. Pittet, D et al. Prevention of Ventilator-associated Pneumonia by Oral Decontamination, American Journal of Respiratory and Critical Care Medicine, August 2001, 164(3): 338-339.

~~American Thoracic Society. 2005. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am. J. Respir. Crit. Care Med. 171:388-416. [PubMed]~~

~~Steven M. Koenig and Jonathon D. Truwit Ventilator-Associated Pneumonia: Diagnosis, Treatment, and Prevention, Clin Microbiol Rev. 2006 October; 19(4): 637–657. doi: 0.1128/CMR.00051-05.~~

~~Elward, A, Warren, D, and Fraser, V. Ventilator-Associated Pneumonia in Pediatric Intensive Care Unit Patients: Risk Factors and Outcomes, Pediatrics, 2002; 109:758-764.~~

All revision dates:

2/15/2025, 2/11/2019

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/6/2025
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/31/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/17/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/17/2025
Pediatric Intensive Care Unit	Jesse Wyatt: MD	7/17/2025
Pediatric Intensive Care Unit	Jennifer Ferrick: Director, Peds/PICU & NICU	2/11/2025



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**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** N/A  
**Next Review:** 3 years after approval  
**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** PEDS/PICU  
**References:**

## P.47 Pupillometer

### PURPOSE:

To define when and how to use the NPi®-300 pupillometer to:

- A. Provide a reliable, objective measurement of pupillary size and reaction
- B. Anticipate potential increases in intracranial pressure (ICP) related to changes in pupillary size or decrease in NPi®

### DEFINITIONS:

- A. **ECLS:** Extracorporeal Life Support
- B. **ECMO:** Extracorporeal Membrane Oxygenation
- C. **Neurological Pupil Index™ (NPi®):** An algorithm developed by NeurOptics® scientists to remove subjectivity from the pupillary evaluation. A patient's pupil measurement (including variables such as size, latency, constriction velocity, dilation velocity, etc.) is compared against a normative model of pupil reaction to light and automatically graded by the NPi™ on a scale of 0 to 5.

Measured Value	Assessment
≥ 3	Normal/Brisk
< 3.0	Abnormal/Sluggish
0	Non-reactive or Atypical
A difference in NPI between right and left pupils of ≥ 0.7 can also be considered an abnormal pupil reading	

- D. **NPi®-300 Pupillometer:** A hand-held, automated infrared device which provides quantitative pupillary measurements by taking 30 pictures per second of the pupil's response to light stimulus.
- E. **NPi®-300 SmartGuard™ Headrest:** Single patient use device with smartcard technology that stores patient data and facilitates data upload into electronic health record. Each SmartGuard™ will hold as many as 168 individual patient and pupil assessments. The NPi®-300 SmartGuard™ attaches to the pupillometer device and is used to position the device at the right angle to the patient's axis of vision.

### POLICY:

- A. Use of the NPi®-300 pupillometer does not require a provider order.
- B. Use of a pupillometer for pupillary assessment may be beneficial in neurological diagnoses such as:

1. Traumatic brain injury
  2. Subarachnoid hemorrhage from aneurysmal rupture or vascular malformation
  3. Intracerebral hemorrhage
  4. Ischemic stroke
  5. Post-op craniotomy
  6. Multisystem trauma presenting the ED unconscious
  7. Brain tumor
  8. Hydrocephalus (post-op endoscopic third ventriculostomy, pre/post shunt revision, suspected shunt malfunction/failure)
  9. Suspected brain death
  10. ECLS/ECMO patients
  11. Seizure/status epilepticus
  12. CNS infections
- C. A baseline pupillometer reading should be obtained as early as possible in the emergency department or upon admission/transfer to the PICU.
- D. Any patient admitted to the PICU should routinely have a pupillometer reading by frequency as clinically indicated by provider order.
- E. Patients with the above diagnoses and any patient with an external ventriculostomy device (EVD) should routinely have pupilometer readings a minimum of every 2 hours or more frequently as clinically indicated.
- F. A pupillometer reading should be obtained with any neurologic change or concern.
- G. For above diagnoses with intracranial pressure (ICP) monitoring in place:
1. Reassessment with the pupillometer should be completed 30 minutes after an intervention to decrease ICP
  2. Once the ICP monitor is removed, pupils should be checked hourly for the first 12 hours following removal. If the patient status changes (decreased level of consciousness), notify the provider and increase the frequency of pupillometer checks.
- H. The provider should be notified of the following significant findings or changes in assessment:
1. NPi < 3.0 (change from baseline)
  2. Difference in Right to Left pupil size of > 1.0 mm (change from baseline)
  3. Difference in Right to Left NPi of  $\geq 0.7$
  4. Note: A downward trend of the NPi may be an indication of impending neurologic deterioration.
  5. NPi < 3.0 (change from baseline)
- I. In the event the patient is unable to cooperate with the pupillometer assessment, or a pupillometer reading is unable to be obtained for any reason, pupils should be assessed using the traditional manual flashlight method.
- J. The nurse will document the pupillometer assessment in the medical record or document "unable to obtain", when appropriate.
- K. Patients receiving barbiturates or very high doses of propofol may lose pupillary response to light. In

these patients, if their pupils no longer react to light, pupillometer assessment should be obtained a minimum of once per shift until barbiturate/propofol therapy is withdrawn.

- L. The NPi®-300 SmartGuard™ headrest is designed for single patient use and may be used on that specific patient throughout their admission to the hospital.
- M. To comply with HIPAA guidelines, the patient data stored on each SmartGuard™ must be disabled prior to being discarded in the regular trash.

## PROCEDURE:

- A. Use above criteria to determine proper indication and frequency of use.
- B. Lift NPi®-300 pupillometer out of the charger (tilt forward then lift).
- C. The NPi®-300 should turn on automatically. If the device was not placed on the charger, then you need to manually start it by pressing the upper arrow for 10 seconds.
- D. Open a new SmartGuard™ headrest. Gently squeeze the SmartGuard™ side tabs to position onto the NPi®-300. There will be an audible click when the SmartGuard® is properly positioned.
- E. For the first patient use, in order to properly input the patient ID into the SmartGuard™, select either Barcode Scanner or Manual ID to indicate the patient ID entry method used.
  - 1. Pairing to the Antimicrobial Barcode Scanner
    - a. Connect the barcode scanner and charging cable to the power supply and plug into a power outlet. Turn on the barcode scanner until an audible beep is heard and a blue light on the device flashes. Position the barcode scanner next to the NPi®-300.
    - b. On the NPi®-300, select Barcode Scanner. The NPi®-300 will display "**Connecting...**" on the touchscreen.
    - c. Once successfully paired, the touchscreen will prompt when the device is ready to scan the patient ID barcode.
    - d. The patient ID will now appear on the NPi®-300 touchscreen. Confirm the patient information is correct and select **Accept**.
    - e. The NPi®-300 will display with the patient ID and be "**Ready to Scan**".
  - 2. Manual Entry of the Patient ID
    - a. Press **Manual Entry**. Using the touchscreen, enter the patient financial identification number (FIN). Select **Shift** to toggle from alpha to numeric, as required. When the patient's FIN has been manually entered, check for accuracy and press **Enter**.
- F. Position the NPi®-300 with SmartGuard™ at a right angle to the patient's axis of vision, minimizing any tilting of the device.
- G. Press and hold either the Right or Left button until the eye is centered on the touchscreen and the display shows a green circle around the pupil. Once the green circle appears, release the button and hold the NPi®-300 in place for approximately three seconds until the result screen is displayed.
- H. Repeat the scan procedure for the patient's other eye to complete the bilateral pupil exam.
- I. When the bilateral pupil exam is complete, the NPi®-300 measurement results will be displayed in yellow for the left eye and in green for the right eye.
- J. Using the touchscreen or keypad, select page 1 (1/2) or 2 (2/2) to display the results of the pupil



measurement parameters and pupillary light reflex waveform.

- K. From the Results screen, select the Video icon to view the video playback of the reading.
- L. Document the NPi and size in the Pupillometer Assessment in the electronic health record.
- M. Immediately report the following abnormal values to the provider:
  - 1. Increase in size between right and left pupil > 1mm following admission assessment of pupils equal in size.
  - 2. Increase in Right to Left NPi of  $\geq 0.7$
  - 3. % change of pupil (before/after light stimulus) < 10%
  - 4. NPi < 3
- N. Compare and trend the values and report any significant change in pupil size/reactivity to the physician immediately.
- O. To visualize the parameter trend display, use either the keypad or the touchscreen to select the **Chart** icon from the main screen of the NPi®-300. Select the Down arrow on the keypad to view a trend display of the patient's NPi® and Size measurements. To trend additional parameters, select **Trending Variables** from the **Settings** menu, and choose the desired parameters to trend.
- P. Remove the SmartGuard™ headrest. Keep the headrest at the patient's bedside for further use.
- Q. Once the patient is discharged from the hospital, permanently disable the patient data by going to the **Settings** menu, press **Disable SG** and follow the prompts. Place the disabled SmartGuard™ in the trash.
- R. Place the pupillometer firmly in the charger when not in use. The touchscreen will display a blue battery icon indicating it is charging. The battery icon will turn green when fully charged.

If the NPi®-300 is not in the charging station, to conserve battery life the pupillometer will:

- 1. Go into sleep mode after 5 minutes. Touch the screen to turn on.
  - 2. Power down after 30 minutes. Press the On/Off button to the right of the device.
- S. To clean the NPi®-300 device, use the Super Sani-Cloth disinfectant wipes (purple top).

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## Attachments

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## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/6/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/11/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/11/2025
Pediatric Intensive Care Unit	Jesse Wyatt: MD	9/11/2025
Pediatric Intensive Care Unit	Kristina Swaim: Nurse Director, Maternal Child Health	9/10/2025



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Owner: Sul Jung: Associate Director of Pharmacy Services  
Policy Area: Pharmacy Services  
References:

## PH.26.01 Training and Evaluation of Pharmacy Staff in Sterile Drug Preparation

### POLICY:

This policy promotes the safe, efficient, and uniform performance of all Pharmacy staff involved in the preparation of compounded sterile preparations (CSPs).

- The Pharmacy Department shall develop and maintain an initial and ongoing competency evaluation process for Pharmacy staff involved in sterile compounding.
- All Pharmacy staff involved in sterile compounding shall have the skills and training required to properly and accurately perform their assigned sterile compounding responsibilities.
- Training shall also include support staff whose jobs are related to the sterile compounding process.
- Pharmacy staff assigned to sterile compounding duties shall demonstrate knowledge about processes and procedures used in sterile compounding prior to compounding any sterile drug preparation, which may include hazardous drugs (HD).

### PROCEDURE:

#### Training and Process Validation

- A. All-sterile Training and competency procedures for all staff who compound or have direct supervisor and control of staff performing compounding ~~staff~~ shall be trained and demonstrate competence on the following:
1. Sterile compounding policies and procedures.
  2. Aseptic technique.
  3. Pharmaceutical calculations and terminology.
  4. Documentation of compounding processes (e.g., master formula and compounding records)
  5. Quality assurance procedures.
  6. Proper hand hygiene and garbing.
  7. General conduct within the compounding area.
  8. Cleaning, disinfection and maintaining of the equipment and the controlled area.
    - a. Principles of movement of materials and personnel.

- b. Maintaining sterility.
  - c. Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO class 5 area.
- 9. Container closure and equipment selection
- 10. Use of equipment-
- 11. Component selection and handling
- B. All sterile compounding staff working with HDs shall also complete HD training and competency (see policy [PH.27.00 Hazardous Drug Overview](#))
- C. Proficiency and continuing training needs shall be reassessed at least every twelve months for each individual involved in sterile compounding.
- D. Training and Evaluation
  - 1. Hand hygiene and garbing competency
    - a. Gloved fingertip and thumb (GFT) sampling shall be successfully completed at least three separate times before initially being allowed to compound CSPs.
    - b. Subsequent gloved fingertip testing shall be successfully completed at least once every 6 months.
    - c. Completed samples shall be incubated at 30-35°C for no less than 48 hours and then at 20-25°C for no less than 5 additional days.
      - i. No growth (0 colony-forming unit or CFU) denotes a pass.
      - ii. Any growth ( $\geq 1$  CFU) denotes a failure.
  - 2. Aseptic technique competency shall be successfully completed initially and once every 6 months in the following sequence
    - a. Medium risk media fill test
      - i. Completed medium samples shall be incubated at 20-25°C and 30-35°C for a minimum of 7 days at each temperature band
        - a. A clear solution denotes a pass
        - b. A turbid solution or presence of precipitate denotes a failure.
      - ii. Manufacturer, lot number, and expiration date of the media fill test shall be documented.
    - b. GFT sampling after media fill testing
      - i. Completed samples shall be incubated at 30-35°C for no less than 48 hours and then at 20-25°C for no less than 5 additional days.
        - a. No growth or growth of  $\leq 3$  CFU for both gloves (not per hand) denotes a pass.
        - b. Growth of  $> 3$  CFU for both gloves (not per hand) denotes a failure.
    - c. Surface sampling of the direct compounding area after GFT sampling
      - i. Completed samples shall be incubated at 30-35°C for no less than 48 hours and then at 20-25°C for no less than 5 additional days.
        - a. No growth or growth of  $\leq 3$  CFU denotes a pass.
        - b. Growth of  $> 3$  CFU denotes a failure.

3. Didactic portion of sterile compounding competency shall be repeated at least every twelve months for each individual involved in sterile compounding.
  - a. Training exams are considered passed if 80% of questions are answered correctly.
  - b. Any results less than 80% shall require additional review and discussion.
  - c. The failed exams shall be retaken until 80% of questions are answered correctly.
4. Certificate of Analysis for agar plates and medium risk media fill test kits should be readily available.
5. One individual staff competency evaluation and re-qualification can be used for different premises if standard operating procedures (SOPs) are identical and secondary engineering control (SEC) and primary engineering control (PEC) are sufficiently similar.

E. Response to failure

1. Pharmacy staff who fail to pass any training exam or evaluation shall be assessed for staff remediation. ~~If deemed appropriate, staff will be prohibited from performing any sterile compounding until all training exams and validation process tests are successfully completed. See Policy PH.26.06 Sterile Compounding Quality Assurance Program.~~
  - a. Compounding personnel will be prohibiting from compounding until all training and validation processes are successfully completed.
  - b. Staff who provide direct supervision or the designed person may continue to perform their duties up to 30 days while applicable aseptic manipulation and training evaluations are successfully completed.
  - c. See Policy PH.26.06 Sterile Compounding Quality Assurance Program.
2. An attempt must be made to identify any microorganism recovered to the genus level for surface sampling growth failures when growth exceeds USP 797 action level.

- F. Documentation of all training and assessments shall be maintained in the Pharmacy Department for at least three (3) years.

References:

- A. USP Chapter <797>, Pharmaceutical Compounding - Sterile Preparations
- B. California Code of Regulations Title 16 Article 4, 5, and 7

All revision dates: 9/9/2025, 9/13/2024, 9/13/2023, 8/16/2022, 11/5/2019, 5/15/2019, 7/19/2018, 7/1/2016, 1/1/2014

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## Approval Signatures

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

Step Description	Approver	Date
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/1/2025
Infection Prevention	Magdy Asaad: Infection Prevention Manager	9/10/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	9/9/2025



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## PH.26.02 Facility and Equipment - Sterile Compounding

### POLICY:

This policy defines the facility and equipment used in preparing compounded sterile preparations (CSPs). The cleaning, disinfecting and maintenance of the facility and equipment are described to ensure safe and accurate compounding of CSPs.

### Definitions:

**Ante Area:** An area with ISO Class 7 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas.

**Biological Safety Cabinet (BSC):** A ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

**Cleanroom/Clean Area/Buffer Area:** A room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control is physically located.

**Compounding Aseptic Isolator (CAI):** A form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air.

**Primary Engineering Control (PEC):** A device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations.

**Secondary Engineering Control (SEC):** Controlled environments in which PECs are placed, such as anterooms and clean rooms.

**Segregated Compounding Area (SCA):** A designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area or in a separate room.

# Procedure:

## Facility

- A. The sterile compounding area is designed for the preparation of CSPs. This area is a restricted location where traffic has no impact on the performance of PEC(s) to minimize the potential for contamination. Access to the sterile compounding area shall be restricted to sterile compounding personnel and trained environmental services staff for cleaning purposes. All other personnel shall be accompanied by a trained pharmacy staff member.
- B. The sterile compounding area shall contain equipment and supplies needed for preparation of sterile drug preparations.
- C. A sink with hot and cold running water shall be in close proximity for hand washing.
- D. The sterile compounding area shall be clean, organized, well-lit and of sufficient size to support a comfortable environment for sterile compounding activities.
1. Sterile compounding area should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below.
  2. Results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device and retrievable.
- E. ~~Clean rooms, clean areas, or buffer areas used for nonhazardous compounding shall have at least 30 air changes per hour of HEPA filtered supply air and a positive pressure differential of 0.02 to 0.05 inch water column relative to all adjacent spaces.~~
- ~~1. Anytime pressures and/or air exchanges are not within these specified ranges for the clean room, the clean room shall be designated as a segregated compounding area until pressure and/or air exchange issues are resolved.~~
  - ~~2. During this time, a more conservative beyond use dating shall be applied to compounded sterile products.~~
    - ~~a. 12 hour room temperature or 24 hour refrigerated~~
  - ~~3. Unclassified segregated compounding areas (SCAs) are exempt from air exchange requirements.~~
- Clean rooms, clean areas, or buffer areas used for nonhazardous compounding shall have at least 30 air changes per hour of HEPA-filtered supply air and a positive pressure differential of 0.02 to 0.05 inch water column relative to all adjacent spaces.
1. When power outages or system malfunctions impact PECs, SECs, drug storage locations, or the airflow systems (e.g., HVAC, exhaust and/or supply fans) supporting these controlled areas, immediate action is taken to protect the integrity of CSPs, components, and the state of control within the controlled compounding areas.
  2. Until normal operations can be restored and appropriate remediation occurs, compounding areas and BUDs assigned to CSPs are subject to the following changes:

a.	Area impacted	Impact to sterile suite
	PEC(s) Only	<u>Sterile Suite: No change unless pressure differentials not maintained</u> <u>CSP BUD: ≤ 4 hours</u> <u>HD BUDs: Do not compound</u>



<u>Area impacted</u>	<u>Impact to sterile suite</u>
<u>SEC(s) Only (ante &amp; butter rooms)</u>	<u>Sterile Suite: Segregated Compounding Area (SCA)</u> <u>CSP BUD: &lt; 12 hr room temp &amp; &lt; 24 hr refrigerated</u> <u>CSP docking proprietary bag and vial system: Use BUD included in the manufacturer's labeling if activity occurs within functioning ISO 5 PEC</u> <u>HD BUD: ≤ 4 hours (emergency use)</u>
<u>PECs &amp; SECs (full sterile suite)</u>	<u>Sterile Suite: Unclassified area</u> <u>CSP BUDs: &lt; 4 hr room temp &amp; refrigerated</u> <u>HD BUDs: Do not compound</u>

3. Unclassified segregated compounding areas (SCAs) are exempt from air exchange requirements.
4. Before the resumption of normal compounding operations, the Designated Person(s) validates all impacted systems and equipment have been restored to normal function, appropriate remediation has occurred and validated, and a state of control has been restored to the compounding environment.
5. Any construction of the SEC or mechanical failure of PEC, then SEC and PEC should be recertified prior to use.
6. Recertification of SEC and/or PEC should be considered for outage or systems disruption that exceeds > 24 hours at the discretion of the DP.
7. Out of specification events impacting facilities, engineering controls, environmental controls, or drug storage areas are investigated, and appropriate corrective actions are taken. These efforts can occur concurrently with the immediate remediation efforts required to restore the sterile suite to a state of control and normal function. Corrective action efficacy is validated, and all aspects of the investigation, corrective actions, and efficacy validation is documented and retained in a readily accessible format.
8. Notify the Board of Pharmacy within 72 hours of immediate use provision of CSP beyond 48 hours.

#### F. Cleaning Procedure

1. Active work surfaces and counter tops shall be disinfected with sterile 70% isopropyl alcohol throughout each shift.
2. Cleaning shall occur from the cleanest area to the dirtiest area of the sterile compounding area to avoid contamination.
3. Daily Cleaning
  - a. All PECs, horizontal work table surfaces, carts, counters, pass-throughs, sinks and floors shall be cleaned daily with a ready to use (RTU) disinfectant cleaner (PreEMPT RTU).
  - b. PEC cleaning agent must be sterile (Contec TB1-3300 (sterile)).
  - c. Daily cleaning shall be documented on the corresponding cleaning log.
  - d. Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
  - e. Note: The VCMC Infusion Pharmacy is open Monday through Friday and closed on weekends and holidays. The VCMC Infusion Pharmacy sterile compounding area will not be cleaned on days the VCMC Infusion Pharmacy is closed. The VCMC Infusion Pharmacy sterile

compounding area shall be cleaned and disinfected at the end of the day every day the pharmacy is operating. The ISO Class 5 and ISO Class 7 environments shall remain in an uninterrupted clean state on days the pharmacy is closed.

#### 4. Monthly Cleaning

- a. All PECs including exterior, all surfaces of the work table surfaces and carts, counters, pass-throughs, sinks, floors, walls, ceilings, storage shelving, bins, ladders, chairs, and stools shall be cleaned monthly with a RTU sporicidal agent (Peridox RTU or bleach).
  - b. PEC sporicidal agent must be sterile (Periodox RTU (sterile)).
  - c. Monthly cleaning must be documented on the corresponding cleaning log.
- G. Control capabilities shall be maintained for refrigeration, freezing, ventilation, and room temperature required for appropriate storage of ingredients, supplies, and pharmacy-prepared compounded sterile products in accordance with manufacturer, USP, and state or federal requirements.
- H. Cleaning supplies and equipment used to clean hazardous drug areas shall not be used to clean non-hazardous drug areas to avoid cross-contamination of hazardous materials. Cleaning supplies and equipment used to clean hazardous drug areas shall be identified with a "Hazardous Drug" label.
- I. Each ISO environment shall be certified at least every six (6) months by a qualified technician.
- J. Cleaning logs, ISO environment certifications, refrigerator and freezer temperature logs shall be stored for a period of three years.

## Equipment

- A. Any equipment used to compound CSPs shall be stored, maintained, disinfected and cleaned in accordance with manufacturers' specifications (see One Source desk icon).
- B. All pharmacy areas shall have ISO Class 5 PECs.
1. Baker SS400 (Santa Paula Pharmacy)
  2. Baker EdgeGARD Laminar Flow Bench EG-6252 (VCMC Pharmacy)
  3. Baker BCG 401 Class II, Type B2 (VCMC Pharmacy, Infusion Pharmacy)
  4. Baker BCG 601 Class II, Type B2 (Infusion Pharmacy)
  5. Baker EGVF 501 Vertical Laminar Flow Clean Bench (Infusion Pharmacy)
- C. PECs must remain on at all times. If the PEC is turned off, when the PEC is turned back on, it shall be on for at least 3 minutes and disinfected prior to use.
- D. All ISO Class 5 PEC surfaces shall be cleaned with an approved cleaning agent.
1. Approved cleaning agent include:
    - i. Contec TB1-3300 (sterile)
  2. Approved cleaning agents with sporicidal activity include:
    - i. Periodox RTU (sterile)
- E. Disinfection using sterile isopropyl 70% alcohol shall occur on all surfaces including gloves in the ISO Class 5 primary engineering control (PEC) frequently, including:
1. Immediately before compounding

2. At least every 30 minutes or before each lot.
  3. After each spill
  4. When surface contamination is known or suspected.
- F. Sterile gloves shall be donned over the sterile CAI isolator gloves immediately before compounding. These sterile gloves shall be changed by each individual whenever continuous compounding is ceased and before compounding starts again.
- G. The integrity of the filtering system shall be tested and certified by a qualified technician at least every six months or when the PEC is relocated. This testing shall include viable and non-viable sampling.
1. Certificates shall be kept on file in the Biomedical Engineering and Pharmacy Departments for three (3) years.
- H. Viable air sampling shall be done at least once every six months and viable surface sampling shall be done at least monthly by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air and viable surface sampling shall be performed under dynamic conditions that simulate actual production.
1. Selected sampling site testing should include locations within each ISO Class 5 environment, ISO 7 and 8 areas, and in the segregated compounding areas (SCA).
  2. A minimum of 1,000 liters of air shall be tested at each location.
  3. The following are considered actionable findings:

Environment	Viable Air Sample	Viable Surface Sample
ISO Class 5	>1 CFU	>3 CFU
ISO Class 7	>10 CFU	>5 CFU
ISO Class 8 or worse	>100 CFU	>50 CFU

4. If levels measured during air sampling or surface sampling exceed the actionable levels on table under section H.3., an attempt must be made to identify any microorganism recovered to the genus level.
5. Any actionable finding shall result in the following:
  - a. Immediate reassessment of the conditions of the engineering controls in consultation with the Infection Control Preventionist.
  - b. Development of an action plan in consultation with the Infection Control Preventionist which shall address assignment of appropriate beyond use dating, remediation, training, and recalls (if applicable).
    - i. Beyond Use Dating shall be one of the following
      - a. SEC associated finding:
        - i. 12 hours room temperature or 24 hour refrigerated BUD
      - b. PEC associated finding:
        - i. 4 hour immediate use BUD for CSP prepared by pharmacy department
    - ii. Remediation shall include cleaning and disinfection of the affected PEC(s) and/or SEC(s).
    - iii. Response shall include retraining of pertinent staff on cleaning and disinfection of affected PEC(s) and/or SEC(s).

- iv. CSP recalls are initiated based on the severity of risk of serious or life-threatening patient harm associated with product quality-related issues, with special consideration given to risk assessment of high-risk patient populations and routes of administration.
- c. Once remediation is completed, viable air and surface sampling shall be repeated to confirm results are below actionable levels.
- I. The outer sleeves of the CAI shall be changed every six months according to manufacturer's instructions for use (see One Source on all desktops) or sooner depending on the condition of the sleeves. The date of the change will be documented.
- J. The prefilters of the LAFW and CAI shall be changed every six months or sooner depending on the condition of the prefilters. The date of the change shall be documented.
- K. Pass-through doors must be interlocking. In the event the pass-through doors are not interlocking, both sides must not be opened at the same time.
- L. Problems with equipment shall immediately be reported to the Designated Person (DP) or the Director of Pharmacy Services.
- M. Refer to PEC operational manual(s) for further details.

## Transport of drugs and supplies into the sterile compounding area

- A. All supplies are wiped prior to being introduced into the sterile compounding area by removing them from shipping cartons with an EPA-registered sporicidal disinfectant, EPA-registered cleaning disinfectant, or ~~sterile~~ 70% isopropyl alcohol (IPA) while they are being transferred to a clean and properly disinfected or other conveyance for introduction into the buffer area.
  - 1. Handling of hazardous drugs shall require donning of appropriate personal protective equipment. Upon receipt, antineoplastic HDs shall remain in the sealed transport bag for transport to the negative pressure room. See policy [PH.27.02 Hazardous Drug Storage, Handling, Labeling, and Transport](#)
  - 2. No corrugated or uncoated cardboard shall be allowed into the sterile compounding area.
- B. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the appropriate area.
- C. Carts used to bring supplies from the store-room cannot be rolled beyond the demarcation line.
- D. Supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.
- E. Nonessential objects that shed particles shall not be brought into the buffer area such as pencils.

## References

- A. California Code of Regulations, Division 17, Title 16, Section 1751
- B. USP Chapter <797>, Pharmaceutical Compounding – Sterile Preparations
- C. BCG 401 Class II, Type B2 Operator's Manual, The Baker Company

- D. BCG 601 Class II, Type B2 Operator's Manual, The Baker Company
- E. EdgeGARD Laminar Flow Bench EG-8252 Operator's Manual, The Baker Company
- F. EdgeGARD VF Operator's Manual Model 501, The Baker Company
- G. SterilSHIELD® Operator's Manual Model SS400, The Baker Company
- H. SterilSHIELD® Operator's Manual Model SS600, The Baker Company

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9/9/2025, 9/13/2024, 9/13/2023, 9/13/2022, 10/12/2021, 12/8/2020, 9/10/2020, 8/11/2020, 11/5/2019, 3/21/2019, 7/19/2018, 7/1/2016, 4/1/2016, 5/1/2014, 1/1/2014, 7/1/2011

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/1/2025
Infection Prevention	Magdy Asaad: Infection Prevention Manager	9/29/2025
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References:

## PH.26.03 Sterile Compounding Attire

### Policy:

Personnel engaged in the sterile compounding area shall wear appropriate garb as defined in the procedure below.

### Procedure:

- A. Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, any lash extension, nail polish or artificial nails, visible non-removable piercing shall be excluded from the International Organization for Standardization (ISO) Class 5 and ISO Class 7 compounding areas until their conditions are remedied. This shall be enforced by the pharmacist with supervision and control of compounding.
- B. Food (including mints, gums, etc) and drinks must not enter into the sterile compounding area. Compounding personnel shall not bring any headphones, earbuds, or personal electronic device into any sterile compounding area. Additionally, coats, purses, jewelry, watches, and other personal items shall be stored in lockers or employee break room.
  1. Eyeglasses are permitted but must be cleaned prior to donning any sterile compounding attire.
- C. Hand hygiene and garbing procedure upon entering the secondary engineering control (SEC):
  1. Put on clean, non-shedding uniform comments in the following order: Face mask, scalp hair and facial hair covers, shoe covers as personnel crosses the demarcation line.
  2. Hand washing shall be done with soap and water using the sink. Debris from underneath fingernails shall also be removed using a nail cleaner under running warm water for the initial handwashing. Pharmacy personnel shall wet hands with water, apply a sufficient amount of soap and rub hands together vigorously for at least 30 seconds covering all surfaces of hands, fingers, and arms up to elbows. Rinse hands with water and dry thoroughly with a disposable, low-lint towel.
  3. Don a clean, non-shedding coverall.
  4. Hand sanitizing shall be performed using a waterless, persistent, alcohol-based cleanser.
  5. Don sterile gloves. Gloved hands shall be sanitized using sterile 70% IPA.
  6. For the Segregated Compounding Area (SCA) only
    - a. Don a clean, non-shedding gown.
    - b. Don gloves. Gloved hands shall be sanitized using sterile 70% IPA.

c. The Compounding Aseptic Isolator (CAI) shall have sterile gloves mounted to the sleeve (gauntlet).

d. In the CAI, a pair of sterile gloves shall be donned over the sterile gauntlet gloves.

7. Donning and doffing garb shall not occur in the anteroom at the same time.

D. Sterile gloves are to be routinely disinfected with sterile 70% IPA before entering or re-entering the primary engineering control and after contact with non-sterile objects.

E. Sterile gloves shall also be routinely inspected for holes, punctures, or tears, and replaced immediately if such are detected.

F. Exiting the sterile compounding area:

1. Temporary exits and exiting for the end of the shift/day: All items must be removed and discarded past the demarcation line.

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## PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping

### POLICY:

To provide and maintain the sterility of prepared products and to ensure final products are correctly prepared prior to dispensing. The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, labeling used during the sterile compounding process. The pharmacist shall review all compounding records to assure that no errors have occurred in the compounding process. The pharmacists are also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

### PROCEDURE:

#### Compounded Sterile Drug Preparations (CSPs)

- A. CSPs shall be prepared under ISO Class 5 conditions.
- B. Any equipment placed in or adjacent to the critical work area shall be cleaned, disinfected, and placed to avoid contamination or disruption of the unidirectional airflow between the high-efficiency particulate air (HEPA) filter and sterile surfaces.
- C. A written master formula shall be created prior to compounding a CSPs. Each master formula shall include:
  1. Active ingredients to be used.
  2. Equipment to be used.
  3. The maximum allowable beyond use date (BUD) for the preparation, and the rationale or reference source justifying the determination.
  4. Inactive ingredients to be used
  5. Specific and essential compounding steps used to prepare the drug.
  6. Quality reviews required at each step in preparation of the drug including physical description of the completed CSP.
  7. Post-compounding processor procedures required, if any.
  8. Instructions for storage and handling of the CSP.



- D. All drugs and supplies shall be gathered before initiating the compounding process. Articles shall be placed into the primary engineering control (PEC) only after they have been wiped with sterile 70% isopropyl alcohol.
- E. Containers shall be checked for cracks, punctures, and clarity before the CSP process begins.
- F. Ingredients used for CSPs should be determined to be stable, compatible, and appropriate for the final product to be prepared, according to manufacturer guidelines, United States Pharmacopeia (USP) guidelines or appropriate scientific references.
  - 1. Each ingredient and container shall be inspected for defects, expiration date, and product integrity prior to use. Expired, inappropriately stored, or defective ingredients shall not be used in preparation of CSPs.
  - 2. The final product shall meet physiological norms for solution osmolarity and pH, as appropriate for the intended route of administration.
- G. Non-essential material (e.g., labels, calculators, pens, pencils, etc.) shall not be placed inside the PEC.
- H. Mathematical calculations shall be performed prior compounding the CSPs.
- I. Employees shall not cough, sneeze, or talk during the sterile product preparation process.
- J. The number of items being prepared in the PEC shall be consistent with the amount of critical work space available.
- K. Materials used in compounding the CSP should be arranged in the critical work area of the PEC in a manner that prevents interruption of the unidirectional airflow between the HEPA filter and critical sites of needles, vials, ampules, containers, and transfer sets.
- L. The surfaces of ampules, vials, and container closures (e.g., vial stoppers) shall be disinfected by swabbing with sterile 70% isopropyl alcohol. Surfaces shall be dry prior to use.
- M. The sterile areas of the syringe (e.g., plunger, shaft, tip or needle) shall not be touch contaminated.
- N. HEPA filters shall not be contaminated with liquid, glass ampule particles, or other means during the sterile product preparation process.
- O. Solutions from ampules shall be properly filtered to remove glass particles.
- P. Solutions of reconstituted powders shall be mixed carefully, ensuring complete dissolution of the drug with appropriate diluent.
  - 1. The diluent, the volume of diluent, final concentration, date and time of reconstitution, and technician initials shall be recorded on the vials of reconstituted powders, if contents are not entirely used.
- Q. Needle entry into vials with rubber stoppers should be done cautiously to avoid the creation of rubber core particles.
- R. A conventionally manufactured single-dose container entered or punctured in an ISO Class 5 air may be used for up to 12 hours (or shorter manufacturer BUD) after initial entry or puncture. The date and time when container was initially punctured and the beyond use date (and time, when applicable) shall be documented on the container. The manufacturer labeled storage requirements during that 12-hour period will be maintained.
- S. Multi-dose vials may be used for 28 days or shorter based on manufacturer's recommendation or reference expiration date. Date and time vial was initially used and beyond use date (and time, when applicable) shall be documented on the vial.

- T. Multiple containers shall be processed in a consistent direction (i.e., left to right) to avoid confusion.
- U. Syringe plungers shall be pulled back to indicate the volume of solution used in the sterile product preparation process.
  - 1. Exceptions: Hazardous drugs, pediatric doses, total parenteral nutrition (TPN) solutions, and high alert ~~medications~~medications are the exception. See [PH.70 High Alert Medications](#). Drawn syringes shall be checked by a pharmacist prior to admixture.
- V. The product label shall be initialed to indicate who prepared the sterile product.

## Labeling

- A. All sterile products shall be labeled with at least the following information:
  - 1. For patient specific products: the patient's name and date of birth.
  - 2. For batch-prepared products: facility specific lot number and expiration date.
  - 3. All solutions and ingredient names, amounts, strength, and concentrations (when applicable).
  - 4. Beyond-use date (and time, when applicable).
  - 5. Prescribed administration regimen, when appropriate (including rate and route of administration).
  - 6. Appropriate auxiliary labeling (including precautions).
  - 7. Instructions for storage and handling.
  - 8. Identification of the responsible pharmacist and/or technician with their initial.
  - 9. Device-specific instructions, when appropriate.
  - 10. Name of compounding ~~and~~ and dispensing pharmacy if different
  - 11. The date compounded
  - 12. Any additional information, in accordance with state or federal requirements.
- B. The label shall be affixed directly to the final product.

## End Product Evaluation

- A. The responsible pharmacist shall verify that the sterile product was prepared correctly. The pharmacist shall check the following:
  - 1. Correct ingredients
  - 2. Correct amount of ingredients
  - 3. Expiration dates of ingredients
  - 4. Visual check for discoloration, particulate matter, precipitate, or haziness in the solution and cracks or leakage in the container.
  - 5. Double-check calculations
  - 6. Auxiliary labels
  - 7. Beyond use date (BUD)
  - 8. Storage conditions
- B. The pharmacist(s) shall initial the label on the final product, which confirms end product evaluation was

performed, and the final product was prepared correctly and adhered to proper sterile compounding procedures.

## Record Keeping

- A. A sterile compounding log shall be maintained and shall include the following:
1. The "IV Worksheet" label that prints with each label for sterile compounded product.
  2. Date and time of preparation and BUD of final product.
  3. Manufacturer, lot number, and expiration date of each component.
  4. Initials of the compounding staff.
  5. Initials of the pharmacist(s) performing in-line and/or end product evaluation.
  6. Results of quality control (e.g., visual inspection)
  7. Santa Paula Hospital Pharmacy only: CAI purge time.
  8. The package size and the number of units prepared.
  9. Pharmacy-assigned batch identification number of the CSP if applicable.

~~Documentation for CSPs shall include the above and the following:~~

- ~~1. Pharmacy-assigned batch identification number of the CSP.~~
- ~~2. The package size and the number of units prepared.~~

- B. Sterile compounding logs shall be maintained by the Pharmacy Department for at least three (3) years.

## References

- A. USP Chapter <797>, Pharmaceutical Compounding – Sterile Preparations  
B. California Code of Regulations Title 16 Article 4, 5, and 7

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/1/2025
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**References:**

## PH.26.05 Beyond Use Dates

### POLICY:

This policy defines beyond-use dating for Pharmacy-prepared compounded sterile preparations (CSP).

### PROCEDURE:

**Beyond Use Date (BUD):** The date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

**Controlled cold temperature:** 2 degrees to 8 degrees Celsius (C).

**Controlled freezer temperature:** -25 degrees to -10 degrees C or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

**Controlled room temperature:** 20 degrees to 25 degrees C.

All staff involved in compounding, filling, and labeling of CSPs shall read this policy and comply with its requirements.

### Beyond Use Dates

- A. The BUD shall not exceed the shortest expiration date or BUD of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation.
- B. In the absence of passing additional sterility testing, the BUD shall not exceed the following time periods before administration. Unless specified differently by the manufacturer or references, beyond-use dates are assigned according to the risk of contamination and storage conditions as outlined in the following table:

Compounding Category	Conditions	Controlled Room Temperature (20 to 25° C)	Refrigeration (2 to 8° C)
Category 1	Prepared in a PEC in a SCA	≤ 12 hours	≤ 24 hours
Category 2	Prepared from only sterile starting	4 days	10 days

	components		
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- C. Category 1 and Category 2 CSPs are distinguished primarily based on the conditions under which they are made, the probability of microbial growth and the time period within which they must be used.
1. Category 1 CSPs are typically prepared in an unclassified Segregated Compounding Area (SCA) and have shorter BUDs.
  2. Category 2 CSPs are prepared in a clean room suite and have longer BUDs.
- D. Category 3 CSPs shall **NOT** be prepared.

## References

- A. California Code of Regulations, Division 17, Title 16, Article 7.
- B. USP Chapter 797, Pharmaceutical Compounding -- Sterile Preparations.

All revision dates:

9/9/2025, 9/13/2024, 9/13/2023, 7/10/2019, 7/1/2016, 4/1/2016, 10/1/2015, 1/1/2014

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Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/1/2025
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 Policy Area: Pharmacy Services  
 References:

## PH.26.06 Sterile Compounding Quality Assurance Program

### Purpose:

This policy defines the quality assurance program for sterile compounding.

### Definitions:

Integrity: ~~retention~~Retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

Potency: ~~active ingredient strength within ±10% of labeled amount.~~

Quality: ~~the~~The absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those noted on the label and the absence of inactive ingredients other than those listed on the master formula.

StrengthLabeled strength: ~~amount~~Amount of active ingredient per unit of a compounded drug preparation.

### Policy:

- A. Random samples of compounded sterile preparations (CSPs) shall be assessed ~~on a quarterly basis~~twice a year for integrity, ~~potency~~, quality, and labeled strength.
- B. The Pharmacy Supervisor or designee(s) shall regularly review sterile compounding documents for accuracy and completeness.
- C. The ~~Medication Safety Officer~~Designated Person or designee(s) shall complete quarterly audits on various aspects of sterile compounding.
- D. All documents shall be available for review for at least three years.

### Procedure:

~~Integrity of the selected CSP shall be assessed by measuring the potency of the selected CSPs.~~

- A. ~~Potency~~Integrity, quality, and labeled strength of the selected CSP shall be assessed by submitting a sample to a ~~to a reference~~ lab for analysis.
  1. The resulting value shall be within ±10% the listed amount of active ingredient.

~~Quality of the selected CSP shall be assessed by submitting a sample of the CSP to a lab for bacterial and fungal growth testing.~~

- B. Quality assurance results shall be kept in the pharmacy's sterile compounding document binder with master formula and compounding record. This record shall be kept in the pharmacy for three (3) years.
- C. Complete Quality Assurance Sampling Action Report (Attachment A) if needed.
- D. Any unacceptable result relating to the ~~potency~~ integrity, labeled strength, or quality ~~or sterility~~ of the CSP shall result in the following:
1. Designated Person or Pharmacist in charge shall start an investigation and review.
  2. The action plan shall include any procedural changes, educational needs, mitigation plan, and monitoring.
  3. Staff Remediation (see policy [PH.26.01 Training and Evaluation of Pharmacy Staff in Sterile Drug Preparation](#))
    - a. For unacceptable results relating to ~~potency and~~ labeled strength, staff shall review of pharmaceutical calculations and syringe measurements.
    - b. For unacceptable result relating to the quality ~~and sterility~~, staff shall complete a revalidation process on aseptic technique and aseptic area practices.
  4. If use of or exposure to the recalled drug may cause serious adverse health consequences or death, the recipient pharmacy, prescriber, or patient and the California Board of Pharmacy shall be notified as soon as possible within 12 hours.
- E. Quality Assurance program shall be reviewed twice a year by the designated person and report to Director of Pharmacy.

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2020, 7/10/2019, 7/19/2018, 11/20/2017, 10/3/2017,  
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## Attachments

 [Ph.26.06 Quality Assurance Sampling Action Report](#)

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## 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 be 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
<b>Step 1:</b>	Physical presentation- Signs/symptoms Medical History <ul style="list-style-type: none"> <li>• Commands- can't follow</li> <li>• Glasgow score less than-13</li> <li>• Combative or lethargic</li> <li>• Voice- none or gurgles</li> <li>• Drools or can't manage secretions</li> </ul>	If patient has any of the findings, <b>STOP</b> the swallow screen <ul style="list-style-type: none"> <li>• Keep the patient NPO (nothing by mouth) and do <i>not</i> proceed with the swallow screen.</li> <li>• Document: Patient failed Step 1 of Swallow screen</li> <li>• Keep patient NPO including oral</li> </ul>



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

Steps	Assessments	Actions
<b>Step 3</b>	<p>Before the "two sips of water" test" is started, the nurse ensures the following:</p> <ul style="list-style-type: none"> <li>• Patient is upright 90</li> <li>• Suction and towel available</li> <li>• Mouth is moist and clean</li> <li>• Patient is Alert</li> <li>• Patient is able to follow simple commands</li> <li>• Patient does not display a facial droop</li> <li>• Patient has understandable speech</li> </ul> <p>Instruct patient to take <b>2 sips</b> of water (no straws) and observe for:</p> <ul style="list-style-type: none"> <li>• Water dribbles or drools from mouth</li> <li>• Swallow multiple times</li> <li>• Immediate cough or within one minute</li> <li>• Voice quality becomes is wet or gurgling</li> </ul> <p>Note: If patient does not exhibit impairments after 2 sips of water, the screen is completed.</p>	<p>If the patient exhibits impairment in any of the Step 3 assessments, <b>STOP</b> and:</p> <ul style="list-style-type: none"> <li>• Keep the patient NPO including oral medications</li> <li>• Document failed screen (Step 3)</li> <li>• If not already addressed, contact the physician for orders, such as: <ul style="list-style-type: none"> <li>◦ formal swallow evaluation by speech</li> <li>◦ orders for strict NPO for all food, fluids meds</li> <li>◦ seek physician order for alternate routes of nutrition, fluid and medication if indicated</li> </ul> </li> </ul> <p>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</p> <p>Follow the physician's prescribed orders for diet and nutrition intake</p> <ul style="list-style-type: none"> <li>• If not already addressed, contact the physician for a diet and nutrition order.</li> </ul>

## 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](http://www.jointcommission.org)

All revision dates:

9/13/2024, 7/19/2018, 7/1/2015

## Attachments

 [A: Competency Checklist](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/30/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/30/2025
Policy Owner	Melody Donate: Stroke Coordinator	9/30/2025



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Last Revised: 4/12/2022  
Next Review: 3 years after approval  
Owner: Erin Olivera: Clinical Nurse Manager, IPU/CSU  
Policy Area: Administrative - Nursing  
References:

## 108.041 Opiate Withdrawal - Clinical Opiate Withdrawal Scores (COWS)

### POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) are dedicated to the delivery of safe, quality patient care. Patient opiate withdrawal may be treated in the Emergency Department (ED), hospital inpatient units, Crisis Stabilization Unit (CSU), Inpatient Psychiatric Unit (IPU) using the Clinical Opiate Withdrawal Score (COWS) protocol.

### PROCEDURE:

**HOSPITAL** refers to Ventura County Medical Center (VCMC), including the Inpatient Psychiatric Unit (IPU), Crisis Stabilization Unit (CSU), and Santa Paula Hospital (SPH). **See Section I below.**

## SECTION I – HOSPITAL

### All locations/departments:

Licensed nursing staff shall:

- Identify patients that are at risk for opiate withdrawal.
- Notify the provider on duty regarding the patient's condition.
- Once COWS orders are placed, assess the patient using the COWS scale.
- Document the COWS assessment in the electronic health record (EHR).
- Medicate the patient based on the COWS opiate withdrawal management orders.

The Provider shall:

- Evaluate the patient for appropriateness of opiate withdrawal management.
- If indicated, order COWS protocol.

Source: <https://www.drugabuse.gov/sites/default/files/ClinicalOpiateWithdrawalScale.pdf>

All revision dates:

4/12/2022

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/8/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/9/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/9/2025
Inpatient Psychiatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	6/9/2025



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Owner: Erin Olivera: Clinical Nurse Manager, IPU/CSU  
Policy Area: Administrative - Nursing  
References:

## 108.042 Alcohol Withdrawal - Clinical Alcohol Withdrawal Assessment (CIWA)

### POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) are dedicated to the delivery of safe, quality patient care. Patient alcohol withdrawal may be treated in the Emergency Department (ED), hospital inpatient units, Crisis Stabilization Unit (CSU), Inpatient Psychiatric Unit (IPU) using the Clinical Institute Withdrawal Alcohol (CIWA) protocol.

### PROCEDURE:

**HOSPITAL** refers to Ventura County Medical Center (VCMC), including the Inpatient Psychiatric Unit (IPU), Crisis Stabilization Unit (CSU), and Santa Paula Hospital (SPH). **See Section I below.**

### SECTION I - HOSPITAL

#### All locations/departments:

Licensed nursing staff shall:

- Identify patients that are at risk for alcohol withdrawal
- Assess for coexisting mental illness.
- Notify the provider on duty regarding the patient's condition.
- Once CIWA orders are placed, assess the patient using the CIWA scale.
- Document the CIWA assessment in the electronic health record (EHR).
- Medicate the patient based on the CIWA alcohol detoxification orders.

#### Crisis Stabilization Unit (CSU) and Inpatient Psychiatric Unit (IPU):

The CSU/IPU psychiatrist shall:

- Evaluate the patient for appropriateness of alcohol withdrawal management in the CSU/IPU.
- Assess for coexisting mental illness.
- If indicated, order CIWA protocol.

#### Emergency Department (ED) and Inpatient Units:

The provider shall:

- Evaluate the patient for appropriateness of alcohol withdrawal management.
- Assess for coexisting mental illness.
- If indicated, order CIWA protocol.

All revision dates:

4/12/2022

## Attachments

No Attachments

## Approval Signatures

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/8/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/9/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/9/2025
Inpatient Psychiatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	6/9/2025



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**Owner:** Kristina Swaim: Nurse Director,  
Maternal Child Health  
**Policy Area:** Maternal Child Health  
**References:**

## MCH.28 Substance Use in Pregnancy

### POLICY:

It is the goal of Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH), and the Ambulatory Care (AC) Clinics to universally screen pregnant women who are admitted to perinatal services for exposure to drugs and alcohol.

### PURPOSE:

To appropriately manage the care of women suffering from substance use disorders and their exposed infants in a compassionate, non-judgmental manner using best practices. Efforts are directed at identification, treatment, parental education/counseling, and appropriate referrals for treatment and services as indicated.

### SCOPE:

Obstetrical and Family Medicine providers, Nursing, and Social Services.

### DEFINITIONS:

- A. Addiction – a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.
- B. Substance Use Disorder (SUD) - a complex medical condition in which there is uncontrolled use of a substance despite harmful consequence and is defined by the DSM-V. Substance Use Disorder (SUD) - a complex medical condition in which there is uncontrolled use of a substance despite harmful consequence and is defined by the DSM-V.
  1. Specific substances have specific DSM-V diagnoses, such as:
    - Opiate Use Disorder (OUD)
    - Alcohol Use Disorder (AUD)
    - Stimulant Use Disorder (StUD)
    - And more
- C. Drug and/or Alcohol Screening- the process of using a standardized and validated tool to inquire about a



patient's history and present use or interactions with substances and alcohol in an attempt to ascertain if a SUD is present. It is important to remember that use of a substance is not synonymous with addiction/ SUD nor does it correlate to parenting capability.

1. The 4Ps plus is recommended at our institution as a validated screening tool.
- D. Toxicology testing – a qualitative test done on a biological specimen to indicate the presence or absence of a substance in the blood, urine or tissue.
- E. Confirmatory Testing – a specific laboratory test which detects metabolites confirming the presence of a substance in the blood, urine or tissue. Confirmatory tests are done as a send out lab to a reference laboratory and may be used for legal purposes if chain of custody of the sample is followed.

## **INDICATORS SUGGESTIVE OF MATERNAL SUBSTANCE ABUSE:**

- A. Obtunded or unconscious
- B. Patient who is falling asleep mid-sentence, shows other evidence of being intoxicated
- C. Patient who smells of alcohol or has alcohol on her breath
- D. Patient with recent physical evidence of injection use (e.g. "track marks")
- E. Patients with acute clinical complications such as placental abruption or unexplained severe hypertension (cocaine, amphetamine)
- F. Patient with unexplained soft tissue infections or endocarditis
- G. At the time of delivery in a patient previously identified as having used certain illicit drugs or inappropriately used prescription medications, at any point in the pregnancy
- H. Patient with no prenatal care at the time of delivery

## **INDICATORS SUGGESTIVE OF DRUG AND ALCOHOL EXPOSURE IN THE NEONATE**

- A. Tremors (when disturbed or undisturbed)
- B. Poor feeding (uncoordinated suck and swallow)
- C. Frantic sucking
- D. High-pitched cry
- E. Seizures
- F. Poor sleeping or excessive wakefulness irritability, increase muscle tone, exaggerated Moro reflex
- G. Lethargy
- H. Loose/watery stools or dehydration
- I. Projective vomiting
- J. Frequent yawning and sneezing
- K. Hyperthermia or sweating
- L. Premature or small for gestational age

- M. Fever
- N. Difficult to arouse
- O. Tachypnea or tachycardia

## PROCEDURE:

Please refer to policy [OB.48 Testing for Prenatal Drug Exposure](#) for details on toxicology testing.

### A. Pain Management

1. All patients should be offered adequate pain control.
2. Pain management options should include analgesic and non-analgesic mediation as well as other adjunctive, non-pharmacologic approaches (ice, heat, local anesthetic, relaxation techniques) with the goal of achieving a function recovery rather than a specific pain score. Pain scores can be used to judge pain level but should not be the goal of treatment with the goal being functional recovery.
3. Neuraxial anesthesia (epidural or combine epidural/spinal) should be encouraged for pain management in laboring women with OUD in early labor or as soon as contractions are perceived to be uncomfortable.
4. Pain management among opioid-dependent women.
  - a. Opioid-dependent women may experience more severe pain in the immediate postpartum period compared with women without opioid dependence due to high tolerance combined with opioid-dependent hyperalgesia (an increased sensitivity to feeling pain and an extreme response to pain).
5. Women on Medication Assisted Therapy (MAT)
  - a. MAT should be continued during and after the pregnancy and the patient maintained on her baseline dosage.
  - b. Some women benefit from receiving their usual daily dosage in divided doses because the half-life for analgesia is much shorter than for opioid withdrawal.
  - c. Some patients, especially those on buprenorphine or methadone maintenance, may require more opioid pain medication than the opioid-naïve patient and may need analgesia with a full agonist with strong affinity for the mu receptor, such as fentanyl or hydromorphone, for 24 hours or more if oxycodone does not suffice.

### B. Breast Feeding and OUD

Exposure	Effect	Recommend Breastfeeding?
Methadone/ Buprenorphine	Reduces severity of NAS in the breastfeeding infant. Unlikely to have negative effects on the infant but monitor for sedation and appropriate weight gain.	Yes
Other opioids	Monitor infant for sedation and appropriate weight gain.	Yes, but drug specific variances exist. CAUTION with codeine due to CYP2D6 ultra-rapid metabolizers.
Cannabis	Monitor for infant sedation.	Recommend minimizing or stopping

	Long term effects unknown but concern for neurocognitive development in some studies.	cannabis use during lactation.
Alcohol	Interferes with milk ejection reflex and may lead to inadequate emptying	Limit maternal exposure to 8 ounces of wine or two beers and waiting 2 hours after drinking to breastfeed.
Tobacco	Combustible/vaped tobacco and second hand smoke increases the risk of Sudden Infant Death Syndrome (SIDS). Data is unclear if nicotine replacement products also increase this risk.	Yes. Consider smoking cessation products and nicotine replacement. Recommend NRT for partners and others to avoid second hand smoke exposure.
Cocaine and methamphetamine being abused	Metabolites are excreted in breast milk. No clear data but case reports demonstrate fetal intoxication. Large doses will reduce milk supply.	Avoid breastfeeding.
Prescription amphetamines	Long-term infant effects are not well studied. Large doses will reduce milk supply.	Yes, but consider non-amphetamine alternatives.
Benzodiazepines	No long-term effects noted. Observe for sedation.	Yes, but drug specific variances exist. Ideal choices are short-acting agents with no active metabolite such as lorazepam. Avoid long-acting agents with active metabolites such as diazepam.
Naltrexone/ Naloxone	No long-term effects noted due to limited data.	Yes
HIV	Virus does excrete in breast milk.	No, per the Centers for Disease Control and American Academy of Pediatrics, in resource-rich settings such as the United States, due to adequate access to clean water and infant formula.
Hepatitis B or C	Blood-borne but does NOT excrete in breast milk.	Yes, unless cracked/bloody nipples present. In that case, wait for nipples to heal before resuming breastfeeding.

### C. Discharge Planning

1. The Social Worker, in collaboration with nursing and the patient's providers, will coordinate a safe discharge plan for the Infant and Mother prior to discharge.
2. The Discharge Plan developed by the Health Care Team shall:
  - a. Identify services needed by the Infant/Parent/Family and specify referrals.

- b. Be developed in conjunction with all team members.
- 3. Primary team should offer women evidence based and patient-centric post-partum birth control options, harm reduction (needle exchange, HIV pre-exposure prophylaxis, etc), and safe disposition including to local residential treatment centers, outpatient programs, or other safe living facilities.

All revision dates:

2/9/2022

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	5/1/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	4/19/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	4/18/2025
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	4/18/2025



## VENTURA COUNTY HEALTH CARE AGENCY

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Effective: Upon Approval  
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Next Review: 1 year after approval  
Owner: Sul Jung: Associate Director of  
Pharmacy Services  
Policy Area: Pharmacy Services  
References:

### PH.26.00 Sterile Compounding Overview

#### Purpose:

The Department of Pharmacy Services is responsible for preparation of compounded sterile preparations (CSPs) for Ventura County Medical Center, Santa Paula Hospital, and Ambulatory Care Campus Clinics. This policy provides an outline of the policies and procedures that the Department of Pharmacy Services will follow in preparation and compounding of sterile drug preparations.

#### Policy:

- A. The Department of Pharmacy Services shall follow all policies and procedures pertaining to Sterile Compounding to ensure that high-quality CSPs are consistently prepared. The policies are as follows:

[PH.26.01 Training and Evaluation of Staff](#)

[PH.26.02 Facilities and Equipment](#)

[PH.26.03 Sterile Compounding Attire](#)

[PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping](#)

[PH.26.05 Beyond Use Dates](#)

[PH.26.06 Sterile Compounding Quality Assurance Program](#)

- B. The Department of Pharmacy Services shall not compound CSPs under high-risk conditions, which includes compounding CSPs from non-sterile ingredients.
- C. Sterile Compounding policies shall be reviewed at least annually.
- D. Any revisions or deletions to any sterile compounding policies shall be communicated to all pharmacy personnel involved in sterile compounding

#### References:

- A. USP Chapter <797>, Pharmaceutical Compounding – Sterile Preparations
- B. California Code of Regulations Title 16 Articles 4.5, 7 and 7.5.

All revision dates:

9/13/2024, 11/5/2019, 10/3/2017, 7/1/2016, 4/1/  
2016, 2/1/2014

## Attachments

No Attachments

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Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	10/1/2025
Infection Prevention	Magdy Asaad: Infection Prevention Manager	9/10/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	9/9/2025



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Last Revised: 7/19/2018  
Next Review: 3 years after approval  
Owner: Sul Jung: Associate Director of Pharmacy Services  
Policy Area: Pharmacy Services  
References:

## PH.30 Antidote Medications

### POLICY:

The Pharmacy Department inventory of approved antidotes to poisonings shall be maintained based on the scope of medical treatments performed at Ventura County Medical Center/Santa Paula Hospital.

### PROCEDURE:

It is the policy of the Pharmacy Department to maintain a supply of antidotes adequate to treat a single patient for 24-hours in the Pharmacy and other appropriate patient care areas throughout VCMC/SPH.

The antidote chart is maintained by the California Poison Control System. This chart is available on the Pharmacy Resources webpage. The antidote chart lists stocking levels for 24-hour supply. This list does not address the need for other supportive measures (i.e., antiarrhythmic agents, vasopressors, anti-convulsants, etc.) which are made available in all VCMC/SPH patient care areas for emergencies of any nature.

The California Poison Control System is available as a reference source for any poisoning situation.

#### California Poison Control System:

Website: <http://www.calpoison.org/>

Phone: 1-800-222-1222

All revision dates:

7/19/2018, 6/1/2015, 6/1/2006

### Attachments

 [Location of antidotes](#)

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	9/9/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	9/9/2025



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Owner: Sul Jung: Associate Director of Pharmacy Services  
Policy Area: Administrative - Operating Policies  
References:

## PH.60 Process of Returning Medication to Pharmacy

### POLICY:

To ensure the timely and appropriate handling, recycling and inventory management of returned medications from the nursing unit back to the Pharmacy Department. Returned medications are reintroduced back into the Pharmacy inventory in a timely fashion. Expired medications or medications that cannot be reused must be processed through pharmaceutical wastage processes or returned to a pharmaceutical returns company. When appropriate, the patient will be credited for the unused medication or supply.

### PROCEDURE:

1. Discontinued and discharged patient-specific medication shall be placed by nursing staff in the Pharmacy Department returns container located in each nursing unit.
2. Medications removed from the Pyxis medstation can be returned and credited by using the "Return" function. The medication can then be returned into the return bin or back into the specific compartment in the Pyxis medstation.
3. Medication return bins are emptied routinely by Pharmacy staff.
4. Medications returned to the Pharmacy Department shall be emptied into the medication sorting container in the Pharmacy. All patient identification labels shall be removed before returning back to inventory.
5. The medication sorting shall be done daily by a pharmacy technician.
  - a. IV Admixtures Prepared by the pharmacy (IVPBs, IVFs, Syringes)
    - i. Return to the IV area
    - ii. Remove the patient-specific label
    - iii. Place back into the inventory when appropriate
    - iv. Discard any expired IV medication, using the pharmaceutical waste container
  - b. Refrigerated Items (Vaccines, Biologicals, etc.)
    - i. Refrigerated medications, vaccines and biologicals shall be returned to its storage location in the appropriate medication refrigerator immediately.
  - c. Oral Liquids (Bulk bottles, oral syringes)



- i. Place standardized unit-dosed oral syringes back into the Pharmacy inventory.
  - ii. Discard patient-specific oral syringes and bulk bottles into the pharmaceutical waste containers.
6. The returns function should be done daily so that returned medications and supplies do not accumulate. The Pharmacy Supervisor shall have oversight of this process.

All revision dates: 10/1/2015

## Attachments

No Attachments

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Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	9/9/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	9/9/2025



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**Next Review:** 3 years after approval  
**Owner:** Sul Jung: Associate Director of Pharmacy Services  
**Policy Area:** Administrative - Patient Care  
**References:**

## PH.75 Use of Herbal or Botanical Products and Dietary Supplements

### POLICY:

Ventura County Medical Center & Santa Paula Hospital do not endorse the use of herbal or botanical products and dietary supplements as part of a standard medication regimen. Some forms of herbal or botanical products and dietary supplements can interfere or interact with medical therapies, rendering medical treatments less effective and may place the patient at potential risk.

### PROCEDURE:

Herbal or botanical products and dietary supplements are non-formulary and will not be stocked by the Department of Pharmacy Services.

Exceptions to this policy require review and approval by the Pharmacy & Therapeutics Committee. Current exceptions are:

- Clove oil
- Melatonin
- Multivitamins

All revision dates:

11/13/2019, 6/13/2018, 4/1/2004

### Attachments

No Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	9/9/2025
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	9/9/2025



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

## Z.22 IPU/CSU Transfers From Outside of Ventura County

### POLICY:

If a Lanterman Petris Short (LPS)-designated facility outside of Ventura County wishes to transfer a patient to the Ventura County Medical Center Inpatient Psychiatric Unit (IPU) or Crisis Stabilization Unit (CSU), the patient is evaluated for medical necessity prior to acceptance; is in stable medical condition for transport; has an appropriate legal status that falls within the outlined time constraints and verification that Ventura County is the County of responsibility. Patients will be accepted for transfer once the IPU/CSU physician accepts transfer. Nurse-to-nurse communication shall be completed within two (2) hours of the physician acceptance of the patient.

### PROCEDURE:

**All calls from LPS-designated facilities outside of Ventura County will be directed to the Crisis Stabilization Unit first (CSU).**

#### CSU STAFF WILL:

1. Determine that the patient is a Ventura County resident. Use Avatar and Cerner to help determine.
2. Determine current bed availability. The IPU or CSU must not be on diversion, and there must be an available bed for the transfer to occur.
3. Determine the patient's legal status. One of the following documents must be present:
  - a. Original signed Voluntary Consent for Admission. The sending facility must be LPS designated for legal status to be valid.
  - b. Original 5150 with adequate time to file for 5250 certification.
  - c. 5250, if the certification hearing has been held and the Certification was upheld; copy of 5250 Certification Review, and/or Writ Record with no fewer than 7 days remaining for involuntary treatment
  - d. 5353 or 5358, only with the following documentation:
    1. Copy of court ORDER of appointment of the Conservator (public or private) for current date.
    2. Contact the Conservator's office, verify 5353/5358 status. Ask for verbal consent for admission and medications, and "letters to treat"

3. Original Letters of Conservatorship authorizing treatment or signature on Voluntary Consent Form
4. Signed consent for psychotherapeutic medication, if applicable
5. Ventura County Public Conservator may give verbal authorization until next business day. Document telephone consent for treatment using telephone order read back (TORB) format on the Consent for Voluntary Inpatient Treatment Form and on the Consent for Psychotropic Medications.
6. Private Conservator must physically bring in a Certified Copy of Letters for Conservatorship and Letters to Treat. Authorized staff will evaluate for LPS versus Probate. If probate, not valid.  
**"Patient presenting for admission on Private Conservatorship shall be admitted on 5150 and progress to 5250 until receipt of Certified Copy of Private Conservatorship Papers are presented for verification."**
7. There shall be no Writ of Habeas Corpus pending.
- e. The following medical records are to be faxed to the CSU unit for review by the psychiatrist prior to accepting the patient.
  1. Biographical information and identification
  2. Legal status papers as outlined above
  3. Current medications list
  4. Current physician orders
  5. Relevant past history
  6. Treatment plan
  7. Critical information
  8. General medical status and history
  9. Name of transferring physician

#### **CSU PSYCHIATRIST:**

1. Communicate directly with the sending psychiatrist or physician and determine if the patient meets admission criteria.
2. Request copies of additional significant medical records if needed.
3. Collaborate with the Shift Supervisor or Charge Nurse regarding questions about physical/nursing care needs.

#### **CSU STAFF:**

Upon determination that the patient is appropriate for admission, CSU staff will notify the Shift Supervisor or Charge Nurse of the transfer and the estimated time of arrival.

All revision dates:

2/9/2021, 8/1/2010, 3/1/2009, 2/1/2007, 10/1/2006,  
 7/1/2004, 9/1/2000, 2/1/2000, 9/1/1998, 2/1/1998,  
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## Attachments

No Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/9/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/9/2025
Inpatient Psychiatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	6/9/2025



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

## Z.74 Inpatient Psychiatric Unit Lobby Entrance Policy

### POLICY:

The Ventura County Medical Center Inpatient Psychiatric Unit identifies the need to ensure patient and staff safety. As a result, the front lobby entrance doors will remain locked 24 hours a day 7 days a week. All individuals seeking services must first pass through metal detector screening.

### PROCEDURE:

- A. The front lobby doors are to remain locked during 24 hours a day 7 days a week.
- A sign will be posted advising patients and visitors they are required to store their belongings, be wanded and have their bags and possessions searched prior to entering the facility.
  - All individuals will place their personal belongings in the storage lockers prior to entering the facility.
  - All individuals will be wanded and/or walk through a metal detector.
  - Individuals carrying contraband will not be allowed access inside the facility.
  - Individuals refusing to store their personal items in the front lockers and/or refusing to pass through the metal detector may not enter the facility.
  - Staff members should call nursing and/or security for assistance in the lobby.

Staff members with access cards may open the front lobby doors with their cards as needed.

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8/11/2022, 2/13/2019

### Attachments

No Attachments

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Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/14/2025
Inpatient Psychiatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	7/14/2025



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

## Z.88 Crimes Committed in the Inpatient Psychiatric Unit/Crisis Stabilization Unit (IPU/CSU)

### POLICY:

The Ventura County Medical Center Inpatient Psychiatric Unit (IPU) and Crisis Stabilization Unit (CSU) identify the need to ensure patient, visitor and staff safety. If a patient commits a crime on the premises, staff should contact the on call psychiatrist and then law enforcement and file a report.

### PROCEDURE:

#### Procedure for contacting Law Enforcement

- A. Immediately ensure staff and patient safety.
- B. Contact and consult with the Administrator on duty (AOD) and the IPU Mental Health Supervisor, Clinical Nurse Manager and/or Medical Director.
- C. If the patient was previously assigned to a treating VCMC psychiatrist, consult with the patient's psychiatrist to determine whether the patient's behavior was due to a symptom of a treatable mental disorder in which the patient did not understand the nature of the criminal act OR if the patient did not understand that what they were doing was morally wrong.
- D. If the patient's behavior was not due to symptom of a treatable mental disorder in which the patient did not understand the nature of the criminal act OR did not understand that what they were doing was morally wrong, contact the Ventura Police Department and inform them of the situation.
- E. Upon law enforcement's arrival, the Charge Nurse will be responsible for explaining the situation to law enforcement. Include details such as the patient's status, if any danger persists and the current location of the patient and any other relevant details (safety concerns, etc.).
- F. Complete a notification form, per hospital policy.
- G. If any patient, visitor or staff injury occurs, follow all current policies and procedures pertaining to follow up care and notifications.

All revision dates:

6/13/2019



## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	10/8/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/14/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/14/2025
Inpatient Psychiatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	7/14/2025



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**Owner:** Danielle Gabele: Chief Nursing Executive, VCMC & SPH  
**Policy Area:** Administrative - Patient Care  
**References:**

## 100.100 Palliative Care Program

### POLICY:

The Ventura County Medical Center Palliative Care Program operates as an interdisciplinary team, providing patients and families with comprehensive services throughout the continuum of their illness addressing physical, intellectual, emotional, social and spiritual needs and facilitating patient autonomy, access to information and choice. Palliative care encompasses care for patients of all ages, ensuring that age-specific needs are met. See Policy N.82, Neonatal Palliative Care, which specifically addresses palliative care for neonates, providing specialized, age-appropriate support for this patient population.

### PROCEDURE:

- A. To alleviate suffering, improve quality of life and facilitate healing for patients and their families facing chronic, debilitating, serious and / or life-threatening illness.
- B. Focus on physical, social, emotional and spiritual needs of patients and their families to assure comfort, dignity and a better quality of life.
- C. Assist and Support the primary medical team across the care continuum.

Palliative Care is an interdisciplinary, patient and family-centered approach to care that promotes quality of life in the context of serious or life-threatening illness. Palliative care may be complementary to curative or life-prolonging therapies that are being used to meet patient-defined goals of care.

**Palliative Care Consultation Team:** In addition to each team members' individual role, they each have a role in the education of Hospital staff and the community about palliative care and associated services (i.e., advanced care planning and end of life issues).

1. **Medical Director** : Provides operational and clinical leadership for all palliative care services. Is a member of the palliative care consultation service. Proactively identifies opportunities to improve the patient and family experience of care and improve the efficiency and effectiveness of resources used.
2. **Palliative Care Physician** : Provides consultation services in palliative care, symptom management and supportive care to meet the general medical needs of the patient. Facilitates clarification of patient and family goals of care. Consults with attending and / or primary physician and the interdisciplinary team to establish plan of care.
3. **Palliative Care Nurse Coordinator** : In collaboration with the palliative care physicians and other

team members, assists in the coordination and delivery of palliative care and related healthcare services to patient and families. Coordinates the interdisciplinary care conferences/family meetings with special focus on care goal clarification, pain and symptom management. Collects and maintains all aspects of palliative care data/statistics.

4. **Palliative Care Social Worker** : Provides psychosocial assessments, ongoing psychosocial interventions, bereavement assessment and implementation of bereavement care plan, community education, outreach and referrals. Collaborates with department-specific social workers and case managers to provide continuity of case management and social services.
5. **Palliative Care Chaplain/Spiritual Care Counselor** : Provides spiritual assessment develops and implements the spiritual plan of care emphasizing the integration of experience of pain and/or loss and anticipatory grief with the families own religious and spiritual practices. Works in partnership with local community clergy to provide continuity of care
6. **Psychologist** : Provides an environment to support patient and family expression of psychosocial needs. Listens actively, supports and refers as appropriate. Integrates psychosocial needs to the plan of care.
7. **Other Team Members** : On-call basis (i.e. pharmacist, dietician, physical and occupational therapists).

**D. Hours of Operations :**

Palliative Care consultant services are available Monday to Friday. Hours vary excluding hospital-observed holidays. The Palliative Care Consultation Team will provide consultation to patients throughout Ventura County Medical Center.

**E. Referrals:**

The Palliative Care Program requires a physician referral to provide consultation services. To request a consultation, contact the Palliative Referral line (805) 652-6093, contact Palliative Care team members directly or place an order via Electronic Health Record (EHR).

Additionally, the Palliative Care Team is available to function as an expert resource to nursing and ancillary personnel without a physician's order for education, advanced care planning and for help in assessing the need for a referral.

Guidelines for referral: The Palliative Care Consultation team is available for patients and their families at any stage of their care and treatment. Types of referrals may include, but are not limited to:

1. Presence of a life-limiting illness for symptom control
2. Difficult symptom management (pain, dyspnea, nausea, anxiety)
3. Lack of response to curative therapies/changing goals of care
4. Patient and/or family support
5. Recurrent hospitalizations for the same illness (i.e., heart failure, COPD, liver failure)
6. Patient and/or family request.
7. Spiritual or emotional distress
8. Uncertainty or conflicts in DNR orders

9. Metastatic or locally advanced cancer progressing despite systemic treatments
10. Parkinson's disease with poor functional status or dementia

**F. Practice Standards:**

The Palliative Care Consultation Team/Service provides patient consultation regarding the goals of treatment and plan of care including, but not limited to:

1. Assessing and managing symptoms and side effects, according to the desires of the patient or surrogate decision maker with special attention to pain control.
2. Provide education to patient and family to promote an understanding of the underlying disease process, treatment choices and as deemed appropriate end of life resources.
3. Based on a comprehensive interdisciplinary assessment of the values, preferences, long and short term goals and needs of the patient and family; formulate, utilize and review a timely plan of care.
4. Spiritual and psychosocial support, integrating the patient's values, religion, cultural beliefs, tradition or rituals and preference for care, including adjunct therapies if patient desires.
5. Assist in and support a comfortable healing environment.
6. Consultation for advance care planning and community resource referral.
7. Assessment and support anticipatory grief needs of patient and families and linkage to community based resources.
8. Coordination with community providers to maintain continuity of care for the palliative care and / or hospice care patient.
9. Provide continuing education to all health professionals on the domains of palliative care and hospice care.

**G. Interdisciplinary Meetings**

Interdisciplinary Meetings will be set up to meet the needs of the patient and family within the designated Palliative Care Services hours. The interdisciplinary team will meet once weekly and ad hoc.

**H. Documentation:**

All consultations are documented/charted the same as any other medical consultation in the patient's chart.

All revision dates:

9/24/2025, 1/10/2023, 4/1/2016

## Attachments

No Attachments

## Approval Signatures

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Medical Executive	Stephanie Denson: Manager, Medical Staff Office	pending

Step Description	Approver	Date
Committee		
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	10/14/2025
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	9/29/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/24/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/24/2025
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/24/2025



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 Owner: Gwendolyn Vontoure: Director  
 Perioperative Services  
 Policy Area: Administrative - Patient Care  
 References:

## 100.215 Preop/PACU/Post-op Electronic Orders Management

### POLICY:

~~Orders~~ Perioperative orders will be entered into the Electronic Health Record by the ~~provider for Preop/PACU/Post-op areas~~ surgery or primary team.

### PROCEDURE:

~~**Preop:** Orders can be entered in a planned or initiated state, depending on the timing of the procedure. Providers and non-providers can initiate planned Pre-op orders when appropriate.~~

- ~~a. Outpatients' current active order profile will remain in place throughout the case in the Operating Room.~~
- ~~b. Inpatients will have the primary nurse suspend all active medication orders immediately upon transfer from unit to surgery EXCEPT for continuous vasoactive and sedation IV infusions as clarified with provider.~~

~~**Post-Op:** The surgeon or designated member of their team will discontinue previous orders no longer intended for the patient after surgery, perform a transfer order reconciliation, and enter Post-Op orders. If the primary care team is not the surgical team (e.g. the patient is on the Medicine service), the surgeon will notify the primary team to perform the order process when the surgery is complete. When the patient arrives to the post-surgical unit, the RN will initiate any phase(s) of the post-op orders that have not been initiated.~~

#### Preoperatively:

- a. **Outpatients:** Preoperative orders are entered in advance. Preadmission testing orders are initiated immediately. The remainder of orders are initiated by the nurse either the day before surgery, or on day of surgery, as specified in the order set. The current active order profile will remain in place throughout the case in the Operating Room.
- b. **Inpatients:** The primary nurse or licensed practitioner will suspend all active medication orders immediately upon transfer from unit to surgery EXCEPT for continuous IV infusions, and IV or subcutaneous anticoagulation as clarified with provider.
- c. **If patient is not on a surgical service:** There will be a discussion between the primary team and the surgery team regarding IV and subcutaneous anticoagulation continuation or suspension prior to transfer to the OR. The discussion should be documented by the primary team and should include a summary of the discussion with the surgical team, who specifically was involved in the discussion, and when

anticoagulation should be resumed post-operatively. The surgery team will complete the Preoperative order set, including the "Anticoagulation Periop Suspend Instructions".

1. Primary nurse will call or otherwise notify the physician listed as "Primary Contact" to inform them when patient is going to the operating room

d. **If patient is on a surgical service:** The surgical team will use the Preoperative power plan including the "Anticoagulation Periop Suspend Instructions" to specify whether to continue or suspend continuous IV infusions and IV or subcutaneous anticoagulation medications, respectively. A member of the surgical team will complete the Post-op order set and Transfer Medication Reconciliation.

e. **Trauma patients:** Please refer to CPG.79 Venous Thromboembolism (VTE) Prophylaxis Practice Management Guideline In Trauma Patients for specific guidelines regarding anticoagulation in trauma patients. Also see attachment below for VTE practice algorithm.

**Postoperatively:** The primary team (either surgery or other service) is responsible for the postoperative orders. If it is not the surgical service, the surgical team will contact the primary team and discuss any recommended order changes, including a discussion of anticoagulant timing. The primary team will:

- Discontinue previous orders no longer intended for the patient after surgery
- Perform a transfer order reconciliation. The transfer reconciliation will resume any suspended medication orders
- Enter Postoperative orders

Emergent surgery: If time does not permit entering the Preoperative and "Anticoagulation Periop Suspend Instructions" order sets into the EMR, there will be clear orders post-operatively using the Postoperative order set and the Transfer Medication Reconciliation to restart or continue anticoagulants and continuous IV medications. This should also be documented in the Operative Report or Post-Operative note to alert the rest of the care team.

When the patient arrives to the post surgical unit, the RN will initiate the "Postoperative" and any "Initiate on Floor" phases of any new order sets.

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10/6/2025, 7/26/2017, 5/1/2014

## Attachments

 [Attachment A - Algorithm VTE Practice Guideline\\_Trauma.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Policy Owner	Gwendolyn Vontoure: Director Perioperative Services	pending



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Policy Area: Administrative - Patient Care  
References:

## 100.224 Emergency Medical Treatment and Labor Act (EMTALA)

### POLICY:

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted both by Congress to regulate and restrict the transfer, for economic or other non-medical reasons, all patients presenting for emergency services. The primary focus of EMTALA is to ensure access for all patients to emergency services and to prohibit discrimination in the provision of emergency services. This policy ~~provides for:~~ aligns with the EMTALA definition of hospital campus which refers to the areas located within 250 yards of the main campus buildings.

This policy provides for:

- A. The Medical Screening Examination (MSE) conducted by a physician or Qualified Medical Person (QMP) will be provided to all patients presenting to the Emergency Department (ED).
- B. The transfer of patients with emergency medical conditions.

### PROCEDURE:

- A. A medical screening examination (MSE) will be offered to any individual presenting for examination or treatment of a medical condition. The examination will be the same appropriate screening examination that would be performed on any individual with similar signs and symptoms, regardless of the individual's ability to pay for medical care.
- B. The medical screening examination or necessary stabilizing treatment shall not be delayed in order to inquire about an individual's method of payment or insurance status. Prior authorizations will not be requested for emergency services until the medical screening examination has been conducted.
- C. The hospital will not transfer any patient with an unstable emergency condition (including a pregnant patient having contractions or a patient with severe pain) unless a physician certifies that the medical benefits reasonably expected from the provision of treatment at the receiving facility outweigh the risks of the transfer.
  - 1. Prior to transfer, the receiving hospital and physician have agreed to accept the patient and to provide appropriate medical treatment.
  - 2. The hospital shall send to the receiving facility all medical records (or copies thereof) available at the time of transfer related to the emergency condition of the patient, including:
    - a. Records related to the patient's emergency condition, observations of signs or symptoms,



preliminary diagnosis, treatment provided, results of any tests and vital signs at the time of transfer; other records (including pending test results or records not available at the time of transfer) must be forwarded as soon as practicable after the transfer;

- b. The patient's informed written consent to transfer or the physician's certification (or copy thereof); and
  - c. The name and address of any on-call physician who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment.
3. The transfer is effected using proper staff and equipment, as well as necessary and medically appropriate life support measures.

If a patient who has or may have an emergency medical condition is transferred to another facility for a test with the intention of the patient returning to the Hospital after the test, the Hospital will transfer in accordance with EMTALA standards.

## PATIENT REFUSAL OF EMERGENCY SERVICES OR TRANSFER

- A. Under EMTALA the patient retains the right to refuse necessary stabilizing treatment and further medical examination, as well as a transfer to another facility.
- B. If a patient leaves the hospital before receiving a medical screening examination, either with or without notice to staff, staff should document the circumstances and reasons (if known) for the patient's departure and the time of departure.
- C. If a patient refuses stabilizing treatment after receiving a medical screening, the physician or QMP at Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) will offer examination and treatment, and inform the patient of the risks and benefits of the examination and treatment and request that the patient sign an *Against Medical Advice (ADA)* form that he/she has refused further treatment. A summary of the risks of not receiving treatment as describes to the patient shall be documented in the medical record.

## SIGNAGE

Signs will be posted in lobbies and other appropriate locations where patients may be waiting for treatment or where examination may occur specifying the rights of individuals to examination and treatment for emergency medical conditions and indicating the participation in the Medi-Cal program. The signs will also ~~state the name, address and telephone for~~ explain how to contact the State Department of Health Services. The signs will be posted in English and Spanish in the ED and Labor and Delivery.

## DOCUMENTATION LOG

Each location that provides medical screening examination will maintain a central log recording the name of the person who presents for emergency services and whether the person refused treatment, was refused treatment or whether the patient was transferred, admitted and treated, stabilized and transferred or discharged.

## ON-CALL RESPONSE

A list of on-call physicians is maintained in the ED. These physicians are to provide consultation or treatment necessary to stabilize a patient with an emergency medical condition. See Physician On-Call Administrative

policy 100.107.

## MAINTENANCE OF RECORDS

Transfer logs, on-call lists and changes to the on-call list and central logs shall be maintained for five (5) years.

## DISPUTES

In the event of any concern over emergency services to a patient, a dispute with another hospital regarding a patient transfer or a concern about VCMC/SPH's compliance with EMTALA, the Hospital Administrator on duty and the Medical Director are to be notified immediately.

## REPORTING

VCMC/SPH will report to the Health Care Finance Administration (HCFA) or State Licensing within 72 hours if it concludes that it has received an individual who has been transferred in an unstable emergency condition from another hospital. All hospital staff who believe an EMTALA violation has occurred shall report the violation to the Hospital Administrator on duty and Medical Director.

The hospital shall not retaliate, penalize or take adverse action against any Medical Staff member or employee for reporting violations of EMTALA or State laws to the proper authorities.

## DEFINITIONS

### Emergency Medical Condition

- A medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in either placing the health of the individual in serious jeopardy; serious impairment of bodily functions; or serious dysfunction of any bodily organ or part; or
- With respect to a pregnant woman who is having contractions, there is inadequate time to effect a safe transfer to another hospital before the delivery or the transfer may pose a threat to the health or safety of the woman or her unborn child.

**Hospital Campus** The physical area immediately adjacent to the hospital's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis by the Centers for Medicare & Medicaid Services ("CMS") Regional Office to be part of the hospital's campus.

### Medical Screening Exam (MSE)

An MSE is the process required to reach, within reasonable clinical confidence, the point at which it can be determined whether the individual has an emergency medical condition (EMC) or not. An appropriate MSE is dependent on the presenting signs and symptoms and may involve a wide spectrum of actions ranging from a simple process involving only a brief history and examination of the presenting symptoms to a complex process that includes ancillary studies and procedures. Medical includes both physiological and psychological symptoms.

### Qualified Medical Person (QMP)

A Qualified Medical Person is a physician, nurse practitioner, physician assistant, and a specialty trained nurse such as obstetrics nurse who performs the examination and communicates the findings to an attending

physician to determine if an EMC exists.

**Transfer** is defined as the movement of an individual outside of a hospital's facility at the direction of any person employed by the hospital, but does not include such movement of an individual who has been declared dead or leaves the facility without permission of any such person.

**Labor** is defined as the process of childbirth beginning with the latent or early phase of labor and continuing through delivery of the placenta. A woman is in true labor unless the physician certifies that after a reasonable time of observation, the woman is in false labor.

**Stabilization** is defined as follows:

**Labor and Delivery patients.** Stabilization is defined as delivery of the child and the placenta. A women having contractions "may not be transferred unless she, or a legally responsible person acting on her behalf, request a transfer or if a physician or other qualified medical personnel, in consultation with a physician, certifies that the benefits to the condition of the woman and/or unborn child out weigh the risks associated with the transfer."

**Medical patients.** Stabilization is defined as no material deterioration of the condition is likely, within reasonable medical probability, to result for or occur during transfer. A patient is deemed stabilized if the treating physician has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved.

**Capacity** refers to the ability of the hospital to accommodate the individual requesting examination or treatment of a transfer patient. Capacity encompasses adequacy of staff, beds, equipment and past practices in accommodating additional patients beyond occupancy limits.

### Psychiatric Patients

**Stable for transfer.** A psychiatric patient is considered "stable for transfer" if the patient has been assessed by the treating physician and determined to have no underlying organic basis for the presenting psychiatric symptoms; initial treatment has been provided as indicated; the patient has been treated sufficiently so that he/she is stable for transfer.

**Stable for discharge.** A psychiatric patient is considered "stable for discharge" if the patient no longer considered to be a threat to himself/herself or others.

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## Attachments

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## Approval Signatures

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Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	10/14/2025
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	9/29/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/19/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/19/2025
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/19/2025



## VENTURA COUNTY HEALTH CARE AGENCY

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Laboratory Services  
**Policy Area:** Administrative - Patient Care  
**References:**

### 100.231 Specimen Labeling and Transport

#### POLICY:

To ensure that all patient specimens collected are properly labeled and transported by staff.

#### PROCEDURE:

- Prior to the collection of a specimen, staff shall validate patient identification using two (2) patient identifiers per procedure.
- All specimens are required to have a patient label. At a minimum, the label shall include the patient's name and date of birth.
- Specimens are to be labeled in front of the patient. The specimen shall not leave the patient's bedside until properly labeled.
- The patient shall acknowledge that the specimen was obtained from the patient and the patient name and date of birth are on the label prior to leaving the bedside (exceptions: patient is under anesthesia, Code Blue, patient is confused or unable to respond to verbal stimuli).
- Lab specimens: Additional information to be written on the label:
  - Date and time of collection
  - Cerner login ID of person collecting the specimen
  - Specimen type
  - For microbiology specimens, identify the site of origin and, as appropriate, the laterality of the specimen (right versus left). If more than one specimen container is submitted, label each container with the site of origin and laterality.
- Specimens are to be tightly sealed and placed in a clear Biohazard-labeled plastic bag before transportation to the Laboratory or Pathology Department.
- When nursing staff collect a specimen, the requisition order will be placed in the plastic sleeve that will accompany the specimen.

NOTE: Red biohazard bags are NOT to be used to transport patient samples to the Laboratory/Pathology Departments.

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Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	10/14/2025
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH	9/29/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/6/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/6/2025
Policy Owner	Erlinda Roxas: Director, Laboratory Services	9/6/2025



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Laboratory Services  
Policy Area: Administrative - Patient Care  
References:

## 100.258 Blood Culture Specimen Collection

### Purpose:

To establish guidelines for the proper collection of blood cultures by personnel trained to perform venipuncture.

### Policy:

1. Personnel trained to perform venipuncture for blood cultures shall show competency prior to independent practice and annually thereafter.
2. Blood cultures aiding in the detection of bacteremia are collected by venipunctures
  - a. In situations where venipunctures are not possible such as in dialysis patients and pediatric patients, blood draw may be collected from angiocath, arterial line, or central venous line after confirmation with the licensed practitioner (LP).

### Considerations:

1. If possible cultures should be obtained before starting antimicrobial therapy; prior antimicrobial therapy may interfere with bacterial growth.
2. A positive culture result from a central line only may be considered a contaminant.

### Equipment List:

1. Non-Sterile Gloves
2. Sterile Gloves
3. Alcoholic chlorhexidine pads for bottle top decontamination
4. Alcoholic chlorhexidine swabs for skin decontamination
5. Appropriately sized syringe(s) and/or needleless transfer device
6. Winged (butterfly) needle
7. Blood culture bottles (aerobic and anaerobic bottles)
8. Laboratory biohazard transport bag
9. Labels

10. 2" x 2" gauze pads
11. Small adhesive bandages
12. Tourniquet

## Procedure:

### Collecting Blood Cultures from Venipuncture in Adults and Pediatrics

*For neonates, refer to section titled "Collecting Blood Cultures in Neonates".*

1. Verify the provider order.
2. Gather all equipment from equipment list.
3. Perform hand hygiene.
4. Confirm the patient's identity using two identifiers.
5. Provide privacy.
6. Explain the procedure.
7. Raise the bed to waist level.
8. Perform hand hygiene.
9. Put on gloves.
10. Choose a venipuncture site.
11. Avoid use of a tourniquet, if possible. If necessary, apply the tourniquet.
12. Disinfect blood culture bottle tops with alcoholic chlorhexidine (CHG) pad by scrubbing the rubber stopper for at least five seconds and let dry for five seconds.
  - a. If alcoholic CHG is not available, use 70% isopropyl alcohol (alcohol pad) and scrub the rubber stopper for at least 15 seconds and let it dry.
13. Clean the skin at the venipuncture site with alcoholic chlorhexidine (CHG) swab by using a back-and-forth scrubbing motion for at least 30 seconds and allow it to dry for at least 30 seconds.
  - a. Don't palpate the site again to avoid transfer of microorganism to the venipuncture site. If palpation is necessary, don a sterile glove.
14. Perform a venipuncture. Discard the initial volume (1-3 mL) of the blood sample into a yellow-top tube or red-top tube. Then draw a quantity that is sufficient for isolating organisms.
  - a. For non-dialysis patients:
    - i. For adults, collect a set of two blood culture bottles (minimum 10 mL in each bottle), one for aerobes and one for anaerobes; two blood cultures (by separate stick) per septic episode is sufficient.
      - Fill the aerobic bottle first, followed by the anaerobic bottle.
    - ii. For pediatric patients, collect 1-3 mL into a yellow-top blood culture bottle.
  - b. For dialysis patients:
    - i. One set of blood cultures from a separate site should be drawn. A second set will be drawn from dialysis access device. Only dialysis nurses can draw samples from dialysis access sites. A



VCMC/SPH RN is responsible for sharing this policy with the dialysis nurse when blood cultures are needed from the line.

ii. For each set, see 14.a.i.

15. Immediately remove the tourniquet if used, unless drawing additional blood specimens.
16. Place a gauze pad over the puncture site and slowly and gently remove the needle from the vein. Apply pressure to the site. Cover the site with a small adhesive bandage.
17. Invert the bottles 8 to 10 times gently.
18. Discard syringes and needles in a puncture-resistant sharps container.
19. Return the bed to the appropriate position.
20. Label bottles at bedside, ensuring proper use of two patient identifiers.
  - a. Include date, time, Cerner ID and site.
21. Place the properly labeled bottles by set into two separate re-sealable biohazardous plastic bags.
22. Doff and discard your gloves. Perform hand hygiene.
23. Bottles must be sent to the laboratory within 2 hours of specimen collection.
24. Document the procedure in the electronic health record (EHR).

### **Collecting Blood Cultures from a Central Line in Adults**

1. Follow steps 1-4 of procedure for Collecting Blood Cultures from Venipuncture.
  - a. Collecting blood cultures from a central venous catheter (CVC) or peripherally inserted central catheter is discouraged. If a patient has a CVC or PICC, the blood culture needs attending physician authorization. See Policy 2.a. for more information.
2. Stop all infusions for a period of time as discussed with the LIP. Ensure central line is clamped.
3. Proceed with steps 5-9 of procedure for Collecting Blood Cultures from Venipuncture.
4. Perform a vigorous mechanical scrub of the hub for at least 5 seconds using an alcoholic CHG pad, and allow to dry for at least 5 seconds.
5. If you're also drawing blood for other laboratory tests, draw blood for culture before drawing the sample for other tests. Maintaining sterility of the syringe tip, connect the empty syringe to the catheter, release the clamp, and withdraw at least 10 mL of blood for each blood culture bottle. Don't discard first drawn blood; this is the blood sample you'll be injecting into the culture bottle.
6. Clamp the catheter and remove the syringe.
7. Perform a vigorous mechanical scrub of the hub for at least 5 seconds using an alcoholic CHG pad, and allow to dry for at least 5 seconds.
8. While maintaining sterility of the syringe tip, connect the syringe with preservative-free normal saline solution, open the clamp and flush and lock the device or resume the infusion(s) as ordered.
9. Place a disinfectant-containing end cap on the hub to reduce the risk of vascular catheter-associated infection.
10. Proceed with steps 17-24 of procedure Collecting Blood Cultures from Venipuncture.

## Collecting Blood Cultures from a Central Line in Pediatrics

1. Refer to the following Lippincott Procedures:
  - a. [Blood Culture Sample Collection, Pediatrics](#)
  - b. [Implanted Port Blood Sampling, Pediatrics](#)
  - c. [Peripherally Inserted Central Catheter \(PICC\) Blood Sampling, Pediatrics](#)

## Collecting Blood Cultures in Neonates

1. Refer to the following Lippincott Procedures:
  - a. [Blood Culture Sample Collection, Neonatal](#)
  - b. [Umbilical Artery Catheter Blood Withdrawal, Neonate](#)
2. Chlorhexidine should not be used in infants younger than two months of age as it can cause irritation and chemical burns.

## References:

1. Blood Culture Sample Collection. (2021). In Lippincott Procedures. <https://procedures.lww.com/lnp/view.do?pld=3379174&hits=culture,cultures.blood&a=false&ad=false&q=blood%20culture>
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All revision dates:

1/10/2023, 12/3/2021, 8/11/2020

## Attachments

 [Competency Validation Tool: Blood Culture Specimen Collection](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive	Stephanie Denson: Manager, Medical Staff Office	pending

Step Description	Approver	Date
Committee		
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	10/14/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/2/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/2/2025
Laboratory Services	M. Anwar Molani: Medical Director, Laboratory Services	10/2/2025
Laboratory Services	Erlinda Roxas: Director, Laboratory Services	9/6/2025
Policy Owner	Erlinda Roxas: Director, Laboratory Services	9/6/2025



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**Next Review:** 3 years after approval  
**Owner:** Tracy Chapman: Director, HCA Medical Staff Administration  
**Policy Area:** Administration - Medical Staff  
**References:**

## 102.042 Department/Division Medical Director Qualifications & Responsibilities

### Qualifications:

The Medical Director of each department/division at Ventura County Medical Center will:

- A. Continually meet the basic requirements outlined in Article 2 of the Medical Staff Bylaws,
- B. Have a minimum of 5 years clinical experience in their specialty,
- C. Demonstrate leadership qualities,
  - 1. Preferred experience in quality improvement, regulatory experience, compliance, medical education, and interdisciplinary collaboration, experience in a teaching or safety-net hospital environment, including familiarity with Graduate Medical Education (GME) requirements and culturally responsive care delivery.

### Responsibilities:

I. The Medical Director is responsible for ensuring compliance with:

- A. Medical Staff Bylaws, Rules, and applicable Department Rules Regulations,
- B. Medical Staff and Hospital policies and procedures,
- C. All applicable federal and California state laws and regulations, including Centers for Medicare & Medicaid Services (CMS) Conditions of Participation, Title 22, and California Department of Public Health (CDPH) requirements,
- D. Hospital accreditation standards (e.g. The Joint Commission),
- E. Duties under this role are separate and distinct from general Medical Staff obligations to ensure compliance with the Stark Law and Anti-Kickback Statute.

II. Supervising the quality, safety, and appropriateness of care within the department/division, including timely documentation, supporting the peer review, morbidity and mortality reviews, and outcome monitoring requirements in conjunction with the Department Chief and/or Department Committee.

III. Ensure adequate daily staffing and call schedule coverage at all applicable practice locations, including preparation and anticipation of patient surges while exercising fiscal stewardship in resource allocation.

IV. Collaborate with the Quality Assessment/Performance Improvement (QAPI) team and Patient Safety

Program to achieve quality benchmarks, fulfill required regulatory reporting, and implement corrective actions where needed.

V. Recommend to Hospital Administration and/or the Medical Staff requirements for equipment, personnel, technology, and medications relevant to the department/division with supporting data and justifications.

VI. Address patient grievances when assigned by Chief Medical Officer (CMO) or other Hospital and/or Medical Staff leader.

VII. Provide support to optimize the department/division practitioner's wellbeing.

VIII. Participate in assigned department/division or medical staff committee meetings. Participation may include, but not limited providing regular reports and monitoring compliance with disciplinary actions.

IV. Provide and/or recommend ongoing continuing medical education and staff development, including orientation and competency training for new staff and trainees.

X. Participating in the development, review, and update of department/division policies and procedures, and clinical practice guidelines to ensure alignment with current regulations, evidence-based practice, and institutional goals.

XI. Work in collaboration with the Chief Medical Officer and the Hospital's Quality Assessment/Performance Improvement (QAPI) team to meet any department/division quality measures, contract-specific requirements, and to prepare for external surveys and audits (e.g., CMS, CDPH, TJC).

XII. Oversee and ensure timely completion of required department/division-specific, Medical Staff, and agency-wide mandatory training and certifications, including those related to compliance, patient safety, Health Insurance Portability and Accountability Act (HIPAA), Confidentiality of Medical Information Act (CMIA), cultural competency (Senate Bill 923), and teaching obligations as applicable.

XIII. Maintain contemporaneous documentation of time and activities performed under the medical directorship to demonstrate bona fide services, consistent with contract terms and Stark, and Office of the Inspector General (OIG) requirements.

XIV. Any additional contract specific responsibilities, if applicable.

All revision dates:

## Attachments

 [Attachment A - Medical Director Scope of Work](#)

## Approval Signatures

Step Description	Approver	Date
Medical Staff Office	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Office	Minako Watabe: Chief Medical Officer, VCMC & SPH	pending
Policy Owner	Tracy Chapman: Director, HCA Medical Staff Administration	10/22/2025



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**Owner:** Magdy Asaad: Infection Prevention Manager  
**Policy Area:** Administrative - Environment of Care  
**References:**

## 106.018 Infection Control Standard Precautions

### POLICY:

Standard Precautions includes a group of infection prevention practices that applies to all patients regardless of suspected or confirmed infection status in any setting where healthcare is delivered. The 2007 revisions and additions to Standard Precautions reinforce existing practices and include additional measures to protect healthcare workers (HCW's) and patients.

### PROCEDURE:

Use **Standard Precautions** for the care of all patients.

#### I. Hand Hygiene

- A. Hand hygiene is the single most important practice to reduce the transmission of infectious agents in health care.
- B. Hand hygiene is addressed in policy *106.055 Hand Hygiene*.

#### II. Gloves

- A. Wear gloves (clean, non-sterile gloves are adequate) when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and non-intact skin.
- B. Change gloves between tasks and procedures on the same patient after contact with material that may contain a high concentration of microorganisms.
- C. Remove gloves promptly after use, before touching non-contaminated items and environmental surfaces, before exiting the room, and before visiting another patient.
- D. Perform hand hygiene immediately to avoid transfer of microorganisms to other patients or environments.

#### III. Mask, Eye Protection, Face Shield

- A. Wear a mask and goggles or a mask with attached face shield to protect mucous membranes of the eyes, nose, and mouth during procedures and patient care activities (including suction and phlebotomy) that are likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.
- B. Wear eye protection for caring of all patients in outbreak situations such as COVID-19

- C. Wear a gown (a clean, non-sterile, fluid resistant gown is adequate) to protect skin and to prevent soiling of clothing during procedures and patient care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.
- D. Wear a gown that is appropriate for the activity and amount of fluid likely to be encountered.
- E. Remove and discard soiled gowns as promptly as possible, especially after exiting a room. Do not reuse gowns or gloves.
- F. Wash hands to avoid transfer of microorganisms to yourself, other patients or environments.

#### IV. Patient Care Equipment

Handle used patient care equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to yourself, other patients and environments. Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and reprocessed appropriately. Ensure that single-use items are discarded properly. See policy *106.061 Cleaning and Disinfection of Patient Care Equipment*.

#### V. Environmental Control

Ensure that there are adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other frequently touched surfaces, and ensure that these procedures are being followed. Decontaminate using only hospital-approved disinfectants and antiseptics. See policy *106.061 Cleaning and Disinfection of Patient Care Equipment*.

#### VI. Linen

Handle, transport, and process used linen soiled with blood, body fluids, secretions and excretions in a manner that prevents skin and mucous membrane exposures. Avoid contamination of clothing and the environment. Linen should be held away from the body and discarded in linen cart. Linen cart should be close to bed being stripped to decrease contamination of yourself and clothing.

#### VII. Occupational Health and Bloodborne Pathogens

- Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices, when handling sharp instruments after procedures, when cleaning used instruments, and when disposing of used needles.
- Never recap used needles, never manipulate used needles using both hands, never use any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed "scoop" technique or a mechanical device designed for holding the needle sheath.
- Do not remove used needles from disposable syringes by hand. Do not bend, break, or otherwise manipulate used needles.
- Always deploy the safety feature after moving from the point of care.
- Always place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant, leak-proof and biohazard-labeled containers.
- Always use the container closest to the point of use. Place reusable syringes and needles in a puncture-resistant container for transport to the reprocessing area.
- Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation methods in areas where the need for resuscitation is predictable.

#### VIII. Patient Placement

For patients who may contaminate the environment or do not (or cannot be expected to) maintain



appropriate hygiene or environmental control, a private room is preferable. Cohorting may be done in accordance with policy 106.028 Isolation Precautions Guidelines, Appendices A and B.

#### IX. Respiratory Hygiene/Cough Etiquette

Any time or at any location, the patient must be triaged at the first point of entry:

- Triage the patient for respiratory illness or rash illness.
- Immediately implement appropriate measures such as respiratory etiquette and isolation.
- The expectation is that all patients, family members and friends will comply.
- Patient must wear mask until segregation is completed. If the patient does not wear the mask, the HCW will wear a mask.
- Move the patient to an appropriate location creating spatial separation or into an isolation room.

#### X. Safe Injection Practices.

- Used needles may not be re-injected into multi-dose vials or intravenous solutions. Use a sterile needle and syringe for each puncture of multi-dose vials. If a multi-dose vials are used, the vial may only be used for one patient, except as noted in Policy PH.79 Multiple Dose vials
- Medications packaged as single-dose or single use may not be used for more than one patient. This includes ampules, bags, and bottles of intravenous solutions.
- Do not use single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution for more than one patient.
- Do not use fluid infusion or administration sets (e.g., IV bags, tubings, connections) for more than one patient.

#### XI. Special Lumbar Puncture Procedures

A surgical mask shall be worn by staff placing a catheter or injecting material into the spinal or subdural space (i.e., during myelogram, lumbar puncture and spinal or epidural anesthesia/analgesia).

### REFERENCES:

Centers for Disease Control Isolation Precautions Guidelines  
<http://www.cdc.gov/ncid>

All revision dates:

1/10/2023, 2/12/2019, 3/1/2014, 11/1/2013, 10/1/  
2012, 6/1/2012, 7/1/2011, 11/1/2007, 6/1/2006, 7/1/  
2004, 9/1/2001, 10/1/2000, 10/1/1998, 7/1/1992

### Attachments

No Attachments

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	10/28/2025



Step Description	Approver	Date
Policy Owner	Magdy Asaad: Infection Prevention Manager	10/28/2025



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**References:**

## 106.023 Infection Control Plan

### Purpose:

Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH) and the Ambulatory Clinics plan processes around the identification, control, and prevention of infection to ensure that the Healthcare Agency has a functioning coordinated process in place, to reduce and minimize the risks of endemic (common cause) and epidemic (special cause) Healthcare Associated Infections (HAIs) in patients, visitors and healthcare workers and to optimize use of resources through a strong preventive program.

### Goals:

The goals of the infection prevention and control program in a broad context include, but are not limited to:

1. Minimizing Healthcare-Associated Infection (HAI) by:
  - Limiting unprotected exposure to pathogens throughout the hospital and clinics
  - Minimizing the risk of transmitting infections with the use of procedures, medical equipment, medical devices and other procedures focused on risk mitigation.
  - Promotion of effective hand hygiene
  - Maintain a sanitary environment to avoid sources and transmissions of infections and communicable diseases.
  - Utilization of data to help guide us in our planning and changing performance.
2. Establishing a reliable surveillance program by:
  - Comprehensive risk-assessment to be conducted on an ongoing basis and at least annually to guide the surveillance activities and goals
  - An active surveillance program to identify risks of infection
  - Concurrent surveillance with feedback to the clinicians
  - Analyzing HAI rates with methodical root cause analysis
  - Establishing annual goals with achievable measures of success
  - Evaluation of the program's success and revising techniques as needed.
3. Developing a system for identifying, reporting, investigating, and controlling infections, and communicable diseases in patients, healthcare personnel (HCP) and physicians
4. Training and educating healthcare workers through:
  - General new hire orientation program

- Annual education
- Departmental education programs
- Special education events
- Ongoing education: verbal, printed and electronic
- Compliance monitoring

5. Ensuring that the hospital-wide performance programs address problems identified by infection control personnel and others, and that subsequent corrective actions plans are successfully implemented and sustained.

6. Development of specific goals and objectives based on the annual risk assessment

## Objectives:

- A. Monitoring and evaluation of all possible hospital associated infections (HAI) with emphasis on key performance aspects of infection control surveillance, prevention and management such as:
  - Healthcare-Associated infections in high-risk areas such as Intensive Care Unit (ICU), Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU)
  - Post-operative wound infections
  - Device-related infections:
    - Catheter-related bloodstream infections
    - Catheter-associated Urinary Tract Infections and
    - Ventilator-associated pneumonia
    - Invasive Device-Associated Skin Infection
  - Antibiotics-resistant organisms
  - Other communicable diseases
  - Occupational Health
    - Employee health trends
    - Disease exposure control plan including blood exposure in compliance with The Division of Occupational Safety and Health (DOSH) also known as CAL/OSHA regulations that require annual review.
    - Aerosol Transmissible Diseases Control Plan including Tuberculosis (TB) Control with ongoing surveillance for TB infection on all hospital employees with annual screening and testing (and semi-annual if needed) based on risk assessment.
    - Compliance with the Hepatitis B (Hep-B) vaccine program.
  - Drug utilization surveillance conducted by the clinical pharmacist to include reports on intravenous to oral switch, review of antibiotics for formulary and restricted use, and other epidemiologically significant areas of concern. An active multidisciplinary Antibiotic Stewardship program
  - Laboratory surveillance reporting on susceptibility patterns of organisms.
- B. Utilizing sound epidemiologic principles and HAI research from recognized authoritative agencies
- C. Continuously collecting and/or screening data to identify isolated incidents or potential infectious outbreaks

- D. Interacting with and reporting to governmental agencies, Centers for Disease Control (CDC)-National Healthcare Safety Network (NHSN) reporting for risk-stratification and benchmark generation through NHSN Standardized Infection Ratio (SIR) system.

## Infection Control Program (ICP)

- A. The VCMC/SPH Infection Control Program incorporates the following in a continuing cycle:
- Surveillance, prevention and control of infections throughout the organization
  - Development of alternative techniques to address the real and potential exposures
  - Selection and implementation of the best techniques to minimize adverse outcomes
  - Evaluation and monitoring of results and revision of techniques as indicated
- B. The program is guided and influenced by sound principles and current information mainly from the following organizations, which include but are not limited to:
- American Hospital Association (AHA) and its Advisory Committee
  - Association for Professionals in Infection Control and Epidemiology (APIC)
  - Centers for Disease Control and Prevention (CDC)
  - Centers for Medicare & Medicaid Services (CMS)
  - Certification Board of Infection Control and Epidemiology (CBIC)
  - Food and Drug Administration (FDA)
  - Department of Health and Human Services (HHS)
  - Institute for Healthcare Improvement (IHI)
  - The Joint Commission (TJC)
  - National Institute for Occupational Safety and Health (NIOSH)
  - Occupational Safety and Health Administration (OSHA)
  - Society for Healthcare Epidemiology of America (SHEA)
- C. The activities of the Infection Control Program fall under the umbrella and auspices of the organization's performance improvement program.
- Active participation in an organizational proactive education program, in a coordinated effort to reduce and control spread of infection.
  - To facilitate a multidisciplinary approach to the prevention and control of infections.
  - Integrating outcomes from surveillance and control activities throughout the facilities to allow for internal comparison for trend analysis.
  - Assuring the implementation of infection control policies and procedures throughout the hospital(s).
  - Communication of infection.

### **Reporting Structure:**

The Infection Prevention and Control (IPC) and the Infection Control/Prevention Committee provide regular updates of information related to program interventions and outcomes as well as the risk assessment and quality improvement projects to the Hospital Administration, the Medical Staff, and other management team members. Appropriate reports of surveillance data are sent to department managers to share with staff. Infection Prevention Committee meeting minutes and reports go to the Performance Improvement and Coordinating Council (PICC). The ICP Committee reports are addressed at the Medical

Executive Committee and the Oversight Committee meetings.

**Infection Prevention and Control (IPC) Responsibilities:**

The responsibilities of the ICP include, but are not limited to:

1. Develop and implement policies governing the prevention and control of infections and communicable diseases.
2. Develop, implement and evaluate systems and measures governing the identification, investigation, reporting, prevention and control of infections and communicable diseases within the hospital, including both healthcare–associated infections and community-acquired infections.
3. Identify and implement the necessary steps to prevent or control the acquisition and transmission of infectious agents
4. Coordinate all infection and control activities within the hospital and clinics
5. Facilitate ongoing monitoring of the effectiveness of prevention and/or control activities
6. Collect and analyze infection data, maintain a log of incidents related to infections and communicable diseases.
7. Participate actively in healthcare worker and patient/family education
8. Evaluation of products and procedures related to disinfection practices.
9. Staffing is based upon guidelines promoted by APIC as well as other regulatory agencies and prevailing community practice.

## **Infection Control Committee**

### **Responsibility:**

The Infection Control Committee (ICC) shall be responsible for:

- A. Directing the hospital-wide infection control program.
- B. Recommending policies and providing direction to prevent, identify, and control infections within the hospital.
- C. Defining the role and scope of Employee Health Services in the Infection Control Program.

### **Authority**

The ICC is a medical staff committee and is responsible to the Medical Executive Committee (MEC).

- A. The ICC makes recommendations and reports to the MEC.
- B. The ICC makes reports, recommendations, and referrals to other medical staff committees and Hospital Administration.
- C. The ICC shall make policies and clinical decisions only when a quorum, one third of the physician members, is present.

### **Membership**

The Infection Control Committee shall be a multi-disciplinary Committee.

The committee membership shall be:

- A. The Committee Chairman: An active Physician with special interest in infectious diseases and infection control.
- B. Hospital Epidemiologist and / or Infectious Disease
- C. Medical staff representatives
- D. Representative from Hospital Administration.

- E. The Chief Nursing Officer or representative
- F. The Infection Prevention and Control team
- G. Employee Health
- H. Pharmacy department representative
- I. Dietary Service
- J. Facilities/Engineering/Maintenance representative
- K. Surgery department/Central service representative
- M. Environmental Services, Central Service/Linen

The Following representation are available to the Infection Control Committee on a consultative and as needed basis:

- a. Surgery Department
- b. Central Service
- c. Laboratory/Pathologist.
- d. Human Resources.
- e. Obstetric, Pediatric unit.

## Meetings

The ICC shall meet monthly but not less than bimonthly. Minutes of the meeting proceedings shall be forwarded to the Medical Executive Committee for approval. Minutes shall be maintained in the Infection Control Office and shall be available to Administration and Department directors.

- B. The committee shall meet more often if needed.

## Functions

The functions of the infection control committee will be as follows:

- A. The committee is responsible for monitoring the infection control program. The committee recommends corrective action based on records and reports of infection and infection potentials among patients and hospital personnel.
- B. The infection control committee is directly responsible to the Medical Staff through its Executive Committee.
- C. The committee reviews, revises and approves all infection control policies and procedures for all departments at least biannually.
- D. The Committee reviews the findings of the infection control coordinator regarding Healthcare-Associated infections and other types of monitoring.
- E. Policies and clinical decisions shall be made by the committee only when a physician member is present.
- F. The infection control committee shall determine the type of surveillance and reporting programs to be used and approve the amount of time needed to carry out the program.
- G. The committee shall approve criteria for reporting all types of infections, including respiratory, gastrointestinal, surgical wound, skin, urinary tract, septicemia and those related to the use of intravascular catheters.
- H. The committee reviews infections within the hospital, particularly with regard to their proper management and epidemic potential. A determination is made as to whether an infection is Healthcare- Associated, and if so, what action the committee recommends be taken to minimize such occurrences. Review may be directed to surveillance data and when available, looking particularly for clusters of infections, infections due to unusual pathogens, or any occurrence of Healthcare-Associated infections that exceeds the usual baseline levels.
- I. The committee will review results of antimicrobial susceptibility/ resistance trend studies.
- J. The committee will review any pertinent findings from other hospital committees or departments.

K. The committee will review and approve all Germicidal products in use throughout the hospital and will review and approve the use of any new germicidal and other infection control related products prior to use of such products in the hospital.

L. In the event of an outbreak of infection, which is felt to be a danger to any patient or personnel, the infection control committee has the authority to institute appropriate control measures or studies.

M. The infection control committee shall report its findings and recommendations to the medical staff through the executive committee, to the chief executive officer, the chief nursing officer and any other concerned department.

N. Written minutes of the all committee meetings are maintained and are available for review by administration, medical staff and concerned department managers.

O. Pertinent findings of the infection control committee are made a part of the continuing education program and the orientation for new employees, in-service for continuing employees and continuing medical education for physicians.

P. Reviewing all dialysis related cultures and endotoxins reports that have to done on monthly basis.

## Infection Control Reporting:

The hospital reports infection control and prevention data to the requisite regulatory and government agencies as well as other entities as required. Required reporting includes but is not limited to the following:

- Outbreaks or unusual incidence of infectious or parasitic disease or infestation, whether or not listed in Title 17, California Code of Regulations (CCR), §2500
- Occurrence of unusual diseases, rare or a newly apparent or emerging disease or syndromes of uncertain etiology which a health- care provider has reason to believe could possibly be caused by a transmissible infectious agent or microbial toxin
- Transfer or discharge of patients with communicable diseases from healthcare facilities
- Emergency response employees (ERE) personnel should be included in the follow-up contact investigations of patients with infectious TB disease
- Reporting of potential bioterrorism agents
- Reportable diseases and conditions outlined in Title 17, California Code of Regulations (CCR), § 2500
- Mandatory annual report per CA State SB 739
- All CDC-NHSN required reports
- Monkeypox cases and all suspects are reported through CalREDIE virtual CMR

### Weekly

- **Patient level discharge information for each hospitalized person** who tests positive for COVID-19 reported to CDPH in compliance with AFL 21-25
- NHSN COVID-19 Vaccination for Healthcare Personnel

### Monthly data reporting elements may include:

- Device-Associated Reporting:
  - Central Line Associated Bloodstream Infection (CLABSI)
  - Catheter-Associated Urinary Tract Infections (CAUTI)
  - Ventilator-Associated Events (optional)
- Surgical Site Infections reporting within 30 Days of inpatient procedure:
  - Abdominal aortic aneurysm repair
  - Limb amputation
  - Appendix surgery

- Shunt for dialysis
- Bile duct, liver or pancreatic surgery
- Carotid endarterectomy
- Gallbladder surgery
- Colon surgery
- Cesarean section
- Gastric surgery
- Abdominal hysterectomy
- Kidney transplant
- Laminectomy
- Neck surgery
- Kidney surgery
- Ovarian surgery
- Prostate surgery
- Rectal surgery
- Small bowel surgery
- Spleen surgery
- Thoracic surgery
- Thyroid and/or parathyroid surgery
- Vaginal hysterectomy
- Exploratory Laparotomy
- Surgical Site Infections reporting within 90 Days of inpatient procedure
  - Cardiac surgery
  - Coronary artery bypass graft with both chest and donor site incisions
  - Coronary artery bypass graft with chest incision only
  - Craniotomy
  - Spinal fusion
  - Open reduction of fracture
  - Herniorrhaphy
  - Hip prosthesis
  - Knee prosthesis
  - Pacemaker surgery
  - Peripheral vascular bypass surgery
  - Ventricular shunt
- Multi-Drug Resistant Organisms (LabID-based):
  - Methicillin/Oxacillin- Resistant Staphylococcus Aureus (MRSA) bloodstream infections
  - Vancomycin-Resistant Enterococcus (VRE) Bloodstream infections
  - Carbapenem-resistant Enterobacteriaceae (CRE)
  - Clostridium Difficile Infections.
- Influenza Vaccination Summary
  - Influenza Vaccination Survey
- Monthly Summary Data

## Annual NHSN survey

- The hospital confers NHSN rights to California Department of Public Health (CDPH) for access of mandated data.



## COVID-19 Related reporting

- **Patient level discharge information for each hospitalized person** who tests positive for COVID-19 reported to CDPH in compliance with AFL 21-25
- **MIS-C (Multisystem Inflammatory Syndrome in Children) Reported to CDPH** Per Monice Wong request
- **EMS Survey for each inpatient admission, update, and discharge**
- **NHSN Weekly Summaries**
- **CalREDIE Reporting Inpatient and Outpatients COVID-19**
- **NHSN COVID-19 Vaccination for Healthcare Personnel**

## Infection Control Surveillance:

Active surveillance consists of both targeted surveillance of selected patient populations or procedures, as well as organization-wide surveillance designed to identify infectious risks or communicable disease issues in any department or care setting.

### A. Total House Surveillance:

All HAIs are monitored in the entire population of the facility. The main benefit of total (or whole) house surveillance is to assist in the comprehensive risk-assessment to identify real and potential infection risks that would guide the targeted surveillance.

While using total house surveillance, infection rates are calculated for specific HAIs in defined populations in the facility, such as CLABSIs per department or surgical site infections (SSIs) related to a specific operative procedure. An overall facility infection rate is not preferred and may only be calculated for self-comparison over time, it is not to be used for target performance improvement activities as crude overall rates are not sensitive enough to identify potential problems.

### B. Targeted Surveillance:

In addition to total house surveillance, targeted focused surveillance narrows the focus on particular care units (e.g., a nursery or ICU), infections related to medical devices (e.g., intravascular and urinary catheters), invasive procedures (e.g., surgery), and organisms of epidemiological significance.

As well, targeted surveillance usually focuses on high-risk, high-volume procedures and on those HAIs and adverse outcomes that are potentially preventable.

### C. Surveillance Timing:

Concurrent or prospective surveillance is initiated while the patient is under the care of the organization and includes active surveillance during the post-discharge period specially when patients present to emergency room with a possible surgical site infection.

Post-discharge surveillance methods have been used with varying degrees of success for different procedures include:

- Direct reporting from associated clinics, or physicians' offices following examination of patients' wounds during follow-up visits.
- Review of admission diagnosis of all emergency room patients as well as other hospital out-patient services.
- Review of all surgical site infections flagging ICD-10 codes as per the post-discharge surveillance.
- Communication with local hospitals and medical centers to refer and receive post-operative information.

A regular review of effective methods for achieving implementation of water management programs (WMPs) intended to reduce *Legionella* growth and transmission in buildings at increased risk.

## Data Collection:

Examples of data elements that are used for infection surveillance include the following:

1. Demographics: name, identification number, age, sex, location in facility, admission date, underlying diseases or diagnoses
2. Clinical information about infection: signs or symptoms specific to infection definition, with date(s) of onset (date of first sign or symptom)
3. Laboratory data: culture results related to site infection, sensitivity reports, colony counts, titers, and other laboratory findings as related to infection definitions and dates of tests
4. Risk factors: Current surveillance strategies make use of risk stratification when it is appropriate. Most risk data are recorded for all of the population, not just for the cases that develop the outcome being studied. Examples include the following:
  - Host-specific risk elements: age, diabetes, obesity, underlying disease, and other intrinsic risk factors.
  - Risk related to therapy and procedures: surgical procedures, IV lines, indwelling catheters, and ventilator use. This factor might include some accounting of days of device use.
  - Interventions: antibiotics, other treatment started, corrective procedures and devices removed.
  - Additional data: response to treatment, length of stay, other statistical data, and costs of care.

## Case Definition:

1. The hospital adheres to the latest Center for Disease Control and Prevention (CDC) National Healthcare and Safety Network (NHSN) Surveillance Definitions for all published specific types of infections.
2. The ICP tracks updated criteria and definitions as soon as they are released.

## Benchmarking:

1. The Standardized Infection Ratio (SIR) is the primary summary measure used by the National Healthcare Safety Network (NHSN) to track healthcare-associated infections (HAIs). SIR is a summary measure used to track hospital acquired infections (HAI) at the hospital level over time. The NHSN adjusts SIR adjusts for our facility and for our patient-level factors that contribute to HAI risk within the facility based on the data submitted to NHSN on a regular basis.
2. In HAI data analysis, the SIR compares the actual number of HAIs reported to what would be predicted/expected, given the standard population, adjusting for several risk factors that have been found to be significantly associated with differences in infection incidence for example, the duration of a surgical procedure and patient morbidity and wound classification of our patient population. For this reason, the NHSN is no longer issuing HAI rates or pooled means as they cannot reflect differences in risk between populations. Based on that, the hospital uses the NHSN SIR for benchmarking.
3. The Standardized Utilization Ratio (SUR) is the primary summary measure used by the National Healthcare Safety Network (NHSN) to compare device utilization at the national, state, or facility level by tracking central line, urinary catheter, and ventilator use.

## Infection Control Risk-Assessment:

The organization monitors high-volume, high-risk events in a specific population, events that have the potential to provide information that can be used to improve outcomes and infection prevention practices.

Examples of outcome events to be monitored include, but are not limited to:

1. Hospital acquired infections HAIs (e.g., bloodstream, urinary tract, pneumonia, surgical site, conjunctivitis, upper respiratory tract, or local intravenous site).
2. Infection or colonization with a specific organism (e.g., C. difficile, CRE, MRSA, VRE, ESBL, Respiratory Syncytial Virus [RSV] or Rotavirus).
3. Phlebitis related to peripheral intravascular therapy.
4. Pyrogenic reaction or pus, redness, or increased swelling at a dialysis vascular access site in hemodialysis patients.
5. Sharps injuries and communicable disease or blood/body fluid exposures in healthcare personnel.
6. QuantiFERON-TB Gold or Tuberculin skin test conversion rates in healthcare personnel.
7. Influenza immunization rates in personnel, medical staff, or patients.
8. Hepatitis B immunization rates in personnel.

Examples of process events include, but are not limited to:

A. Personnel compliance with infection prevention protocols, such as:

- Standard precautions
- Transmission-Based precautions
- Central line insertion, maintenance, and removal
- Urinary catheter insertion, care, and removal
- Safe injection and medication handling practices
- QuantiFERON-TB Gold or Tuberculin skin testing
- Hand hygiene
- Instrument processing
- Sterilization quality assurance testing
- Environmental cleaning and disinfection
- Communicable disease reporting
- Antimicrobial prescribing and administration
- Installing and maintaining barriers during construction and renovation project

B. Results of quality a quality assurance testing, such as:

- Monitoring of negative airflow in airborne infection isolation rooms
- Biological monitoring of sterilizers
- Testing of high-level disinfectants.
- 3. Admission of a patient or resident known to be infected or colonized with a multidrug resistant organisms (MDRO).

Examples of other events of significance to be monitored include, but are not limited to:

1. Occurrence of reportable diseases and conditions.
2. Communicable and potentially communicable diseases in personnel.
3. Organisms or syndromes indicative of a bioterrorism event.

## Risk Mitigation:

Practices to Decrease the Risk of Transmission.

- A. Monitoring compliance with and the effectiveness of the facility's infection prevention and control policies and procedures.
- B. Monitoring compliance with and the effectiveness of the facility's infection prevention and control policies and procedures.
- C. Adherence to appropriate infection prevention measures (e.g., hand hygiene, barrier precautions, aseptic techniques).
- D. Adherence to CDC guidelines and toolkits which include but are not limited to:
  - Disinfection and sterilization
  - Environmental infection control
  - Hand hygiene
  - Isolation precautions specially Category IA, Category IB and Category IC
  - Multidrug-resistant organisms (MDRO)
  - Catheter-associated urinary tract infections (CAUTI)
  - Intravascular catheter-related infection (BSI)
  - Surgical site infection (SSI)
  - Disease and Organism-specific guidelines
- E. Adherence to [Institute for Healthcare Improvement \(IHI\) device-specific bundles](#) including:
  - Prevent Central Line-Associated Bloodstream Infection Bundle
  - Prevent Obstetrical Adverse Events Bundle
  - Prevent Ventilator-Associated Pneumonia Bundle
- F. Measures for the early identification of patients who require isolation in accordance with CDC guidelines.
- G. Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices.
- H. Use and techniques for "isolation" precautions as per by the CDC.
- I. Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as a protocol to assure that antibiotic prophylaxis to prevent surgical site infection for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery.
- J. Addressing aseptic technique practices used in surgery and during invasive procedures performed outside the operating room which includes instrument/equipment sterilization.

## Program Evaluation:

Evaluation of the Infection Control Program includes, but is not limited to:

1. The organization formally evaluates and revises the Infection Control Risk-Assessment at least annually or more frequently based upon goals and program (or portions of the program) on ongoing basis and/or whenever risks significantly change.

2. The evaluation addresses emerging and re-emerging problems in the health care community that potentially affect the hospital.
3. The evaluation addresses changes in the scope and the results of the program.
4. The evaluation addresses the assessment of the success or failure of interventions for preventing and controlling infection.
5. The evaluation addresses responses to concerns raised by leadership and others within the organization.
6. The evaluation addresses the evolution of relevant infection prevention and control guidelines that are based on evidence or, in the absence of evidence, expert consensus
7. The Infection Control Manager facilitates the program evaluation and submits the evaluation to the Infection Control Committee for review and approval.
8. When aggregate data for any indicator is different from the expected benchmark, analysis of patterns, trends, or problems will be done to determine whether an opportunity to improve the quality of patient care or provide safer work environment for employees exists. This analysis will include, as applicable, review of the total process involving all departments and or services which has an input into the aspect of care being evaluated. Lines of communication are maintained with all services and departments involved. Information is also presented to the Infection Control Committee and the Performance Improvement Coordinating Council.
9. If an opportunity for improvement of the quality of patient care is determined, or a problem area is identified, a plan of corrective action will be initiated. This corrective action will identify the person, condition or activity that is expected to change, the person responsible for implementing action, the appropriate action in view of the effect on patient care, cause, scope, and severity and when change is expected to occur. Action is implemented through existing channels of the department, administration, or medical staff organization. Every activity will be documented, and conclusions, changes, and reevaluation will be reported.
10. Monitoring and evaluation does not end when actions are taken. Further evaluation of the important aspects of care or service should continue to evaluate the effectiveness of the actions taken, to assure that performance improvements are maintained and to further improve the quality of care and service given. If ongoing monitoring indicates that actions did not result in improving care, further evaluations and further actions should be taken. Ongoing and follow-up monitoring should ultimately show that meaningful improvement has taken place and is maintained.
11. Monitoring and evaluation data, conclusions, recommendations actions and follow-up will be communicated and disseminated through established channels to individuals and groups who are involved and affected by the information including:
  - The department(s) concerned.
  - The Infection Control Committee
  - The Performance Improvement Coordinating Council
  - The Medical Executive Committee
  - The Oversight Committee (Board)

## List of Attached Addendum:

1. Previous year annual report

## COVID-19 Surveillance and Protocol:

1. Allocation Of Critical Care Resources During A Public Health Emergency
2. Cardiopulmonary Arrest Protocol During COVID-19 Pandemic
3. Care Of the COVID-19 Positive Mother and Her Newborn
4. Convalescent Plasma as Exploratory Treatment for COVID-19
5. COVID-19 Screening of Healthcare Personnel
6. COVID-19 Trauma Activation Policy
7. CPG.73 Acute Management of Anaphylaxis
8. Discontinuation of Transmission-Based Precautions for Patients with COVID-19
9. Guidelines for Respiratory Therapy During COVID-19 Pandemic
10. Hygienist Role During COVID-19 Pandemic
11. Initiating Medication Therapy to Treat COVID-19 Infections
12. Medication Management Protocols During COVID-19 Pandemic
13. Operative Management Of COVID positive and COVID unknown patients during COVID-19 Pandemic
14. Pandemic Respirators
15. Reprocessing N95 Respirators During COVID-19 Pandemic
16. Standardized Procedure for Ordering COVID-19 Testing
17. Swabbing Asymptomatic Patients for COVID-19

## References:

Joint Commission Hospital Accreditation Standards

CMS Conditions of Participation for Acute Care Hospitals, §482.42

APIC Text, 2021

CDC COVID Updates <https://www.cdc.gov/socialmedia/syndication/405380/404364.html>

CDC guidelines as updated:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

All Facilities Letters (AFLs) ad published by California Department of Public health at

<https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL.aspx>

All revision dates: 10/9/2024, 11/17/2022, 6/9/2020, 3/21/2019, 5/1/2016, 5/1/2015, 5/1/2014, 10/1/2012, 10/1/2010, 4/1/2009, 5/1/2008, 6/1/2006, 3/1/2006, 8/1/2004, 6/1/2004, 1/1/2003, 1/1/1999, 1/1/1995

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	10/14/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	8/18/2025



**Origination:** 9/1/1996  
**Effective:** Upon Approval  
**Last Approved:** N/A  
**Last Revised:** 10/15/2025  
**Next Review:** 3 years after approval  
**Owner:** Magdy Asaad: Infection Prevention Manager  
**Policy Area:** Administrative - Environment of Care  
**References:**

## 106.028 Isolation Precautions

### POLICY:

Isolation precautions are used to care for the patient with a transmissible infectious agent. The purpose of isolation precautions is to interrupt the transmission of disease and prevent transmission of infection to staff and other patients.

The use of isolation precautions is a two-tiered process. Standard precautions are used for all patients and the category of isolation precautions is added according to the mode of transmission of the disease.

The following policy applies unless advised/directed otherwise by Infection Prevention and/or Infectious Diseases. All Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH) and hospital-based Ambulatory Care clinic staff shall follow the guidelines below which are designed to prevent transmission of organisms to patients, care providers and multi-use equipment. Multiple drug-resistant organisms (MDRO), defined by the Centers for Disease Control and Prevention (CDC) as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents, are a threat to patient and staff health and safety. It is essential to keep these organisms contained. Compliance with the following transmission-based precaution guidelines is required to prevent transmission of organisms and enhance patient and staff safety.

See References for an alphabetical list of infectious diseases and the correct category of isolation to be used.

### PROCEDURE:

#### Initiation of Isolation Precautions:

1. The nurse may initiate isolation precautions based on information obtained in the nursing assessment. The nurse then informs the physician of the need for an Isolation Precautions order.
2. Physician orders the appropriate isolation/precautions.
3. Infection Prevention department representative, Infectious Diseases physician or Infection Control Committee (ICC) Chairman may initiate isolation precautions.
4. Post the appropriate Isolation/Precautions sign outside the patient room.

#### Discontinue Isolation Precautions:

A physician's order is required.

#### Patient Transport



1. Notify receiving department of isolation status by entering the information in the electronic health record (EHR). Verbal communication must also occur with the receiving department prior to the patient's arrival.
2. Limit movement of the patient throughout the hospital or clinic.
3. When transport or movement is necessary, cover or contain the infected or colonized areas of the patient's body. Airborne and droplet isolation precautions require a surgical mask be placed on the patient.
4. Remove and dispose of contaminated Personal Protective Equipment (PPE) and perform hand hygiene prior to transporting patients on Contact Precautions.
5. Don clean PPE to handle the patient at the transport location.
6. Family members and visitors are required to conform to this policy and wear appropriate PPE as directed.

## Airborne Precautions

Diseases requiring airborne precautions are transmitted via airborne droplet nuclei or small particles in the respirable size range carrying infectious agents.

### Patient Placement

1. Place the patient in a designated negative air pressure room.

#### ***Santa Paula Hospital:***

Call the Maintenance Department at 652-3219 between 0800 and 1700h. After hours, page the Maintenance Department through Paging at 652-6075.

2. The doors of these rooms must remain closed at all times when the rooms are being used for airborne isolation.
3. In the event that additional negative air pressure rooms are required, contact the nursing supervisor or the Maintenance Department.

All staff entering airborne isolation rooms shall follow the proper procedure: enter the anteroom and allow the anteroom doors to completely close. Once the green light is illuminated, staff may enter the patient room. Once in the patient room, the green light will signal that the patient room doors have completely closed.

1. Place the patient in a private room, until airborne isolation room is available.
2. Patients in airborne isolation rooms must have doors closed.
3. RNs should respond to pressure alarms in a timely manner. If staff is unable to deactivate the alarm, call Facilities Maintenance at ext. 6683 for assistance.

**Surgery Patients:** Any patient who has been placed on Airborne Isolation for suspected or diagnosed illness and has surgery will be recovered in the OR suite and then be transported to the negative pressure room with the appropriate staff.

**Ambulatory Care Clinics:** Each clinic has a designated room for isolation precautions.

**Behavioral Health Clinics:** Clinic Administrator or designee will be made aware and client or participant will be instructed to wait outside until consultation is made with trained medical personnel, the Ventura County Behavioral Health Safety Officer or Infection Control. Client or participant may be referred for medical clearance.

## Respiratory Protection

1. Healthcare workers shall wear a N95 mask or Portable Air-Powered Personal Respiratory (PAPR) when in patient room.
2. Susceptible persons should not enter the room of patients known or suspected to have rubeola (measles) or varicella (chickenpox) if other immune caregivers are available.
3. Patients with respiratory symptoms (e.g., cough, fever, sore throat, congestion, or known/suspected COVID-19 or influenza) should be advised to wear a well-fitting mask (as tolerated) while in healthcare facilities.
4. Visitors may be offered respiratory protection (i.e., N95) and should be instructed on the use of the respirator before entering an Airborne Illness Isolation (AII) room.

## Droplet Precautions

Diseases requiring droplet precautions are transmitted a short distance, approximately three (3) feet, from the respiratory tract of infectious individuals to susceptible mucosal surfaces of the recipient.

### Patient Placement

- Patients on droplet precautions should be placed in a private room.
- Cohorting only after discussion with Infection Prevention.

### Respiratory Protection

- ~~Wear a surgical mask.~~
- Wear a surgical mask.
- Patients with respiratory symptoms (e.g., cough, fever, sore throat, congestion, or known/suspected COVID-19 or influenza) should be advised to wear a well-fitting mask (as tolerated) while in healthcare facilities.

## Contact Precautions

Diseases requiring contact precautions are transmitted by infectious agents via direct and indirect contact with the patient or their environment.

Isolation supplies (PPE's, masks, etc.) are now kept in hallways closets adjacent to patient rooms.

### Gloves and gown

1. Gloves and gown must be worn upon entering the room.
2. Gloves and gown must be removed immediately upon exiting the room.
3. Perform hand hygiene after removal of gloves and gown.

### Hand Hygiene and the Patient with Clostridium Difficile Infection:

1. Wash hands with soap and water.
2. Do not use alcohol gel for hand hygiene.
3. Use the Contact Precautions sign with the brown color for patients with Clostridium difficile infection.

### Patient Care Equipment

1. Do not share patient care equipment.
2. Return to the designated department for cleaning and disinfection.

### Room Cleaning After Discharge

Proper cleaning and disinfection of the patient's room after discharge is important to prevent the spread of infection from a contaminated environment. Inspection of the mattress for intactness between patients is also recommended.

1. Isolation sign remains outside of the room after discharge.
2. The room is thoroughly cleaned, and then disinfected using the hospital-approved disinfectant (e.g. bleach-based disinfectant for *Clostridium difficile*).
3. The housekeeper reverses the isolation sign in its holder so that nursing staff know the room has been cleaned and disinfected and is ready for the next patient.

## Multi-Drug Resistant Organism (MDRO) Isolation Quick Sheet

	Current Infection WITH Active Drainage/ Excretions	Current Infection WITHOUT Active Drainage/ Excretions	Current Colonization	History of
Methicillin-Resistant <i>Staphylococcus Aureus</i> (MRSA)	✓			
<i>Candida Auris</i> (CAURIS)	✓	✓	✓	✓ up to 3 years
Carbapenem-Resistant <i>Enterobacteriaceae</i> (CRE), Carbapenem-Resistant <i>Pseudomonas aeruginosa</i> (CRPA)	✓	✓	✓	✓ up to 6 months
Vancomycin-Resistant <i>Enterococcus</i> (VRE)	✓			
Resistant <i>pseudomonas</i> , resistant <i>acinetobacter</i> spp, or resistant <i>stenotrophomonas</i> spp	✓			
Extended-Spectrum Beta-Lactamase (ESBL)				

## Candida Auris Screening and Isolation

Screen patients coming from high acuity post-acute care facilities including long-term acute care hospitals [LTACHs] and ventilator-capable skilled nursing facilities [vSNFs] if they are admitted to ICU unit.

Empiric contact isolation should be applied on admission of those patients pending screening results.

Consider screening such patients if they have high risk and admitted to other location.

Patients with risk factors for acquiring *C. auris*, including:

- mechanical ventilation
- indwelling medical devices, including central lines, feeding tubes, urinary catheters, etc.
- receipt of complex or high acuity medical care
- frequent or long healthcare stays, especially at high-risk facilities
- colonization or infection with other multidrug-resistant organisms

For Santa Paula Hospital, screen patients coming from high acuity post-acute care facilities including long-term acute care hospitals [LTACHs] and ventilator-capable skilled nursing facilities [vSNFs]) if they have one of the above risk factors for acquiring *C. auris*.

**Extended-Spectrum Beta-Lactamase (ESBL):** No Isolation needed

**Clostridioides difficile:** Contact precautions are required until 48 hours after resolution of all symptoms (fever, abdominal pain, and diarrhea, formed stool)

Diarrhea for *Clostridioides difficile* testing is defined as 3 or more watery stools in a 24 hour period). Only stool corresponding to 6 or 7 on the Bristol Stool Chart will be accepted by the laboratory for *C. difficile* testing.

**Other MDRO's:** As identified by Infection Control Committee.

## Personal protective Equipment (PPE) utilization for care of all patients under Standard Precautions:

- Wear gloves when anticipating contact with blood or other potentially infectious materials, mucous membranes, or nonintact skin, or potentially contaminated intact skin.
- Change gloves and sanitize hands during patient care if the hands will move from a contaminated body-site (e.g., perineal area, wound) to a clean body-site (e.g., face).
- Wear a gown to protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities when contact with blood, body fluids, secretions, or excretions is anticipated
- Use PPE to protect the mucous membranes of the eyes, nose and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions and excretions. Select masks, goggles, face shields, and combinations of each according to the need anticipated by the task performed. If a patient is coughing, use a mask.
- During aerosol-generating procedures (e.g., bronchoscopy, suctioning of the respiratory tract [if not using in-line suction catheters], endotracheal intubation) in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended (e.g., *M. tuberculosis*, SARS or hemorrhagic fever viruses), wear one of the following: a face shield that fully covers the front and sides of the face, a mask with attached shield, or a mask and goggles (in addition to gloves and gown)

## Contact Precautions

MRSA – methicillin resistant staph aureus

VRE – Vancomycin Resistant *Enterococcus faecium*, *Enterococcus faecalis*

CRE – Carbapenamen Resistant *Escherichia coli* and/or *Klebsiella pneumoniae*

*Acinetobacter baumannii* - multidrug resistant

*Stenotrophomonas maltophilia* – multidrug resistant

*Clostridium difficile* – **Enteric Contact Precautions**

If there is any evidence of multidrug resistance with any other organisms, please contact the Infectious Disease physician for guidance. In addition, continue isolation practices for other communicable diseases according to policy.

## References:

- Centers for Disease Control and Prevention - [CDC Isolation Transmission-Based Precautions Guidelines](#)
- Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>.
- Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, Healthcare Infection Control Practices Advisory Committee (HICPAC) Management of Multidrug-Resistant Organisms in Healthcare Settings 2006; <https://www.cdc.gov/infectioncontrol/guidelines/mdro/>Last update: February 15, 2017.

All revision dates:

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## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	10/15/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	10/15/2025



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**Next Review:** 3 years after approval  
**Owner:** Magdy Asaad: Infection Prevention Manager  
**Policy Area:** Administrative - Environment of Care  
**References:**

## 106.030 Bloodborne Pathogen Exposure Control Plan

### POLICY:

Ventura County Medical Center/Santa Paula Hospital and Ambulatory Care Administration recognizes bloodborne pathogen exposure (BPE) as an important health risk for many employees. The Bloodborne Pathogen Exposure Control Plan (BPECP) has been put in place to protect the health of employees.

#### Applicability:

Agency/Department employee job classifications are categorized by exposure determination into three categories listed below. Category 1 and 2 job classifications are required to follow all aspects of this plan. Category 3 job classifications need to be aware of the BPECP. Managers/Supervisors must coordinate with Risk Management on any changes in exposure levels or job tasks.

- *Category 1* – those with high potential for exposure to blood or Other Potentially Infectious Materials (OPIM), i.e., those doing regularly assigned duties (e.g. first aid, cardiopulmonary resuscitation (CPR), collecting blood specimens, providing direct patient care, clean-up of bloody spills, etc.) that are exposed to blood, body fluids, or tissues.
- *Category 2* – those with moderate potential for exposure to blood or OPIM, i.e. those whose normal work tasks do not involve routine exposure to blood, body fluids, or tissues, but exposure may occur as a condition of employment based on specific job tasks with BPE risk potential (collecting or handling bloody evidence, controlling an assaultive client, assisting someone injured, clean-up of a bloody spill, etc.).
- *Category 3* – those with very low potential for exposure to blood or OPIM, i.e., those whose normal work tasks do not involve routine exposure to blood, body fluids, or tissues, and exposure is not required as a condition of employment.

### Responsibilities:

#### Program Administrator

The Program Administrator has authority and overall responsibility for the design, implementation, interpretation, and revision of the BPECP. Duties include:

- Direct and plan an effective BPECP program for the Ventura County Health Care Agency (VCHCA).
- Coordinate BPE control needs by providing appropriate professional and technical resources.
- Approve all aspects of this BPECP and any changes hereto.

- d. Recommend engineering and administrative controls as needed and determine which job classifications and job tasks are to be included in this BPECP.
- e. Ensure the Licensed Health Care Professional (LHCP) has a copy of this BPECP, and after an exposure incident provide LHCP: (1) a description of the exposed employee's duties allied with the incident; (2) documentation of the routes of exposure and circumstances under which exposure occurred; (3) the source person's blood testing results, if known, or a contact to request same; and (4) all employee health records relevant to the appropriate treatment of the employee including vaccination status that are the employer's responsibility to maintain.
- f. Obtain and provide the employee a copy of the LHCP's written opinion within 15 days of the completion of the exposure evaluation.
- g. Arrange for and/or conduct initial training within 10 days of hire/transfer. Annual training is conducted via the electronic education system per Administrative policy 101.025.
- h. Evaluate the BPECP's overall quality and effectiveness by reviewing policies yearly and making recommendations for revisions if necessary.
- i. Maintain required records.

## Health Care Management

LHCPs authorized and/or administered by the Program Administrator provide services for health maintenance, medical surveillance, and exposure care. The Program Administrator shall use resources from the *County of Ventura Authorized Medical Panel* of providers and Workers' Compensation consultants along with VCHCA/Employee Health Services (EHS) to:

- a. Provide Hepatitis B vaccination for employees in identified risk job classifications.
- b. Validate agency/department verification of occupational occurrences and exposure incidents and provide initial and follow-up exposure care (after initial exposure evaluation and medical care, follow-up care will be managed and completed by EHS unless employee refuses per item c of this section) based on established protocols per the U.S. Department of Health and Human Services Centers of Disease Control and Prevention.
- c. Advise employees following an exposure incident that she/he/they may refuse post-exposure evaluation and follow-up from County's chosen healthcare professional. If consent is refused, notify Risk Management and make immediately available to the exposed employee(s) a confidential medical evaluation and follow-up from a LHCP other than from the County's Employee Health Service or one connected with their Agency/Department for post-exposure follow-up care.
- d. Provide a written opinion 15 days after an exposure incident to the Program Administrator to include: (1) for hepatitis B vaccination the opinion shall be limited to whether hepatitis B vaccination is indicated, and if the employee has received such vaccination, and (2) for post-exposure evaluation and follow-up, the opinion shall be limited to whether the employee has been told about any medical conditions resulting from exposure to blood or OPIM that requires further evaluation or treatment. All other findings or diagnoses shall remain confidential and shall not be included in the written opinion.
- e. Maintain medical evaluations, exposure data, and related BPECP documentation in medical records per CCR Title 8 §5193 (h)(1) ensuring appropriate notification and documentation of vaccination, declination of vaccination, exposure medical evaluation (including test results), limitations and counseling.
- f. Keep a log of verified occupational occurrences sending same to HCA/EHS.
- g. Maintain the Sharps Injury Log.



- h. Coordinate with the Program Administrator for hazard evaluations or training deficiencies noted.

## **Management**

Management is responsible for ensuring the BPECP has an approved budget to meet the needs of the agency/department/clinic. Duties of management include:

- a. Identify at risk job classifications and tasks;
- b. Coordinate with LHCPs for hepatitis B vaccination, medical evaluations, and exposure care;
- c. Implement BPECP and submit annually to the Program Administrator for review any changes in exposure risk potential or job tasks or specific methods of compliance.
- d. Assess the BPECP yearly for overall effectiveness by evaluating Agency/Department program against all aspects of this BPECP.
- e. Follow-up and take corrective action after all occupational occurrences or exposure incidents especially sharps incidents resolving deficiencies promptly.

## **Managers and Supervisors**

Managers/supervisors shall ensure that this BPECP is implemented in their areas. In addition to being knowledgeable about the BPECP for their own protection, supervisors must ensure that the BPECP is understood and followed by those in their charge. Duties include:

- a. Ensuring work activities within area of responsibility have been surveyed for BPE exposure potential and identified by job classification (hazard evaluation), and exposure history.
- b. Continually monitoring job tasks to identify new or unrecognized BPE hazards.
- c. Being knowledgeable about BPE and how this issue impacts employees (i.e., know exposure incident trends and injury rates).
- d. Using resources and programs available within the County and through the Program Administrator to address bloodborne pathogen concerns or needs.
- e. Ensuring they and those they direct follow this BPECP, receive and document BPECP training and vaccination prior (i.e., within 10 days of hire or transfer) to carrying out work tasks with BPE potential.
- f. Reviewing and verifying all reported occupational occurrences and exposure incidents along with taking action to prevent reoccurrence.
- g. Processing, based on verification, either a Bloodborne Pathogen Employer's Report of Injury or an Occupational Occurrence Incident Form and a Sharps Injury Log per applicable incident.
- h. Ensuring prompt medical evaluation is provided for employees involved in an exposure incident, and that each involved employee contacts EHS at 654-3813 the next duty day after an exposure incident for further follow-up.
- i. Providing budgetary resources to ensure information/training and control measures are available to those they direct.
- j. Conduct monthly inspections of engineering and work practice controls to ensure use as intended and re-evaluate annually for effectiveness, efficiency and cost.
- k. Completing a Manager/Supervisor evaluation semi-annually or as otherwise required.



## Employees

Employees are responsible for using the control measures, wearing PPE, and following the *Methods of Compliance* (IDCP §2.5 below) when and where required and in the manner in which they were trained. Duties include:

- a. Understanding and participating fully in the BPECP.
- b. Using engineering/administrative controls established and reporting problems to managers/supervisors.
- c. Using all PPE as outlined in established procedures.
- d. Participating in initial (within 10 days of hire or transfer) and annual BPECP training.
- e. Reporting all occupational occurrences and exposure incidents immediately to their managers/supervisors.
- f. Contact EHS at 654-3813 the following duty day after an exposure incident for further follow-up.
- g. Evaluating their BPECP participation, use and effectiveness of control measures semi-annually via checklist or as required by the Program Administrator.

## Methods of Compliance

The following controls and work practices will be adhered to when BPE potential has been determined based on job classification, hazard evaluation (exposure determination), and exposure history. Other engineering or administrative controls and personal protective equipment (PPE) will be implemented as needed per Program Administrator review and approval.

**Standard Precautions:** please see **Administrative policy 106.018 Infection Control Standard Precautions.**

## Engineering and Work Practice Controls -- General Requirements

Engineering and work practice controls shall be used to eliminate or minimize BPE. Examine these controls for use, maintenance, and/or replacement monthly to ensure their effectiveness and re-evaluated annually for effectiveness and efficiency. All procedures involving blood or OPIM must be done in a manner that minimizes the splashing, spraying, spattering, and generation of droplets of these substances.

## Engineering and Work Practice Controls -- Specific Requirements

- a. *Rules for Needleless Systems, Needle Devices, and non-Needle Sharps.*

Needleless systems shall be used for: (a) withdrawal of body fluids after initial venous or arterial access is established, (b) administration of medications or fluids, and (c) any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices.

  1. Needle devices with engineered sharps injury protection shall be used if needleless systems are not used for: (a) withdrawal of body fluids, (b) accessing a vein or artery, (c) administration of medications or fluids, and (d) any other procedure involving BPE potential for which a needle device with engineered sharps injury protection is available.
  2. Non-Needle Sharps shall include engineered sharps injury protection.
  3. The following exceptions apply to the engineering controls required by §5193:
    - a. If the control is unavailable in the marketplace;
    - b. If a LHCP involved in a patient's care reasonably determines, which is to be documented per

§5193(c)(1)(B)6, that use of the control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient;

- c. If the agency/department/clinic can demonstrate by objective criteria that the control is not more effective in preventing BPE incidents than that used by the agency/department/clinic; or
- d. If the agency/department/clinic can demonstrate that reasonably specific and reliable information is unavailable on the safety performance of the control for the subject procedure, and that the agency/department/clinic is actively determining by objective criteria whether use of the control will reduce the risk of BPE incidents occurring in the subject workplace.

b. *Prohibited Practices*

- 1. Shearing or breaking of contaminated needles and other contaminated sharps.
- 2. Bending, recapping or removing contaminated sharps from protective devices (**exception:** contaminated sharps may be bent, recapped, or removed from devices if done using a mechanical device or a one-handed technique, and the agency/department/clinic can show that no alternative is feasible or that such action is required by a specific medical or dental procedure);
- 3. Storing or processing sharps contaminated with blood or OPIM in a way that requires reaching by hand into the containers where these sharps have been placed.
- 4. Reusing disposable sharps.
- 5. Directly using hands to pick up sharp objects that may be contaminated.
- 6. Accessing the contents of sharps containers unless properly reprocessed or decontaminated.
- 7. Opening, emptying, or cleaning manually sharps containers or in any other manner that would cause expose to the risk of sharps injury.
- 8. Pipetting/suctioning by mouth of blood or OPIM.
- 9. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in work areas where there is a reasonable likelihood of BPE.
- 10. Keeping food and drink in refrigerators, freezers, shelves, and cabinets or on countertops or bench tops where blood or OPIM are present.

c. *Handling Contaminated Sharps, Broken Glassware or Sharp Objects.*

- 1. All procedures involving sharps in connection with patient care shall:
  - a. be done using effective patient-handling techniques and other methods designed to minimize the risk of a sharps injury;
  - b. put contaminated sharps in containers per §5193(d)(3)(D) as applicable immediately or as soon as possible after use; and
  - c. use containers for contaminated sharps that are: (1) easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries); (2) maintained upright throughout use, where feasible; and (c) replaced when 2/3 full.
- 2. Pickup broken glassware potentially contaminated with blood or OPIM using tongs, a broom and dustpan, or a HEPA vacuum (not the hands) and disposed of into a sharps container if regulated waste or bagged and containerized to prevent any further contact or injury.
- 3. Other sharp objects potentially contaminated with blood or OPIM if to be repaired are to be cleaned

and disinfected first per §2.5.3.i. Don't pick up the object directly with the hands. Use tongs, shovel, or other extended tool to lift and transport via a cart in another container. Clean and disinfect all equipment used per §2.5.3.i. Other broken or unusable sharp objects potentially contaminated with blood or OPIM to be discarded are to be put in a sharps container if regulated waste, or bagged and containerized as regulated waste, or bagged and containerized to prevent any further direct contact or injury.

d. *Sharps Containers for Contaminated Sharps*

1. All containers for contaminated sharps shall be: (a) rigid, (b) puncture resistant, (c) leak-proof on the sides and bottom, (d) portable if necessary to ensure easy access by the user per §5193(d), and (e) labeled per §5193(g).
2. If discarded sharps are not to be reused, the container shall be closeable and sealable so that when sealed, the container is leak resistant and can be reopened only with great difficulty.

e. *Cardiopulmonary Resuscitation Precautions.* To minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, pocket masks, or other such device shall be used. Such devices will be supplied to individuals for their use and stored in designated kits or cabinet locations.

f. *Regulated Waste*

1. Handling, storage, treatment, and disposal of regulated waste shall be per Health and Safety Code Chap. 6.1, §117600 through §118360, other applicable regulations, and the *Ventura County Medical Waste Management: A Guide to Compliance for Medical Waste Generators*.
2. When any container of contaminated sharps is moved from the area for disposal, it shall be: (a) closed prior to removal to prevent spillage or protrusion of contents during handling, storage, or transport; and (b) if leakage is possible, put in a secondary container that is: closeable, made to prevent leakage during handling, storage, or transport; and labeled per §5193(g).
3. Regulated waste not consisting of sharps shall be disposed of in containers that are: (a) closeable and made to prevent leakage, spillage, or protrusion of contents during handling, storage, or transport; (b) labeled and color-coded per §5193(g); and (c) closed prior to removal.
4. If outside contamination of a regulated waste container occurs, put it in a second container that is: (a) closeable and made to prevent leakage, spillage, or content protrusion during handling, storage, or transport; (b) labeled and color-coded per §5193(g), and (c) closed prior to removal.

g. *Handling Specimens of Blood or OPIM.* Specimens of blood or OPIM shall be put in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

1. The container shall be labeled or color-coded per §5193(g), and closed prior to being stored, transported, or shipped. When a facility uses Standard Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens and they remain within the facility. Labeling or color-coding per §5193(g) is required when such specimens/ containers leave the facility.
2. If the specimen could puncture the primary container, it shall be put within a secondary container that is puncture-resistant in addition to the above characteristics.

h. *Servicing or Shipping Contaminated Equipment.* Equipment that may become contaminated with blood or OPIM shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the Agency/Department can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. In such cases:

1. A readily observable label per §5193(g) shall be attached to the equipment stating which portions remain contaminated; and
2. Information concerning all remaining contamination shall be conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

i. *Cleaning and Decontamination of the Worksite.*

1. General Requirements.

- a. Managers/supervisors shall ensure that the worksite is maintained in a clean and sanitary condition via, at minimum, a written schedule for cleaning and decontamination.
- b. The cleaning or decontamination method used shall be effective and appropriate for the location and type of surface or equipment to be treated, the type of contamination present, and the tasks or procedures performed in the area.
- c. All equipment, environmental, and work surfaces shall be cleaned and decontaminated after contact with blood or OPIM no later than at the end of the shift. Cleaning and decontamination of equipment and work surfaces is required more often as specified below.

2. Specific Requirements.

Contaminated work surfaces and equipment (brooms, mops, clean-up tools, etc.) shall be cleaned and decontaminated immediately or as soon as possible when: (i) item becomes overtly contaminated; (ii) there is a blood or OPIM spill; (iii) procedures are done; and (iv) at the end of the work shift if the item has become contaminated since the last cleaning.

### **Spill Response Procedures**

- Stop all operations.
- Alert personnel via the telephone/overhead paging system.
- Remove all potential sources of ignition and chemical interaction (incompatibles).
- Apprise the Safety Officer or designee of the situation.
- Immediately enact spill response procedures under the direction of the Safety Officer or designee.
- Consult *3E FAX-ON-DEMAND* to obtain SDS
- Block all possible routes of spreading:
  - dike floor drains, sanitary sewer manholes, storm sewer drains and manholes
  - surround spill area with absorbent material

The following spill kits are available throughout the facilities:

- Mercury Spill Kit
- Chemo-therapy spill kit
- General Spill kit
- Large Spill kit
- Cytotoxic spill kit
- Acid Spill Kit

- Base Spill Kit
- Solvent Adsorb
- Absorbent pad
- Large kit in 10 gallon trash can

In the event of a spill, leakage or release of any hazardous material, proper DISPOSAL of the hazardous substance(s) is an integral part of the waste management system. By following the outline below, proper disposal can be assured:

#### **DISPOSAL SEQUENCE**

- A. Carry out general or specific spill procedure.
- B. Notify the Facilities Maintenance Supervisor who will arrange for the appropriate packaging and disposal of the hazardous material spill waste with Ventura County Risk Management.
- C. State law required EPA shipping number, an approved hauler and a hauler's permit number.
- D. Non-spilled hazardous waste will be disposed of by placing compatible materials in a clearly marked hazardous materials drum.
  - a. **DO NOT MIX** recovered material with any other materials.
  - b. All receptacles (bins, pails, cans, and the like) intended for reuse that have a reasonable likelihood for becoming contaminated with blood or OPIM shall be inspected weekly and cleaned and decontaminated immediately or as soon as possible upon visible contamination. Clean as for "Small spills" noted above.
  - c. Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible after use, when they become overtly contaminated, at the end of a specific procedure, or at the end of the work shift.

#### *j. Hygiene.*

1. Agencies/departments/clinics shall provide handwashing facilities readily accessible to employees.
2. When the provision of handwashing facilities is not feasible, the agencies/departments/clinics shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.
3. Managers/supervisors shall ensure that employees wash their hands immediately or as soon as possible after removal of gloves or other PPE.
4. Managers/supervisors shall ensure that employees wash hands and any other skin area with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or OPIM.

#### *k. Laundry*

1. Contaminated laundry shall be handled as little as possible with a minimum of agitation.
  - a. Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

- b. Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded per §5193(g). When a facility uses Standard Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring Standard Precautions.
  - c. through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers, which prevent soak-through and/or leakage of fluids to the exterior.
- 2. The manager/supervisor shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate PPE.
- 3. When contaminated laundry is sent off-site to a second facility that does not use Standard Precautions in the handling of all laundry, the facility generating the subject laundry must place such laundry in bags or containers that are labeled or color-coded per §5193(g).

### **Personal Protective Equipment (PPE)**

- a. *Provision.* Where occupational exposure remains after applying engineering and administrative controls, the agency/department/clinic shall provide, at no cost to the employee, appropriate PPE (gloves, gowns, face shields, eye protection, mouthpieces, resuscitation bags, pocket masks, etc.). PPE is "appropriate" only if it does not permit blood or OPIM to pass through to or reach the worker's clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the time that the PPE is used. For fire fighters, these requirements are in addition to and consistent with those in CCR Title 8 §3401-3411.
- b. *Use.* The manager/supervisor shall ensure that the employee uses appropriate PPE unless the manager/supervisor shows that the employee temporarily and briefly declined to use PPE when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the issue shall be investigated and documented to determine if changes can be made to prevent such occurrences in the future. The manager/supervisor shall encourage employees to report all such instances without fear of reprisal per CCR Title 8 §3203.
- c. *Accessibility.* The agency/department/clinic shall ensure that appropriate PPE in the appropriate sizes is readily accessible at the worksite or is issued to employees.
- d. *Maintenance.* The agency/department shall clean, launder, and dispose of PPE required per §5193 at no cost to the employee. The Agency/Department shall also repair or replace PPE as needed to maintain its effectiveness at no cost to the employee.
- e. *Removal.* Employees will remove PPE as follows:
  - 1. If a garment(s) is penetrated by blood OPIM, it shall be removed in a manner to not contaminate self or others as trained as soon as safe to do so.
  - 2. All PPE shall be removed in a manner to not contaminate self or others as trained prior to leaving the work area.
  - 3. When PPE is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.
- f. *Gloves.* Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in §5193(d); and when handling or touching contaminated items or



surfaces. These requirements are in addition to those in CCR Title 8 §3384.

1. Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
2. Disposable (single use) gloves shall not be washed or decontaminated for re-use.
3. Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, torn, punctured, or show other signs of deterioration or when their ability to function as a barrier is compromised.
4. Unless the Agency/Department can demonstrate by objective criteria to the contrary, gloving is required for all phlebotomies.
5. Hypoallergenic gloves, glove liners, powder-less gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

*g. Masks, Eye Protection, Face Shields, and Respirators.*

1. Masks in combination with eye protection devices shall be worn whenever splashes, spray, spatter, or droplets of blood/OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated. These rules are in addition to those in CCR Title 8 §3382.
2. Disposable (single use) protection shall be replaced as soon as practical when contaminated or as soon as possible if they are scratched over 25% of the visual field, cracked, punctured, or when their ability to function as a barrier is compromised.
3. Disposable (single use) protection shall not be washed or decontaminated for re-use.
4. Re-usable protection may be decontaminated for re-use if the integrity of it is not compromised. However, they must be discarded if they are scratched over 25% of the visual field, cracked, torn, punctured, or when their ability to function as a barrier is compromised.
5. Where respiratory protection is used, the provisions of the County's Respiratory Protection Program and CCR Title 8 §5144 and 5147 shall apply. (Note: surgical masks are not respirators.)

*h. Gowns, Aprons, and Other Protective Body Clothing.*

1. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, or similar outer garments shall be worn in occupational exposure situations (e.g., tasks likely to generate bloody fluid splashes). The type and characteristics will depend upon the degree of exposure anticipated. These requirements are in addition to those in CCR Title 8 §3383.
2. Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (autopsies, orthopedic surgery, evidence collection, etc.). These requirements are in addition to those in CCR Title 8 §3383.
3. Protective clothing is to be changed when soiled or before leaving the work area.
4. If disposable, protective clothing will be discarded as regulated waste (see §2.5.3.f) or, if possible, as regular trash.
5. Non-disposable protective clothing will be laundered as contaminated/non-contaminated through the Agency/Department. At no time will protective clothing be laundered at home or outside of internal County/County contracted facilities.

## **Hepatitis B Vaccination**

Employees with potential BPE based on identified job classifications, hazard evaluation and exposure history will be offered the hepatitis B vaccine after receiving training per CCT Title 8 §5193 and within 10 working days of hire or transfer unless the employee: (1) has completed the hepatitis B vaccine series, (2) is positive for hepatitis B carriage or immunity, or (3) has a medical contraindication.

Employees must have received training concerning bloodborne pathogens prior to receiving the vaccination. Employees must acknowledge, in writing, if declining the vaccine at that time with the understanding that it can be given at a later date if requested. Employees who have not received the vaccination and have an occupational occurrence incident will be offered the hepatitis B vaccine at the time of incident reporting (Note: the hepatitis B vaccine will be given as soon as possible, preferably within 24 hours), and must acknowledge in writing if they decline understanding the vaccination can be given by request at a later date.

*Routine Booster:* Booster doses of hepatitis B are not necessary. If the U.S. Public Health Service recommends a routine booster of hepatitis B vaccine at a future date, such booster(s) shall be made available in accordance with CCR Title 8 §5193(f)(1)(B).

**POST-EXPOSURE EVALUATION AND FOLLOW-UP** - See policy [EHS.03 Bloodborne Pathogen Post-Exposure Evaluation and Management](#).

All revision dates:

11/17/2022, 5/1/2016, 5/1/2014, 7/1/2009, 5/1/2006

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	10/14/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	10/14/2025





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Effective: Upon Approval  
Last Approved: N/A  
Last Revised: 9/2/2025  
Next Review: 3 years after approval  
Owner: Magdy Asaad: Infection Prevention Manager  
Policy Area: Administrative - Environment of Care  
References:

## 106.037 Methicillin Resistant Staphylococcus Aureus (MRSA) Admission Screening and Decolonization

### Policy:

To describe the actions that will be taken to comply with the requirements for Methicillin Resistant Staphylococcus Aureus (MRSA) admission screening mandated by California Senate Bill 1058. [To outline the practice for targeted MRSA decolonization for high risk patients.](#)

### Procedure:

#### General MRSA Screening Procedures

~~On admission, within 24 hours, a culture of the anterior nares will be performed on qualifying patients according to Senate Bill 1058.~~

- A. The electronic health record may automatically order MRSA screening in accordance with Senate Bill 1058, otherwise, the nurse performing the admission assessment on the nursing unit will enter the order and collect the specimen. No separate physician order is necessary.
- B. Minimum requirements identifying patient risk groups that necessitates MRSA Admission Screen:
  1. Nasal Swabs for the following sources of patients:
    - a. Patients readmitted within 30 days of discharge from any acute care hospital.
    - b. Patients received from Skilled Nursing Facility or Rehab facility
    - c. Patients admitted to Intensive Care Units.
    - d. Patients scheduled for inpatient surgery and have documented medical condition that would increase susceptibility to infection.
    - e. Patient receives inpatient dialysis treatment.
  2. ~~Note:~~ Patients undergoing hip and knee arthroplasty have MRSA screening done in Orthopedic Clinic at the preoperative visit.
  3. Attending physician shall discuss the positive results with patient or patient's representative as soon as practically possible.

4. Patient shall be given oral and written information as an educational tool at the time results are discussed or prior to discharge.
5. Contact precautions is only necessary when the infected site of the MRSA cannot be contained, such as an open draining wound, abscess at IV site, or multiple secondary sites.
6. Nasal carriage on its own is not sufficient to require contact precautions.
7. Patients with a negative MRSA swab whom the licensed provider (LP) feels are at increased risk of invasive MRSA should be retested for MRSA prior to discharge.

## **MRSA Screening and Management for High Risk Surgeries**

### **A. Applicable Surgeries**

1. Neurosurgery
2. Orthopedic Surgery (including joint replacements)
3. Cardiothoracic Surgery (including heart and lung surgeries)

### **B. Screening protocol**

1. All patients scheduled for high-risk surgeries will be screened for MRSA colonization within 48 hours prior to surgery. If patient is not screened prior, patient will be screened in pre-op and treated empirically pending results.
2. Screening will be done using nasal swabs for MRSA, which will be processed in the microbiology lab.
3. Additional screening may be performed at the discretion of the surgeon or based on patient risk factors (e.g., recent hospitalization, known MRSA history, or immunocompromised state).

### **C. Decolonization Protocol**

1. Mupirocin Ointment (5-day course intra-nasal)
  - a. All MRSA-positive patients undergoing high-risk surgery will undergo a decolonization regimen with mupirocin nasal ointment applied to both nares twice daily for 5 days prior to surgery. If <5 days before surgery, patient should begin treatment and continue post-operatively.
  - b. Patients will also use chlorhexidine gluconate (CHG) bathing at least once daily for 5 days prior to surgery.
2. Povidone-iodine and Mupirocin
  - a. In cases where Mupirocin decolonization 5-day course is not complete, a single-dose povidone iodine treatment will be administered within ten minutes to one hour prior to surgery, alongside a preoperative CHG bath. If surgery is delayed 12 or more hours after the povidone iodine has been applied, re-apply again at least one hour prior to surgery. After surgery, patient should resume Mupirocin until 5-day course is complete.
  - b. In cases where Mupirocin has not been started on day of surgery, a single-dose povidone iodine treatment will be administered within ten minutes to one hour prior to surgery, alongside a preoperative CHG bath. If surgery is delayed 12 or more hours after the povidone iodine has been applied, re-apply again at least one hour prior to surgery. Patient will also be started on 5-day Mupirocin course.

#### D. Postoperative Considerations

1. MRSA positive patients who undergo surgery should continue the mupirocin and CHG regimen up to 5 days postoperatively, depending on the surgeon's discretion and individual patient factors.

### MRSA Screening and Management for Adult ICU patients

- A. All patients admitted to the ICU will undergo MRSA screening upon admission, including nasal swabs for MRSA.
- B. Colonized patients will not be isolated.
- C. All Adult ICU patients will undergo decolonization protocol.
  1. Mupirocin Ointment (5-Day Course) and CHG bathing will be used.
- D. If patient transfers out of ICU, mupirocin will continue until 5 days are complete.

### MRSA Screening and Management for Dialysis Patients

- A. All patients scheduled for dialysis will be screened for MRSA colonization at the time of admission or prior to initiating dialysis.
- B. Decolonization Protocol for MRSA-positive patients:
  1. CHG Washes bathing will be used to eradicate colonization before starting dialysis.

### MRSA Screening and Management for Patients from Skilled Nursing Facilities (SNFs)

- A. All patients admitted from skilled nursing facilities (SNFs) will undergo MRSA screening upon admission and will undergo CHG bathing.

### MRSA Screening and Decolonization in Other High-Risk Groups

- A. High-risk groups such as patients with a history of MRSA infection or those with compromised immune systems (e.g., transplant patients, patients on immunosuppressive therapy) should be screened based on risk factors and risk of MRSA associated bloodstream infections.

### Isolation and Infection Control

- A. MRSA-positive patients will not be routinely isolated in the hospital unless they exhibit active MRSA infection or meet other criteria for isolation based on hospital infection control protocols.

- B. Contact precautions should be observed for MRSA-positive patients if they have open wounds, invasive devices, or active infections.
- C. Standard infection control practices will be maintained for all patients, including hand hygiene, proper use of personal protective equipment (PPE), and environmental cleaning.

## **Education and Documentation**

- A. All healthcare providers involved in the care of MRSA-positive patients will receive training on MRSA screening, decolonization protocols, and infection control measures.
- B. Patient Education: Patients and their families will be informed about MRSA colonization, the importance of decolonization, and strategies to minimize the spread of MRSA including hand hygiene.
- C. Documentation of screening results, decolonization treatments, and infection control practices will be maintained in the patient's medical record.

## **Policy Compliance and Review**

- A. This policy is intended to meet the CMS, CDC, and California state guidelines to minimize MRSA infections, particularly bloodstream infections.
- B. The policy will be reviewed annually and updated as necessary to reflect the current best practices, regulatory requirements, and institutional needs.

## **REFERENCES:**

- A. ~~California Senate Bill 1058, Chapter 296.~~
- A. California Senate Bill 1058, Chapter 296.
- B. CDC: <https://www.cdc.gov/infection-control/media/pdfs/Strive-MRSA202-508.pdf>
- C. SHEA: <https://pmc.ncbi.nlm.nih.gov/articles/PMC10369222/>

All revision dates:

9/2/2025, 4/12/2023, 2/14/2023, 9/27/2018, 5/1/  
2016, 3/1/2014, 3/1/2011

## **Attachments**

No Attachments

## **Approval Signatures**

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: ICU &	Stephanie Denson: Manager, Medical Staff Office	11/4/2025

Step Description	Approver	Date
Surgery		
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	9/9/2025
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	9/9/2025
Policy Owner	Magdy Asaad: Infection Prevention Manager	9/9/2025



Origination: 10/1/1984  
Effective: Upon Approval  
Last Approved: N/A  
Last Revised: 1/28/2020  
Next Review: 3 years after approval  
Owner: Sherri Block: Associate Chief  
Nursing Executive, VCMC &  
SPH  
Policy Area: Administrative - Nursing  
References:

## 108.023 Blood Warmer Usage and Safety

### POLICY:

To ensure that blood delivered to patients through the blood warmer is undamaged and at a safe temperature. This device is intended to aid in the prevention of inadvertent hypothermia during administration of blood, blood products, and other fluids.

### PROCEDURE:

#### INDICATIONS

- A. Trauma
- B. Shock
- C. Hypothermia (<96 degrees Fahrenheit)
- D. Any condition requiring rapid multiple infusions

#### EQUIPMENT

- A. EnFlow warming unit on intravenous (IV) pole
- B. Blood warming disposable cassette
- C. Y-blood tubing solution set with pressure pump if needed
- D. Normal saline or preferred IV solution as per physician order.
- E. Filter for blood if needed per anesthesia
- F. Plug machine in; attach sliding warmer cable into controller

#### PROCEDURE (See attachment 1)

- A. Attach warming unit to IV pole and secure with clamp on side of unit. Power on the controller.
- B. Remove the warming cassette from its sterile packaging.
- C. Prime the cassette with the desired sterile IV fluid
- D. Connect the primed cassette to the patient IV tubing. Recommended to use the port closest to the patient's IV insertion site.

- E. Place the cassette into the warmer, by sliding the two halves of the warmer apart. Place the cassette in the warmer using the arrow guides. Then slide the halves closed. An audible beep will confirm correct placement.
- F. Secure the warmer using the attached clamp. Do not cover warmer with towels, sheets or blankets.
- G. Removing the cassette from the warmer immediately stops warming but not fluid flow.

## DOCUMENTATION

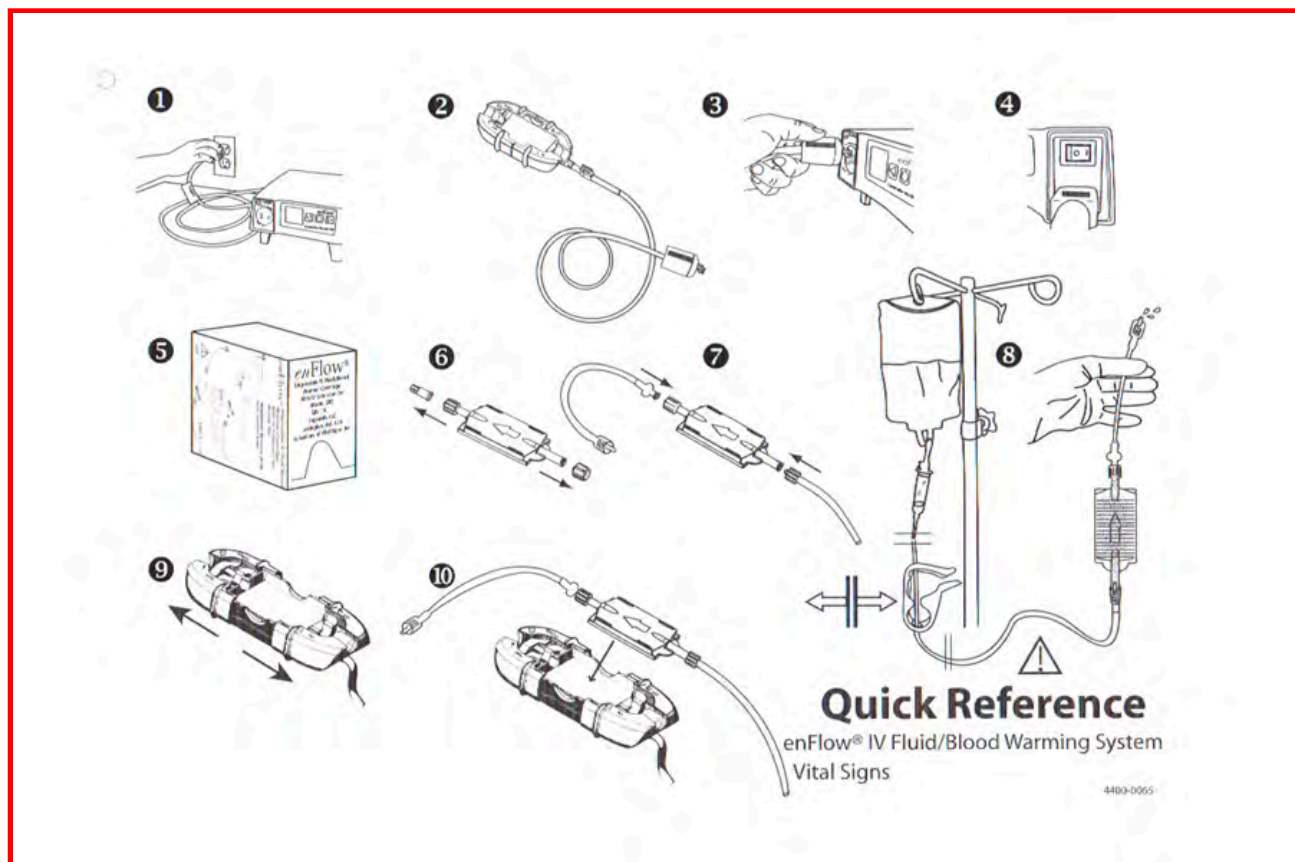
- A. Blood bank record of transfusion and Anesthesia Record
- B. Document in electronic health record (EHR) interactive iView

## KEY POINTS

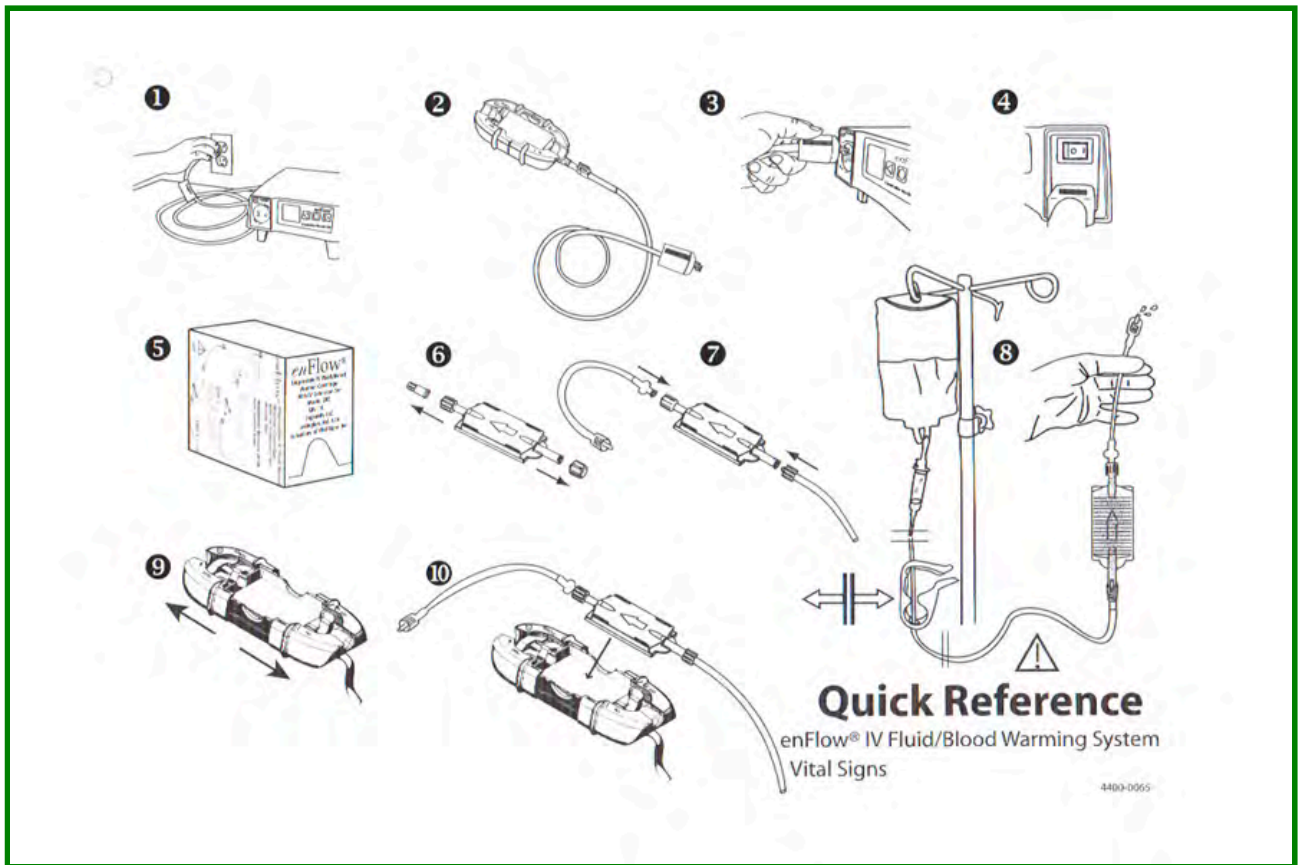
- A. Biomedical staff will check blood warmers with frequency per hospital policy.
- B. Temperature is selectable from 38 degrees – 43 degrees Celsius.
- C. Clean the surface of blood warmer with clear warm water, alcohol or non-staining germicidal disinfectant after each use.
- D. This device does not provide fluid flow rate control.

## REFERENCE

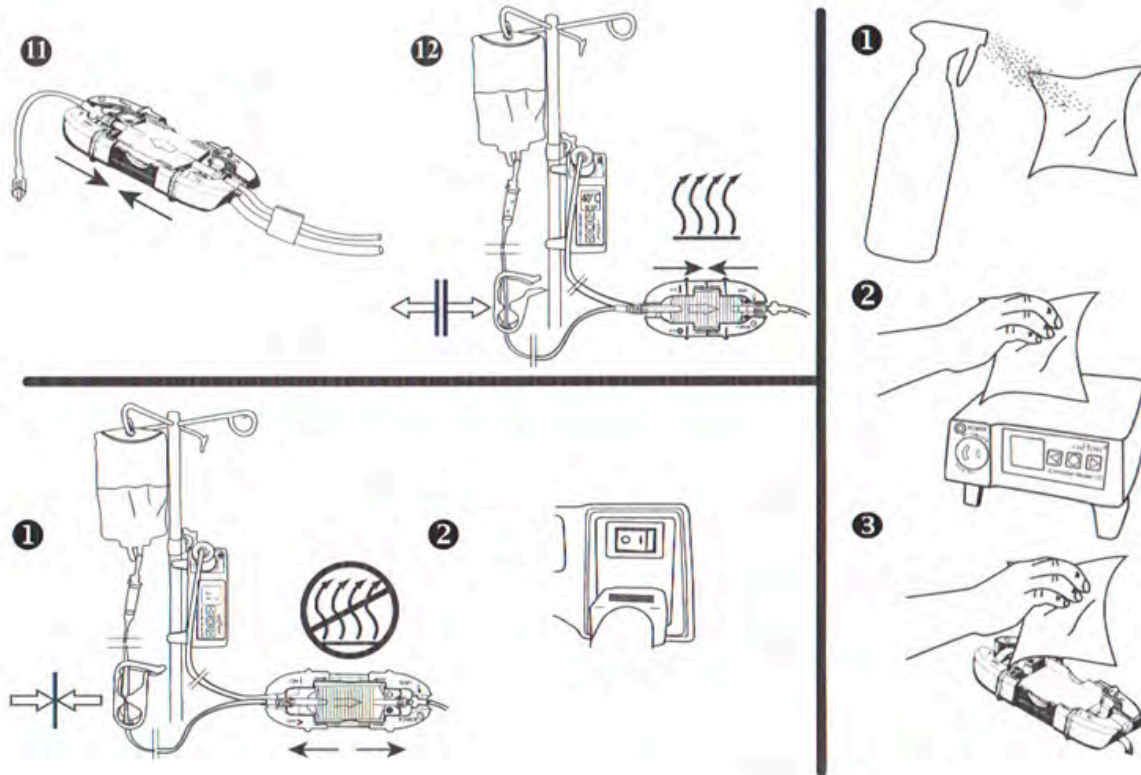
- A. EnFlow system manual, GE Medical Systems. Manufactured for Vital Signs, a Division of Carefusion, 2015











All revision dates:

1/28/2020, 1/1/2017, 2/1/2012, 5/1/2011, 6/1/2006,  
1/1/2005, 1/1/1997, 2/1/1996, 11/1/1992, 8/1/1990

## Attachments

 [A: Quick reference](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/28/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/28/2025
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/28/2025



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Owner: Danielle Gabele: Chief Nursing Executive, VCMC & SPH  
Policy Area: Administrative - Nursing  
References:

## 108.039 Nursing Documentation

### POLICY:

To document the nursing care for each hospitalized patient from admission through discharge. Documentation is managed and organized within the Ventura County Health Care Agency's (VCHCA) Electronic Health Record (EHR) system; Health e Connect. The most important purpose of documentation is to communicate to other members of the healthcare team the progress and condition of the patient and also to provide:

- A. Assessment documentation and response to treatments
- B. Care planning and achievement of outcome goals
- C. Justification for reimbursement
- D. Data for education and research
- E. Auditing and evaluating patient care for quality improvement
- F. Data for administrative and legal reviews

### PROCEDURE:

Nursing documentation must be objective, comprehensive, concise, timely and must accurately reflect the status of the patient, nursing care administered and other occurrences during hospitalization.

In accordance with American Nurse Association (ANA) Standards of Clinical Practice, The Joint Commission and Title XXII, nursing documentation will include:

- A. Relevant assessment data upon admission and regularly thereafter
- B. Interdisciplinary Plan of Care (IPOC)
- C. Measurable goals
- D. Plan of care
- E. Interventions provided by nursing staff
- F. Patient responses to procedures and treatments and outcomes of the care provided
- G. Abilities to manage continuing care needs after discharge, discharge/transfer summary
- H. Relevant patient/family/caregiver education
- I. Pain assessment, treatment for pain, and patient's response to relief measures

- J. Change in the patient's condition including resolution or lack of patient improvement and physician notification
- K. Signs and symptoms
- L. Name, dosage and time of administration of medications, route of administration and site of injections shall be recorded if other than oral administration and patient's response.
- M. Physician's orders that are carried out and patient's response
- N. Relevant statements made by the patient
- O. Pertinent observations including psychosocial and physical manifestations as well as incidents and unusual occurrences and relevant nursing interpretation of such observations.
- P. Record restraints per hospital restraint policy (Admin policy 100.075).

## EQUIPMENT

(available within the EHR on computer terminal):

- A. Adult Admission Assessment (or unit-specific Admission Assessment)
- B. IPOC
- C. Flowsheets and profiles
- D. Progress Notes
- E. Nursing Discharge/Transfer Summary
- F. Patient/Family Teaching record
- G. Documented Intervention Profile

## PROCEDURE:

- A. Nursing Admission Assessment
  1. The Nursing Admission Assessment must be completed by a Registered Nurse as soon as possible but no later than 4 (four) hours after patient admission to the nursing unit. It includes a physical assessment by systems.
  2. Collect data from patient and/or family and friends by interviewing, physical examination, reviewing patient history, and reviewing the laboratory results.
  3. Unlicensed Assistive Personnel and LVN's may assist with gathering data. However, the RN must review the documented information and incorporate into the admit assessment.
  4. Patient Referral, Follow-up Services, Discharge needs, risk screenings are addressed in the admission assessment and will be shared with other healthcare team members to optimize patient care:
    - a. Follow up from Public Health, Home Health Care, Spiritual Support, Hospice, Support Groups or Community Services will require a phone call to set up the needed referral. Palliative care consults are set up through order entry.
    - b. Safety/Risk Screens (advanced directives, smoking status/cessation, functional screening, nutritional screening, pain assessment, fall risk, abuse/violence) will be reviewed by the departments respectively.

5. Patient and/or Family need to be educated to: Smoking Policy (NO SMOKING) Electrical Appliances (must be cleared by Biomed), Call Light, Bed Control, TV Lights, Visiting Hours, and Phone/ Emergency numbers will be documented on the admission assessment.
  6. Advance Directives: confirm if patient has any Advanced Directives including a Living Will or POLST, Organ Donation Card and/or a Durable Power of Attorney for Health Care, and document on Admission Assessment.
- B. Clinical Parameters (recorded in the Interactive View and I&O flow sheets within the EHR)
1. Record vital signs (Temperature, Pulse, BP, Respiratory rate, pulse oximetry and Pain Scale).
  2. Record patient's height and weight.
  3. Record intake/output.
    - a. The system will autopopulate type of solution from the provider order. M/S infused are manually entered.
    - b. Enter PO intake under "Oral" and tube feeding under "Enteral".
    - c. Outputs: enter amount of urine, N/G drainage/emesis, drains or tubes, stool.
- C. Blood Glucose Point of Care (record chemstrip (blood glucose) results in Powerforms and Interactive View and I&O flow sheets)
- D. Daily Care/Activity/Equipment/Safety (record in Interactive View & I&O Flow sheets)
1. Document interventions.
  2. Document response on Patient Notes.
  3. Diet:
    - a. Type of diet, as ordered.
    - b. Identify mode of intake.
    - c. % of amount taken.
- E. Patient Shift Assessment
1. A head-to-toe assessment must be done each shift and recorded in the Assessments sections of the EHR. IPOCS should be reviewed once per shift.
  2. A REGISTERED NURSE MUST ANALYZE ALL DATA AND DOCUMENT THE ASSESSMENT. (IF LVN, RN MUST BE CONSULTED AND DOCUMENT ASSESSMENT AND INTERVENTION(S) FOR ALL CHANGES IN ASSESSMENT FROM PREVIOUS SHIFT.)
- F. Patient/family/care provider teaching (document in Adult/Pediatric Education sections found in Interactive View and I&O flow sheets)
- G. Patient Notes/Annotations
- Document a narrative note or comment for the following:
1. Abnormal assessment finding (you must make a notation for each abnormality you have identified).
  2. Change in conditions.
  3. Patient's response to interventions.
  4. Significant events/occurrences during shift (i.e. significant changes in patient's condition, adverse drug reactions, etc.).

#### H. Nursing Discharge/Transfer Summary

1. To be completed by an RN or LVN when a patient is discharged or transferred to another nursing unit or discharged from hospital. EHR Powerforms Discharge Summary, Interfacility Transfer Summary and Intrahospital Transfer Summary are to be utilized, as appropriate.
2. Discharge – Interventions
  - a. Nursing Discharge Summary
  - b. Patient Education
  - c. Discontinue peripheral intravenous catheter
  - d. Discharge Progress Note
  - e. Discharge encounter

10/22/2025, 7/12/2023, 7/14/2020, 10/1/2016, 12/1/2013, 8/1/2012, 11/1/2009, 12/1/2007, 12/1/2004, 10/1/2001, 12/1/1998, 12/1/1995, 9/1/1993, 9/1/1992, 11/1/1991, 11/1/1990, 12/1/1989, 12/1/1988, 8/1/1987, 8/1/1986

All revision dates:

### Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
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## 108.050 Patient Safety Attendant Care

### PURPOSE:

To define Patient Safety Attendant Care and the guidelines for the use of Patient Safety Attendants within Ventura County Medical Center and Santa Paula Hospital (VCMC/SPH).

### POLICY:

1. An individual assigned to the role of a Patient Safety Attendant is a member of the healthcare team of Ventura County Medical Center/Santa Paula Hospital who will remain with a patient throughout a designated period of time for the purpose of maintaining patient's safety (prevention of falls, disruption of patient care, suicidal/homicidal/5150/5585, delirium, confusion, etc.).
2. A Patient Safety Attendant assures patient safety for individuals deemed to be either suicidal or on 5150 status. This requires 1:1 Observation in which an assigned staff member stays within close proximity of the patient and provides direct observation at all times (must maintain line of sight).
3. A Patient Safety Attendant provides and maintains a safe environment (for pulling tubes, airway devices, etc.) for identified patients who have not been classified as either suicidal, homicidal or on 5150/5585 status. A Patient Safety Attendant can observe 1-2 patients in close proximity for these purposes.
4. Patient's families will be encouraged to partner with VCMC/SPH Hospital staff in order to provide a safe environment for the patient. As families provide a stabilizing emotional support for the patient, they will be asked to participate by staying with the patient to prevent pulling tubes, climbing out of bed, etc. Primary RN or Charge Nurse approval required to allow family or other visitor to replace Patient Safety Attendant. The patient's visitor will be instructed to notify the nurse to resume Patient Safety Attendant care when they are leaving the room. Family and visitors will not be permitted to provide sitter care for suicidal/homicidal or 5150/5585 patients.

### PROCEDURE(S):

#### A. Assessment of Safety Attendant Usage

1. The nurse will assess the patient's physical condition, behaviors, and emotional status to determine if constant observation of the patient is required to ensure the patient's safety.
2. The nurse assesses for the following:
  - a. The patient is on suicide precautions, which requires a sitter 1:1.

- b. Patient is on a legal hold.
  - c. The patient is confused, disoriented or cognitively impaired and at high risk to injure themselves (either by falling, wandering, etc.).
  - d. A confused, disoriented or cognitively impaired patient pulling at medically necessary tubes/lines and hand mittens have been unsuccessful.
  - e. Patient has been placed in restraints due to patient exhibiting a danger to self or others.
3. If the patient meets the above criteria c., d., and e., the nurse will first consider the following alternate options to safety attendant usage. The use of a safety attendant for those criteria should only be considered if no other feasible alternative provides a solution, to include the following interventions with documented ineffectiveness in the medical record.
- a. Can the patient's family members provide supervision of the patient? The nurse will approach the family to determine feasibility.
  - b. Can the patient be moved closer to the nursing station to provide more frequent observation by nursing staff?
  - c. Have the medications, electrolytes, and blood gases been reviewed as a reversible cause of confusion/delirium?
  - d. Where appropriate, can the patient be placed in a room with another patient who has a sitter?
  - e. Can current shift assignment be adjusted to utilize scheduled staff to provide adequate supervision?
4. If the patient meets safety attendant criteria and all alternatives have been unsuccessful and documented, the justification for the need is documented on the 'Patient Safety Attendant Care Justification for the Non-Suicidal Patient' form (Attachment C). The patient's bedside nurse completes the form and submits to the Charge Nurse. If criterion is met, the Charge Nurse will speak to the Nursing Supervisor to arrange a Patient Safety Attendant. All completed forms are submitted to the Unit Nursing Clinical Director. Initiation of patient safety attendant will require review and approval each shift or with a change in condition.

#### B. General Expectations for all Safety Attendants

- 1. The Charge Nurse will assign a Patient Safety Attendant to provide observation of the patient. A Patient Safety Attendant may be assigned to monitor two patients in the same room or in adjoining rooms for non-suicidal and non-homicidal patients only. The Patient Safety Attendant will position him/herself to maintain an unobstructed view of both patients. If one patient requires individual attention, the Patient Safety Attendant will notify the Primary RN or Charge Nurse to provide temporary monitoring for the other patient.
- 2. Once Patient Safety Attendant care is initiated, patient will not be left unattended until the nurse notifies the Patient Safety Attendant that the assignment is discontinued. If a patient is in a private room, the safety attendant needs to be in the room with the patient.
- 3. The Patient Safety Attendant will immediately inform the nurse if there is a sudden change in the patient's condition/behavior.
- 4. Care provided by a Patient Safety Attendant will be delegated and overseen by the assigned bedside nurse. The nurse will retain the responsibility of the nursing process and administration of medications. A Patient Safety Attendant will provide physical care, within their scope of practice and training, for the patient for whom they are assigned including the documentation of vital signs and



intake and output. Patients who are suicidal/homicidal require every 15 minute documentation on the patient observation log (see Attachment B).

5. The Patient Safety Attendant as directed by the nurse will complete all aspects of Activities of Daily Living (ADL's) for the patient provided they have demonstrated competency. This includes, but is not limited to, the following: bathing, feeding, toileting, and range of motion (ROM). Exception: Security Personnel may provide observation only, not the ADLs/physical care. Patient Safety Attendants (unless Registered Nurses) may not perform assessments.
6. The Patient Safety Attendant will accompany the patient for any clinical tests or procedures off the unit unless patient is already accompanied by the bedside nurse. The staff member accompanying the patient will remain within line of sight of the patient unless otherwise directed by the person performing the test or procedure.
7. The Patient Safety Attendant will remain within arm's reach of the patient while patient is using the bathroom or shower. The Patient Safety Attendant will attempt to maintain the patient's dignity and privacy by having same gender assistant assume temporary responsibility of the patient as needed.
8. While on duty, the Patient Safety Attendant will not leave the patient's room without the bedside nurses' approval and/or relief. If a break is needed, a hand-off to the temporary staff member will occur prior to reporting off the unit.
9. As operationally feasible, employees assigned as a patient sitter will be assigned for no more than half of their regularly scheduled shift. Upon request of the employee, and approval of management, employees may be permitted to take sitter assignments for their entire shift. When operations demand, management reserves the right to schedule an employee to a patient sitting assignment to best support the operations.
10. The Patient Safety Attendant will refer the patient to the nurse or physician to answer any questions regarding the plan of care.

#### **9. Patient Safety Attendant/Suicidal/Homicidal or Patient on a 5150/5585**

- a. If a Patient Safety Attendant is required for a suicidal or patient on a 5150/5585, the Charge Nurse will assign a staff member to provide 1:1 observation of the patient.
- b. If a patient is a danger to self or others, creating a safe environment is essential. The patient will not be permitted to use sharps or other items that could be used to harm self or others. For assistance in creating a safe environment see policy 100.268 Suicidal Environmental Risk Assessment. In addition, the safety attendant should not have any objects on his/her person that could be used to cause harm.
- d. Verify dietary order specifies no sharp objects and/or finger foods only. No utensils will be given to patient.
- e. The Patient Safety Attendant will immediately inform the nurse:
  1. If the patient expresses an intention to hurt self/others.
  2. If there is a sudden change in the patient's condition/behavior.
  3. The Patient Safety Attendant may not leave the patient for any reason until coverage is obtained and present.
- e. The Patient Safety Attendant may not be discontinued without Licensed Practitioner order.

#### **11. Documentation**

- a. All patient care will be documented in the Electronic Health Record.



b. Patient Safety Attendant will complete the Patient Observation Log (Attachment B).

c. Patient Safety Attendant will complete the C.A.S.E. Safety Check form (Attachment A).

#### 12. Competency

a. All Patient Safety Attendants must complete training prior to assuming the role. Training includes a didactic course and results in a competency Assessment.

b. All Patient Safety Attendants used for violent or aggressive behavior must have Crisis Prevention Institute (CPI) training or comparable (e.g., AVADE) by June 1, 2026.

c. All Patient Safety Attendants must participate in an annual refresher course to ensure maintenance of competency.

All revision dates:

10/31/2025, 6/11/2025, 10/9/2024, 12/20/2023, 7/12/2023, 4/28/2023, 4/13/2023, 4/11/2023, 4/11/2023

## Attachments

-  [C.A.S.E. Safety Checklist.pdf](#)
-  [Patient Observation Record.PDF](#)
-  [Patient Safety Attendant Care Justification for the Non-Suicidal Patient.docx](#)
-  [SBAR Safety Attendant](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/29/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/29/2025
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/29/2025



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 DOU/Telemetry  
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**References:**

## 108.061 Standards of Nursing Practice ICU

### ~~Nursing Practice Protocol~~

#### I. PURPOSE

- A. To establish Clinical Practice Standards for the Intensive Care Unit Registered Nurse (RN) when performing patient assessments and providing care during the patient's admission to and stay in the Intensive Care ~~Units~~Unit at Ventura County Medical Center ~~and Santa Paula Hospital~~.

#### II. SCOPE

- A. Intensive Care Unit ~~RN licensed staff~~RNs

#### III. DEFINITIONS

- A. **Standards** – authoritative statements that describe the level of care or performance common to the profession of nursing by which the quality of nursing practice can be judged. (AACN Scope and Standards for Acute and Critical Care Nursing Practice-2019).
- B. **Standards of Clinical Practice** – describe a competent level of nursing practice., which include performance expectations, or competencies, that describe how the critical care nurse may demonstrate competent practice. (AACN Scope and Standards for Progressive and Critical Care Nursing Practice-2019)
- C. **Scope of Practice** – defines the boundaries of the practitioner's license (ie, the procedures, nursing actions, and processes for which the practitioner has received the education, training, licensure, and, if required, certification to practice in the state where the nurse works). (AACN Scope and Standards for Progressive and Critical Care Nursing Practice-2019)
- D. **Assessment** – the systematic collection and review of patient-specific data
- E. **Physical Assessment** – the part of the health assessment representing a synthesis of the information obtained in the detailed examination of the body from head to toe using the techniques of observation/ inspection, palpation, percussion, and auscultation, and measurements such as, vital signs, and other physiological parameters.
- F. **Environment of Care Checks** – for the purpose of this policy, environment of care checks consist of confirming or verifying that specific environment of care related routine tasks have been accomplished. Refer to **Appendix B** for a list of these tasks.

#### IV. POLICY

- A. Consistent with the ~~Watson~~[AACN Synergy Model of Nursing Care](#), the ICU nurse in collaboration with all disciplines, manages the care for the ICU patient across the continuum including physical, psychosocial, spiritual, age specific, cultural and educational needs. 1
- B. Registered nurses (RNs) are responsible for the assessment and prioritization of patient's needs at the time of initial assessment and throughout the patient's stay.
- C. Initial assessment of a patient admitted to ICU completed by the RN within two (2) hours of admission and, includes but is not limited to physical, psychological, functional and development assessments. See ~~Attachment A for additional specific care intervention timeframes~~[Policy 100.015 Patient Assessment for more information](#).
- D. Physical reassessments are to be done at least every four (4) hours and as patient's condition or needs warrant. Findings are documented in the Electronic Health Record (EHR).
- E. Any changes noted in physical reassessment will be recorded as they occur, or as patient condition warrants.
- F. The patient/ family will be assessed for educational needs at the time of admission, throughout the hospital stay, or at point of patient contact. As learning needs arise, a teaching plan is formulated. Documentation of education will be completed in the EHR.
- G. Documentation in the EHR will include assessments, re-assessments, problem identification, interventions, patient response to interventions and outcomes of care
- H. The ICU nurse will review and integrate information from patient assessments to identify and assign priorities to patient's care needs.
- I. Documentation in the EHR of physical assessment findings and/ or care interventions must be done at the same frequency that each is performed
- J. The ICU nurse recognizes and works to start the discharge planning process early in the patient's episode of care, treatment, and services.

## V. BACKGROUND

Based on AACN Scope and Standards for Progressive and Critical Care Nursing Practice – 2019

- A. Standards of Care for Critical Care Nursing Practice build upon *American Nurses Association (ANA) Nursing: Scope and Standards of Practice* to delineate expectations in this specialty environment.
- B. The nursing process is used as the framework; it includes assessment, diagnosis, outcomes identification, planning, implementation and evaluation.
- C. The professional practice of the critical care nurse is characterized by the application of relevant theories, research, and evidence-based guidelines to diagnose and treat human responses to injury and illness. Such application also provides a basis for prevention, intervention, and evaluation of outcomes.

## VI. PROCEDURE – CARE OF THE PATIENT – Primary Care Nurse's Responsibility

- A. **ASSESSMENT**– Collect comprehensive data pertinent to the patient's health or situation.
  1. Collect data from the patient, family, other healthcare providers, to develop a holistic picture of patient care needs.
    - a. Completes a comprehensive head to toe physical assessment and/ or reassessment.
      - i. Within two (2) hours of admission to the ICU.

- ii. Within one (1) hour of the beginning of each shift
- iii. At the time of readmission to the unit following surgical or diagnostic procedures
- iv. Every four (4) hours while patient receives ICU level of care. (For a description of a comprehensive physical assessment, refer to **Appendix A**)

2. Prioritizes data collection based on patient characteristics related to the immediate condition and anticipated needs.

3. Uses valid evidence-based assessment techniques, instruments and tools.

4. Document relevant data in EHR according to pre-established documentation screens.

**B. NURSING DIAGNOSES** – analyze and synthesize data from the assessment in determining nursing diagnosis or conditions relevant to care.

1. Derive diagnoses or relevant conditions from the assessment of data.

2. Validates diagnoses with the patient, family and other healthcare providers.

**3. DOCUMENT IN PLAN** – document nursing diagnoses and relevant issues in EHR under interdisciplinary plan of care (IPOC).

- a. Initiate the interdisciplinary plan of care within twelve (12) hours of admission to the ICU, and update every 12 hours of care, and more often as necessary.
- b. Consult the patient, family and/ or significant others on the development of the plan of care. The patient's identified needs will serve as the basis for the individualized IPOC.
- c. Coordinate and involve other disciplines that are specific to the patient's and family/ caregivers needs in the IPOC's development, review and updates.

**4. OUTCOME IDENTIFICATION** – identify expected outcomes (Care goals) for the patient.

- a. Identify outcomes from assessments and diagnoses
- b. Respect patient and family perspectives and values in formulating culturally appropriate outcomes in collaboration with the patient and family and with the interdisciplinary team.
- c. Consider associated risks, benefits, current evidence, clinical expertise, and cost when formulating expected outcomes.
- d. Modify expected outcomes based on changes in patient condition or situation.
- e. Document outcomes as measurable goals and time frames required to meet those goals in a clear and retrievable format.

**5. PLANNING** – develop a plan that prescribes strategies and alternatives to attain outcomes/ care goals within timeframes required to meet the care goals.

- a. Develop an individualized plan using best evidence.
- b. Collaborate with the patient, family, and interdisciplinary team to develop the plan.
- c. Establish priorities and continuity of care within the plan.
- d. Include strategies for health promotion and prevention of further illness or injury within the plan.
- e. Consider associated risks, benefits, current expertise, resources, and cost when developing the plan.
- f. Document the plan in a clear and retrievable manner.

## **6. IMPLEMENTATION – Implement the plan**

- a. Use strategies to promote and maintain safe environment.
- b. Coordinate implementation of the plan with the patient, family, and interdisciplinary team.
  - i. Administer treatments, and medications according to current policies and procedures
  - ii. Follow attached ICU Clinical Practice Standards in performing routine physical assessments, physiological monitoring, and other care interventions in the ICU.
- c. Intervene to prevent and minimize complications and alleviate suffering.
- d. Facilitate learning for patients, and family/ significant other.
- e. Document implementation in a clear and retrievable format.
- f. Provide age and developmentally appropriate care in a culturally and ethnically sensitive manner.

## **7. EVALUATION - Evaluate processes and outcomes.**

- a. Conduct systematic and ongoing evaluations using evidence-based techniques, tools, and instruments.
- b. Collaborate with the patient, family and interdisciplinary team in the evaluation process.
- c. Revise the assessment, diagnoses, outcomes, and interventions based on the information gained during the evaluation process.
- d. Document the results of evaluation in a clear and retrievable format.
  - i. Evaluate the patient's progress every 12 hours based on plan of care goals and expected outcomes.
  - ii. Update and/ or revise the expected outcomes, or goals and respective timeframes to meet respective care outcomes every 12 hours.

## **VII. REFERENCES**

~~Watson, J. Human Caring Science: A Theory of Nursing, 2<sup>nd</sup> Edition. (2011, March 8). Jones and Bartlett Learning; 2<sup>nd</sup> Edition~~

- A. American Nurses Association (2021). *Nursing: Scope and Standards of Practice* (4<sup>th</sup> Ed.). Silver Spring, MD.
- B. American Association of Critical Care Nurses. (2019). AACN Scope and Standards for Progressive and Critical Care Nursing Practice. Aliso Viejo, CA.
- C. American Association of Critical Care Nurses. (2018). AACN TeleICU Nursing Practice: An Expert Consensus Statement Supporting High Acuity, Progressive and Critical Care. Aliso Viejo, CA.

## **VIII. RELATED POLICIES AND PROCEDURES**

- A. Policy MST. 48 Nursing Care Plan
- B. Policy 108.039 Nursing Documentation

## **IX. APPENDICES**

- A. Appendix A – Nursing Assessment/ Reassessment Grid for ICU

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## Attachments

No Attachments

## Approval Signatures

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/28/2025
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**References:**

## AC.43 Standardized Nursing Protocol in Ambulatory Care Clinics: Treatment of Hypoglycemia

### Policy:

To provide a registered nurse (RN), and Licensed Vocational Nurse (LVN) with a standardized procedure for the treatment of hypoglycemia in the Ambulatory Care Clinics (AC).

It is the policy of Ambulatory Care Clinics that all standardized procedures which are developed collaboratively and approved by the Interprofessional Practice Committee (IPC), whose membership consists of Physicians, Registered Nurses (RN), Pharmacists, Advanced Practice Nurses and Administrators. Standardized procedures are reviewed every three years.

To outline and define responsibility in performing interventions requiring a physician order in accordance with the California Board of Registered Nursing and the Nursing Practice Act, all approved standardized procedures will be kept in Policy Stat. The Registered Nurse, or Licensed Vocational Nurse as outlined in the Nurse Practice Act, Business and Professions Code Section 2725, is authorized to implement appropriate standardized procedures or changes in treatment regimen after observing signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determining that these exhibit abnormal characteristics.

### Function to Be Performed:

The Clinic RN or LVN may recognize the signs and symptoms of hypoglycemia in a presenting clinic patient who is conscious, confirm and treat adults and children with juice ~~or glucose~~.

### Applicable Departments:

All Ambulatory Care Clinics will follow this protocol.

### Roles and Responsibilities

This Standardized Protocol procedure will be completed by the Clinic RN or LVN.

- A. Scope of supervision required

1. The RN and LVN is responsible and accountable to the Clinic Licensed Provider (LP).
2. Overlapping functions are to be performed in areas which allow for a consulting provider to be available to the RN by phone or in person.
3. Provider consultation is to be obtained under the following circumstances
  - a. Emergency conditions requiring prompt medical intervention
  - b. Upon the request of the patient, RN or physician
  - c. Anytime any deviation from this protocol is necessary
4. Limitations on Settings - This Standardized Protocol is limited to the Ambulatory Care Clinics and Urgent Care.

**B. Requirements for the RN or LVN**

1. Active California RN or LVN license
2. Active BLS as indicated
3. Special training: formal orientation to specific procedure referenced in this policy with demonstrated competency validation

**C. Evaluation of the RN competence**

1. Initial upon hire to department: the Director of AC Nursing/delegate will assess the RN's and LVN's ability to perform this procedure
2. Annually: the Director of AC Nursing/delegate will evaluate the RN's and LVN's ability to perform this procedure during performance review cycle

**D. A list of RNs and LVNs who demonstrate competency to perform this procedure is held by the Director of Nursing in the Ambulatory Care Clinical Operations department.**

## Definitions:

**Hypoglycemia:** Blood glucose less than or equal to 70 mg/dL (3.9 mmol/L)

**Severe Hypoglycemia:** Blood glucose level less than 45 mg/dL (2.5 mmol/L)

## Procedures:

**A. Patient History:**

1. All patients with symptoms of hypoglycemia shall be screened and a history of hypoglycemia shall be reviewed at each patient encounter and evaluated.

**B. Assessment:**

1. Initial Evaluation: Identify signs and symptoms of hypoglycemia
  - a. Symptoms include shakiness, dizziness, headache, confusion, irritability, weakness, decreasing level of consciousness, hunger, tachycardia, pallor and/or diaphoresis.
  - b. If symptoms are present, treat per protocol as follows:
    - i. Have patient stop all activity
    - ii. Perform a STAT blood glucose (BG)
    - iii. Initiate treatment if BG is less than or equal to 70 mg/dL and patient is conscience



- iv. If BG is less than or equal to 45 mg/dL, notify LP and refer to Severe Hypoglycemia Policy.

C. Treatment:

1. If patient is responsive and able to take oral medications and swallow, give 15 grams of fast acting carbohydrates<sup>1</sup>:
  - a. 120 mL (4 oz) of apple juice, cranberry or orange (do not give orange juice to patients with renal insufficiency), **OR**
  - b. 120 mL (4 oz) of non-diet soda, ~~OR~~  
~~15 grams of glucose gel OR~~  
~~4 glucose tablets~~
2. Recheck the BG in 15 minutes after treatment. If BG remains less than 70 mg/dL, repeat above treatment, and recheck the BG in 15 minutes. Repeat this process until BG is over 70 mg/dL.

D. Documentation:

1. Document all interventions including symptoms, BG levels and patient tolerance in the electronic health record (EHR) and notify the Licensed Practitioner (LP).

## References:

1. American Diabetes Association Professional Practice Committee. 6. Glycemic goals and hypoglycemia: Standards of Care in Diabetes-2024. Diabetes Care 2024;47(Suppl.1):S111-S125
2. Deshmukh H, Wilmot EG, Gregory R et al. Effects of flash glucose monitoring on glycemic control, hypoglycemia, diabetes-related distress, and resource utilization in the Association of British Diabetologists (ABCD) nationwide audit. Diabetes Care 2020;43:2153-2160
3. Lee W, Neumiller J, Hypoglycemia Prevention and Treatment in the Ambulatory Care Setting. US Pharm.2020;45(11):24-30
4. Policy Viewing DM.008 Hypoglycemia Management in Adults

All revision dates:

## Attachments

 [Hypoglycemia Reference for DM Educators.pdf](#)

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/28/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/28/2025
Policy Owner	Torri Boghossian: Pharmacy Consultant, Ambulatory Care	10/28/2025



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**Next Review:** 3 years after approval  
**Owner:** Jennifer Ferrick: Cancer Program Coordinator  
**Policy Area:** Cancer Program  
**References:**

## CA.17 Cancer Registry Clinical Research

### POLICY:

To promote advancement in cancer treatment through the provision of clinical trial information and patient accrual to cancer-related clinical trials to facilitate advancement of evidence-based medicine. Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) understand the importance of the use of data gathered through clinical research to promote the advancement of evidence-based cancer treatment modalities and cancer prevention, to study economics of care, and to assess patient quality of life. The Cancer Program at VCMC/SPH has developed a list of resources to educate patients and provide easy access to information related to the benefits and availability of clinical trials.

### PROCEDURE:

- Prior to presentation at the cancer conferences each patient on the agenda will be evaluated by a pharmacist for possible enrollment in local open clinical trials identified through review of the website [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The information will be discussed at the appropriate Tumor Board meeting, and the patient will be referred to the participating facility through either their Medical Oncologist or Surgeon.
- The pharmacist presents patient-specific clinical trial information during the case discussion at the cancer conference.
- Patients identified within the clinic system and hospitals that fall within the category of on-site approved IRB clinical studies will be referred to the physician conducting the study for evaluation and possible inclusion.
- Participating physician obtains patient consent prior to participation in IRB approved on-site research studies.
- Physicians will refer patients to facilities known to participate in clinical trials appropriate to the patients' needs. The referring physician will notify the clinical trials representative of all patients referred for evaluation of inclusion in an open study.

#### MOST COMMON REFERRAL SITES FOR RESEARCH STUDIES/CLINICAL TRIALS:

- Angeles Clinic - Los Angeles, California
- USC - Los Angeles, California
- UCLA - Los Angeles, California
- Children's Hospital Los Angeles - Los Angeles, California
- City Of Hope, Duarte, California
- The Clinical Research Coordinator will report activity to the VCMC/SPH Cancer Committee on an annual

basis. The Cancer Committee will evaluate the effectiveness of the clinical trial program and make suggestions for modifications in processes and procedures as necessary.

## REFERENCE:

American College of Surgeons, Commission on Cancer Standards:Optimal Resources for Cancer Care 2020

All revision dates:

11/17/2022, 1/31/2020, 4/28/2016

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Cancer Committee	Jennifer Ferrick: Cancer Program Coordinator	10/27/2025
Cancer Program Manager	Jennifer Ferrick: Cancer Program Coordinator	10/27/2025



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**Owner:** Fernando Medina: Director,  
Support Services  
**Policy Area:** Dietary - Patient Care  
**References:**

## D.29 Nutritional Assessments

### POLICY:

To provide medical nutritional therapy for patients and to provide the physician and healthcare team with information regarding the patient's nutritional status and nutritional plan of care. ~~Patients will be assessed based on a priority basis.~~

### PROCEDURE:

#### Inpatient Nutritional Assessments

1. The Registered Dietitian will assess the patient's nutritional status according to the following guidelines, as appropriate:
  - A. Review of anthropometric data.
    1. Adults - present weight, usual weight, desirable weight, height.
    2. Adolescents - weight, height, weight for height, BMI for age.
    3. Children - weight for age, length for age, weight for length, head circumference for age < 3 years, BMI for age > 2 years.
    4. Growth charts for children and adolescents will be plotted by nurses, see ~~Children's Services NICU/PEDS~~ Policy PMCH.12 Neonatal and Pediatric Physiologic Monitoring, Hygiene and Comfort Management Protocol. 6.0
  - B. Review of biochemical data.
    1. Electrolytes.
    2. Serum glucose, lipids.
    3. ~~BUN and Creatinine~~ BUN and creatinine.
    4. Other pertinent laboratory data.
  - C. Review of clinical data.
    1. Physician's progress notes.
    2. Patient care notes.
    3. Current medications.

4. Other pertinent clinical information.
- D. Review of nutrition-related data.
  1. Current diet prescription.
  2. Functional capacity of the GI tract.
  3. Tolerance to feeds/intake.
  4. Food allergies, intolerance.
  5. Other pertinent nutrition-related information.
- E. Interview with patient, family.
2. The Registered Dietitian will develop a nutritional care plan based on the assessment:
  - A. Determine appropriate diet order.
  - B. Determine protein and calorie needs, when appropriate.
  - C. Develop plan for initiation and advancement of enteral or parenteral nutrition, when appropriate.
3. The Registered Dietitian will perform assessments based on the following priority levels:
  - A. Level III within 48 hours of admission.
  - B. Level II within 4 days of admission.
  - C. Level I within 6 days of admission.

4. Reassessments will be ~~done~~performed within the following time frame:

<del>A. Level III</del>	<del>5-7 days</del>
<del>B. Level II</del>	<del>7-10 days</del>
<del>C. Level I</del>	<del>10-14 days</del>

- A. Level III: 5 to 7 days
- B. Level II: 7 to 10 days
- C. Level I: 10 to 14 days
5. Reassessments may result in a change in priority level from the initial assessment and may include development of a new plan for nutritional care.

~~Patients transferred between the hospital and the Inpatient Psychiatric Unit (IPU) will be considered new admits.~~

## Outpatient Nutritional Assessments

1. The Registered Dietitian will assess the patient's nutritional status according to the following guidelines, as appropriate:
  - A. Review of anthropometric data that may include:
    1. Adults - present weight, usual weight, desirable weight, ideal body weight, height, and BMI.
    2. Gestational weight gain.
    3. Adolescents - weight, height, weight for height, BMI for age.
    4. Children - weight for age, length for age, weight for length, head circumference for age < 3

- years. BMI for age > 2 years.
  - 5. Growth charts for children and adolescents will be plotted as appropriate utilizing the U.S. Centers for Disease Control and Prevention (CDC) growth charts as part of the electronic health record (EHR), and this will also include use of specialized growth charts as appropriate, such as for a patient with Down Syndrome, for example.
  - 6. And/or other appropriate anthropocentric factors.
- B. Review of biochemical data that may include:
  - 1. Electrolytes.
  - 2. Serum glucose, lipids.
  - 3. A1C.
  - 4. BUN and creatinine.
  - 5. And/or other pertinent laboratory data.
- C. Review of clinical data that may include:
  - 1. Physician's progress notes.
  - 2. Patient care notes.
  - 3. Current medications.
  - 4. And/or other pertinent clinical information.
- D. Review of nutrition-related data that may include:
  - 1. Current diet prescription, as available.
  - 2. Past diet prescription, as available.
  - 3. 24-hour food recall.
  - 4. Functional capacity of the GI tract.
  - 5. Tolerance to feeds/intake.
  - 6. Food allergies, intolerance.
  - 7. And/or other pertinent nutrition-related information.
- E. Interview with the patient. This will include a parent/guardian if the patient is a minor/pediatric patient. As appropriate, it may include other family members/individuals who are present.
- 2. The Registered Dietitian will develop a nutritional care plan based on the assessment:
  - A. Determine appropriate dietary/eating plan.
  - B. Determine calorie, fat, carbohydrate, and protein needs, when appropriate.
  - C. Incorporate physical activity as part of the overall nutritional care plan as appropriate.
  - D. Determine and choose specific goals that the patient agrees to work toward as part of the plan.
- 3. The Registered Dietitian will perform assessments based on a referral or order from a physician, or if requested by a member of the healthcare team, the patient, or the patient's family.
- 4. Reassessments scheduled as a follow-up appointment will be performed within a time frame determined by the dietitian, and as appropriate in consultation with the physician.
- 5. Reassessments at a follow-up appointment may result in a change from the initial or prior assessment

and may include development of a new plan for nutritional care.

All revision dates:

10/29/2025, 4/12/2022, 12/1/2015, 11/1/2008, 12/1/  
2007, 9/1/2006, 8/1/2001, 12/1/1998

## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Dietary Department	Fernando Medina: Director, Support Services	10/29/2025



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**Owner:** Fernando Medina: Director, Support Services  
**Policy Area:** Dietary - Patient Care  
**References:**

## D.46 Nutritional Consultations

### POLICY:

To provide nutritional assessment, patient education, and other nutritional consultations by ~~Dietary staff~~ Registered Dietitians. ~~Diet~~ A nutrition consultation may be ordered by a physician or requested by a member of the ~~health-care~~ healthcare team, the patient, or the patient's family. Consultation will be conducted within 48 hours of notification.

### PROCEDURE:

#### Inpatient Nutritional Consultations

1. All requests for consultation will be entered into the electronic health record (EHR) by the physician as "Consult to Nutritionist" in order to populate the "Multi-Patient Task List."
2. Registered Dietitians will review the "Multi-Patient Task List" to determine consultation orders.
3. Consultations may include patient initial assessment, follow-up assessment, patient education, ~~calorie count calculations~~, or other assessments, i.e. enteral or parenteral nutrition.
4. Consultations that involve patient education may be delayed if the patient is NPO. Discussions involving patients' eating habits are best done when the diet is advanced and the patient is eating. If NPO status is prolonged, diet education may be delayed beyond 48 hours.
5. Consultations for education of pediatric patients will include the patient, parents and other family members as appropriate.
6. Consultations will be documented in the dietary progress note in the patient's EHR.

#### Outpatient Nutritional Consultations

1. All requests for consultation will be entered into the electronic health record (EHR) by the physician, or appropriate member of the healthcare team, as a referral to the dietitian.
2. Registered Dietitians will review their schedule to determine consultation orders.
3. Consultations will include a patient initial assessment or follow-up assessment.
4. Consultations will include patient education, establishment of a nutritional care plan, incorporation of physical activity as appropriate, goal setting, and may include other additional nutritional assessments as needed.



5. Consultations for education of pediatric patients will include the patient, parent/guardian, and other family members as appropriate.
6. The Registered Dietitians will request follow-up appointments for patients based on the outcome of the consultation and the need as appropriate.
7. Consultations will be documented in the dietary progress note in the patient's EHR.

All revision dates:

10/29/2025, 2/1/2016, 9/1/2015, 7/1/2013, 11/1/  
2008, 12/1/2007, 8/1/2001, 9/1/1998, 12/1/1995

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Dietary Department	Fernando Medina: Director, Support Services	10/29/2025



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Owner: Julia Feig: Nurse Director,  
Emergency Services  
Policy Area: Emergency Services  
References:

## ER.45 Telephone Medical Advice in the Emergency Department

### POLICY:

To inform Emergency Department staff of the rules and regulations for giving medical advice to callers by telephone.

### PROCEDURE:

Nursing and Ancillary Staff will not give medical advice to callers over the telephone. It is neither legally nor medically safe to give specific information via the telephone, except under unusual circumstances. Staff can instead inform callers that, "We cannot diagnose over the telephone" or "We are available to see you 24 hours a day."

When speaking to callers, staff should identify themselves by name and title, identify the patient's problem to the best of their ability, and then refer the patient to seek appropriate medical care by calling 911, visiting the nearest Emergency Department or visiting their primary care physician.

All revision dates: 11/17/2022, 12/1/2004, 11/1/2001, 1/1/1995, 10/1/1992

### Attachments

No Attachments

### Approval Signatures

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Emergency Department Committee	Stephanie Denson: Manager, Medical Staff Office	10/20/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/19/2025

Step Description	Approver	Date
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/19/2025
Policy Owner	Julia Feig: Nurse Director, Emergency Services	9/19/2025



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Owner: Julia Feig: Nurse Director,  
Emergency Services  
Policy Area: Emergency Services  
References:

## ER.53 Infant/Child Security in the Emergency Department

### Policy

The purpose of this policy is to help Emergency Department staff identify the essential steps to be taken for an infant or child suspected of being cared for by unauthorized person(s) and/or to assist staff in the protection of infants/children from removal from the facility by unauthorized person(s).

### Procedure

If an infant/child is brought to the Emergency Department for care and the adult is unable to produce documentation (Identification) that they are the parent or legal guardian, please request/perform the following AFTER the infant/child is Triage and Medical Screening Examination (MSE) has been completed (emergency needs/care must be addressed):

1. Foster Care Provider: Inquire if a Foster Care provider has a copy of the legal documents outlining temporary/permanent custody. If the caretaker holds that they are the Foster Care provider but are unable to produce the document(s), please contact a Ventura County Medical Center/Santa Paula Hospital Social Worker at (805) 652-3280 (7 days/week from 8-4:30) for assistance. Outside of the aforementioned hours, please contact Ventura County Children and Family Services (CFS) at (805) 654-3200 (24-hour hotline) for immediate/off-hours and weekend assistance. Do not leave the infant/child unattended until custody has been verified. If CFS is unable to address please contact the Ventura Police Department at (805) 339-4400.

**If at any time, the adult attempts to leave with the child prior to custody being verified, phone 911 and attempt to detain the adult and infant/child.**

2. Other Adult/Caretaker: When an adult or caretaker presents with an infant/child and is unable to produce Identification or documentation that the infant/child is to be in their care please contact a Ventura County Medical Center/Santa Paula Hospital Social Worker at (805) 652-3280 (7 days/week from 8-4:30) for assistance. Outside of the aforementioned hours, please contact Ventura County Children and Family Services (CFS) at (805) 654-3200 (24-hour hotline) for immediate/off-hours and weekend assistance. Do not leave the infant/child unattended until custody has been verified. If CFS is unable to address please contact the Ventura Police Department at (805) 339-4400.

**If at any time, the adult/Caretaker attempts to leave with the child prior to custody being verified,**

phone 911 and attempt to detain the adult and infant/child.

All revision dates:

10/11/2022

## Attachments

No Attachments

## Approval Signatures

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Emergency Department Committee	Stephanie Denson: Manager, Medical Staff Office	10/20/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	9/22/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/19/2025
Policy Owner	Julia Feig: Nurse Director, Emergency Services	9/19/2025



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**Owner:** Gwendolyn Vontoure: Director  
 Perioperative Services  
**Policy Area:** Surgical Services  
**References:**

## S.27 Prevention of Retained Foreign Objects

### POLICY:

To provide guidance to perioperative staff for preventing retained foreign objects (RFO's) during operative or other invasive procedures. The expected outcome is that the patient is free from unintended retained foreign objects.

### PROCEDURE:

It is the policy of **Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH)** that:

- All perioperative team members are responsible for the prevention of RFO's.
- All surgical items opened and used during a surgical procedure will be accounted for.
- Manual counts of radiopaque soft goods, sharps, miscellaneous items, and instruments opened onto the sterile field will be performed in all surgical invasive procedures.
- Instrument counts may be waived for surgical invasive procedures in which accurate instrument counts may not be achievable or practical, including:
  - complex procedures involving large numbers of instruments (e.g., anterior-posterior spinal procedures),
  - emergency trauma procedures, [\(please defer to T.22 Prevention of Inadvertent Retained Foreign Objects \(RFO\)\).](#)
  - procedures that require complex instruments with numerous small parts, and
  - procedures where the width and depth of the incision are too small to retain an instrument.
- When instrument counts are waived, unless the patient's safety is at risk, intraoperative imaging will be performed before the patient is transferred from the operating room (OR).
- Any individual who observes an item dropped from the surgical field will immediately inform the registered nurse (RN) circulator and other members of the perioperative team.
- Any perioperative team member (e.g., anesthesia professional, float RN) who assists the surgical team by opening sterile items onto the sterile field will:
  - count the items with the scrub person,
  - add the counted items to the count documentation (e.g., count sheet, whiteboard), and
  - promptly inform the RN circulator of what was added.
- A count may be initiated by any member of the perioperative team involved in the counting process.
- All unnecessary activity and distractions will be curtailed during the counting process.
- Counts and events that require a count (e.g., relief of scrub person or RN circulator) will not be performed during critical portions of the operative or other invasive procedure.

- A variance report will be completed for any incorrect count or adverse event.
- A critical investigation will be conducted regarding any adverse event or near miss related to RFOs.
- The RN circulator will:
  - actively participate in safety measures to prevent RFOs during all phases of a surgical invasive procedure and
  - initiate the count, perform count procedures in concert with the perioperative team, document count reconciliation activities, and report any count discrepancy.
- The scrub person will:
  - maintain an organized sterile field according to the standardized sterile setup for the procedure type;
  - confine and contain sharps in the specified area of the sterile field or within a sharps containment device;
  - maintain awareness of the location of soft goods (e.g., radiopaque sponges, towels, textiles), miscellaneous items, and instruments on the sterile field during the course of the surgical invasive procedure;
  - know the character and configuration of soft goods, sharps, instruments, and other items that are used by the surgeons and assistants;
  - verify the integrity and completeness of soft goods when they are counted;
  - ensure that the RN circulator sees surgical items being counted; and
  - confirm that instruments or devices that are returned from the operative site are intact.
- The surgeon and first assistant will
  - maintain awareness of all soft goods, sharps, instruments, and other items used in the surgical wound during the course of the surgical invasive procedure and
  - facilitate the count process by:
    - using only radiopaque surgical soft goods in the wound,
    - communicating placement of surgical items in the wound to the perioperative team for notation (e.g., whiteboard),
    - acknowledging awareness of the start of the count process,
    - removing unneeded soft goods and instrumentation from the surgical field at the initiation of the count process,
    - performing a methodical wound exploration when closing counts are initiated,
    - accounting for and communicating about surgical items in the surgical field, and
    - notifying the scrub person and RN circulator of surgical items returned to the surgical field after the count.
- The anesthesia professional will
  - plan anesthetic milestone actions so that these actions do not pressure the perioperative team to perform insufficient accounting practices;
  - not use counted items; and
  - verify that throat packs, bite blocks, and other similar devices are removed from the oropharynx and communicate to the perioperative team when these items are inserted and removed.

## Procedure Interventions

### *General Accounting Practices*

- Counts of sponges, sharps, instruments, and other miscellaneous items will be performed in order from **large to small items**.
- The perioperative RN circulator will retrieve, show the scrub person, isolate, and include in the final count any counted items either passed off or dropped from the sterile field.

- The final count will not be considered complete until all items (e.g., sponges, malleable retractors, needle holders, scissors) used in closing the wound are removed from the wound and returned to the scrub person.
- Counted items and linen or waste containers will not be removed from the OR or procedure room until all counts are completed and reconciled.
- All items accounted for will be removed from the room during end-of-procedure cleaning.

#### *Surgical Soft Goods*

- Non-radiopaque sponges used for skin preps will be isolated before beginning the operative or other invasive procedure.
- The seal will be maintained on dressing sponges included in custom packs, and dressing sponges will be isolated until the final count is resolved.
- Dressing sponges will be withheld from the sterile field until the final count is completed.
- Radiopaque sponges and all soft goods should be left in their original configuration and should not be cut or altered in any way, with the exception of products designed to be cut, such as hemostatic packing gauze (i.e. Quickclot). If an item is cut, the number of pieces after cutting will be communicated clearly to the circulating nurse and scrub tech.
- The following items will be included in the count:
  - all radiopaque sponges (e.g., 4x4s, 4x8s, laparotomy, cottonoids, kittners),
  - radiopaque towels, and
  - radiopaque textiles.
- Soft goods will be counted:
  - before the procedure (ie, initial count);
  - when new items are added to the field;
  - before closure of a cavity within a cavity (e.g., uterus);
  - when wound closure begins;
  - at skin closure at the end of the procedure or at the end of the procedure when counted items are no longer in use (ie, final count); and
  - at the time of permanent relief of either the scrub person or the RN circulator, although direct viewing of all items may not be possible.
- When counting radiopaque sponges,
  - break the band and discard it;
  - separate each sponge;
  - count audibly (e.g., restarting at 1 with each new package or counting the total of each type of sponge);
  - two individuals, one of whom is the RN circulator, will view the actual sponges during the count process;
  - record each type of sponge separately (e.g., radiopaque 4x4s, laparotomy sponges, large tonsil sponges, small tonsil sponges); and
  - if an incorrect number of radiopaque sponges or a manufacturing defect is discovered in a package upon initial count,
    - remove the items from the sterile field and then bag, label, isolate, and exclude these items from the count, or
    - remove the defective packages from the room if they are discovered before the patient's entry.
- When counting radiopaque objects used as therapeutic packing,
  - document the location, type, and number of objects retained after confirming with the surgeon and
  - during the transfer-of-patient-care information, inform the receiving caregiver of the location, type,



- and number retained and the plan for the eventual removal, if known.
- The number and type of retained objects will be recorded directly on the temporary wound closure when possible.
- During the removal of intentionally retained foreign objects (e.g. radiopaque sponges) used for therapeutic packing,
  - document the number and type of objects removed in OR documentation as well as the surgeon's brief operative report and operative report;
  - intentionally retained foreign object(s) that is/are being removed will be isolated and not included in the count, but recorded in the Electronic Health Record.
  - consult with the surgeon regarding the need for an intraoperative radiograph.
  - Prior to final abdominal closure of a patient with previous therapeutic packing and temporary abdominal closure:
    - Surgical sweep will be performed by the surgeon to ensure no retained foreign bodies.
    - X-ray will be obtained to ensure no retained foreign object.
    - Final counts will be performed.
    - Prior operative report will be reviewed to ensure any documented foreign bodies are accounted for.
    - A timeout will be performed to ensure that the entire OR team agrees that all appropriate steps have been performed to ensure no unintentional retained foreign object remains.
- Vaginal Packing used in the Operating Room (OR) or Labor and Delivery Suites
  - Vaginal packing is considered a dressing and is not included in the surgical sponge count.
  - Use only sterile x-ray detectable vaginal packing.
  - When in the OR, documentation will be completed in the Dressing/Packing section of the intraoperative record. Nursing documentation will indicate the type of packing, the location of the pack(s), and the number of pack(s) placed.
  - When packing is placed while in a Labor and Delivery Suite, documentation will be completed in the Vaginal Packing section of the Delivery band. The nurse will indicate the type of packing, the location of the packs, and the number of packs placed.
  - The physician's documentation will indicate:
    - that vaginal packing(s) were placed
    - record the number of vaginal packs placed
    - Indicate the date when the pack(s) is/are to be removed
  - A blue "vaginal packing" wrist band will be placed on the patient's wrist any time vaginal packs are placed.
  - A physician and nurse will be present at the time of removal. Both the nurse and physician will document the date, time, and number of packs removed. The team will confirm that the number of pack(s) removed corresponds with the number of pack(s) initially placed. Once confirmed, the blue vaginal packing wrist band can be removed.
  - An X-Ray will be ordered if any discrepancies are found.

#### *Sharps and Other Miscellaneous Items*

- Sharps and miscellaneous items will be counted
  - before the operative or other invasive procedure (ie, initial count),
  - when new items are added to the field,
  - before closure of a cavity within a cavity (e.g., uterus),
  - when wound closure begins,
  - at skin closure at the end of the procedure or at the end of the procedure when counted items are no

- longer in use (ie, final count), and
- at the time of permanent relief of either the scrub person or the RN circulator.
- When counting sharps and miscellaneous items,
  - count suture needles according to the number marked on the outer package;
  - the scrub person will verify the number when the package is opened;
  - count audibly, counting the total number and types of needles (e.g., hypodermic, suture, spinal);
  - two individuals, one of whom is the RN circulator, will view the actual sharps and miscellaneous items during the count process;
  - record each type of type of needle (e.g., hypodermic, suture, spinal, micro);
  - keep used sharps on the sterile field in a disposable, puncture-resistant container; and
  - if an incorrect number of items or a manufacturing defect is discovered in a package on initial count,
    - remove the package and its contents from the sterile field and label, isolate, and exclude these contents from the count, or
    - remove the package from the room if it is discovered before the patient's entry.
- Include the following items in the count:
  - all needles, regardless of size (e.g., suture, hypodermic, spinal);
  - all sharps (e.g., scalpels); and
  - all miscellaneous items, including:
    - defogger solution bottle, bottle cap, and associated accessories (e.g., wipe, sponge);
    - electrosurgery active electrode blades;
    - electrosurgery scratch pads;
    - endostapler reload cartridges;
    - laparotomy sponge rings;
    - Raney clips;
    - trocar sealing caps;
    - umbilical and hernia tapes;
    - vascular inserts;
    - vessel clip bars; and
    - vessel loops.

### *Instruments*

- Instruments will be counted:
  - before the procedure (ie, initial count),
  - when new instruments are added to the field,
  - at wound closure or at the end of the procedure when counted items are no longer in use (ie, final count), and
  - at the time of permanent relief of either the scrub person or the RN circulator.
- Record the counted instruments on the preprinted count sheet.
- When counting instruments,
  - count audibly, and
  - two individuals, one of whom is the RN circulator, will view the actual instruments during the count process.
- Individual pieces of assembled instruments (e.g., suction tips, wing nuts, blades, sheaths) will be accounted for separately and documented on the count sheet.
- Count and record on the count sheet additional instruments when they are added to the sterile field.
- The scrub person will assess the condition of each item returned from the operative site to verify that the item is intact and immediately notify the OR team when an item may have broken or become separated

within the confines of the surgical site.

#### *Count Discrepancy Investigation and Reconciliation*

- A post operative x-ray will be utilized under the following circumstances:
  - Greater than forty (40) sponges used;
  - Size of the patient body mass index (BMI) >40 in an open chest/open abdomen procedure;
  - Greater than four (4) hour duration in an open chest/open abdomen procedure
  - Significant change from the intended procedure (ie laparoscopic to open)
  - ~~The x-ray will be evaluated by the attending surgeon and/or the radiologist prior to leaving OR unless the patient's condition warrants otherwise.~~ Micro-needles (8-0 or smaller) and non-visualizable foreign objects
- If a missing item or device fragment is not recovered, perform intraoperative imaging before the final closure of the wound if the patient's condition permits.
  - If the patient's condition is unstable, take a radiograph as soon as possible.
- Perioperative team member responsibilities:
  - The perioperative RN circulator will
    - inform and receive active verbal acknowledgment from the surgeon and surgical team;
    - visually inspect the area surrounding the surgical field, including the floor, kick buckets, and linen and trash receptacles;
    - consult with the radiologist for guidance on the most appropriate available radiographic equipment to use; and
    - request radiological support and provide the following information:
      - the room where the procedure is being performed or where the patient is located,
      - the type of radiograph and views needed (e.g., intraoperative imaging coverage area includes the surgical site and any views deemed necessary by the surgeon or radiologist),
      - a description of the missing surgical item,
      - the operation performed, and
      - the surgical site.
  - The surgeon(s) will:
    - suspend closure of the wound if the patient's condition permits,
    - perform a methodical wound examination by actively looking for the missing item,
    - cooperate in the attainment of radiography or other modalities as indicated to find the missing item, and
    - remain in the OR until the item is found or is determined with certainty not to be in the patient.
  - The scrub person will:
    - assist with visual inspection of the area surrounding the sterile field and
    - visually inspect the sterile field.
- In the event of a count discrepancy or a device fragment being retained, the surgeon will notify the patient and/or the patient's significant other or caregiver both of the event and the following:
  - material composition of the item (if known);
  - size of the fragment (if known);
  - location of the fragment;
  - potential mechanisms for injury (e.g., migration, infection);
  - procedures or treatments that should be avoided, such as magnetic resonance imaging (MRI) examinations in the case of ferrous metallic fragments; and
  - ~~risks and benefits of retrieving the item, as opposed to leaving it in the wound.~~
  - risk-benefit analysis will be required to determine whether to proceed with closure if the foreign

- object cannot be identified, ensuring patient safety is prioritized.
- documentation of the decision-making process regarding the imaging and potential risks associated with retained objects will be mandatory for compliance and transparency.
- disclosure to the patient (and documentation) must include risks and benefits of both removal and retention of fragment
- x-ray will be evaluated by the attending surgeon and/or the radiologist prior to leaving OR unless the patient's condition warrants otherwise.

#### *Waived Counts*

- Complete an initial instrument count, though subsequent counts may be waived for **laparoscopic procedures in which the patient is not opened.**
- In situations when accurate counting of surgical items is not possible, unless the patient's safety is at risk, perform intraoperative imaging before the patient is transferred from the OR.
- Reference policy T.22 Prevention of Inadvertent Retained Foreign Objects (RFO).  
<https://vcmc.policystat.com/policy/18695161/latest>

## Documentation

- The RN circulator will document:
  - the types of counts (e.g., radiopaque sponges, sharps, instruments, miscellaneous items);
  - the number of counts;
  - the names and titles of perioperative staff performing the counts;
  - the results of surgical item counts (e.g., correct, incorrect, initial count is documented as complete);
  - surgeon notification of the count results;
  - any adjunct technology used and associated records;
  - any explanation for any waived counts;
  - the number and location of any instruments intentionally remaining within the patient;
  - details about radiopaque sponges intentionally retained as therapeutic packing, including:
    - the number of sponges,
    - the types of sponge,
    - the locations of sponges,
    - confirmation of the above documented items by the surgeon,
    - correct document count if the number is confirmed by the surgeon and by the counts,
    - incorrect document count if the number is not confirmed by the surgeon or by the counts, and
    - notification of the receiving caregiver;
  - unretrieved device fragments left in the wound, including:
    - material composition,
    - size,
    - location (if known), and
    - manufacturer;
  - actions taken if count discrepancies occur, including all measures taken to recover the missing item or device fragment and any communication regarding the outcome;
  - a rationale if counts are not performed or completed as prescribed by policy; and
  - the outcome of actions taken.
- Document the counted instruments and pieces of assembled instruments (e.g., suction tips, wing nuts, blades, sheaths) separately on the preprinted count sheets.

## Competency

Perioperative staff will receive education and complete competency verification activities on the principles and processes for the prevention of RFO's, the risks of injury (e.g., needle sticks) to the patient and to health care staff, and corrective actions that should be implemented when a process failure occurs.

## Quality

Perioperative staff will participate in quality assurance and performance improvement activities related to RFO's.

## Glossary

*Instruments:* Surgical tools or devices designed to perform a specific function, such as cutting, dissecting, grasping, holding, retracting, or suturing.

*Miscellaneous items:* In relation to items on the sterile field that require counting, this may include vessel clip bars, vessel loops, umbilical and hernia tapes, vascular inserts, electrosurgery scratch pads, trocar sealing caps, and any other small items that have the potential for being retained in a surgical wound.

*Sharps:* Items with edges or points capable of cutting or puncturing other items. In the context of surgery, items include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electrosurgical needles and blades, instruments with sharp edges or points, and safety pins.

*Sponges:* Soft goods (e.g., gauze pads, cottonoids, peanuts, dissectors, tonsil/laparotomy sponges) used to absorb fluids, protect tissues, or apply pressure or traction.

*Waived count:* Surgical procedures in which accurate accounting for sponges, instruments, and miscellaneous items is determined to be unachievable or in situations in which the time required to perform the count may present an unacceptable delay in patient care (e.g., trauma procedures, anterior-posterior spinal procedures).

## References

Petersen C, ed. Retained foreign object. In: *Perioperative Nursing Data Set*. 3rd ed. Denver, CO: AORN, Inc; 2011:146-149.

Guideline for prevention of retained surgical items. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc.

[Reference Policy T.22 Prevention of Inadvertent Retained Foreign Objects \(RFO\).](https://vcmc.policystat.com/policy/18695161/latest)

<https://vcmc.policystat.com/policy/18695161/latest>

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## Attachments

No Attachments

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Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Surgery Committee	Stephanie Denson: Manager, Medical Staff Office	11/4/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/29/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/29/2025
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	10/29/2025



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**Owner:** Jeff Warren: Manager, Sterile Processing  
**Policy Area:** Sterile Processing Department  
**References:**

## S.93 Cleaning And Transporting Surgical Instruments Decontamination Patient Care Areas

### Purpose

To provide guidance to personnel in all patient care areas, located outside of the operating room, on requirements for point of use treatment, transporting surgical instruments, and powered equipment in preparation for terminal sterilization. The expected outcome is that the patients and staff members are free from signs and symptoms of infection and that instruments are treated in line with regulatory standards.

### Policy

It is the policy of **Ventura County Medical Center and Santa Paula Hospital** that:

- Preparation for cleaning and decontamination of instruments will begin at the point of use in the patient care area.
- Pretreatment, and decontamination of instruments and equipment will occur as soon as possible after instruments and equipment are used at the point of use.
- Contaminated instruments will be placed after use into ~~a Humipak pouch embedded with a pretreatment agent~~ sealed biohazard container after being pretreated as soon as possible ~~after~~ at the point of use.
- Staff will call the Sterile Processing Department for pick-up of the soiled instruments.
- Once in the decontamination area the Sterile Processing Personal will remove the instruments from the biohazard container ~~and bag to~~ begin the cleaning process for all instruments.
- Contaminated instruments ~~are~~ must be contained during transport in the biohazard container and kept moist ~~in the Humipak Pouch up to 72 hours per the MIFU with a wet towel.~~  
~~Contaminated instruments must be contained during transport in the bag and a biohazard container.~~
- ~~If no pretreated pouch is available, the~~ The staff must ~~instead~~ pretreat all instruments opened onto the sterile field whether or not they were used during the procedure with a pretreatment agent.
  - Instruments must be kept moist if there is a delay with transport to the decontamination area.
    - Reapplication of pretreatment agent.
    - Application of wet towel to cover instruments.

# Procedure Interventions

## Point of Use Treatment

- Staff must wear the appropriate Personal Protective Equipment (PPE) including Goggles, or Face Shield, Mask, Gown, Gloves
  - ~~Wipe instruments as needed with sterile surgical sponges moistened with sterile water during the procedure to remove gross soil.~~
  - ~~Do not use saline to wipe instrument surfaces: saline may cause corrosion of surgical instruments.~~
  - ~~Irrigate instruments with lumens using sterile water as needed to maintain clear channels throughout the surgical procedure.~~
- ~~The Humipak pouch must be activated using the required amount of water (tap or sterile is acceptable) per bag size and sealed per MIFU and moved to the soiled utility area.~~
- ~~Segregate sharp instruments from other instruments.~~
- ~~Remove and discard disposable sharps (eg, scalpel blades, suture needles) into the designated puncture-resistant, leak-proof containers.~~
- Staff will obtain red biohazard bin which contains towel prior to procedure and bring to bedside. Staff will ensure towel is moistened.
- After procedure, dirty instruments will be placed immediately into the biohazard bin. Instruments are open, disassembled, instruments composed of multiple parts are arranged in a manner that will permit contact of the pretreatment agent on all surfaces of the instruments.
- After pretreatment is complete, staff will cover the instruments with the wet towel and leave in the red biohazard bin. The bin is sealed and moved to the soiled utility area for SPD pick up.
- SPD will pick up instruments from the soiled utility areas at regular intervals. Staff may also call SPD to arrange for pickup.
- ~~Protect~~SPD staff will protect delicate instruments from damage during transport.
  - Place delicate and other easily damaged instruments on top of heavier instruments or segregate them into separate containers.

### **Post Procedure**

~~Place dirty as well as unused instruments into the pretreated bag and transport to the soiled utility room. Notify the sterile processing department for pick up.~~

- ~~Before transport to the decontamination area~~
- ~~Discard liquid used to soak instruments at the point of use before transport, or transport in a leak-proof container.~~

## Transport

- Separate contaminated instruments and other items from clean and sterile supplies before transport to the decontamination area.
- Transport soiled instruments to the soiled utility room ~~in the pretreated bag~~inside a sealed red biohazard bin.
- If the instrument containment device has been contaminated
  - clean at the point of use, or
  - place it inside another containment device and label as biohazard.
- Upon arrival to the decontamination area, complete the decontamination log, print name, and ~~provide~~signatureinitial.



# Competency

Personnel involved in the cleaning and care of surgical instruments and equipment will receive education ~~through Target Solutions~~ and complete competency verification activities on point of use cleaning and transporting surgical instruments upon hire.

# Quality

Patient Care personnel involved in the cleaning and care of loaned surgical instruments and equipment will complete quality assurance and performance improvement activities related to point of use cleaning and transporting surgical instruments:

Implementation of real-time observations in the decontamination area and auditing instrument conditions on arrival.

# 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.

*Gross Soil:* Organic material (eg, blood, tissue bone) and debris (eg, bone cement) that accumulates on surgical instruments during operative or other invasive procedures.

*Lumen:* A channel or path through a tubular structure.

# References

Petersen C, ed. Infection. In: *Perioperative Nursing Data Set*. 3rd ed. Denver, CO: AORN, Inc; 2011:254-276.

Guidelines for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc.

Association for the Advancement of Medical Instrumentation ANSI/AAMI ST79:2017; Handling, collection, and transport of contaminated items;33-36

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## Attachments

No Attachments

## Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Surgery Committee	Stephanie Denson: Manager, Medical Staff Office	11/4/2025
Infection Prevention Committee	Magdy Asaad: Infection Prevention Manager	7/31/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/23/2025
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	7/23/2025
Sterile Processing Department	Jeff Warren: Manager, Sterile Processing	4/9/2024



## VENTURA COUNTY HEALTH CARE AGENCY

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Owner: Gina Ferrer: Manager, Trauma Services  
Policy Area: Trauma Services  
References:

# T.06 Trauma Service Injury Prevention Protocol

## POLICY:

1. To identify potentially preventable causes of injury in each trauma patient admitted to Ventura County Medical Center and to utilize this information to prevent each of our patients from suffering future injuries.
2. To identify trends of preventable causes of injuries in our patient population, and to plan and implement community injury prevention programs specific to our patients' injury patterns.

## PROCEDURE:

Our facility's injury prevention goals will require collaborative effort between the nurses and physicians assigned to our Trauma Service, other hospital staff, and our community. Our trauma prevention approach is as follows:

1. The Trauma Service will assess each admitted trauma patient as to whether the injury was potentially preventable.
2. The Trauma Service will document whether the injury was preventable, and identify those specific diseases, behaviors, actions that may have been causative. Examples of such diseases, behaviors or actions include transient ischemic attacks, cardiac disease, poorly controlled diabetes, poor balance, poor vision, alcoholism, drinking and/or drug use while driving, not wearing seatbelts, not wearing protective helmets, failing to utilize child safety seats appropriately or not using child safety seats, unsafe home environment.
3. The Trauma Service, in collaboration with other hospital staff, will formulate and document a prevention strategy for each patient, in order to minimize the risk that further injuries will occur. Examples of these strategies include treatment of carotid artery disease, treatment of arrhythmias, better diabetic control, physical therapy for improved balance and ambulation, vision correction, education and intervention for alcohol and drug use/abuse, reporting impaired driving to the DMV, education regarding seatbelt and correct child safety seat selection/use, education regarding wearing protective helmets when riding bicycles, scooters or skateboards, referral to The Ventura County Fall Prevention Coordinator or to the Violence Intervention Program.
4. The Trauma Service will maintain a computerized database of each preventable injury and those preventable factors, which we identify. This database will then be utilized to identify common preventable injuries in our patients.
5. The trauma service will analyze preventable injuries in our patients for patterns of injury in our community.

Potential injury prevention strategies will then be formulated. The trauma service and other hospital staff will work with the community to implement these programs. Examples of community injury prevention programs include education regarding drinking and driving, new teen drivers, fall prevention programs, identification of hazardous roads, education and warning signs in areas of frequent injuries, education on proper child restraint selection and use, education on protective helmets/equipment when riding bicycles, skateboards, and/or scooters.

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3/1/2016, 5/1/2012

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No Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Trauma Operations, Performance & Patient Safety (TOPPS) Committee	Gina Ferrer: Manager, Trauma Services	10/29/2025
Nursing Administration	Gina Ferrer: Manager, Trauma Services	10/29/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/30/2025
Trauma Services	Thomas Duncan: Trauma Medical Director	9/30/2025
Trauma Services	Gina Ferrer: Manager, Trauma Services	8/20/2025



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Owner: Gina Ferrer: Manager, Trauma Services  
Policy Area: Trauma Services  
References:

## T.10 Violence Intervention Program: Emergency Entry to Exit (VIP-EEE)

### POLICY:

To provide a collaborative, multidisciplinary program to reduce violent gang activity through the use of evidence-based prevention, intervention and suppression activities for at-risk/high-risk youth residing in Ventura County.

To promote positive alternatives to violence in order to reduce retaliation, criminal involvement and re-injury among youth injured by violence

### PROGRAM GOAL

- Reduce risk factors and increase protective factors for violence
- Reduce recidivism, promote positive alternatives to violence

Protective factors include:

- Peer groups, schools, and communities that emphasize positive social norms;
- Warm, supportive relationships and bonding with adults;
- Opportunities to become involved in positive activities;
- Recognition and support for participating in positive activities; and
- Cognitive, social, and emotional competence.

### PROCEDURE:

- A. Target population: Patients of any age who are identified as at-risk/high-risk for violent crime.
- B. Identification/criteria of activation: All patients who are victims of violent crime will be offered services.
- C. Once the patient is identified as a VIP-EEE candidate, he/she will be informed about the program at any point in their treatment which allows for such intervention. The following language will be utilized in the initial brief interaction: "Are you willing to receive a visit from someone to talk about what happened and refer you to services that may help you?"
- D. To initiate the VIP-EEE process, the Trauma Team shall refer the patient to community partners.
- E. The clinicians from the Trauma Department shall call the community partners. A Community Outreach Worker shall respond to VCMC to discuss the VIP-EEE Program services with the patient. If the patient

wants to participate in the program, the patient will be asked to sign an Assent Form (see Attachment B).

F. Those who enroll will be followed by a VCMC Volunteer Community Outreach Worker.

G. If a patient declines, nothing further will be done.

H. The Community Outreach Worker responding to the referral signs in and out in the VIP-EEE log located at the Security kiosk in the VCMC lobby. An access badge will be released by a member of the Security team. The badge will need to be returned after the patient evaluation is completed.

I. Clinicians from the Trauma Department shall document the referral in the patient's EHR.

J. In order to protect the identity of victims of violence, the trauma nurse or Medical Office Assistant in the Emergency Department will notify the admitting supervisor that the patient's information needs to be flagged as confidential in the EHR, so that the patient will not show up on the information desk census.

K. Outreach organizations shall report to the VCMC Trauma Services for feedback and program evaluation.

## ATTACHMENTS:

Attachment A - Schema of the VIP-EEE program

Attachment B - Assent Form in English and Spanish

All revision dates:

6/13/2019, 11/1/2014

### Attachments



[A: Schema of the VIP: EEE Program](#)



[B: Assent form for Emergency Entry to Exit Program \(Violence Intervention Program\)](#)

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Trauma Operations, Performance & Patient Safety (TOPPS) Committee	Gina Ferrer: Manager, Trauma Services	10/29/2025
Nursing Administration	Gina Ferrer: Manager, Trauma Services	10/29/2025
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	9/30/2025
Trauma Services	Thomas Duncan: Trauma Medical Director	9/30/2025
Trauma Services	Gina Ferrer: Manager, Trauma Services	9/2/2025



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**Policy Area:** Administrative - Nursing  
**References:**

## Intraosseous (EZ - IO) Insertion and Removal Procedure

### I. Purpose

To provide the indications and procedure for initiating intraosseous access.

### II. Policy

Intraosseous (IO) access via the EZ-IO® device may be used in infants, children, and adults when rapid vascular access is required for emergency administration of medications, contrast media, blood products, and intravenous fluids.

#### A. Qualified Personnel

1. Qualified personnel include:
  - a. **Insertion and Removal:** Rapid Response team (RRT) registered nurses (RNs) and Emergency Department (ED) Educator who have:
    - i. Completed one-time hands-on training
    - ii. Annual competency to be determined by the individual unit
  - b. **Insertion and Removal:** physicians (attending, fellows, and residents who have completed their own training)
  - c. **Removal:** Clinical Nurse Specialists and ICU/PICU Senior RNs who have demonstrated a one-time competency

#### B. IO Indications:

1. No vascular access can be established within 60 - 90 seconds
2. Temporary measure in emergent circumstances, ideally for 12 to 24 hours
  - a. Emergency circumstances include but are not limited to:
    - i. Cardiac arrest
    - ii. Respiratory arrest
    - iii. Hypovolemic shock
    - iv. Others not listed here are decided by the licensed provider (LP)

C. IO Contraindications:

1. Recently fractured bone, crush injury, grossly contaminated skin, or prior surgery in target extremity
2. Previous puncture of same bone by unsuccessful IO attempt
3. IO catheter use in past 48 hours of the target bone
4. Overlying skin or soft tissue infection (e.g., cellulitis, infected burn)
5. Recent orthopedic procedures near infection site, prosthetic limb, or joint
6. Bone disorders affecting bone integrity of proper land marking (e.g., osteoporosis, osteogenesis imperfecta, or osteopetrosis (Osgood-Schlatter disease)
7. Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks
8. Compartment syndrome in target extremity

D. Requirements:

1. Physician order
2. Aseptic technique
3. Use of personal protective equipment (PPE). Cap, gown, gloves, and mask.

### III. IO Insertion/Removal Procedure

A. Obtain/set-up equipment:

1. PPE
2. EZ-IO® kit - select appropriate needle size
3. Chlorhexidine antiseptic solution/swabs
4. Alcohol (for infants < 2 months of age)
5. Extension tubing (drawing blood and attach to IV tubing)

B. Select appropriate insertion site using landmarks (e.g., away from large veins, nerves, and organs):

1. **Anteromedial Tibia** - first choice for all ages. Slight flexion of the knee with joint support by a rolled towel is recommended. **NOTE:** hyperextension of the knee may distort landmarks.
  - a. Less than 12 years of age: hold the anterior aspect of patient's leg with non-dominant hand to stabilize this site. Locate tibial tuberosity and move medial and 1 to 3 cm (approximately one fingerbreadth) below the tibial tuberosity, away from joint and epiphyseal plates.
  - b. Over 12 years of age: hold the anterior aspect of patient's leg with non-dominant hand to stabilize this site. Locate tibial tuberosity, move medial and 1 - 2 cm above, ensuring away from joint space.
2. **Distal Tibia** (for older children and adults)
  - a. Identify the appropriate landmark; one fingerbreadth above the medial malleolus
  - b. Attempt at the same location on the other ankle if puncture unsuccessful at this site
  - c. Do not use this site on same limb in which an anteromedial tibial IO was attempted
3. **Proximal Humerus** (for older children and adults)
  - a. Identify the appropriate landmark:



- i. Adduct elbow at 90 degrees by placing patient's hand under same side buttock
  - ii. Hold the humeral head with non-dominant hand and palpate for greater tubercle of proximal humerus, which is on the lateral midline of shoulder
  - iii. Attempt at the same location on the other shoulder if puncture unsuccessful at this site.
4. **Distal femur** (young children and infants)
- a. Identify the appropriate landmark: two fingerbreadths above the superior border of the patella at midline
  - b. Needle length may need to be increased to account for more subcutaneous tissue above bone surface
  - c. Attempt at the same location on the other femur if puncture unsuccessful at this site

#### C. Insertion Procedure: EZ - IO® Intraosseous Device

1. Open EZ - IO® kit and cleanse site
2. Attach needle/catheter set to EZ - IO® Power Driver only handling it by the plastic hub
3. Remove Safety Cap needle/catheter
4. Hold barrel of device with non-dominant hand, at 90° (45° for proximal humerus) to insertion site
5. Push needle/catheter set through skin until the tip touches bone
6. Squeeze the trigger and apply moderate steady downward pressure and allow needle rotation to penetrate the bone
7. Advance the needle and release the trigger
  - a. **Pediatrics:** release trigger when sudden "give" or "pop" is felt, indicating entry into medullary space
  - b. **Adults:** Advance needle approximately 1 - 2 cm after entry into medullary space. When proximal humerus site is used, the needle should be advanced 2 cm or until the hub is flush against the skin
8. Stabilize needle hub, disconnect Driver and remove stylet
9. Placed stylet into the Needle VISE® for sharps containment
10. Obtain samples for lab analysis if needed
11. Place EZ - Stabilizer® over catheter hub
12. Attach a primed EZ - Connect® extension set to the hub and twist clockwise to secure it firmly
13. Attach EZ - Stability dressing by pulling the tabs to expose the adhesive and adhere to skin
14. Aspirate slightly for visual confirmation of bone marrow
15. Flush EZ - IO® with normal saline:
  - a. Infant: 2 ml
  - b. Child: 5 ml
  - c. Adult: 10 ml
16. Administer fluids or medications as indicated

#### D. Care and Monitoring of Site

1. Ensure EZ - Stability® dressing is intact
2. Administer medications/fluids as ordered and remember that IO sites have higher resistance to flow
  - a. **Adults:** pressure bag may be required to aid flow of IV fluids
  - b. **Pediatrics and Infants:** must use IV infusion pump device or measure volume in syringe via direct push
3. Use standard flush procedure after medications given via the IO route
4. Monitor limb circulation distal to insertion site and site/limb for other complications:
  - a. Extravasations - improper placement, dislodgement or leakage around IO puncture site results in IV fluids/medications escaping into surrounding tissue resulting in firm swelling near or under insertion site
  - b. Compartment Syndrome - extravasations of large volumes of fluid may result in impaired blood flow and tissue necrosis to limb
  - c. Infection - osteomyelitis, cellulitis, abscesses and septicemia can results from improper aseptic technique and extended time frame of IO use
  - d. Bone injury - IO insertion may produce bone injury. X-ray or IO site or IO puncture attempt site is recommended only if clinical indications of fracture (e.g., decreased movement, limb instability) are present
  - e. Pain - IO insertion produces pain, like the insertion of a peripheral intravenous (PIV) catheter. Localized use of lidocaine at insertion site and for high pressured infusions in conscious patients is recommended. Administration of lidocaine requires an LP order.
5. IO blood can be used for the following laboratory tests: type and screen, electrolytes, chemistries, blood gas values, drug levels, and hemoglobin levels. Specimen samples from the bone marrow have a lower correlation to serum levels after 30 minutes of resuscitation
6. Medication action onset is like IV medications; however, administration via the IO route may result in lower peak serum concentrations versus IV route for certain medications including by not limited to: amphenicol antibiotics, phenytoin, tobramycin, ceftriaxone, and vancomycin
7. All resuscitation medication and fluids (e.g., crystalloids, colloid, Ringer's lactate), contrast, and blood products may by given via IO route. Okay to utilize rapid fluid infusion device through the IO route.

#### E. Intraosseous Catheter Removal

1. Remove dressing and tape from site
2. Remove EZ - Connect®
3. Remove EZ - Stabilizer® adhesive dressing
4. Attach luer-lock syringe to hub of catheter
5. Withdraw the catheter by applying traction and rotating the syringe and catheter **CLOCKWISE** and maintain axial alignment. **DO NOT** rock or bend the catheter.
6. Hold direct pressure on site until hemostasis is achieved
7. Place syringe/catheter in sharps container
8. Cover site with dressing
9. Monitor site for bleeding and signs of infection

#### IV. Documentation

- A. Document date, time, IO site, needle size, name of person performing procedure in the electronic health record (EHR)
- B. Document medications and IV fluids in the EHR
- C. Document removal date, time, person performing in the EHR

All revision dates:

### Attachments

 [IO attachment.docxv2.pdf](#)

### Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	10/20/2025
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	10/20/2025
Policy Owner	Tess Slazinski: Clinical Nurse Specialist, Critical Care	10/20/2025

**Oversight Committee  
Policies and Procedures**

November 13, 2025

**Policies & Procedures**

The following Policies are recommended for approval by the Compliance Committee.

#	Title	Summary	Frequency	Page
1	109-006 Sanctions for Privacy and Security Violations	Moderate reformatting; addition of appendices; rewrite Procedure section supported by appendices to provide guidance for evaluating violations and applying corrective actions; aligned with state and federal regulations, brought up to date with health and safety codes; updated investigation processes to specify coordination among departments; updated language for clarity, consistency and alignment with best practices.	Annual	4
2	109.035 Use of Business Associates Contracts	In concern with Legal, updated Business Associate Addendum to ensure it included language for California requirements and CFR Part 2 redisclosure tracking requirement.	Annual	9
3	109-044 Definition of HIPAA Breach	Expanded to ensure full understanding of definition of “breach” to include federal and California State requirements, including presumption of a breach and four factor risk assessment criteria. Updated formatting and references and reworded to make more readable.	Annual	14
4.	109-047 Unauthorized Use, Access and Disclosure of PHI	Clarified inclusion of Behavioral Health, Reproductive Health, Genetic Information; updated reporting procedures to clarify responsibility across all HCA entities.	Annual	16
5.	109-049 Health Insurance Portability and Accountability Act	Updated references, added CMIA protections regarding AB 81 requirements (Reproductive Health, Immigration Status, and gender affirming care) and required immediate breach reporting, CMIA notification laws, annual training and periodic audits by privacy office, controls for electronic data sharing.	Annual	19

6.	109-051 Patient Refund Policy	Updated references, aligned with California requirements, including Affordable Care Act 60 day payment requirement.	Annual	24
7.	109-057 HCA CIA Certification	No changes	Annual	28



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Owner Rhondi Shannon:  
Compliance Officer  
Policy Area Administrative - Compliance

## 109.006 Sanctions for Privacy and Security Violations

### PURPOSE

The Ventura County Health Care Agency (HCA) is committed to complying with all applicable federal, state, and local laws, statutes, regulatory mandates, and internal policies governing the protection and security of health information. This policy establishes guidelines for the consistent and appropriate application of sanctions upon workforce members and business associates, and other individuals under HCA's control for privacy or security violations involving Protected Health Information (PHI) or other sensitive personal information.

### POLICY

It is the policy of HCA to monitor compliance with privacy and security policies, promptly investigate all suspected or confirmed violations, and mitigate harm to individuals and the organization. HCA shall impose appropriate sanctions on workforce members and business associates who fail to comply with privacy or security requirements under applicable law or policy.

Sanctions will be applied fairly and consistently, taking into account:

- The nature and severity of the violation;
- Whether the violation was intentional, reckless, negligent, or inadvertent;
- The potential or actual harm to the patient, HCA, or others;
- Whether the violation reflects a pattern or repeated behavior; and
- The employee's disciplinary history.

Violations include inappropriate access, use, or disclosure of PHI, including but not limited to medical information protected under the California Confidentiality of Medical Information Act (**CMIA; Cal. Civ. Code §§ 56 - 56.37**), **HIPAA Privacy, Security, and Breach Notification Rules (45 CFR Parts 160 and 164)**, and other applicable laws such as the California Health & Safety Code **§ 1280.15** (unauthorized access, use, or disclosure of medical information), and California Government Code **§ 7284.10** protecting immigration status and sensitive personal information.

## DEFINITIONS

**Agency Workforce:** Includes employees, volunteers, trainees, students, contractors, and other persons whose conduct in the performance of work for HCA is under its direct control, whether or not they are paid directly by the County of Ventura.

**Business Associate:** Any person or entity, including subcontractors, that performs functions or activities involving the use, creation, receipt, maintenance, or transmission of PHI on behalf of HCA, such as data transmission, billing, analytics, or record hosting. (See Appendix A for examples.)

**Privacy or Security Violation:** Any unauthorized access, use, disclosure, alteration, or destruction of PHI or sensitive personal information that violates HCA policy, HIPAA, CMIA, or other applicable laws.

## PROCEDURE

### *Pre Sanction Process*

- **Reporting:** All workforce members must immediately report suspected or actual privacy or security incidents to the Office of Compliance and Privacy (OCP) through the Compliance Helpline or other designated reporting mechanisms.
- **Investigation:** The OCP will review and investigate all reported incidents in accordance with established internal procedures. When a violation is substantiated, OCP will coordinate with Human Resources (HR) and, when applicable, Labor Relations to initiate the appropriate sanction process.
- **Documentation:** The OCP will document investigation findings, corrective actions, and decisions in the Incident Management System and coordinate with HR to ensure proper recordkeeping.

### Employee Sanction Procedure

1. **Fair and Consistent Application:** HR shall apply sanctions uniformly in accordance with County of Ventura Employee Disciplinary Guidelines and Memoranda of Understanding with the County of Ventura. Details can be found here: <http://www.ventura.org/human-resources/memorandums-of-agreement>
2. **Repeat Offense Review:** HR will review the individual's personnel file to assess any past privacy or security violations for the purpose determining sanctions.
3. **Sanction Determination:** HR, OCP, and the individual's manager will collaborate to decide

appropriate sanctions based on violation type, severity, frequency and prior history. See Appendix B and C for examples.

4. **Documentation.** All sanctions will be documented in the employee's personnel file maintained by HR and in the Incident Management System in Compliance.
5. **Exceptions.** No sanctions shall be imposed for disclosures made in good faith under lawful whistleblower protections, including disclosures to regulatory agencies, participation in investigations, or opposition to unlawful practices consistent with 45 CFR § 164.502(j).

## Non-Employee Sanction Procedure

Non-employees including students, volunteers, vendors, contractors, and business associates, are subject to HCA's privacy and security policies, Code of Conduct, and applicable contract provisions.

- Sanctions for non-employees will be determined by HR, OCP, or the applicable department manager on a case-by-case basis.
- Corrective actions may include removal of system access, termination of contract or assignment, retraining, or referral to licensing or regulatory authorities.

## APPENDIX A

### Examples of Business Associate Functions or Activities Regulated by HIPAA

- Patient Safety Organizations
- Health Information Exchanges or Organizations
- E-prescribing Gateways
- Vendors maintaining or hosting PHI (e.g., electronic health record systems, cloud storage)
- Third-party data analytics or billing companies
- Subcontractors handling PHI on behalf of a Business Associate

## APPENDIX B

### Types of Privacy and Security Violations

Type	Description	Example
<b>Accidental / Unintentional</b>	Human error without intent to harm or gain.	Sending PHI to the wrong recipient; failing to log off workstation.
<b>Negligent / Reckless</b>	Failure to follow policy despite prior training or notice.	Sharing passwords; leaving PHI visible or unattended; repeated carelessness.
<b>Willful / Malicious</b>	Intentional or repeated violations for personal, financial, or harmful purposes.	Snooping into records; selling or posting PHI; altering or deleting PHI improperly.



# APPENDIX C

## Examples of Corrective Actions

- Verbal or written warning
- Counseling and retraining
- Formal letter of expectation
- Suspension or wage reduction
- Termination of employment or contract
- Reporting to licensing board or credentialing body
- Reporting to law enforcement or regulatory authorities (e.g., OCR, CDPH)

## REFERENCES

- **HIPAA Privacy Rule:** 45 CFR § 164.530(e)(1)
- **HIPAA Security Rule:** 45 CFR § 164.308(a)(1)(ii)(C)
- **HIPAA Breach Notification Rule:** 45 CFR § 164.400–414
- **California Civil Code § 56 - 56.37** – Confidentiality of Medical Information Act (CMIA)
- **California Health & Safety Code § 1280.15** – Unauthorized Access, Use, or Disclosure of Medical Information
- **California Government Code § 7284.10** - Prohibition on disclosure of immigration status and related personal data.

## All Revision Dates

11/10/2025, 8/18/2025, 6/1/2013, 6/1/2006, 12/1/2004

## Approval Signatures

Step Description	Approver	Date
Oversight Committee	Rhondi Shannon: Compliance Officer	Pending

COPY



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Next Review 3 years after approval

Owner Rhondi Shannon:  
Compliance Officer  
Policy Area Administrative - Compliance

## 109.035 Use of Business Associates Contracts

### POLICY:

Under the Health Insurance Portability and Accountability Act (HIPAA), contracts that are entered into by health care organizations with persons or entities that handle Protected Health Information (PHI) on their behalf must contain certain provisions. These persons or entities are referred to in HIPAA as "business associates."

A "business associate" is any person or entity engaged by the Ventura County Health Care Agency (HCA) that:

- i. Creates, receives, maintains, or transmits individually identifiable health information for a function or activity covered by HIPAA, including claims process or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefits management, practice management and re-pricing, or
- ii. Provides legal, actuarial, accounting, consulting, data aggregation, or financial services, if the provision of services involves the disclosure of individually identifiable health information.

Business associate also includes vendors providing technology, data storage, or cloud services where PHI may be created, received, maintained, or transmitted; even if access is incidental. This includes vendors or contractors defined under **California Civil Code § 56.05(d)** performing services for or on behalf of a provider, regardless of whether PHI access is routine or incidental.

This policy applies to requirements under HIPAA (45 CFR §§164.502(e), 164.504(e), 164.532(d), Subpart C), the HITECH Act (including breach notification requirements under 45 CFR §§ 164.400-414), and California's Confidentiality of Medical Information Act (CMIA, Cal. Civ. Code §56 et seq.). Where state law provides stricter requirements, those standards will apply. For disclosures involving federally

protected substance use disorder information, 42 CFR Part 2 also applies, requiring a Qualified Service Organization Agreement (QSOA) in addition to a HIPAA BAA.

For California residents, breach notification obligations under Cal. Civ. Code § 1798.82 also apply. The definition of “medical information” under Cal. Civ. Code § 56.05(j) includes information such as immigration status and place of birth, consistent with the current language of the Confidentiality of Medical Information Act.

The purpose of this policy is to ensure that contracts with business associates contain provisions required by law and that HCA maintains adequate oversight.

## PROCEDURE:

### General

HCA may disclose PHI to a business associate, or allow a business associate to create, receive, maintain, or transmit PHI on HCA's behalf, only if HCA first obtains adequate written assurances, through a Business Associate Agreement (BAA) or equivalent legally binding instrument, that the business associate will appropriately safeguard the PHI consistent with HIPAA, the HITECH Act, the California Confidentiality of Medical Information Act (CMIA), and other applicable federal and state laws.

All BAAs must be reviewed and approved by Compliance and Legal prior to execution. Any deviation from the standard template must be approved by County Counsel.

This requirement does not apply with respect to:

- i. disclosures made to a health care provider concerning the treatment of the individual; or
- ii. uses or disclosures by a health plan that is a government program providing public benefits if an individual's eligibility or enrollment is determined by another entity and the activity is authorized by law.

If the business associate and HCA are both governmental entities, HCA may comply with this requirement by executing a Memorandum of Understanding (MOU) or similar document covering the required terms, or by relying on other law that imposes equivalent obligations on the business associate.

If the business associate is required by law to perform a function, activity, or service on behalf of HCA, HCA may disclose PHI to the extent necessary to comply with that mandate, provided HCA:

- i. makes a good-faith attempt to obtain the required assurances, and
- ii. documents the attempt and the reasons that such assurances could not be obtained.

If the business associate will have access to information protected under 42 CFR Part 2 (substance use disorder records), a Qualified Service Organization Agreement (QSOA) must also be executed.

When QSOA agreements are required, disclosures and redisclosures must be tracked separately to comply with 42 CFR § 2.32 and § 2.33 restrictions.

All BAAs, MOUs, and related documentation must be centrally tracked by Contracting and retained for at

least six (6) years from the date of creation or last effective date, whichever is later.

Compliance will conduct a biennial review of active BAAs to verify currency, scope, and ongoing applicability.

Disclosures to business associates will be limited to the minimum necessary information required to perform contracted functions. For certain categories of information (e.g., mental health, HIV, reproductive health, substance use disorder), California law may impose stricter standards; HCA must ensure such restrictions are reflected in the BAA.

BAs must implement encryption of all electronic PHI at rest and in transit, unless infeasible, consistent with 45 CFR § 164.312(e) and NIST SP 800-111.

## **Business Associate Agreement Content Requirements**

The agreement between HCA and the business associate must, as applicable:

- Establish permitted and required uses or disclosures of PHI that are consistent with those authorized for HCA, except that the agreement may permit the business associate to use or disclose PHI for its own management and administration and to fulfill any legal responsibilities if such use or disclosure is permitted under applicable law (or, with respect to disclosure, the business associate obtains reasonable assurance that the confidentiality of the PHI will be maintained).
- Require that the business associate will:
  - Not use or disclose PHI except as authorized under the agreement or required by law.
  - Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic PHI, to prevent unauthorized use or disclosure.
  - Report to HCA, without unreasonable delay and in no case later than ten (10) business days after discovery, any unauthorized uses or disclosures of PHI, including breaches of unsecured PHI as required by 45 CFR §164.410, and any Security Incident of which the business associate becomes aware. In no event shall reporting exceed ten (10) business days from discovery, and HCA may require shorter timeframes for vendors supporting high-risk systems or functions.
  - Pass on, in writing, the same obligations relating to protection of PHI to the business associate's employees, representatives, agents, and subcontractors, including compliance with HIPAA, HITECH, CMIA, and applicable breach notification laws. Subcontractors must agree in writing to the same restrictions, safeguards, reporting timelines, and audit rights that apply to the business associate.
  - Make PHI available for access by the individual who is the subject of the PHI, in accordance with HIPAA, CMIA, and applicable HCA policy.
  - Incorporate any approved amendments to PHI, and maintain documentation of such

amendments, in accordance with HIPAA, CMIA, and applicable HCA policy.

- Provide an accounting of disclosures as required by HIPAA, HITECH, and HCA policy, including disclosures made through subcontractors.
- Comply with the requirements of Subpart E of 45 CFR Part 164 that apply to HCA, to the extent the business associate carries out one or more of HCA's obligations under Subpart E.
- Make its internal practices, books, records, and system access logs relating to PHI available to HCA during normal business hours, or to the Secretary of HHS upon request, for compliance review. HCA reserves the right to audit the business associate's relevant security and privacy practices, directly or through an independent third party, on reasonable notice.
- If feasible, return or destroy all PHI upon termination of the agreement. If return or destruction is not feasible, the business associate must document the reasons and continue to extend full protections to the PHI for as long as it is retained.
- Cooperate fully with HCA investigations, audits, or breach remediation activities, including providing root-cause analyses and corrective action plans when requested.
- Authorize immediate termination of the agreement by HCA if the business associate violates a material term. If termination is not feasible due to patient care or operational needs, HCA must document the reasons and report to HHS as required under 45 CFR §164.504(e)(1)(ii).

## **Oversight Responsibilities**

Contracting will maintain the centralized repository and tracking matrix of all Business Associate Agreements (BAAs). Contracting is responsible for re-reviewing BAAs with Compliance and/or Legal upon contract renewal, vendor scope changes, or when advised by Compliance or Legal due to regulatory or policy updates.

Compliance will periodically audit the repository to verify that all required BAAs are in place, current, and compliant with applicable federal and state requirements. Legal will review any deviations from the approved BAA template or material amendments to ensure continued compliance with HIPAA, HITECH, CMIA, and 42 CFR Part 2.

If HCA knows of a pattern or practice by a business associate that amounts to a material violation, HCA must make a good-faith effort to cure the violation. If such effort is unsuccessful, HCA must terminate the agreement. If termination is not feasible, HCA must document the reasons, mitigate the risk to the greatest extent possible, and report to HHS as required.

## **Retention**

All BAAs, MOUs, and related documentation must be retained for at least six (6) years from the date of creation or last effective date, whichever is later.

## All Revision Dates

11/10/2025, 9/1/2013, 6/1/2006

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## Attachments

 [VCHCA BAA\\_TEMPLATE.docx](#)

## Approval Signatures

Step Description	Approver	Date
Oversight Committee	Rhondi Shannon: Compliance Officer	Pending
Compliance & Privacy Office	Rhondi Shannon: Compliance Officer	11/10/2025

COPY



Origination	12/30/2024
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Next Review	3 years after approval

Owner	Rhondi Shannon: Compliance Officer
Policy Area	Administrative - Compliance

## 109.044 Definition of HIPAA Breach

### POLICY:

The Ventura County Health Care Agency (HCA) is committed to protecting and safeguarding the privacy and security of patients' Protected Health Information (PHI). HCA will comply with all applicable federal and state laws regarding the definition and notification of breaches involving PHI.

The purpose of this policy is to define what constitutes a breach under the Health Insurance Portability and Accountability Act (HIPAA) and the California Health and Safety Code (HSC).

### Applicable Laws and Regulations

- 45 CFR Parts 160 and 164 (Subparts C, D, and E)
- California Health & Safety Code §1280.15 (b)–(c)

### DEFINITIONS

#### Breach (HIPAA):

A *breach* is the acquisition, access, use, or disclosure of PHI in a manner not permitted by the HIPAA Privacy Rule that compromises the security or privacy of the PHI.

There is a *presumption of breach* unless a documented risk assessment demonstrates a low probability that the PHI has been compromised. The assessment must consider:

1. The nature and extent of the PHI involved, including the types of identifiers and likelihood of re-identification;



2. The unauthorized person who used or received the PHI;
3. Whether the PHI was actually acquired or viewed; and
4. The extent to which the risk has been mitigated.

**Breach (California Health & Safety Code §1280.15):**

A *breach* means any unlawful or unauthorized access to, use, or disclosure of patient medical information maintained by a health facility, clinic, or health care provider.

**Exceptions (HIPAA):**

A breach does **not** include the following:

- Unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of a covered entity or business associate, if done in good faith and within the scope of authority.
- Inadvertent disclosure of PHI from one authorized individual to another within the same covered entity or organized health care arrangement, if both are authorized to access the information.
- Situations in which the covered entity or business associate has a good faith belief that the unauthorized person to whom the PHI was disclosed would not reasonably have been able to retain the information.

See Administrative policy 109.047 - Unauthorized Use, Access and Disclosure of Protected Health Information (PHI) Breach

## All Revision Dates

10/17/2025, 12/30/2024

## Approval Signatures

Step Description	Approver	Date
Oversight Committee	Rhondi Shannon: Compliance Officer	Pending
Compliance & Privacy Office	Rhondi Shannon: Compliance Officer	10/17/2025



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Last Approved N/A

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Next Review 1 year after approval

Owner Rhondi Shannon:  
Compliance  
Officer

Policy Area Administrative -  
Compliance

## 109.047 Unauthorized Use, Access and Disclosure of Protected Health Information (PHI)

### POLICY

Ventura County Health Care Agency (HCA) has the responsibility to safeguard Protected Health Information (PHI) and to ensure that its workforce is knowledgeable regarding unlawful access, use or disclosure of PHI.

It is unlawful to view ("glance"), review, use, or disclose a patient's PHI without a direct need for purposes of treatment, payment, or healthcare operations or other lawful use, as required by a staff member's job duties and as permitted by the Health Insurance Portability and Accountability Act (HIPAA), the California Medical Information Act (CMIA; Cal. Civ. Code § 56 et seq), and other applicable laws.

Such improper activity constitutes a **privacy breach**. HCA is required to notify the affected individual(s) and, when applicable, the California Department of Public Health (CDPH) and the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

It is the responsibility of HCA and all members of its workforce, business associates, contractors, and volunteers to protect and safeguard PHI, including all sensitive medical information protected by law, such as HIV test results, genetic data, reproductive health information, mental health and substance use disorder (SUD) treatment records, immigration status, place of birth, and to prevent unlawful or unauthorized access as required by state and federal laws and internal policies.

### PROCEDURE

Authority for the release of PHI rests with the Health Information Management (HIM) Manager or

designee, guided by HIPAA regulations, applicable federal and state privacy laws, and HCA's Privacy Policies and Procedures regarding the Use and Disclosure of PHI.

All HCA workforce members you are required to follow this policy.

Workforce members may not directly access their own PHI via the Electronic Health Record (EHR) system or request another person to do so without following the procedures outlined in the HIM Policy HIM.10 Patient Right to Access, Inspect and Copy Protected Health Information (Patient Access to Medical Records).

Refer to HIM Policy [HIM.10](#) for instructions on obtaining copies of PHI with the appropriate authorization.

## Examples of Unauthorized Access, Use, or Disclosure

Through any media or platform (paper, electronic, oral, or visual), unauthorized actions include but are not limited to:

- Accessing or viewing one's own PHI without following HIM Policy [HIM.10](#).
- Accessing PHI of family members, friends, or coworkers without a treatment or operational need.
- Accessing, using, or disclosing PHI for a patient no longer under your care.
- Viewing or sharing PHI for reasons unrelated to treatment, payment, or operations, or without proper authorization.
- Discussing PHI in public areas, hallways, or elevators.
- Sending PHI to an incorrect recipient via fax, email, or text.
- Sharing PHI for personal gain or in exchange for remuneration.
- Using or disclosing PHI related to **behavioral health, HIV status, reproductive health, genetic testing, immigration status, or place of birth** without proper authorization or legal basis.

## Sanctions for Violations

Due to the sensitive nature of PHI, significant federal and state sanctions may apply to individuals and organizations for non-compliance.

Violations may result in disciplinary action, up to and including termination, and may carry civil and criminal penalties under HIPAA, CMIA, or 42 CFR Part 2.

## Reporting Unauthorized Access, Use, or Disclosure

All HCA workforce members must **immediately report** any actual or suspected unauthorized access, use, or disclosure of PHI, whether intentional or accidental **within 24 hours** to:

1. **Office of Compliance and Privacy** – (805) 677-5241

2. **Compliance & Privacy HelpLine** – 1-833-823-6631 (anonymous reporting available)
3. **Their supervisor or manager**

Failure to report may itself result in disciplinary action.

The Office of Compliance and Privacy will investigate, document findings, determine whether a breach occurred under HIPAA or CMIA, and coordinate any required patient and regulatory notifications.

## Behavioral Health and 42 CFR Part 2

For Behavioral Health programs, confidentiality requirements under **42 CFR Part 2** apply in addition to HIPAA and CMIA. PHI related to substance use disorder treatment cannot be disclosed without explicit patient consent, court order, or other legal exception.

## REFERENCES

- 45 CFR Parts 160 and 164 (HIPAA Privacy, Security, and Breach Notification Rules)
- California Civil Code §§ 56–56.37 (Confidentiality of Medical Information Act)
- California Health & Safety Code § 1280.15 (Health Facility Breach Reporting)
- California Constitution, Article I, § 1 (Right to Privacy)
- 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records)
- See Privacy policies 109.006, 109.044.

## All Revision Dates

11/10/2025, 4/22/2025, 2/11/2019, 9/1/2013

## Approval Signatures

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Oversight Committee	Rhondi Shannon: Compliance Officer	Pending
Compliance & Privacy Office	Rhondi Shannon: Compliance Officer	11/10/2025



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Owner	Rhondi Shannon: Compliance Officer
Policy Area	Administrative - Compliance

## 109.049 Health Information Portability and Accountability Act (HIPAA)

### POLICY:

Under the Health Insurance Portability and Accountability Act (HIPAA) and the California Confidentiality of Medical Information Act (CMIA), health care organizations must limit the use and disclosure of Protected Health Information (PHI) and Electronic PHI (ePHI) (referred to as sensitive data) to the minimum necessary to accomplish the intended purpose.

Under the California Confidentiality of Medical Information Act (CMIA), medical information includes reproductive health data, immigration status, place of birth, and gender-affirming care information. These categories must receive heightened protection and may not be disclosed without patient authorization or other legal authority.

The purpose of this policy is to ensure that all uses, disclosures, and requests for PHI and ePHI with applicable Federal and State privacy and security laws, including 45 CFR Parts 160 and 164 (Subparts A, C, and E), California Civil Code §§ 56–56.37 (CMIA), and Welfare & Institutions Code § 5328 regarding the confidentiality of behavioral health and mental health information.

This policy applies to all divisions, programs, and workforce members of the Ventura County Health Care Agency (HCA), including Ventura County Medical Center, Santa Paula Hospital, Ambulatory Care, Behavioral Health, and Managed Care, as well as all contractors, volunteers, students, and affiliates performing work on behalf of HCA.

# PROCEDURE:

When using, disclosing, or requesting PHI from from another entity, HCA will make reasonable efforts to limit the information to the minimum necessary to accomplish the intended purpose, unless an express regulatory or statutory exemption applies.

## Exceptions for Minimum Necessary Standard

- Disclosures to or requests by a health care provider for treatment purposes
- Disclosures to the patient or personal representative
- Uses or disclosures made pursuant to a valid patient authorization
- Disclosures required by law or for HIPAA administrative compliance
- Disclosures to the Department of Health and Human Services (HHS) for enforcement
- Court orders, subpoenas, or authorized investigative demands consistent with law
- Disclosures to public health authorities as permitted under 45 CFR §164.512(b) and California law

## PROCESS:

1. Identify categories of PHI and ePHI needed by each workforce member or role, and limit access to the minimum necessary to perform assigned job duties.
2. Limit the access of persons, or classes of persons, to only that portion of PHI/ePHI that is needed to perform their job duties. Facilities are to minimize physical access, such as isolating and locking file cabinets or records rooms, or providing additional security. Workforce members are not permitted to share passwords or to leave their workstation when access would be made available to other persons, etc.
3. The Privacy Office and HCA IT will make the final determination of appropriate access by employee classification/title/job function/organization. Access determinations must align with role-based access controls established under the HIPAA Security Rule (45 CFR §164.308(a)(4)) and are reviewed at least annually or upon change in role, termination, or transfer.
4. Regardless of their role or level of access, workforce members may only access, use, or disclose PHI necessary to perform their assigned job duties in connection with the care or services they are responsible for providing.
5. Accessing or viewing PHI for patients not under their direct care, or for personal reasons (including information about yourself, friends, relatives, coworkers, or public figures), is strictly prohibited and may result in disciplinary action up to and including termination.
6. Behavioral Health and Substance Use Disorder records are subject to additional confidentiality requirements under California Welfare & Institutions Code §5328 and 42 CFR Part 2. These records must be restricted to authorized treating providers and may not be accessed, viewed, or disclosed without the patient's specific written consent, except as permitted by law. Information systems containing such records must include separate access controls or other safeguards to prevent unauthorized access.



7. HCA will only use, disclose, or request an entire medical record when the entire medical record is specifically justified as being reasonably necessary to accomplish the purpose of the use, disclosure or request. The following categories of employees are permitted unrestricted access to protected healthcare information for the purpose of providing patient care:
  - a. Attending physician (resident)
  - b. Attending physician assistant
  - c. Attending nurse practitioner
  - d. Consulting physicians (medical, surgical and specialists)
  - e. Nursing personnel to include registered and licensed nurses, students
  - f. Respiratory therapy practitioners,
  - g. Rehabilitation therapists
8. The following categories of the workforce are permitted limited access with supervision to confidential healthcare information for the purpose of providing an element of patient care:
  - a. Laboratory personnel: laboratory records, order entry, pharmacy
  - b. Radiology personnel: radiology records, order entry
  - c. Pharmacy personnel: medication history, laboratory, nursing, order entry
  - d. Social Services personnel: socioeconomic information and history, nursing
  - e. Dietary personnel: socioeconomic information and history, laboratory, pharmacy, nursing
  - f. Billing/Accounts Payable personnel: demographic and insurance information to include name, address, city, state, zip code, telephone number, insurance carrier, social security number, date of birth, medical record number, ancillary reports when necessary.
9. Minimum Necessary Uses, Disclosures, or Requests Involving Outside Party
  1. Determine whether the minimum necessary standard applies to the use, disclosure or request for protected health information. De-identified health information, as described in the Privacy Rule, is not PHI, and thus is not protected by the Privacy Rule.
  2. For all uses, disclosures, or requests, for which the minimum necessary standard applies:
    - a. Identify routine and recurring disclosures of information by HCA (for example, claims processing) and requests for information by HCA and determine the minimum necessary amount of information required to accomplish the purpose of the disclosure. Implement methods of separating this information from the remainder of the record. Identify the justification when access to the entire medical record is needed.
    - b. Electronic data sharing and automated disclosures (including API connections, data exports, and third-party integrations) must also comply with the minimum necessary rule. Bulk or full-record extractions must be justified in writing and approved by the Privacy Office. All access and

disclosures must be auditable and logged in accordance with HIPAA Security Rule requirements (45 CFR §164.312(b)).

- c. For all non-routine disclosures by HCA of protected health information the Privacy Official will review, on an individual basis, the request or disclosure to ensure that minimal necessary PHI will be disclosed.
  - d. In certain circumstances, the Privacy Rule permits a covered entity to rely on the judgment of the party requesting the disclosure as to the minimum amount of information that is needed. Such reliance must be reasonable under the particular circumstances of the request. This reliance is permitted when the request is made by:
    - Other covered entities (health plans, health care providers, health care clearinghouses) for treatment;
    - A public official or agency who states that the information requested is the minimum necessary for a purpose permitted under 45 CFR 164.512 of the Rule, such as for public health purposes (45 CFR 164.512(b));
    - Research:
      - PHI may be used and disclosed for research with an individual's written permission in the form of an Authorization.
      - PHI may be used and disclosed for research without an Authorization in limited circumstances: Under a waiver of the Authorization requirement, as a limited data set with a data use agreement, preparatory to research, and for research on decedents' information.
  - e. Disclosures to the individual who is the subject of the information
  - f. Uses and disclosures made pursuant to an individual's authorization
- 3. Subpoena and/or Court orders will be handled in accordance with current state laws and requested information will be supplied appropriate to that order.
  - 4. Business Associates are required to establish protocols that define the minimum necessary PHI for routine uses, disclosures and requests, and how to apply the minimum necessary standard with respect to non-routine uses, disclosures and requests.
  - 5. Any suspected or confirmed unauthorized access, use, or disclosure will be reported to the Privacy Office immediately. The Privacy Office will determine whether notification is required under the HIPAA Breach Notification Rule (45 CFR §§164.400–414) and the California Civil Code §§1798.29 and 1798.82.
  - 6. The Privacy Office shall review workforce access determinations at least annually and conduct periodic audits to verify appropriate access levels. All workforce members must complete annual HIPAA and CMIA privacy training, which includes reinforcement of the minimum necessary rule and confidentiality of behavioral health information.



**NOTE:** The rule does not require such reliance, however, and the covered entity always retains discretion to make its own minimum necessary determination for disclosures to which the standard applies.

## References:

**45 CFR 164.514(d)(1) (Minimum Necessary Standard)**

**California Civil Code §§56–56.37 (Confidentiality of Medical Information Act)**

**Welfare & Institutions Code §5328 (Behavioral Health Confidentiality)**

See also policy [100.019 Release of Patient Information](#).

## All Revision Dates

11/5/2025, 10/5/2022, 5/1/2013, 6/1/2006

## Approval Signatures

### Step Description

### Approver

### Date

Oversight Committee

Rhondi Shannon: Compliance  
Officer

Pending

Compliance & Privacy Office

Rhondi Shannon: Compliance  
Officer

11/5/2025



Origination 4/1/2000  
Last Approved N/A  
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Next Review 1 year after approval

Owner Rhondi Shannon:  
Compliance Officer  
Policy Area Administrative - Compliance

## 109.051 Patient Refund Policy

### POLICY

It is the policy of Ventura County Health Care Agency (HCA), including Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), to ensure that all patient account credit balances and overpayments are accurately identified, verified, and refunded promptly in accordance with applicable federal and state laws, payer contract requirements, and internal financial controls.

HCA is committed to maintaining transparent, compliant refund processes that safeguard patient and payer funds and ensure accurate financial reporting.

### PROCEDURE

#### 1. Identification of Overpayments

All patient accounts must be routinely reviewed to identify credit balances that may result from:

- Duplicate or incorrect payments by patients, guarantors, or payors.
- Coordination of benefits issues or retroactive coverage changes.
- Incorrect contractual adjustments or claim processing errors.
- Misapplied payments, erroneous postings, or other billing discrepancies.

#### 2. Timeframes for Refunds

- Verified overpayments must be refunded **within sixty (60) days** from the date the overpayment is identified, consistent with **42 U.S.C. §1320a-7k(d)** (the federal 60-day repayment rule) and applicable **California law**.

- Refunds to government or commercial payors must also comply with each payor's specific refund and reporting requirements.
- No credit balance shall remain unresolved beyond required timeframes without written justification and approval from the **Chief Financial Officer (CFO)** or designee.

### 3. Research and Verification

- Credit balances shall be researched by Patient Financial Services to confirm the validity of the overpayment before any refund is issued.
- Adjustments may be made when the credit is due to data entry, posting, or contractual errors.
- Documentation supporting the cause of the overpayment and its resolution shall be retained in the patient's financial record.

### 4. Refund Processing

- Once verified, overpayments shall be refunded to the appropriate party (patient, guarantor, or third-party payor).
- Refunds shall be issued through approved accounting methods (e.g., check, electronic payment, or payor offset).
- Each refund shall be documented in the billing system and reconciled to ensure proper accounting.

### 5. Medicare, Medi-Cal, and TRICARE Requirements - For Medicare, Medi-Cal, and TRICARE accounts, credit balance reporting and refund processing must comply with each program's specific rules and timeframes, including:

- Submission of required **credit balance reports** (e.g., **CMS-838**) on a quarterly basis.
- Adherence to any payor-initiated adjustments, take-backs, or recoupments required to resolve overpayments.
- Prompt reporting and refund of overpayments identified through internal review, payor notification, or audit.

### 6. Monitoring and Oversight

- The **Patient Financial Services Manager** shall maintain a **Credit Balance Log** to track refund requests, processing dates, payor type, and completion status.
- The log shall be reviewed monthly for timeliness and accuracy.
- A summary of refund activity and any identified trends shall be reported quarterly to the **Chief Financial Officer (CFO)** and the **Compliance Committee**.
- Any unusual patterns or high-risk areas shall be investigated in collaboration with the **Office of Compliance and Privacy (OCP)**.

### 7. Documentation and Record Retention

- All refund records, supporting documentation, and correspondence shall be retained for **a minimum of seven (7) years**, or longer if required by law, regulation, or contract.
- Records must be made available for review by auditors, CMS, DHCS, or other

regulatory agencies upon request.

#### 8. Compliance and Reporting

- Failure to identify, report, or refund known overpayments within the required timeframe may result in non-compliance with federal or state law.
- Employees must immediately report any suspected improper retention of funds or other irregularities to the **Office of Compliance and Privacy** or through the **Compliance Hotline (1-833-823-6631)**.
- Violations of this policy may result in corrective or disciplinary action consistent with **Policy 109.006 – Sanctions for Privacy and Security Violations**.

## REFERENCES

- **2 U.S.C. § 1320a-7k(d)** – Reporting and Returning of Overpayments (Affordable Care Act § 6402(a))
- **42 C.F.R. § 401.305** – Requirements for Reporting and Returning of Overpayments
- **CMS Medicare Financial Management Manual (Pub. 100-06), Ch. 3** – Overpayments and Credit Balance Reporting
- **CMS Form 838** – Medicare Credit Balance Report (Quarterly Submission Requirement)
- **California Welfare and Institutions Code § 14115.5** – Medi-Cal Overpayments and Recovery
- **California Health & Safety Code § 1280.15** – Facility Responsibilities Related to Disclosure and Accountability
- **California Code of Regulations, Title 22, § 70713** – Fiscal Management Requirements for Hospitals
- **TRICARE Operations Manual, Chapter 10, Section 3** – Recoupment and Refunds
- **OIG Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987, Feb. 23, 1998)** – Recommended Internal Controls and Refund Processes
- **DHCS Provider Manual and Medi-Cal Managed Care Contract Requirements** – Obligations for Prompt Return of Overpayments
- **Healthcare Financial Management Association (HFMA) Best Practices** – Credit Balance Monitoring and Refund Controls

## All Revision Dates

11/10/2025, 6/23/2024, 9/28/2018

## Approval Signatures

Step Description	Approver	Date
Oversight Committee	Rhondi Shannon: Compliance Officer	Pending
Compliance & Privacy Office	Rhondi Shannon: Compliance Officer	11/10/2025

COPY



Origination 8/1/2022  
Last Approved N/A  
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Next Review 1 year after approval

Owner Rhondi Shannon:  
Compliance Officer  
Policy Area Administrative - Compliance

## 109.057 HCA Corporate Integrity Agreement Certification

### SCOPE

This policy is applicable to all Ventura County Health Care Agency (HCA) Certifying Employees as defined.

### PURPOSE

To define the process required for Certifications for each of the five annual Reporting Periods under the "Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Ventura County (CIA)".

### DEFINITIONS

- A. **"Certifying Employees"** means certain Ventura County employees who are expected to monitor and oversee activities within their areas of authority. This includes, at minimum, HCA Director, Ventura County Medical Center (VCMC) Chief Executive Officer, VCMC Chief Financial Officer, VCMC Chief Operating Officer, Ventura County Chief Executive Officer, HCA Chief Financial Officer and the HCA Compliance Officer as well as other members of senior management with operations that are related to Federal health care programs as defined by the CIA dated August 11, 2022.
- B. **"Certification"** means a written assurance provided by each Certifying Employee that includes:
1. *"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department] with all applicable Federal health care program"*

*requirements, requirements of the Corporate Integrity Agreement, and Ventura County Health Care Agency policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Ventura County Health Care Agency is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."*

- C. **"Reporting Periods"** means each of the five annual periods following the effective date of the CIA.

## POLICY

Certifying employees will complete the Corporate Integrity Agreement (CIA) Certification for each of the five Reporting Periods as required within the specified timeframe. To complete the Certifications, all Certifying Employees must follow the procedure outlined by this Policy.

## PROCEDURE

- A. Certifying Employees must submit completed Certifications to HCA Compliance Officer within a reasonable time after the end of each annual Reporting Period.
- B. If at any time during the Reporting Period, a Certifying Employee becomes aware of any issue that would hinder their ability to complete the Certification, HCA Compliance Officer will be notified immediately.
- C. To ensure the Certification is accurate and complete, the Certifying Employees should take the following steps for their areas of responsibility, as applicable:
1. Determine the individuals for which you will require a sub-certification. At a minimum, sub-certifications should be obtained from individuals with either departmental supervisory responsibilities or whose work has a direct impact on any of the specific areas covered by the CIA, including coding and billing. The sub-certification should state the following:
    - a. *"I have been trained on and understand the compliance requirements of the Corporate Integrity Agreement as it relates to my job responsibilities. To the best of my knowledge:*
    - b. ☐ *Ventura County Health Care Agency and Ventura County Medical Center (VCMC) are in compliance with all applicable Federal Healthcare Program requirements and the obligations of the Corporate Integrity Agreement; or,*
    - c. ☐ *I have disclosed the following matters for investigation and follow-up:*  

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    - d. *I understand that this certification is being provided to and relied upon by [insert name and title of Certifying Employee]."*
- D. Certifying Employees will review reports to ensure Covered Persons are compliant with the training requirements of the HCA and VCMC CIA.

- E. Certifying Employees will review the results of any internal or external audits along with corrective action plans, including validating that any Overpayments are refunded.
- F. Certifying Employees will review any disciplinary actions taken related to compliance.
- G. Certifying Employees will review disclosures including those received through the HCA Compliance Line and related corrective actions for any identified issues or questions associated with HCA or VCMC policies, procedures, or practices with respect to Federal or State Healthcare Programs.
- H. Other information, as applicable, may be added to certification review materials to ensure a comprehensive review.

## REFERENCES:

"Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Ventura County California dated August 11, 2022.

### All Revision Dates

6/23/2024

### Attachments

[Attachment A.docx](#)

[Attachment B.docx](#)

### Approval Signatures

Step Description	Approver	Date
Oversight Committee	Rhondi Shannon: Compliance Officer	Pending
Compliance & Privacy Office	Rhondi Shannon: Compliance Officer	10/14/2025