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

Ventura County Health Care System Oversight Committee
Administrative Policies
October 12, 2023

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

1. 100.011 Hospital Visitation
2. 107.013 Record Retention
3. 108.002 Education Policy and Procedure
4. EVS.38 Cleaning of Refrigerators, Microwaves, and Ice Machines
5. IS.24 Lead Apron and Glove Survey
6. IS.58 Request for Outside Images
7. PH.31 Drug Packaging
8. PH.99 Pyxis CII-Safe (Narcotic Vault) Control Station
9. PH.81 Pharmacy Operations During Electronic Health Record Downtime
10. Elements Of The Psychosocial Assessment

Status **Active** PolicyStat ID **13943665**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	11/22/2017	Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices
Last Approved	7/6/2023		
Effective	7/6/2023		
Last Revised	7/6/2023	Policy Area	Administrative - Operating Policies
Next Review	7/5/2026		

100.011 Hospital Visitation

POLICY:

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

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

PROCEDURE:

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

HOSPITAL VISITATION GUIDELINES

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

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

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

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

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

E. Service animals will continue to be allowed entrance.

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

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

G. Shoes and shirts are required for all visitors.

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

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

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

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

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

M. Neonatal Intensive Care Unit (NICU)-We invite parent participation in the NICU Unit. Parents will be required to wear their identification armband when visiting. One parent may stay with the patient at all time as space allows. Grandparents or other significant adult(s) may visit with a parent unless otherwise specified. See policy *P.32 PICU, NICU and PEDS Visiting Policy* for more information.

N. Emergency Department

    1. No children under the age of 13 unless they are the patient, the parent of a patient, or the support person of a pregnant person.
    2. Children must be accompanied by an adult, when in the ED or the waiting room.
    3. In critical situations, family members can stay at bedside at the nurse's discretion.
    4. The Quiet Room may be utilized for families in critical situations.
    5. To provide a safe environment, visitors are asked to refrain from multiple entries and

exits from the patient care area.

6. The ED is not to be used as a thoroughfare to other areas of the hospital. Visitors should use an alternate entrance to gain entry into the hospital, with the exception of off hours when the front lobby is closed.
7. Visitation for ED Hold patients will follow the rules for visitation in the ED.

O. Obstetrics Unit

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

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

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

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

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

The VCMC entrance will be open daily from 5:00 am until 9:00 pm. The Customer Service desk at VCMC will be staffed by one to two Security Guards 24 hours a day, 7 days a week, as well as a Customer Service employee from 5:00 am to 9:00 pm. At SPH the entrance will be open from Monday through Friday 6:30 am to 9:00 pm and Saturday through Sunday 8:30 am to 6:30 pm. Entrance can be gained through the Emergency Department when the front lobby is closed.

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

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

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

VCMC Loma Vista MRI Trailer Entrance. This entrance will be designated for staff only via badge

access. No patients or visitors will be permitted to enter the Hospital through this entrance. Staff may enter through this entrance 24 hours a day, 7 days a week.

VCMC Radiology Entrance. This entrance is closed to everyone.

VCMC Ortho Clinic Entrance. This entrance is closed to everyone.

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

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

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

REFERENCE:

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

All Revision Dates

7/6/2023, 3/8/2023, 11/22/2017

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	7/6/2023
Policy Owner	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/6/2023

Status **Active** PolicyStat ID **13843847**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	5/1/1983	Owner	Mary Jane Green: HIM Manager
Last Approved	7/5/2023	Policy Area	Administrative - Operating Policies
Effective	7/5/2023		
Last Revised	7/5/2023		
Next Review	7/4/2026		

107.013 Record Retention

POLICY:

It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) to retain all hospital records in accordance with California legal requirements, Administrative Codes 22 and 17 and The Welfare and Institution Code, as well as the Code of Federal Regulations (CFR). See **Guide to Record Retention**, published by the California Association of Hospitals and Health Systems for further information.

Patient medical records shall be retained in accordance with California Administration Code, Title 22, as follows:

Title 22 CCR § 72543 (a) states that "All health records of discharged patients shall be completed and filed within 30 days after discharge date and such records shall be kept for a minimum of 7 years, except for minors whose records shall be kept at least until 1 year after the minor has reached the age of 18 years, but in no case less than 7 years. All exposed X-ray film shall be retained for seven years."

Due to space constraints, less active records are stored off-site and retrieved as needed. The storage facility will be decided at the time, when the operation of specific services has ceased.

Guidelines for retention of other hospital records, by department, are as follows. Please refer to the **Guide to Hospital Records Retention**, on file in the Health Information Management Department, for a more inclusive list. All time periods represent at least the minimum required retention time established, as required by The Joint Commission (TJC), Centers for Medicare and Medicaid Services (CMS), California Department of Public Health (CDPH), College of American Pathologists and any other accreditation agency.

1. **Administration**

Insurance Policies, expired	Permanent

Physician Contracts	3 Years after termination
Grants & Consultant Reports	6 Years
Incident Reports (Notification System)	6 Years
Annual Reports to Government Agencies	Permanent
Reports of Unusual Occurrence	2 Years
Blueprints	Permanent
Minutes of Administrative Meetings	2 Years
Licensing & Inspection Reports	3 Years
Census (daily)	6 Years
2. Admitting	
Admission and Discharge Reports (Census)	6 years
3. Business Office	
Cash Receipts/Canceled Checks	6 Years
Rate Schedules	2 Years
4. Cardiology	
EKG & EEG Tracings	10 Years (except for minors)/19 years (retain only those rare and unusual portions which are specifically selected by the physician to accompany the report in the patient's Electronic Health Record (EHR))
5. Central Supply	
Sterilizers/Monthly Bacteriology Tests	3 Years
Appointment Books	2 Years
6. Clinics	
Appointment Books	2 Years
7. Dietary	
Menus	3 Months
Meal Counts/Food Costs	2 Years
8. Engineering/Maintenance	
Calibration Records	6 Years
Sterilization/Monthly Bacteriological Tests	3 Years
Thermometer Charts	3 Years
9. Family Care Same as Medical Records	
10. Fetal Heart Monitoring Strips	
Tracings	10 years

11. Housekeeping	
Exterminator Records	6 Years
12. Laboratory	
Blood Donor Histories	10 Years (except for minors)/19 years
Cytology Slides	5 Years
Cytology Reports	20 Years
Equipment Inspection, Validation, Calibration, Repair and Replacement Records	2 Years
Pathology Reports and Slides	20 years
Unusual Path. Reports and Slides	Permanent
Procedure Manual	2 Years
Specimen Records	6 Years
13. Medical Records	
Index to Patient's Medical Records	10 Years (except for minors)/19 years
Patient's Medical Records	Adults: 10 Years following discharge Active/In Hospital - 3 Years
Inactive/Off-site Storage --	4 Years
Minors:	At least one year after they have attained the age of 18 years of age, but no less than 10 years after discharge
Death Certificates/Logs	Permanent
Family Care Clinic Records	Same as above
ER Logs	6 years
Diagnostic, Procedural & Physician Indices	Permanent
Blood Alcohol Reports	10 Years
Medicolegal Exams	Adults: 10 Years Minors: At least one year after they have attained the age of 18 years of age, but no less than 10 years after discharge.
CD for Outside Records	1 year
14. Medical Staff Records	
Medical Staff Committee Minutes & Records	Permanent
Physician Credential Files	Permanent
15. Medicare & Medi-Cal Records	
Billing Materials/Cost Reports	5 Years

16. Nuclear Medicine	
Calibration Records	3 Years
Exposure Records	Permanent
Film Body Records	6 Years
17. Nursing	
Personnel Records-Staffing (Including Schedules/Time Records	6 Years after termination
Staffing Data Sheets	18 months
Nursing Assignment Sheet	3 years
Surgery – Register of Operations	6 years
Emergency Room Log	6 years
Delivery Room Log	6 years
ICN Log	6-10 years
Transfer Log	3 years
Unit Meeting Minute	3 years
Nursing Management Minutes	3 years
18. Personnel	
Employee Health Records	Duration of employment plus 30 Years
Employee Personnel Records	3 Years after termination
Collective Bargaining Records	5 years
19. Pharmacy	
Record of Drug dispensed for each patient	3 Years
Controlled Substance Dispensed	7 Years
Radioactive Drugs	3 Years
20. Public Relations/Development	
Contributors Records & Historical Clippings	Permanent
21. Purchasing/Accounting	
Purchase Requisitions & Purchase Orders	2 Years
For Major Purchases	3 - 5 Years
22. Radiology	
X-Ray Films Mammography	Adults: 10 Years Minors: At least one year after they have attained the age of 18 years of age, but no less than 10 years after discharge

	Forever
23. Individual Departments	
Budget/Correspondence/Memos	2 Years
Procedure Manuals (Outdated)	6 Years
Employee Schedules & Time Records	6 Years
Employee Signatures (Patient Care Areas)	6 Years
Department Meeting Minutes	2 Years

All Revision Dates

7/5/2023, 2/23/2021, 5/1/2006, 7/1/1995, 8/1/1992, 5/1/1986

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Diana Zenner: Chief Operating Officer, VCMC & SPH	7/5/2023
Policy Owner	Mary Jane Green: HIM Manager	6/20/2023

Status **Active** PolicyStat ID **13930310**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	9/1/1998	Owner	Sharon Waechter: Clinical Nurse Manager, Nursing Education
Last Approved	7/13/2023		
Effective	7/13/2023	Policy Area	Administrative - Nursing
Last Revised	7/13/2023		
Next Review	7/12/2026		

108.002 Education Policy and Procedure

POLICY:

The mission of the Education Department is to provide quality educational opportunities for employees in a cost-effective manner. The Education Department will assist in the maintenance and improvement to the foundation of healthcare by providing staff with educational opportunities to sustain and improve their practice. Assists to facilitate the provision of patient/family diabetes education in order to improve patient health outcomes.

PROCEDURE:

The Education Department is responsible for the following core functions:

1. Ensuring nursing and nursing support staff receive mandated and regulatory education.
2. Tracking education provided to ancillary departments as needed for regulatory compliance.
3. Ensure newly hired staff (including temporary staff) receive orientation to hospital before patient care or other duties are assigned.
4. Will develop competency education in conjunction with nursing departments. The unit leadership determines the method of competency validation in conjunction with education team.
5. Develop education and training based on current evidence-based research and national nursing organization guidelines.
6. Will conduct nursing staff needs assessment as needed to identify practice gaps.
7. Collaborate on policy related to nursing practice and education.

The Education Department's goal is to use adult learning principles in the provision of education opportunities. The adult learning principles are defines as follows:

1. Healthcare workers must take responsibility for their own professional development.
2. Lifelong learning is essential to maintain competence and increase knowledge of current best practices.
3. Educational opportunities will be offered equitably to staff taking into consideration learning styles and delivery modes.
4. Education provided will relate to worker experience and current practice setting.

Deliverables:

1. Standardized orientation for new nursing and nursing support staff (including temporary staff) to hospital including ECG assessment and testing upon hire and annually. Nurses must demonstrate unit competencies annually. ECG testing can be remediated once.
2. Conduct education needs assessment of nursing departments.
3. Facilitate communication process between the Ventura County Medical Center (VCMC)/ Santa Paula Hospital (SPH) campuses and the educational institutions in Ventura County and and those contracted with VCMC/SPH.
4. Maintain compliance with California Board of Registered Nursing (BRN) as a continuing education provider.
5. Classes provided with Continuing Education Units will have the "Continuing Education Course Provider Request" form (See Attachment) submitted to the Nursing Education Department for pre-approval prior to the course offering.
6. For nursing departments, provide regulatory education in conjunction with Clinical Nurse Managers.
7. For nursing departments, provide education in relation to survey findings from regulatory agencies.
8. Create system and associated documents for tracking education provided to employees at VCMC/SPH.

All Revision Dates

7/13/2023, 8/10/2022, 9/15/2017, 11/1/2013, 6/1/2006, 12/1/2004, 8/1/2000

Attachments

Continuing Education Course ProviderRequest.pdf

Approval Signatures

Step Description	Approver	Date

Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/13/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/13/2023
Policy Owner	Sharon Waechter: Clinical Nurse Manager, Nursing Education	7/13/2023

Status **Active** PolicyStat ID **13916705**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	10/1/2011	Owner	Fernando Medina: Director, Support Services
Last Approved	7/3/2023		
Effective	7/3/2023	Policy Area	Environmental Services
Last Revised	7/3/2023		
Next Review	7/2/2026		

EVS.38 Cleaning of Refrigerators, Microwaves, and Ice Machines

POLICY:

To ensure that patient care refrigerators, microwaves, and ice machines are cleaned and disinfected by Environmental Services (EVS) staff in a safe, sanitary, and timely manner.

PROCEDURE:

Refrigerators

All patient food refrigerators are cleaned twice per month, or as requested by the unit manager or their designee, using hospital-approved food-grade sanitizing wipes.

- All exterior surfaces will be cleaned daily.
- Remove all food items from the refrigerator and place in an alternate refrigerator or freezer for temporary storage while cleaning.
- Clean all surfaces (shelves, tracks, hinges, gaskets, etc.) with hospital-approved food-grade sanitizing wipes.

All patient care, non-food refrigerators, such as medication or specimen refrigerators, are to be inspected weekly by the unit managers or their designees.

- Unit leadership, such as unit managers or their designees, will coordinate with EVS to address interior cleaning of refrigerators.
- Interior surfaces will be cleaned using hospital-approved sanitizing wipes.
- All exterior surfaces will be cleaned weekly, or as needed.

Microwaves

Microwaves for patient use shall be cleaned after each use by staff and will be sanitized daily by EVS staff using hospital-approved food-grade sanitizing wipes. Cleaning will include the cavity and seal of the unit, as well as the exterior surfaces.

Ice Machines

EVS will clean the exterior surfaces weekly, or as needed. Ice machines will have preventative maintenance performed by the Facilities Maintenance Department as per Policy F.98 Ice Machines.

All Revision Dates

7/3/2023, 6/28/2021, 3/1/2013

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/3/2023
Infection Prevention	Magdy Asaad: Infection Prevention Manager	6/30/2023
Housekeeping Manager	Michael Lopez: Supervisor, Environmental Services	6/30/2023
Housekeeping Manager	Fernando Medina: Director, Support Services	6/30/2023

Status **Active** PolicyStat ID **13798947**

VENTURA COUNTY
HEALTH CARE AGENCY

Origination	1/18/1992	Owner	Matt McGill: Director, Imaging Services
Last Approved	7/25/2023		
Effective	7/25/2023	Policy Area	Imaging Services
Last Revised	7/25/2023		
Next Review	7/24/2026		

IS.24 Lead Apron and Glove Survey

POLICY:

The Imaging Services Department conducts routine checks on all protective aprons, gloves, gonadal shields, thyroid shields, and glasses.

PROCEDURE:

- Radiology specific personal protective equipment (PPE) such as aprons, gloves, gonadal shields, thyroid shields, and glasses shall be visually inspected on an annual basis. Any items found to be unsafe or defective shall be removed from service and replaced as soon as possible.
- Upon inspection, if any fabric tears, holes, creases, chips/cracks are found, the item shall undergo a fluoroscopic inspection with a KVP setting of 85 to determine its level of radiation protectiveness.
- New PPE specific to protection from ionizing radiation will be added to the tracking log and labeled so it can be identified as being inspected and ready for use within the specified wear period.

All Revision Dates

7/25/2023, 10/3/2017, 5/26/2006, 3/14/2006

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/25/2023
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	7/25/2023
Imaging Services	Matt McGill: Director, Imaging Services	7/18/2023

Status **Active** PolicyStat ID **14088921**

VENTURA COUNTY
HEALTH CARE AGENCY

Origination	7/25/2023	Owner	Matt McGill: Director, Imaging Services
Last Approved	7/25/2023		
Effective	7/25/2023	Policy Area	Imaging Services
Last Revised	7/25/2023		
Next Review	7/24/2026		

IS.58 Request for Outside Images

PURPOSE:

To provide a reference for departmental and organizational staff on the process to request outside images for our patients.

When a patient was seen at a facility we share a virtual private network (VPN) with, reference the information below:

Outside Facility Contacts for Requesting Imaging Studies

Request that studies be "DICOM Pushed" to VCMC through the VPN.

- ***St. John's Oxnard/Pleasant Valley***: From the hours of 07:00am –4:30pm Monday – Friday, call Radiology Front Office (805)-988-2872.
  From the hours of 5:00pm - 07:00am, 7 days a week, call the automated attendant at 805-988-7070. When prompted by the automated "Vocera" system, ask for "Radiology" to connect to the X-Ray Tech.

- ***CMH***: To request a study from CMH during the hours of 8:00am - 5pm, Mon-Fri, call CMH Radiology Scheduling office at 805-948-8160. Please ask them to **"push"** the requested exams via PACS directly to VCMC.

- ***Simi Valley Adventist Health:*** Send an email requesting imaging studies to AHSV Film Release dept. at: ahsvfilmrelease@ah.org or, call 805-955-6360 from M-F 7am-6pm and ask staff to **"push"** the requested studies to VCMC. Contact Monica Torres at 805-955-6369 for any issues.

- ***Grossman Imaging***: 805-988-0616 (Opt #2) Med Records, M-F 7:30am – 5:00pm. Request staff to **"push"** requested studies to VCMC.

- ***Palms Imaging***: 805-604-9500 (Opt #5) Med Records, M-F 7am – 7pm. Request staff to **"push"** requested studies to VCMC.

- ***Rolling Oaks***: 805-644-7300 (Opt #2 then Opt #1) Med Records, M-F 8am – 5pm. Request staff to **"push"** requested studies to VCMC, or email requests for imagining studies to medrecrollingoaks@radnet.com

***Please contact Mike Maloy, PACS Administrator for any assistance needed 24/7 @ 805-320-0099**

When a patient was seen at a facility NOT listed above:

Complete the "Authorization for Use and Disclosure of Protected Health Information" form attached to

this policy and send to the facility you are requesting the patient information from.

All Revision Dates

7/25/2023

Attachments

Auth for Use and Disclosure of PHI.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	7/25/2023
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	7/25/2023
Imaging Services	Matt McGill: Director, Imaging Services	7/25/2023

Status **Active** PolicyStat ID **14252819**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	2/1/2004	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	8/24/2023		
Effective	8/24/2023		
Last Revised	8/24/2023	Policy Area	Pharmacy Services
Next Review	8/23/2026		

PH.31 Drug Packaging

POLICY:

All drug products shall be packaged, labeled and stored in accordance with California State Board of Pharmacy laws and regulations and official guidelines prescribed by the American Society of Health-System Pharmacists and the United States Pharmacopoeia. The packager shall be properly trained and familiar with the unit dosing materials as well as this policy prior to proceeding with the unit-dose process. This policy defines how to prepare and label single unit and unit-dose packages of medications such as oral solid and oral liquid dosage forms.

PROCEDURE:

Equipment:

Unit Dose technology shall be used for drug packaging.

Packaging

A. The Unit-Dose area shall be thoroughly cleaned before and after each packaging of a drug item. Eating and drinking is NOT permitted in the unit-dose area at any time.

B. The packager's hands must be thoroughly washed and dried. Gloves are NOT a substitute for hand washing before starting the unit-dose process.

C. All packaging materials and medication(s) shall be gathered before beginning the unit-dose process. If more than one bulk bottle is used, each should be of the same lot number and expiration date.

D. Enter the product information into the Unit-Dose Software Program.

E. After each individual job is complete, the packaged items, the packaging log and empty bulk

containers will be placed in a segregated area for end-product evaluation by the pharmacist.

F. Once one medication is unit dosed into proper package, a pharmacist must complete final end-product evaluation prior to unit dosing a different medication.

Labeling

A. Labels should not be written by hand, except for in emergency situations.

B. The label must contain the following information:

1. **Facility** (i.e. Ventura County Medical Center, Santa Paula Hospital)
2. **Name:** The generic (non-proprietary) name shall be the most prominent part of the package label. It is NOT necessary to include the brand (proprietary) name.
3. **Strength:** Strength should be stated in accordance with terminology in the American Hospital Formulary Service.
    a. A unit dose package containing a 600 mg dose as two 300 mg tablets shall be labeled: "600 mg (2 x 300 mg)".
    b. A 500 mg dose of a liquid or injections containing 100 mg/mL shall be labeled as "500 mg/5 mL".
4. **Dosage Form:** Special characteristics of the dosage form shall be a part of the label (e.g., extended release). Medication packages shall specify route of administration if other than oral (e.g., topical use).
5. **Barcode:** Upon medication administration to patients, the barcode shall be readable at the patient's bedside.
6. **Internal Lot Number:** Lot number is assigned by the pharmacy. It shall appear both on the label and pharmacy Unit Dose Pre-Packaging Log, and serve as a means of complete product identification and packaging history of batch products.
7. **Manufacturer Name and Lot Number:** The original manufacturer name shall appear on both the package label and Unit Dose Pre-Packaging Log.
8. **Packaging Expiration Date:** The expiration date for non-sterile solid and liquid dosage forms packaged in single -unit and unit-dose containers shall be one year or less, unless the stability data or manufacturer's labeling or product indicates otherwise. The date shall be assigned according to the United States Pharmacopoeia guidelines or the manufacturer's expiration date, whichever is less.
    a. Oral Solids: 12 months (unless product expires before 12 months).
    b. Oral Liquids: 12 months (unless product expires before 12 months).
    c. Reconstituted Liquids: See manufacturer's labeling or USP guidelines.
    d. For short-dated products with expiration ≤4 days, the **date** and **time** shall be noted together.

End-Product Evaluation

A. The pharmacist shall verify that the unit-dose process was performed accurately and all

components of the label are correct.

B. The pharmacist shall verify the barcode scans properly in both the automated unit dose system and the electronic health record.

C. The pharmacist shall initial the Unit-Dose Pre-Packaging Log once the verification process is complete.

Documentation

A. The Unit-Dose Pre-Packaging Log shall be used to document:

1. Internal Lot Number
2. Packaging date and time
3. Packaging expiration date
4. Drug name, strength, and dosage form
5. Manufacturer's name and lot number
6. Manufacturer's expiration date
7. National Drug Code (NDC)
8. Barcode
9. Quantity of Pre-Packaged Number
10. Technician's Initials
11. Pharmacist's Initials

References:

I. California Business and Professions Code, Division 2, Chapter 9, Article 7.6 Centralized Hospital Packaging Pharmacies Section 4128

II. ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs

All Revision Dates

8/24/2023, 2/15/2023, 3/17/2020, 1/1/2014, 9/1/2011

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	8/24/2023

Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	8/24/2023

Status **Active** PolicyStat ID **14129335**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	3/1/2015	Owner	Sul Jung: Associate Director of Pharmacy Services
Last Approved	8/2/2023		
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Last Revised	8/2/2023	Policy Area	Pharmacy Services
Next Review	8/1/2026		

PH.99 Pyxis CII-Safe (Narcotic Vault) Control Station

POLICY:

The Pharmacy Department maintains procedures to distribute or to securely store controlled substances, other high cost drugs with diversion potential, patient controlled analgesia (PCA) keys, medication lockbox keys, and the storage of keys to refrigerators. This includes inventory maintenance, authorized access, restocking, and authorized distribution from the Pyxis CII Safe Narcotic Vault.

Note: This policy does not apply to pharmacy areas that do not have a Pyxis CII Safe Narcotic Vault.

PROCEDURE:

1. **Education**
    a. All users shall be trained to use the BD Pyxis Enterprise Server prior to being given authorization to access the Pyxis CII Safe Narcotic Vault (CII Safe).
    b. All users shall be responsible for assuring competency in the functionality to their professional designation.
    c. Pyxis CII-Safe v9.1 User Guide is available in pharmacy shared drive under "CII Safe NarcVault" for proper use of the CII Safe, trouble shooting, and support instructions.
2. **Access**
    a. The Pharmacy Director and Pharmacy Supervisors shall have access and security levels as follows:
        i. Authorize new user access to the CII Safe system.
        ii. Provide training and complete CII Safe competency to new user.
        iii. Allow to reset or re-register login, BioID and password for old and existing

users.

iv. Have full access to the Administrative Menu and be able to correct transactions.

v. Resolve discrepancies with a witness requirement.

vi. Responsible for maintaining inventory in the CII Safe.

vii. Log on with Username and Password/BioID.

viii. Responsible for updating/maintaining the medication database, location database, location inventories, user database and vendors database.

ix. Responsible for creating and maintaining standard compounds.

b. Pharmacists shall have access and the following privileges:

i. Complete training and competency on how to receive or to distribute controlled substances.

ii. Log on with Username and BioID.

iii. Be familiar and use the following functions: Compound, Expire/Outdate/ Recall, Restock, Access Inventory/Put away the compound, run Compare report of Pyxis vs. CII Safe, Receive, Return and Send and Med Movement.

iv. Resolve discrepancy with a witness requirement.

c. Pharmacy technician staff shall have access and the following privileges:

i. Complete training and competency on how to Restock for Pyxis Medstations and Send controlled substances for specific patient from the CII Safe.

ii. Run "Compare Report".

iii. Reconciling all the narcotic delivery receipts.

d. Upon termination of employment, access to the CII Safe shall be removed.

3. **Inventory Maintenance**

a. All controlled substances shall be linked in the CII Safe between all Unit Medstations through BD Pyxis Enterprise Server.

b. The unit of issue for all unit dose tablets, capsules, liquids, ampules, or vials (single dose) is EACH.

c. The unit of issue for all bulk bottles of tablets or capsules is also EACH.

d. The unit of issue for all bulk liquids and multiple dose vials is PER FLUID VOLUME (ML).

4. **Stocking**

a. All controlled substances (CII-CV) are stocked in the CII Safe, CII Safe remote location, or as secure stock in a secure location in the pharmacy.

b. Refrigerated stock is listed in the CII Safe remote location and stocked in the designated secure medication refrigerator.

c. Non-controlled medications that are at risk for diversion may be subject to control through the CII Safe. This is determined by Pharmacy Department administration.

d. A separate storage pocket for all Medstations keys will be established in CII Safe.

5. **Authorized Distribution**

   a. A station listing is maintained for any authorized hospital nursing station or patient care area. Distribution or receiving occurs by signing on to CII Safe, from Main Menu choose one of the following actions;

      i. Compound

      ii. Expire, waste, or recall

      iii. Restock

         - Using this function for dispensing medication to all Pyxis Medstations
         - The quantity of medications will be based on the usage of each station.

      iv. Access Inventory (Narcotics Vault access/inventory)

      v. Receive

         - Using this function for receiving medications from different vendors.
         - Examples of vendors include CardinalASSIST, Cardinal Health, and Quva.

      vi. Return

         - For returning narcotics from Pyxis MedStation system or non-Pyxis location.

      vii. Send

         - Sending medications to station or specific patient per request or demand.
         - Sending medications to Hospital Clinics or Contracted County Services such as Ventura County Fire Departments or Ventura City Fire Departments.

   b. Hospital nursing stations and patient care areas include hospital areas that have been authorized to distribute and administer controlled substances under the Hospital's Drug Enforcement Agency (DEA) registration number. This includes Pyxis Medstations and hospital areas maintaining controlled substances in locked cabinets.

   c. Transfer of controlled substances to outside organizations requires transfer to another DEA registration number. CII controlled substances shall require completion of a DEA 222 form.

   d. Single doses of controlled substances can be withdrawn for an inpatient for direct administration if the drug is not stocked in the patient's treatment area. From the

Main Menu, select Send medications to specific patient.

6. **Reports and Monitoring**
    a. Pyxis® vs Pyxis® CII Safe™ Compare Report:
        i. Verifies the integrity of the movement of medications between the CII Safe system and Pyxis MedStation.
        ii. Verifies the restock and return functions, reporting the errors or discrepancies that occurred between the nursing units and the Pharmacy Department.
        iii. Verifies the accuracy of the correct medication, quantity, and Pyxis Medstation system and links medications unloaded from a Pyxis MedStation system to return transactions in the Pharmacy.
        iv. A pharmacist shall review this report at the end of day.
        v. Report to Pharmacy Director or Pharmacy Supervisor if any discrepancies are identified for further investigation.
    b. Suggested Medication Reorder Report:
        i. Report may be run by the Pharmacy Director or the Pharmacy Supervisor.
        ii. Report identifies medications that need to be reordered based either on average daily use or a minimum/maximum level. Average daily use is based on a floating 90-day usage pattern that more weighted towards the most recent 10-20 days.
    c. All CII-Safe Events Report:
        i. Report provides a detail of all transactions for one or more controlled substances for a specific time period.
        ii. The report should be reviewed by the Pharmacy Supervisor for any suspicious activities.
7. **CII Safe NarcVault - Downtime Procedures:**
    a. On-duty staff should call the Carefusion Helpdesk at 1-800-727-6102 or notify their supervisor.
    b. CII Safe keys are stored in the Pharmacy Supervisor's office.
    c. All CII Safe narcotic transactions should be recorded in the Narcotic Disaster Book.

All Revision Dates

8/2/2023, 11/24/2021, 2/15/2018, 3/1/2015

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	8/2/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	8/2/2023

Status **Active** PolicyStat ID **14104001**

VENTURA COUNTY HEALTH CARE AGENCY

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Last Approved	9/13/2023		
Effective	9/13/2023		
Last Revised	9/13/2023	Policy Area	Pharmacy Services
Next Review	9/12/2026		

PH.81 Pharmacy Operations During Electronic Health Record Downtime

POLICY:

To provide a system which allows the Pharmacy Department to provide pharmaceutical care during an electronic health record (EHR) downtime at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH). *Please refer to Pharmacy Workflow Diagram for Downtime below.*

PROCEDURE:

I. **PRIOR TO A PLANNED DOWNTIME**

This section may be skipped if the downtime occurrence is **unplanned** .

Medication Administration Record (MAR) : The Pharmacy Department is to begin the process of printing the MAR's from the EHR four (4) hours prior to the scheduled downtime following directions outlined in the Pharmacy Department downtime binder.

II. **AT THE BEGINNING OF DOWNTIME**

Obtain Pharmacy Department Downtime Binder : The Pharmacy Department has prepared a downtime binder in each Pharmacy for the purposes of operations in a downtime event.

Request Nursing for Faxed Orders : During downtime, computerized provider order entry is not possible. It is important that the Pharmacy Department aid in communicating to nurses that all new orders should be faxed to the Pharmacy.

- VCMC orders to be faxed to the VCMC Pharmacy at 1-805-652-6190
- SPH orders:
    - Between hours of 08:00 and 16:30 fax to SPH Pharmacy at 1-805-525-7091

- Between hours of 16:31 and 07:59 fax to VCMC Pharmacy at 1-805-652-6190

III. **PROCEDURES DURING DOWNTIME: AUTOMATED DISPENSING CABINETS (ADC's) AND PYXIS MEDSTATIONS**

Critical Override : During an EHR downtime, all ADC's will be placed on critical override if the downtime exceeds 30 minutes.

- **Purpose** : During downtime, no new orders will crossover to the ADC. Critical override will allow the nurses to obtain drugs for new orders.
- **Existing Orders** : Will remain on the patient's ADC profile.
- **Pharmacy-to-Nursing Communication** : Critical override status will be communicated to the nursing floors via communications directly or by email to the Clinical Nurse Managers.

Medication Administration of Medications Removed by Critical Override

- **Second Nurse Verification** : After first nurse removes a medication, a **second nurse** is to verify the order and medication.
- Medications removed without a pharmacist review should be reviewed for appropriateness prior to administration:
    1. Drug, dose, frequency and route of administration.
    2. Therapeutic duplication.
    3. Real or potential allergies or drug sensitivities.
    4. Food-drug or drug-drug interactions.
    5. Other contraindications or other issues or concerns.

IV. **DURING DOWNTIME: NEW ORDERS**

- Upon receipt of orders faxed to the Pharmacy, orders will be processed manually.
- Faxed copies of the orders are kept as records for data re-entry when the EHR is back to functioning status.
- Refer to Pharmacy Department Downtime Binder for further detailed procedure of order processing during downtime.

Labeling : Pre-printed labels will be used during downtime for the labeling of medications dispensed from the Pharmacy. The required information will be handwritten on oral and IV labels affixed to the drug following instructions on policy PH.55 Medication Order management.

V. **Order Clarifications:** Refer to directions outlined in the Pharmacy Department Downtime Binder.

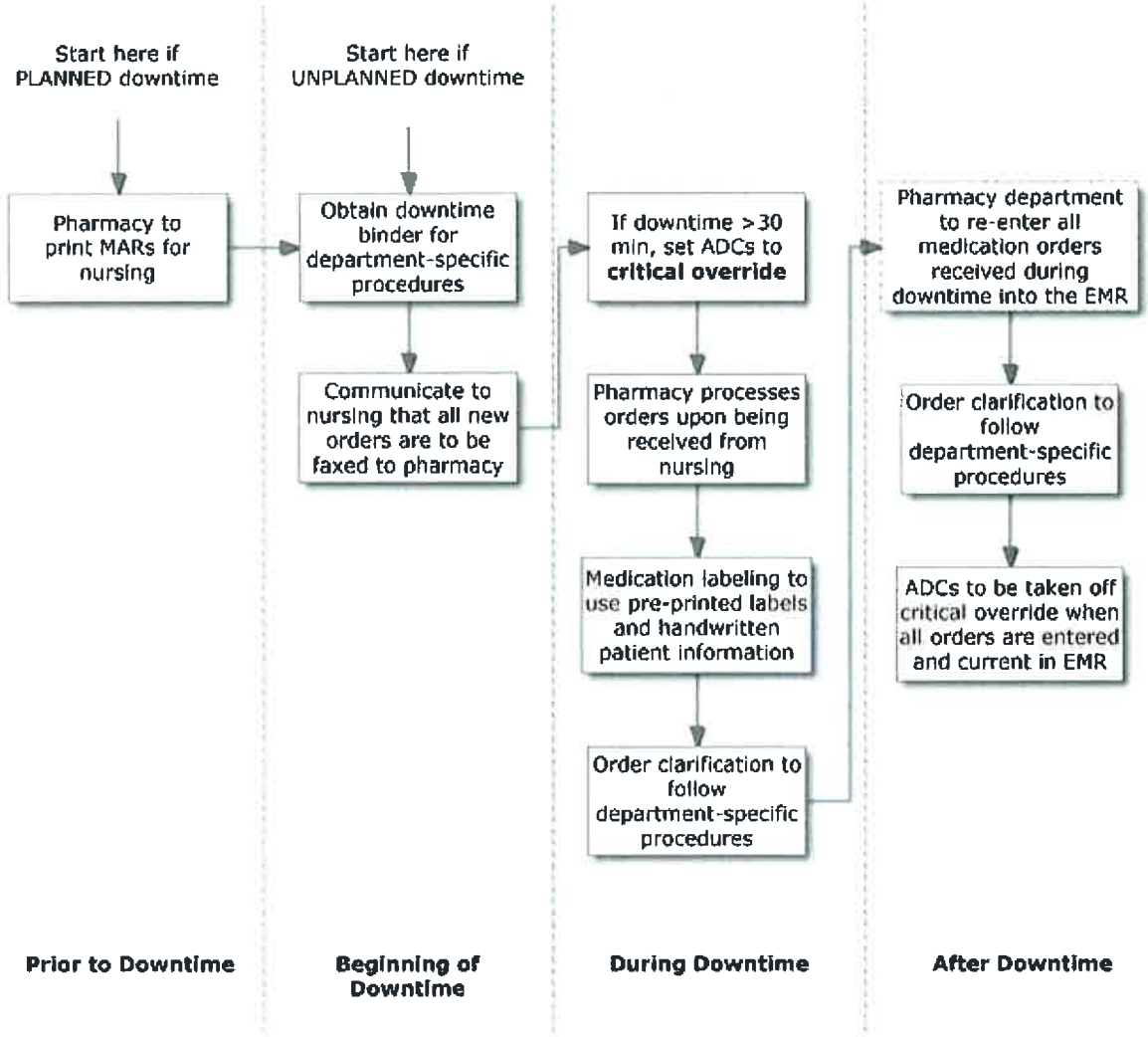
VI. **PROCEDURES AFTER DOWNTIME**

Post-Recovery Data Entry : Pharmacists will enter all medication orders that were received during downtime into the EHR.

Order Clarifications: Refer to directions outlined in the Pharmacy Department Downtime Binder.

Critical Override: ADC's will be taken off critical override when all the orders have been entered and are current.

Pharmacy Workflow Diagram for Downtime



All Revision Dates

9/13/2023, 9/10/2020, 5/31/2017, 12/1/2013, 8/1/2008, 6/1/2006, 11/1/1998, 6/1/1995, 10/1/1992

Attachments

Pharmacy Workflow Diagram for Downtime

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator-AncillaryServices	9/13/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	8/30/2023

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VENTURA COUNTY HEALTH CARE AGENCY

Origination	8/24/2023	Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH
Last Approved	8/24/2023		
Effective	8/24/2023	Policy Area	Administrative - Nursing
Last Revised	8/24/2023		
Next Review	8/23/2026		

Elements Of The Psychosocial Assessment

Policy

All nursing staff caring for behavioral health patients.

Purpose

To provide guidance and outline the elements of the psychosocial assessment.

Procedure

Psychosocial Assessments will be completed within 24 hours of admission and include at a minimum the required elements defined in this guideline.

A. Presenting problem including suicide risk factors
B. Childhood to present history (including sensory, developmental or physical impairments, accommodations and limitations)
C. Current living situation/environment safety
D. Legal
E. Work history
F. Educational history
G. Military history
H. Significant medical/psychiatric history
I. Sexual history and orientation
J. Preferred pronouns and gender identity
K. History of hospitalization

L. Suicidal/Homicidal Risk
M. History of abuse/neglect (sexual, physical, emotional). Identify abused or perpetrator.
N. Trauma history
O. History of substance use/abuse
P. Financial status
Q. Spiritual issues, including religion, spiritual orientation, beliefs and values that may impact treatment
R. Cultural factors related to current problem that could impact treatment
S. Family/support systems are identified by interviews with family members or others as appropriate
T. Patient strengths and liabilities
U. Patient family/significant other educational needs
V. Discharge planning needs/alternatives identified
W. Diagnostic summary ends in problem statement with focus of treatment date, time, and signature with credentials upon completion

All Revision Dates

8/24/2023

Approval Signatures

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/24/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/24/2023
Policy Owner	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/24/2023

VENTURA COUNTY MEDICAL CENTER

Property of the Medical Staff, Privileged and Sensitive Information

CONFIDENTIAL

Medical Executive Committee Document Approvals

September 2023

a. Policies & Procedures / Forms / Orders

The following were reviewed and recommended for approval by the appropriate Departments, Committees, and the Medical Executive Committee.

1.	100.082 Medication Reconciliation (with attachments)	page	2-11
2.	100.112 Code White – Pediatric Medical Emergency	page	12-16
3.	108.021 Pressure Injury Prevention and Wound Management	page	17-24
4.	ER.17 Health Care Agency (HCA) Employee Industrial Blood Borne Pathogen and Infectious Agent Injuries	page	25-28
5.	ER.26 Law Enforcement in the Emergency Department	page	29-30
6.	ER.32 Minimum Law Enforcement Staffing in the Emergency Department	page	31
7.	IS.31 MRI Screening of Pregnant Patients	page	32-33
8.	IS.41 CT Medical Physicist Inspections	page	34-35
9.	IS.42 Imaging Protocols Review	page	36
10.	IS.43 MRI Hearing Protection	page	37
11.	MCH.04 Infant and Child Car Seat Safety	page	38-40
12.	MCH.07 Infant Identification Bands and Security Tag Procedure	page	41-44
13.	MCH.25 Care of the Infant with Hyperbilirubinemia	page	45-53
14.	MS.102.023 Family Medicine Obstetrical Risk Stratification	page	54-57
15.	OB.13 Admission and Assessment of the Post-Partum Patient	page	58-61
16.	OB.31 Cervical Ripening	page	62-66
17.	OB.47 Magnesium Sulfate for Pre-Eclampsia and Tocolytic Therapy	page	67-71
18.	OB.48 Testing for Prenatal Drug Exposure	page	72-77
19.	PH.26.00 Sterile Compounding Overview	page	78-79
20.	PH.26.01 Training and Evaluation of Pharmacy Staff in Sterile Drug Preparation	page	80-83
21.	PH.26.02 Facility and Equipment – Sterile Compounding	page	84-90
22.	PH.26.03 Sterile Compounding Attire	page	91-93
23.	PH.26.04 Sterile Drug Preparation, Labeling, End Product Evaluation and Record Keeping	page	94-98
24.	PH.26.05 Beyond Use Dates	page	99-102
25.	PH.26.06 Sterile Compounding Quality Assurance Program (with attachment)	page	103-110

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*1/1/2006*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*8/2/2023*
Next Review:	*3 years after approval*
Owner:	*Sara Pendleton: Medication Safety Officer*
Policy Area:	*Administrative - Patient Care*
References:	

100.082 Medication Reconciliation

POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) shall reconcile all patients' medications within 48 hours of admission at any point of entry, at transitions of care unless an urgent situation indicates that immediate care take precedence, and prior to discharge.

Definitions:

1. **Medications** includes ~~all~~"any prescription medications, sample medications, ~~herbals~~herbal remedies, vitamins, nutraceuticals, over~~-the-~~-the-counter drugs, vaccines, diagnostic and contrast agents used on or administered to persons to diagnsoe, treat, or prevent disease or other abnormal conditions, radioactive medications, ~~vaccines, diagnostic and contrast agents, radioactive medications,~~ respiratory therapy treatments, ~~parental~~parenteral nutrition, blood derivatives, ~~IV~~intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug administration (FDA) as a drug. This definition ~~excludes~~of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases."[1]

~~2. **Best Possible Medication History (BPMH)** is the most accurate list of medications the patient should be taking and includes medications the patient is actually taking prior to admission. The BPMH includes drug name, dose, route, frequency as well as date and time of last dose taken.~~

2. **Best Possible Medication History (BPMH)** is a medication history obtained by a clinician which includes a thorough history of all regular medication use (prescribed and non-prescribed), using a number of different sources of information.[2]

See Attachment A for Quick Tips on Obtaining a Best Possible Medication History.[3]

3. **Medication reconciliation** is the process of identifying the ~~most accurate list of all~~ medications ~~a patient is taking and using this list to provide correct~~currently being taken by an individual, and these medications ~~for patients anywhere within the health system~~are compared to newly ordered medications, and discrepancies are identified and resolved. [1]

Per Joint Commission NPSG 03.06.01, medication reconciliation "is intended to identify and resolve discrepancies -- it is a process of comparing the medications a patient is taking (or should be taking) with newly ordered medications. The comparison addresses duplications, omissions, and interactions, and the need to continue current medications."[4]

4. **Point of entry** includes all admissions to any nursing unit, department, or area where a licensed personnel

could or would have the potential to administer medications. Exclusions are encounters during which medications are not given.

5. **Transitions of care** is the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation center) to another.[5] **Intra-hospital transfer** is the stepping up or down between levels of care.

6. ~~**Intentional**~~ **Undocumented Intentional discrepancy** is when the ~~prescriber~~Licensed Provider (LP) has made an intentional choice to add, change, or discontinue a medication ~~and their~~but this choice is not clearly documented.[2]

7. **Unintentional discrepancy** is one in which the ~~prescriber~~LP unintentionally changed, added, or omitted a medication the patient is taking prior to admission.[2,6-8]

PROCEDURE:

A. Obtaining and documenting the patient's home medication history or list into the electronic health record (EHR) is the collaborative responsibility of providers, nurses, pharmacy staff, and licensed health care personnel involved in the patient's medication management.

B. If a medication history or list cannot be obtained despite best faith effort, the ~~licensed~~ health care ~~personnel~~professional shall document this effort into the EHR.[4]

C. The specific decision of whether a patient should continue or discontinue a specific medications and treatments at various stages of their hospitalization (i.e., upon admission, upon transfer, upon discharge) shall be completed by the ~~provider~~LP.

D. The patient (or ~~family~~caretaker as needed) shall be provided with written information on the medications the patient should be taking when ~~he or she~~the patient is discharged from the hospital. This includes explanations about the importance of medication information management.[4]

EMERGENCY DEPARTMENT (ED) ADMISSION

~~A medication list or history~~When available, a pharmacy technician shall ~~be initiated and documented~~obtain a BPMH for ED patients and document this into the EHR ~~for all ED visits as part of the initial triage assessment. For admitted high risk patients, the medication reconciliation pharmacy technician shall obtain a BPMH and document this into the EHR within 48 hours~~ (See California State Senate Bill 1254). Registered nursing or LPs shall assist in obtaining and documenting the medication history in the EHR when the pharmacy technician is not available. The admitting medical team shall be responsible for reconciling the patient's home medication list within 48 hours of admission.

DIRECT ADMISSION

~~A medication history or list~~When available, a pharmacy technician shall ~~be obtained and documented into~~obtain a BPMH for high risk patients and document this in the EHR ~~by either the admitting nurse or the admitting provider while conducting the~~within 48 hours of admission ~~assessment. For high risk patients, the medication reconciliation pharmacy technician shall obtain a BPMH and document this into the EHR~~ (see California State Senate Bill 1254). The admitting nurse shall assist in obtaining and documenting the medication history in the EHR when the pharmacy technician is not available. The admitting LP shall review and reconcile the home medications in the EHR within 48 hours of admission. ~~The admitting provider shall review and reconcile the home medications in the EHR within 48 hours of admission.~~

TRANSFER PROCEDURES

Transfer reconciliation within the inpatient setting is required and any unintentional discrepancies shall be brought to the attention of the accepting provider(s) for clarification.

PRE-ADMISSION

For planned surgical procedures, the home med list shall be obtained by the surgical service before admission. Preop nursing shall document the home meds into the EHR. Upon admission, the surgical service or accepting service shall be responsible for completing medication reconciliation upon transfer out of recovery (post-anesthesia care unit, PACU) and prior to discharge. Unintentional discrepancies shall be brought to the attention of the surgical service or accepting service for clarification.

OUTPATIENT/AMBULATORY

Patients seen in the outpatient/ambulatory setting shall have medications reconciled across the continuum of care. Upon departure, the patient shall receive a reconciled, active medication list.

DISCHARGE PROCEDURES

A. It is the discharging providers' responsibility to reconcile the patient's medications prior to any discharge orders being placed. Unintentional discrepancies shall be brought to the attention of the discharging provider for clarification. If the discharging provider cannot be reached, chain of command shall be followed:
    1. Resident who placed discharge orders --> Senior resident --> Attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
    2. Nurse practitioner/Physician assistant --> Attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
    3. Surgical resident --> Surgical attending provider --> Medical Director of Inpatient Quality --> Chief Medical Officer
B. When a patient is discharged, a complete list of the patient's medications shall be communicated to the patient. When a patient is referred to, or transferred to another setting, service, practitioner, or level of care outside the health care system, a complete list of the patient's medications shall be communicated to the next provider.
C. Patients shall be educated regarding the importance of managing their medication information.
D. Documentation and communication of discharge medication orders occurs via:
    1. The medication reconciliation form which is given to the patient should be faxed, mailed or sent via courier directly to the next facility/clinic/provider of care. When the next provider of care is unknown, the patient is responsible for providing the information to the next provider.
    2. The physician discharge order form and Medication Administration Record for next provider of service shall be completed when transferring a patient to a receiving facility/treatment setting.
    3. A discharge summary for the patient's primary care provider.

CALIFORNIA STATE SENATE BILL 1254

On January 1, 2019 Senate Bill 1254 requires a pharmacist at a hospital pharmacy of >100 beds to obtain and document in the EHR an accurate medication history or list for each admitted high risk patient during the pharmacy's normal hours of operation as pharmacy staffing permits. The law allows for the facility to establish the criteria for identifying high risk patients in addition to establishing the time frame for completion. The facility shall also be responsible for training, competencies, and quality assurance.

Admission - At VCMC only, a medication reconciliation pharmacy technician shall be responsible for obtaining and documenting the BPMH for high risk patients within 48 hours of admission. See attachment ~~A~~B - Pharmacy Tech Home Med List Program.

~~Discharge - At VCMC only, a medication reconciliation pharmacist should provide discharge medication counseling for high risk patients who have completed discharge medication reconciliation orders. See attachment B.~~

The Pharmacy department shall maintain training, competencies, and quality assurance for pharmacy staff involved in obtaining and documenting a BPMH and pharmacy staff involved in providing discharge medication education.

References

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All revision dates:	8/2/2023, 9/17/2019, 4/1/2012

Attachments

Attachment A - Best Possible Medication History Quick Tips
Attachment B - Pharmacy Tech Home Med List Program

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/4/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/8/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/8/2023
Policy Owner	Sara Pendleton: Medication Safety Officer	6/8/2023

MARQUIS 2

Multi-Center Medication Reconciliation Quality Improvement Study

Best Possible Medication History (BPMH) Quick Tips

Goal → Obtain complete information on the patient's medication regimen, including:

- Name of each medication
- Formulation (e.g., extended release)
- Dosage, Route, Frequency
- Non-prescription medications (e.g., herbals, OTCs, vitamins)

Try to use at least two sources of information and explore discrepancies between the different sources.

If your starting point is a medication list:

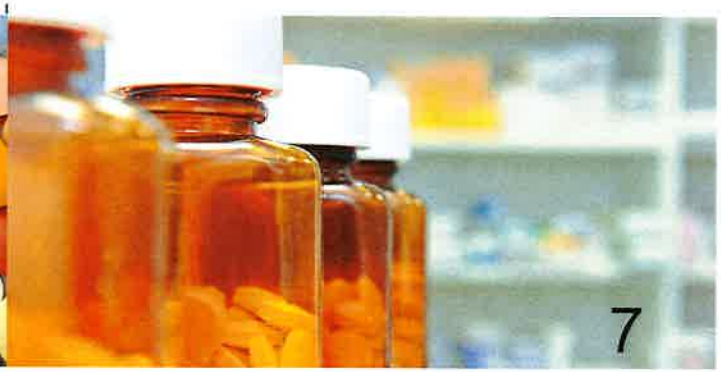
- Review and verify each medication with the patient.
- It is best to start by having the patient tell you what he or she is taking; do not read the list aloud asking if it is correct.

Questions to elicit a complete medication list:

- For each medication, elicit the dose and time(s) of day taken.
- When appropriate, ask about formulation and route of administration.
- Start with an open-ended question: What medications do you take at home?
- Use ***Probing Questions*** (on the back) to minimize missed medications.

Time-saving tips:

- ✓ Start with easily accessible sources (e.g., outpatient EMR med list, recent hospital discharge orders).
- ✓ If patients use a list or pill bottles and seem completely reliable (and data are not that dissimilar from the other sources, and/or the differences can be explained), then other sources are not needed.
- ✓ If patients are not sure, relying on memory only, or cannot clearly "clean up" the other sources of medication information, then use additional sources such as community pharmacy data.
- ✓ If the medication history is **still not clear** (e.g., suspected differences between what the patient is supposed to be taking and what they actually take) then contact outpatient physician office(s) and/or have the family bring in the pill bottles from home.



Probing Questions:

- ✓ Ask about **scheduled medications.**
- ✓ Ask about **PRN medications.**
  - Which medicines do you take only sometimes?
  - What symptoms prompt you to take them?
  - How many doses per week do you take?
  - What is the most often you are allowed to take it?
  - Do you often take something for headaches? Allergies? To help you fall asleep? When you get a cold? For heartburn? For constipation?
- ✓ **Assessing the purpose of each medication** may lead to additional prompts.
  - What is each medicine for?
  - Do you take any other medications for that?
- ✓ Ask about **medications for specific conditions** that the patient has.
  - What medicines do you take for your diabetes, high blood pressure, etc.?
- ✓ Ask about **medications prescribed by subspecialists** who follow the patient.
  - Does your [arthritis doctor] prescribe any medications for you?
- ✓ Ask about **medications that are easy to forget.**
  - Do you take any inhalers, nebulizers, nasal sprays, ointments, creams, eye drops, ear drops, patches, injections or suppositories?
  - Do you take any medications in the evening or at night?
  - Do you take any medicines once a week or once a month?
- ✓ Ask about **non-prescription products.**
  - Which medicines do you take that do not require a prescription? (Over-the-counter medicines, vitamins, herbals and minerals)
- ✓ Assess **recent medication use and adherence.**
  - When did you take the last dose of each of your medicines?
  - Tell me about any problems that you have had taking these medicines as prescribed.
  - Many patients have difficulty taking their medications exactly as they should every day. In the last week, how many days have you missed a dose of your [medication]?

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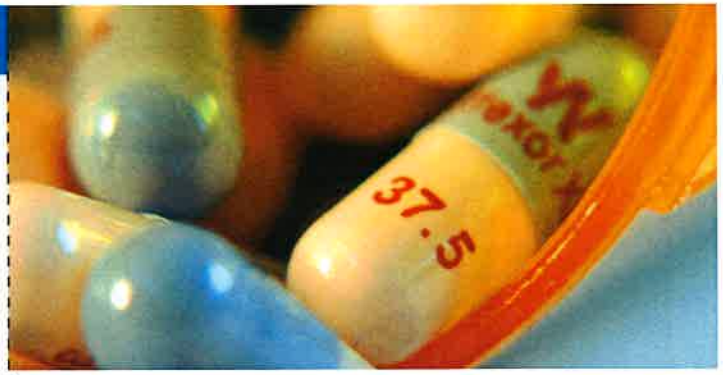

shm MARQUIS 2

Multi-Center Medication Reconciliation Quality Improvement Study

Best Possible Medication History (BPMH)

Quick Tips

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

Pharmacy Technician Admission Home Med List Program:

Schedule: Daily 1000-1830
Tiger Text: Pharmacy Technician Phone: 805-652-6682

Overview

1000-1200 Review admission task lists and complete admission home med lists for high-risk inpatients approaching 48 hours.
- Desk location: VCMC Pharmacy Administrative Office
- First 15-minute break at 1200-1215

1215-1830 Complete home medication lists for ED patients prioritizing those patients about to be admitted.
- Desk location: ED Triage
- 30-minute meal break at 1330-1400
- Second 15-minute break at 1730-1745

Identification of patients

Pharmacy technicians shall prioritize patients (48h > 24h > ED patients)

1. Admissions approaching the 48h mark
   a) Review the admission task list for follow-up.
   b) Interview and update the home med lists in Cerner as soon as possible.

2. Admissions within the past 24 hours
   a) Review admission task list for follow up
   b) Pharmacy technician shall sort through this report for the following:
      i. Exclusion criteria (i.e. exclude these patients)
         - SPH, OB, PSY/CSU patients
         - Patients with completed home med lists (review Med Rec progress note)
      ii. Inclusion criteria (i.e. include these High Risk patients)
         - Patients with pending clarifications to home med list (review Med Rec progress note)
         - Age greater than or equal to 65 years of age
         - 10 or more home medications
         - List of high risk medications that was completed by MD or RN
            a. Opioids (e.g. tramadol, codeine, suboxone, CII meds)
            b. Anti-diabetic (e.g. insulin, glyburide, metformin)
            c. Anticoagulants and/or anti-platelets (e.g. warfarin, apixaban, aspirin, Plavix)
         - HOSPITAL Score ≥ 5 out of 13 (PowerChart → Flowsheet → HOSPITAL score)

3. ED patients
   a) Checks in with ED Charge RN to confirm and prioritize patients (2>3>4; soon to be admitted, etc.)
   b) Review ED Tracker board for appropriate patients prioritizing ESI triage 2-4

Patient Interview

Pharmacy technician shall prepare for patient interview

4. Review patient's chart for patient information (allergies, language spoken, home medication list) and reviews any prior MedRec progress notes if applicable
5. Obtain patient's home med list. Review External
6. Check in with patient's assigned nurse to coordinate appropriate timing and to identify any potential barriers (e.g. language, isolation precautions, pending procedures).
7. Perform proper hand hygiene and if applicable, don appropriate personal protective equipment (PPE) prior to entering room.

Pharmacy technician shall perform patient interview for an accurate medication history list

8. Utilize Language Line if patient is non-English speaking. Document the Language Line translator number.
9. Proper introduction (**A**cknowledge, **I**ntroduce – name/role, **D**uration of interview, and **E**xplain why)
10. Ask patient/caregiver for a medication list and/or bottles.
11. Confirm patient's current/preferred pharmacy(ies) for discharge prescriptions
12. Confirm allergies, intolerances, and reactions
13. Determine who manages patient's home medications and if that person can be contacted
14. Ask open-ended questions about home medications
    a) Do NOT read from list and ask if it's correct
    b) Ask about scheduled and PRN (as needed) medications
    c) Ask about OTC (over the counter) and easy to forget medications (topical, patches, inhalers)
    d) Ask about adherence, any missed doses, and when the last dose(s) were taken
15. Explain importance of carrying a medication list
16. Address questions appropriately and route to appropriate licensed healthcare provider if necessary.
17. Thank patient/family at interview conclusion
18. Perform hand hygiene upon leaving the room

Documentation of accurate home medication list

Pharmacy technician shall confirm medication history

19. Use at least two sources for medication history (e.g. patient and bottles/retail pharmacy/caregiver)
    a) Calling an outpatient pharmacy
        i. Proper introduction (Acknowledge, Introduce – name/role, Explain reason for call)
        ii. Ask pharmacy to fax medication list from past 3 months, if not:
        iii. Go over each medication one by one on the phone
            - Medication name, strength/dose, route, directions, special instructions, last fill
            - Ask if any medications were missed
        iv. FAX requests for authorization for medication information release if indicated
    b) Calling patient's caregiver
        i. Proper introduction (Acknowledge, Introduce – name/role, Explain reason for call)
        ii. Go over every medication including OTC, inhalers, etc.
    c) Calling a patient's skilled nursing facility (SNF)
        i. Proper introduction (Acknowledge, Introduce – name/role, Explain reason for call)
        ii. Ask for SNF medication administration record (MAR) to be faxed
20. Uses resources to look up drug information when needed (e.g. pill identifiers, drug info database)
21. Return to patient to review any new information if necessary
22. Resolve remaining discrepancies

Pharmacy technician shall update the home med list in the electronic health record (EHR)

23. Document findings into EHR accurately
24. Update/discontinue outdated and inaccurate information/medications from HER
25. Complete med history note (PN/Power form)

Pharmacy technician shall sign off to RN/MDs when accurate home med list is complete (verbal or tiger text)

26. Notify patient's RN that home med list is updated
27. Notify patient's MD that home med list is updated

End of day sign out

Pharmacy technician shall identify those admitted patients who are excluded or who do not qualify as "high risk"

28. Document "Patient does not meet criteria" on daily report

Pharmacy technician shall identify any outstanding issues/discrepancies/patients that need follow-up

29. Document "needs follow-up" on daily report and file in the Med Rec Admission Binder

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Approved:	*N/A*
Last Revised:	*7/28/2023*
Next Review:	*3 years after approval*
Owner:	*Sherri Block: Associate Chief Nursing Executive, VCMC & SPH*
Policy Area:	*Administrative - Patient Care*
References:	

100.112 Code White - Pediatric Medical Emergency

POLICY:

The rapid application of Cardiopulmonary Resuscitation (CPR) is essential to patient survival in the event of respiratory or cardiac failure. For "DO NOT RESUSCITATE" orders, see Administrative policy 100.013 Do Not Resuscitate (DNR) Orders.

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.***

CLINIC refers to Ventura County Health Care Agency Ambulatory Care (AC) Clinics. ***See Section II below.***

Section I - Hospital:

A. **Cardiopulmonary Resuscitation (CPR) – Preliminary Steps**:

1. Follow Basic Life Support (BLS) guidelines.
2. In the event of patient respiratory or cardiac failure, call for help by dialing x7-6666 at VCMC or x7-8666 at SPH. Communicate the patient's location and whether an adult or child. If in on a nursing unit, also press the "CODE" button at head of the patient's bed. "CODE WHITE" shall be used for a medical emergency resulting in pulseless arrest or near pulseless arrest in a patient less than 18 years old.
3. Telephone Operator: Shall announce "CODE WHITE" on the paging system.
4. State the patient location and repeat this information two (2) times.
5. In the event of patient respiratory or cardiac failure in the NICU (Neonatal intensive care unit) the patient will be internally managed and a "CODE WHITE" will not be paged.

B. **Code White Response Team:**

1. VCMC members are Pediatric Advance Life Support (PALS) certified.
   a. Pediatric Intensive Care Unit (PICU) Attending Physician or designee.
   b. Residents On call Intensive Care Unit, Medicine, and Surgical residents.

c. Rapid Response Nurse if available
d. PICU Nurse
e. Respiratory Therapist
f. Laboratory
g. Radiology
h. House Supervisor

2. SPH
   a. Hospitalist or Emergency Department (ED) attending
   b. ~~ED or Intensive Care Registered Nurse (RN)~~Designated Critical Care RN
   c. House Supervisor
   d. Respiratory Therapist
   e. Laboratory
   f. Radiology

C. **Personnel Duties:**

1. First on the scene:
   a. Assess airway, breathing and circulation.
   b. Initiate "Code White" by: Dialing x7-6666 at VCMC or x7-8666 at SPH. Communicate the patient's location and whether an adult or child. If in on a nursing unit, also press the "CODE" button at the head of the patient's bed.
   c. Do not leave the patient alone.
   d. Begin CPR.
   e. Participate in the debrief session.
2. First responding physician (and any additional physicians):
   a. Assume the role of team leader; may transfer responsibility of team leader to attending physician or ED physician.
   b. Assign roles to code participants.
   c. Provide a report to the patient's primary physician, if the physician has not attended the code.
   d. Initiate and facilitate the debrief session.
   e. Ensure accuracy of code documentation (code sheet).
3. Departmental personnel (personnel from the department, calling the code):
   a. Obtain a crash cart and bring it to the patient's location.
   b. Attach monitor leads and defibrillation pads to the patient.
   c. Ensure that end tidal carbon dioxide (CO_2) capnography is in place.
   d. Assist with CPR as needed.
   e. Participate in the debrief session.
   f. Exchange the used crash cart (refer to policy 100.113 Crash Cart Check and Restocking for

process roles and responsibilities).

4. Nurse assigned to care for the patient:
    a. Provide a report to the Code Team, including but not limited to:
        i. pertinent history;
        ii. vital signs;
        iii. events leading to the arrest; and
        iv. medication allergies.
    b. Remain with the patient during the code.
    c. Assist with CPR as needed.
    d. Participate in the debrief session.
5. Critical Care or Emergency Department nurse:
    a. Bring the emergency medication box and refrigerated medications to the patient's location.
    b. Ensure placement of monitor leads and defibrillation pads.
    c. Ensure that end tidal CO_2 capnography is in place.
    d. Ensure venous access.
    e. Administer medications as directed.
    f. At SPH the ED or Intensive Care RN will assist in the administration of medications as directed.
    g. Ensure the code record accurately reflects the medications administered.
    h. Assist with CPR as needed.
    i. Participate in the debrief session.
6. Scribe:
    a. Complete the Cardiopulmonary Resuscitation Record.
    b. Ensure that the yellow carbon copy is provided to the Quality Assessment Performance Improvement (QAPI) department and the pink carbon copy is provided to the Pharmacy department.
    c. Complete the Code Debrief Form.
    d. Complete the Electronic Notification Form.
    e. Obtain the team leader's signature on the Cardiopulmonary Resuscitation Record.
    f. At SPH the Medical Surgical nurse responding will act as the Scribe
    g. Participate in the debrief session.
7. Respiratory Therapist:
    a. Bring the airway kit to the bedside, for ventilatory aspects of the procedure.
    b. Manage oxygenation and ventilation with the team leader and identified support physicians.
    c. Assist with oxygen set-up and ventilation, using ambu-bag and oxygen.
    d. Ensure that end tidal CO_2 is monitored.
    e. Provide CPR as needed.

f. Participate in the debrief session.

8. House Supervisor:
    a. Assist with obtaining a bed if the patient is to be transferred to another unit.
    b. Arrange family support.
    c. At **SPH** the House Supervisor will act as the central point of communication. Will contact VCMC Neonatal Intensive Care Unit (NICU) at 805-652-6130 if needed.
    d. Participate in the debrief session.
    e. Collect the Debrief Forms and send them to the QAPI department.
9. Pharmacy:
    a. Obtain and transport medications as needed.
    b. Add the medication tray to the newly obtained crash cart.
    c. Verify medications in the replacement tray have not expired.
10. Nursing Assistant:
    a. Bring the 12 lead electrocardiogram (EKG) machine to the patient.
    b. Stand by to act as runner.
    c. Participate in the debrief session.
    d. At SPH this role is not applicable.
11. Central Supply:
    a. Ensure that the replacement cart is available and that equipment and supplies are not expired (refer to policy 100.113 Crash Cart Check and Restocking for process roles and responsibilities).

D. **Magnetic Resonance Imaging (MRI)**

See Policy 100.055 Code Blue Adult - Medical Emergency for process.

Section II - Clinic:

A. The Ambulatory Care clinics do not house crash carts. The clinics maintain Emergency Response Equipment (refer to Ambulatory Care Policy AC.001 Emergency Response Equipment).

B. ~~In the event of an emergency, clinic staff shall call 911.~~ In the event of an emergency, clinic staff shall call 911. NON-CPR certified staff shall only call 911 and stay with the patient until Certified staff arrives, or until EMS arrives for patient transport to Emergency Department.

1. First on the scene, check the scene for safety
2. Shout for nearby help
3. Call 911
4. Basic Life support certified personnel to initiate high-quality CPR
5. Other responding personnel:
    a. Obtain Emergency Response Cart or Tote
    b. Obtain AED

6. When AED is available, turn on the device and follow prompted instructions and proceed with the BLS algorithm.

CPR certified clinic staff shall initiate CPR if needed, apply the Automated External Defibrillator (AED), maintain an open airway and administer oxygen. Non-CPR certified staff shall **only** call 911 and stay with the patient until help arrives.

Cardiopulmonary Resuscitation Outside of Hospital Buildings:

First on the scene, check for safety, shout for help, call 911, and Initiate BLS protocol ~~and call 911~~. Staff to attend codes on Hospital Campus in accordance with Policy 100.224 Emergency Medical Treatment and Labor Act (EMTALA) Guidelines.

ATTACHMENTS:

A. 2015 American Heart Association, Summary of High Quality CPR Components for BLS Providers

B. Cardiopulmonary Resuscitation Record

C. NICU Cardiopulmonary Resuscitation Record

All revision dates: 7/28/2023, 3/14/2023, 8/10/2022, 1/14/2020

Attachments

Attachment A- BLS-CPR 2015 American Heart Association Guidelines.pdf
Attachment B- Cardiopulmonary Resuscitation Record.pdf
Attachment C- NICU Cardiopulmonary Resuscitation Record.pdf

Approval Signatures

Step Description	Approver	Date
Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	pending
Ambulatory Care	Cynthia Fenton: AC Director of Nursing	8/3/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/28/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/28/2023
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/28/2023

Current Status: *Pending* **PolicyStat ID:** *14137659*

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Alicia Casapao: Director of Quality and Performance Improvement*
Policy Area:	*Administrative - Nursing*
References:	

108.021 Pressure Injury Prevention and Wound Management

POLICY:

~~Patients identified as being at risk for alteration in skin integrity or with pressure injuries will be managed by nursing personnel in collaboration with the provider team, if needed.~~

~~Goals:~~

Ventura County Medical Center and Santa Paula Hospital are committed to providing quality care to all its patients. Risk for pressure injury development will be evaluated upon admission to a nursing care unit as indicated using the age appropriate Braden scale, appropriate tool, or procedure. Based on assessment, a plan of care will be developed and implemented using appropriate prevention and treatment interventions (see appendices). The primary Licensed Practitioner (LP) shall be informed of patient skin integrity issues and documented in the patient's medical record.

PURPOSE

The ~~purpose of this~~ policy ~~is to~~and procedure establish guidelines for ~~assessments/ reassessments~~assessment of risk, early detection, prevention, and identification of occurrence of skin breakdown in hospital patients. It also describes interventions, management and documentation ~~to identify, prevent, and manage patients with~~of potential or actual cases of alteration in skin integrity during the patient's hospital stay. ~~Goals are to:~~

~~A. Maintain the integrity of the patient's skin.~~

~~B. Minimize the causes and risk factors of skin breakdown.~~

~~C. Provide for early detection and intervention of skin breakdown upon admission.~~

~~D. Prevent the occurrence of skin breakdown.~~

~~E. Promote prompt evaluation and intervention of any changes in skin integrity during hospitalization.~~

~~EQUIPMENT~~

~~A. Electronic Health Record (EHR) skin assessment tool~~

~~B. EHR - Braden Risk Assessment Tool~~

C. Pressure reducing devices

PERFORMED BY: All licensed nursing personnel.

RESPONSIBILITY

- The prevention and management of pressure ulcer requires interdisciplinary collaboration to identify and manage contributory factors and implement a plan of care that promotes wound healing
- **WOUND CARE TEAM**
  - consulted for treatment recommendations
  - responsible for confirming the stage of suspected pressure injuries beyond Stage I
  - will confer with the licensed practitioner (LP) and primary nurse regarding the appropriate treatment to effectively manage the patient's skin breakdown
- The primary Licensed Practitioner (LP) will disclose the occurrence of pressure ulcer meeting the criteria of an adverse event to the patient or designated family member / significant other. The disclosure shall be documented in the Electronic Health Record (EHR). (See also 102.002 Disclosure of Unanticipated Outcomes)

PROCEDURE:

All adult and pediatric patients will be evaluated for pressure injury risk by using the age appropriate Braden Scale (See Attachments B & C) on admission and every shift. Risk assessments will be performed more often when the patient condition warrants more frequent assessments. Nursing staff will assess the skin integrity of all patients throughout their hospital stay. In addition, nursing will manage and collaborate with the health care team regarding patient's skin integrity. Patients and family are to be encouraged by health care providers to participate to the extent possible in the care and prevention of skin breakdown.

Skin and Risk Assessment / Reassessment

Assessment

1. Risk assessment
   a. Assess total skin condition upon admission and every shift utilizing the "Four Eyes Skin Assessment" (two sets of eyes = four eyes). This collaborative method utilizes two different licensed professionals (e.g., Two Registered Nurses (RNs) or One RN/One Nurse Practitioner (NP), Physician, or Physician Assistant (PA) to identify, describe and record suspected pressure injuries. Thorough skin assessment will be completed:
      - within four hours of a patient's admission – or
      - patient transfer to another unit - or
      - when greater than four (4) hours have passed since patient is off the unit - or
      - as necessary - with changes in patient condition - and/or
      - day of discharge / transfer
   b. A skin assessment includes, but is not limited to: skin color, description, integrity, temperature, turgor, and mucous membrane color
   c. Assess level of mobility
   d. Assess neurological status

e. ~~Assess circulatory status~~

f. ~~Review nutritional status~~

g. ~~Complete age-appropriate Braden Scale risk assessment tool every shift (Braden score of 14 or less places a patient at moderate or severe risk)~~ [1][2][3]

A. **Assessment/Reassessment**

1. Risk assessment

a. Use age-appropriate Braden Scale on all inpatients to assess for pressure injury risk (refer to Attachment B and C):

- Utilize Braden Scale for patients greater than 8 years old
- Braden Q Scale for patients 21 days old up to 8 years old
  - On Admission
  - Daily
  - Transfers
  - As needed (PRN) (e.g. decline in patient condition)
  - After prolonged procedure/surgery (longer than 2 hours

b. Skin assessment, on ALL patients, which includes a head-to-toe, physical inspection of the skin (between skin folds, buttocks, areas under and around respiratory therapy medical devices and medical equipment)

- Frequency minimum (may perform more frequently based on patient condition):
  - Every 4-hours
    - ICU
    - PICU
    - NICU
  - Every shift
    - Nursery
    - Pediatric
    - Post-Partum
    - Labor & Delivery
    - Med-Surg
    - Tele
    - DOU
    - Behavioral Health
- Preventive/protective padding placed over intact, non-broken skin are temporarily removed when performing a skin inspection.
- Therapeutic/Immobilization devices, e.g. cervical collars, trach collar, boots, braces, halo vests, and thoracic lumbosacral orthoses (TLSOs) may require a licensed practitioner's order prior to removal. The device is still to be checked for tightness around skin and bony

prominences, moisture, surrounding skin status, and patient comfort.

- Perform a skin assessment upon patient's return from prolonged procedures/surgeries.
- When there is a decline in patient's condition
- Per primary LP order

c. On admission, transfer, and discharge the Four Eyes check shall be performed by two licensed professionals (e.g. Two RNs or One RN/One Nurse Practitioner (NP), Licensed Practitioner (LP), or Physician Assistant (PA) and documented in the electronic health record (EHR), noting the name of the second licensed professional.

d. In the **Emergency Department**, perform a skin assessment with Four Eyes check as soon as decision to admit to inpatient or observation is made and prior to transfer.

e. Surgical Department - See Policy S.49 Perioperative Nursing Standards of Practice

B. **Treatment/Interventions**

Registered Nurses (RNs) to initiate Interdisciplinary Plan of Care (IPOC), related to skin integrity, for patients
with actual or at risk for impaired skin integrity (Braden Score of 16 or less).
Licensed vocational nurses, nursing attendants, and student nurse workers are to collaborate with the RN ensuring the plan of care compliments the patient's needs and interventions are carried out.

C. **Treatment/Equipment Interventions**

1. Braden Score of 19 or greater
   a. Assess for skin integrity risk every shift and as necessary with changes in patient condition
   b. Encourage or assist patient to change position every two (2) hours
   c. Provide patient/family education
2. Braden Score ≤ 18 (18 or below)

~~Implement pressure relieving devices per nursing judgment:~~

~~i. Assist with turning at minimum every two hours. Use the Patient Positioning tracker to assist in displaying turn schedule.~~

~~ii. Implement appropriate pressure relieving devices:~~

- ~~Mattress overlay~~
- ~~Heel offloading boots~~
- ~~Foam wedges~~
- ~~Pillows~~
- ~~Special therapy beds~~
- ~~Protect skin underneath restrictive devices (i.e. restraints, splints, medical devices/ equipment)~~

~~iii. Assess the need for measures to control incontinence~~

- ~~Condom catheter / Purewick external catheter~~
- ~~Frequent diaper changes~~

- ~~Barrier creams / barrier cream-infused cleansing cloths~~
- ~~Linen changes, as needed~~
- ~~Super absorbent chux pads~~

~~iv. Initiate Dietary consult if patient screens positive for any of the following:~~

- ~~Body Mass Index < 18[4]~~
- ~~Poor intake~~
- ~~Excessive fluid loss (i.e. diarrhea, vomiting, blood loss, large wounds)~~

~~v. Initiate appropriate care plans in EHR (i.e. pressure injury management, pressure injury prevention, impaired tissue perfusion). Update care plans as indicated.~~

~~vi. Request a wound care consult, if indicated.~~

a. Assist with turning at minimum every two hours.

b. Implement pressure relieving devices:

i. Mattress overlay

ii. Heel offloading boots

iii. Foam wedges

iv. Pillows

v. Special therapy beds

vi. Protect skin underneath restrictive devices (i.e. restraints, splints, medical devices/ equipment)

c. Initiate appropriate care plans in EHR (i.e. Pressure Ulcer Management, Pressure Ulcer Prevention, Impaired Skin Integrity). Update care plans as indicated.

d. Request a wound care consult, if indicated.

e. Complete nutritional screening within 24 hours of admission.

3. Assess the need for measures to control incontinence

- External catheter
- Frequent diaper changes
- Barrier creams / barrier cream-infused cleansing cloths
- Linen changes, as needed
- Super absorbent chux pads

4. Braden Score ≤ 14 (14 or below), pressure injury is present~~, or per nursing judgment~~:

a. Initiate a wound care consult as soon as patient is identified as moderate or severe risk (Braden ≤ 14)

b. Implement Pressure Injury Prevention Measures (see above Section 2~~.a.~~)

c. Initiate a ~~dietary~~nutrition consult

d. Initiate order for turn schedule (nurse-initiated order in EHR)

e. Initiate appropriate Interdisciplinary Care Plans (see 2.a.v), and update as indicated

f. Consult with Wound Care ~~Nurse~~Team for staging of Hospital Acquired Pressure Injuries (HAPI's) or Community Acquired Pressure Injuries (CAPI's) See Attachment A.

5. Patients with medical devices

   a. RN to ensure that skin in contact with medical devices are padded accordingly and observed for skin breakdown. Examples of devices (nasal cannula, nasogastric tubes, tracheostomy, cervical collar, brace, splints, CPAP, sequential compression device (SCD), gastric tube, boots, external catheters)

6. End-of-Life Patients

   a. Reposition and turn the patient periodically to maintain patient's comfort.

~~**Documentation**~~

~~1. I-View Documentation~~

~~a. Skin-ADL-Nutrition flow sheet~~

~~i. Skin assessment on admission, every shift, transfer to another unit, and with changes in patient condition(as indicated)~~

~~ii. Braden Scale assessment~~

~~iii. Documentation of positioning devices, pressure relieving devices, and special surfaces/ beds in use~~

~~iv. Documentation of incision/ wound, if present, create a dynamic group~~

~~v. Position changes/ patient's ability to turn~~

~~vi. Documentation of skin integrity under medical equipment/ device(s)~~

~~vii. Patient response to interventions~~

~~viii. Patient/ family education~~

~~b. Document/ Update Interdisciplinary Plan of Care (IPOC)~~

~~c. Nursing progress notes~~

~~i. Describe wound(s) in detail and consult with Wound Care Team for staging~~

~~d. Measure and photograph on discovery, prn changes, weekly (Wound Wednesday) and on day of discharge~~

~~i. Wounds with negative pressure wound therapy~~

~~ii. Suspicious wounds~~

~~iii. Pressure Injuries~~

D. **Documentation**

1. Skin assessment on admission, every shift, transfer to another unit, and with changes in patient condition (as indicated)
2. Nursing progress notes: Describe wound(s) in detail and consult with Wound Care Team for staging beyond Stage 1
3. Braden Scale assessment
4. Interdisciplinary Plan of Care (IPOC)

5. All pertinent information related to skin abnormalities (e.g., skin integrity under medical devices, incision/wound if present
6. Pressure injury prevention interventions (e.g., positioning devices, pressure relieving devices, special surfaces in use, position changes, patient's ability to turn)
7. Photos taken
8. LP that was notified
9. Patient/Caregiver/Family education
10. Patient response to intervention(s)

E. **Photos**

1. Measure and photograph any skin impairment on:
   - Admission
   - Upon discovery of a new skin impairment
   - When significant changes occur
   - Weekly (Wound Wednesdays)
   - Within a week of discharge or transfer to outside facility
   - Photos must include medical record number, date and time
   - For photos that include a ruler, document measurement in iView

F. **Notifications**

1. Notify Primary Licensed Practitioner (not limited to) of:
   - Wound/skin abnormalities present on admission and upon discovery
   - Deterioration of existing wound/skin abnormality
   - Need for possible debridement
   - Signs of infection
   - Orders for wound treatment

G. **Reporting**

1. All actual or suspected pressure injuries must be reported immediately to department manager or designee~~, as well as an entry made into the notification system~~. (See attachment D - HAPI Reporting Workflow and attachment D.1 CAPI Reporting Workflow)
2. All actual or suspected pressure injuries must be reported via the notification system, utilizing the "Skin Integrity" category (See attachment E - Skin Integrity Reporting Workflow).

   ~~Notify physician and/or licensed independent practitioner~~

   ~~Notify wound care nurse~~
3. Notify primary LP
4. Notify Wound Care Team
5. Wound Care RN to activate reporting workflow (See attachment)

References

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3. Wolters Kluwer Health, Inc. (2004). By the Numbers: Braden Score Interventions. *Advances in Skin & Wound Care, 17(3), 150.* http://www.journals.lww.com/aswcjournal/citation/2004/04000/By_the_Numbers_Braden_Interventions.16.aspx.
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All revision dates: 8/3/2023, 1/10/2023, 9/13/2022, 1/28/2020, 2/1/1992

Attachments

Attachment A - Pressure Injury Staging
Attachment B - Braden Scale for Predicting Pressure Sore Risk.pdf
Attachment C - Braden Q Scale.pdf
Attachment D - HAPI Reporting Workflow.pdf
Attachment D.1 - CAPI Reporting Workflow.pdf
Attachment E - Skin Integrity Workflow.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/3/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/3/2023
Policy Owner	Alicia Casapao: Director of Quality and Performance Improvement	8/3/2023

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*12/1/1989*
Effective:	*Upon Approval*
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Next Review:	*3 years after approval*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.17 Health Care Agency (HCA) Employee Industrial Blood Borne Pathogen and Infectious Agent Injuries

POLICY:

To establish guidelines for completing paperwork and treating an HCA employee industrial injury involving blood borne pathogens or infectious agents in the Emergency Department (ED).

PROCEDURE:

A. Patient:
   1. Reports injury/illness to manager/supervisor.
   2. Receives Employee's Claim for Workman's Compensation Benefits form #RM 135/DWC.
      a. Employee completes section 1 through 8. The manager/supervisor completes section 9-18.
      b. When completed, the goldenrod copy is kept by the employee.
   3. Patient then presents to ED to be treated.

B. Manager/Supervisor/House Supervisor
   1. Manager/supervisor is notified of the exposure.
      a. If an exposure occurs after hours or on the weekend, the House Supervisor on duty must be informed **immediately** and will be responsible for following the steps below.
   2. Manager/supervisor meets with the employee and supplies the Employee's Claim for Workers' Compensation Benefits form-as stated above.
      a. The employee completes section 1 through 8. The manager/supervisor completes section 9-18.
      b. When completed, the goldenrod copy goes to the employee.
   3. Manager/supervisor also completes the Employer's Report of Occupational Injury or Illness Involving Bloodborne Pathogens and Infectious Agents form #RM75B.
   4. The employee is referred to the ED for medical treatment.
   5. The manager/supervisor forwards the following forms via brown mail to the Health Care Agency Human Resources Department:

a. Employer's Claim for Workers' Compensation Benefits.

b. Employer's Report of Occupational Injury or Illness Involving Bloodborne Pathogens and Infectious Agents.

C. ED Admitting Clerk

1. Admitting Clerk will supply the Doctor's First Report of Occupational Injury or Illness form #VCMC 390-220 to the employee.
    a. Employee completes sections 1-17 and returns the form to the Admitting Clerk.
2. Admitting Clerk will then attach the two (2) forms to the ED chart:
    a. Doctor's First Report of Occupational Injury or Illness, partially completed by the patient.
    b. Physician's Notice of Return to Work or Temporary Medical Restrictions' form #RM505.

D. ED Registered Nurse (RN):

1. The ED RN will attach the Blood Exposure/Needle Stick packet to the patient's ED record. Packets are located at the nurse's station in the ED and include:
    a. Employee Health Services' business card
    b. Post Exposure Follow-Up letter
    c. Employee Checklist Post Exposure Prophylaxis
    d. Exposure to Blood, Centers for Disease Control (CDC) Pamphlet
    e. Responsibilities of ER RN Checklist
    f. Brief History of Exposure
2. ED RN will follow the Responsibilities of ED RN checklist which includes:
    a. Notify Public Health Lab at (805) 981-5131, you may leave a message and state MR# only, date/time of exposure. Also notify Nursing Supervisor and the Infection Control Department at ext. 3256 of the exposure.
    b. Document MR# ONLY of source on ED chart.
    c. Give employee the Exposure to Blood, Centers for Disease Control (CDC) Pamphlet.
    d. Give employee Post Exposure Follow-up letter from Employee Health Services for their records
    e. Make sure that blood work has been ordered and drawn on the patient--Needle Stick Employee (NSE).
    f. Complete the Employee Checklist Post Exposure Prophylaxis form with employee and place in the ED chart.
    g. If source is available, make sure that blood is ordered and drawn Needle Stick Protocol (NSP).

E. ED Physician:

1. Patient is treated.
2. Complete the Brief History of Exposure Progress Record.
3. Contact the Infectious Disease Consultant as needed.
4. Order NSP on source (NSP includes Rapid Plasma Reagin (RPR), Hepatitis B Surface Antigen, ~~Hepatits~~Hepatitis C Antibody, Human Immunodeficiency Virus STAT).

5. Order NSE on patient (NSE includes RPR, Hepatitis B Surface Antibody, Hepatitis C Antibody, Human Immunodeficiency Virus).
6. Discuss treatment options with patient.
7. If placing on post exposure prophylaxis (PEP) medications perform baseline Chem Panel, Complete Blood Count with Differential (CBCD) and Pregnancy Test (ICON).
8. Refer patient to Employee Health Services (805) 654-3813 for follow up care the next business day.
9. Complete the Doctor's First Report of Injury or Illness form, section18-26, including signature and license number.
10. Complete the Physician's Notice of Return to Work or Temporary Medical Restrictions form, goldenrod copy goes to the patient for their supervisor.
11. Both completed forms, Doctor's First Report of Injury or Illness and Physician's Notice of Return to Work or Temporary Medical Restrictions, are placed on top of the ED chart and given to the ED Clerk.

F. ED Clerk:

1. Gathers all ED records and forwards them to the ED Clerical Supervisor for processing.

G. ED Clerical Supervisor:

1. Receives the ED chart along with the two (2) completed forms, Doctor's First Report of Injury or Illness and Physician's Notice of Return to Work or Temporary Medical Restrictions.
2. Doctor's First Report of Injury or Illness and Physician's Notice of Return to Work or Temporary Medical Restrictions forms are faxed to:
   a. Health Care Agency Human Resources at (805) 677-5188
   b. Employee Health Services at (805) 654-5028
3. ED Clerical Supervisor distributes the forms accordingly:
   a. The pink copy stays with the original ED chart.
   b. The goldenrod copy is filed in the ED Clerical Supervisor's office.
   c. The white and canary copies remain are forwarded via brown mail to the Insurance Department.

All revision dates:	8/16/2023, 8/26/2020, 11/1/2016, 12/1/2013, 5/1/2011, 5/1/2006, 12/1/2004, 11/1/2001, 1/1/1995, 10/1/1992

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Emergency Department	Tracy Chapman: VCMC - Med Staff	pending

Step Description	Approver	Date
Committee		
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	6/28/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/28/2023
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	6/28/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*5/1/2006*
Next Review:	*3 years after approval*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.26 Law Enforcement in the Emergency Department

POLICY:

To outline policy regarding communications and process between the Emergency Department (ED) and area Law Enforcement.

PROCEDURE:

In conformity with the ruling of the Office of the Attorney General of the State of California concerning the relative rights of law enforcement personnel and hospital staff or physicians to control the scope of a criminal investigation in the situation where either the subject or the victim of a crime requires hospitalization or other immediate medical treatment, the following conclusions of the Deputy Attorney General will be used as guidelines:

1. A hospital may not enforce rules preventing a police officer from interviewing or otherwise gathering evidence from a patient if admitted to the hospital.
2. There is no distinction between publicly supported hospitals and private hospitals in regard to the above.
3. A doctor may not lawfully prohibit an investigation concerning his patient, but may affect the timing and scope of the investigation for medical reasons.
4. The right of the police to investigate is greater if the patient is a suspect rather than merely a victim.
5. The attending doctor may not prevent an officer from attempting to obtain a dying declaration.
6. Doctors and other hospital staff may be subjected to criminal prosecution if they willfully attempt to prevent a lawful investigation.
7. The classification of a crime under investigation as a felony or misdemeanor does not in itself affect the permissible scope of investigation.
8. As a general guideline, it is not permissible for police to withhold medical treatment for the purpose of obtaining evidence. On the other hand, it may be permissible to delay medical treatment in order to minimize existing danger.
9. In any given situation, the totality of circumstances will determine what a law enforcement officer may properly do.
10. Any situation involving questions of legality should be brought to the attention of Hospital Administration

and Nursing Administration.

All revision dates: 5/1/2006, 2/1/2005, 11/1/2001, 1/1/1995, 10/1/1992

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Emergency Department Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/12/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/12/2023
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	7/12/2023

Current Status: *Pending* **PolicyStat ID:** *13986396*

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*7/12/2023*
Next Review:	*3 years after approval*
Owner:	*Julia Feig: Clinical Nurse Manager, Emergency Services*
Policy Area:	*Emergency Services*
References:	

ER.32 Minimum Law Enforcement Staffing in the Emergency Department

POLICY:

To ensure consistent, minimum law enforcement officer staffing coverage in the Emergency Department (ED) at Ventura County Medical Center (VCMC) through a priority listing of positions.

PROCEDURE:

Ventura Police Department will determine the specific law enforcement officer to be assigned to the ED at VCMC. The hours of assignment will be:

Sunday – Thursday	1:00 PM to 12:00 AM
Friday – Saturday	2:00 PM to 1:00 AM

with 30 minutes travel time at start of shift. Hours may change on the weekends and are also subject to change based on staffing levels and other factors.

All revision dates: 7/12/2023, 9/3/2020, 5/1/2010

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Emergency Department Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/12/2023
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/12/2023
Policy Owner	Julia Feig: Clinical Nurse Manager, Emergency Services	7/12/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*7/14/2020*
Next Review:	*3 years after approval*
Owner:	*Matt McGill: Director, Imaging Services*
Policy Area:	*Imaging Services*
References:	

IS.31 MRI Screening of Pregnant Patients

POLICY:

There is currently no known fetal risk from MRI scanning during pregnancy. However, due to the relative short history of this technology, its long term effects cannot yet be fully determined. Ventura County Medical Center and Santa Paula Hospital will follow a conservative approach to scanning pregnant patients.

PROCEDURE:

All female patients will be asked if they are pregnant or suspect that they could be pregnant.

Any patient that states they may be pregnant will not be scanned until the ordering physician and radiologist consult with each other.

A pregnancy consent form must be filled out and signed by any pregnant patient prior to an MRI scan (see Attachment A, copy of attached form).

After satisfactory radiologic consultation, MRI scanning is generally acceptable in the second and third trimester of pregnancy, but should be excluded in the first trimester unless there are extremely emergent circumstances. In general, all scans of pregnant patients should be deferred as long as possible. Additionally, MRI should not be withheld for the following symptoms or cases:

- Patients with active brain or spine signs and symptoms requiring emergent scanning.
- Patients with active cancer requiring imaging.
- Patients with chest, abdomen and pelvic symptoms of active disease when ultrasound is non-diagnostic.
- In suspected cases of fetal anomalies or complex fetal disorders.

Gadolinium Based Contrast Agents (GBCAs) are FDA category C agents and may cause fetal harm based on animal data. GBCA's do cross the placenta and because it is unclear how GBCAs affect the fetus, these agents should not be used in pregnant or potentially pregnant patients. GBCA's should only be used if their usage is considered critical and potential benefits outweigh the potential but unknown risk to the fetus. If used, the following must take place*:

The radiologist must confer with the ordering physician. The ordering physician shall document the following in the electronic health record (EHR):

- The information requested from the MRI cannot be acquired without the use of IV contrast or other imaging modalities.
- The information needed affects the patient or fetus during the pregnancy.

- The referring physician is of the opinion that it is not prudent to wait to obtain this information until after the patient is no longer pregnant.
- Informed consent should be obtained from the patient after discussion with the referring physician.

All revision dates: 7/14/2020, 1/1/2016

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: VCMC - Med Staff	pending
Imaging Services	Matt McGill: Director, Imaging Services	7/18/2023
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	6/9/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*7/18/2023*
Next Review:	*3 years after approval*
Owner:	*Matt McGill: Director, Imaging Services*
Policy Area:	*Imaging Services*
References:	

IS.41 CT MEDICAL PHYSICIST INSPECTIONS

POLICY: All CT scanners located at Ventura County Medical Center and Santa Paula Hospital will have an annual inspection performed on them by a Medical Physicist.

PROCEDURE: The three CT scanners located at Ventura County Medical Center and the one CT scanner at Santa Paula Hospital will have an annual Medical Physicist inspection performed on the machines to meet the regulatory requirements for the State of CA and The Joint Commission.

Any deficiencies or items that do not meet the State of CA or Joint Commission requirements will be corrected within 30 days by Philips Healthcare Service Engineers.

The Medical Physicist will validate that the CT units meet the requirements of the American College of Radiology and The Joint Commission specific testing requirements. The following items will be a part of the Medical Physicist Inspection:

Review of CT protocols, Scout position accuracy, Alignment Light Accuracy, Table travel accuracy, Slice thickness accuracy, Radiation Beam width, High Contrast resolution, Low Contrast resolution, Geometric accuracy, CT number accuracy, CT number uniformity, Artifact evaluation, Acquisition Monitor display calibration.

~~The Medical Physicist will review all of the current CT protocols with the Radiologists and with the CT technologists. A portion of the Physicist report will state that the protocols were reviewed and approved as part of the annual inspections.~~

The Medical Physicist will review all measured doses against current CT protocols to ensure they are within the limits established by the ACR for credited scanners and will review DLP Dose Log information as specified with the Radiation Safety Committee.

All revision dates: 7/18/2023, 7/14/2020

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: VCMC - Med Staff	pending
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	7/25/2023
Imaging Services	Matt McGill: Director, Imaging Services	7/18/2023

Current Status: *Pending* **PolicyStat ID:** *13798933*

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*7/14/2020*
Next Review:	*3 years after approval*
Owner:	*Matt McGill: Director, Imaging Services*
Policy Area:	*Imaging Services*
References:	

IS.42 IMAGING PROTOCOLS REVIEW

POLICY: All imaging exam protocols will be reviewed every three years.

PROCEDURE: To validate that all imaging exam protocols meet the current American College of Radiology standards of care, the Medical Director of Imaging Services for Ventura County Medical Center and Santa Paula Hospital will review these protocols every three years.

The Imaging modality protocols that will be reviewed every three years will be for: CT, MRI, Ultrasound, Nuclear Medicine, Diagnostic Fluoroscopy procedures and Interventional Radiology.

A typed signature page will be placed into each modalities protocol binder with the Medical Director of Imaging's signature and date of the review.

All revision dates: 7/14/2020

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: VCMC - Med Staff	pending
Imaging Services	Matt McGill: Director, Imaging Services	7/18/2023
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	6/9/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*10/3/2017*
Next Review:	*3 years after approval*
Owner:	*Matt McGill: Director, Imaging Services*
Policy Area:	*Imaging Services*
References:	

IS.43 MRI Hearing Protection

POLICY:

Acoustic noise produced during an MRI procedure represents a potential risk to patients, staff and visitors in the MRI environment. Hearing protection shall be worn in the MRI scanner room during MRI exams to protect against hearing damage.

PROCEDURE:

The MRI scanner (Zone 4) creates loud noise associated with the rapid acceleration of electromagnetic currents within the gradient coils. During an MRI, the gradient coils move and vibrate against their mounting devices which creates loud tapping, knocking or squealing.

All patients will be informed about the noises that will be emitted from the MRI scanner during the course of the exam and will be given hearing protection such as earplugs or headphones to dampen the noise. All medical providers and all family members that will be in the MRI scanner room will also be given hearing protection.

All revision dates: 10/3/2017

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medicine Committee	Tracy Chapman: VCMC - Med Staff	pending
Imaging Services	Matt McGill: Director, Imaging Services	8/1/2023
Imaging Services	Michael Hepfer: Medical Director, Imaging Services	7/27/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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Last Revised:	*1/1/2016*
Next Review:	*3 years after approval*
Owner:	*Kristina Swaim: Clinical Nurse Manager, OB*
Policy Area:	*Maternal Child Health*
References:	

MCH.04 Infant and Child Car Seat Safety

POLICY:

To provide information regarding the California Child Passenger Safety Law to all parents/ guardians of children discharged from Ventura County Medical Center (VCMC). California Health & Safety Code Section 1268(b) requires hospitals at the time of, or before the discharge of, a child **under the age of eight (8) years or of height less than 57 inches** to provide and discuss information on the law requiring child passenger restraint systems to the parent or to whom the child is released.

It is with intent to ensure that children, who are, because of their tender years, helpless dependent passengers, are provided with the safest transportation possible per vehicle code 27364.

PROCEDURE:

A. VCMC nursing shall provide to and discuss with the parent or person to whom the child is released information on child passenger restraint systems. If the child is under eight (8) years of age, provide the parents/guardian with contact information to direct the person to a website or other resource that can provide at no cost or low cost, information and assistance relating to child passenger restraint system requirements, installation and inspection. Pursuant of California Vehicle Code 27363.5, VCMC nursing /staff **DOES NOT** have any additional obligation to provide patients with any assistance relating to child passenger restraint systems, other than providing the contact information as set forth.

   1. Call 1-866-SEAT-CHECK or visit www.seatcheck.org to find a nearby Seat Inspection location (see Attachment A).
   2. The telephone number of the local office of the Department of the California Highway Patrol (see Attachment A).
   3. The Internet Web site for the National Highway Traffic Safety Administration's Child Seat Inspection Station locator (www.nhtsa.gov) (see Attachment A).
   4. The website for the State Department of Public Health's child passenger restraint system safety inspection locator (www.cdh.ca.gov) (see Attachment B).

B. VCMC shall not be responsible for the failure of the parent or person to whom the child is released to properly transport the child.

C. VCMC nursing will provide a summary of current State laws requiring child passenger restraint systems to be used when transporting children in motor vehicles (See Attachment B).

D. VCMC nursing will provide information describing the risk of death or serious injury associated with the

failure to utilize a child passenger restraint system.

GUIDELINES

A. Provide parents/guardians child passenger restraint information/education that encompasses the following:
   1. Handout on local seat inspection stations (Attachment A)
   2. State Department of Public Health handout, "Knowing California Laws Will Keep Your Family Safe in the Car"
   3. Parents and healthcare providers sign V C Section 27360 Child Passenger Restraint System

B. **Health Care Providers DO NOT touch, carry, or place car seat in automobile.**

C. **Health Care Providers DO NOT place infant/child in car seat upon discharge; this is the parents'/guardians' responsibility.**

DOCUMENTATION

A. Document in electronic health record (EHR) all education and resources given.

B. A signed copy of V.C. Section 27360 Child Passenger Restraint System will be placed in chart (Attachment C).

C. Document the mode and time of discharge in EHR.

REFERENCES:

- Department of Motor Vehicles, California Vehicle Code 27360, 27360.5, 27363, 27363.5 and 27364
- National Highway Traffic Safety Administration (www.nhtsa.gov)
- State Department of Public Health (www.dph.ca.gov)
- Pro Care Seat Safety (www.procarseatsafety.com)

All revision dates: 1/1/2016, 4/1/2013, 1/1/2010, 10/1/2004, 7/1/1997, 4/1/1995, 1/1/1994, 1/1/1993, 1/1/1992, 11/1/1991

Attachments

ChildSafetyBrochure_EnglishVer.pdf
ChildSafetyBrochure_SpanishVer.pdf

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	7/25/2023

Step Description	Approver	Date
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	7/25/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	7/25/2023

VENTURA COUNTY
HEALTH CARE AGENCY

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

MCH.07 Infant Identification Bands and Security Tag Procedure

POLICY:

To describe nursing responsibility regarding identification banding (ID) and security tag placement of newborns/infants and children born and/or treated at Ventura County Medical Center and Santa Paula Hospital.

DEFINITIONS:

Identification (ID) Band: A set of four bands used to identify and associate the newborn, infant or child to their birth parent and/or primary caretaker(s).

Security Tag: Using a sensor based tracking system, a security tag placed on infant to prevent abduction. For purposes of this policy, security tags will be used only at Ventura County Medical Center.

Centrak: Infant Security System

EQUIPMENT:

Four (4) infant identification bands with inserts

Centrak Security Tag and disposable band

Centrak Information Technology System

PROCEDURE:

I. Obstetrics Department-Labor and Delivery/Postpartum

A. The infant identification bands will be placed in the birth parent's chart upon admission to the hospital. The ID band inserts will be accurately filled out to include the birth parents first and last name and medical record number.

B. At the time of delivery of the newborn, the delivery or nursery nurse will write the date, time of birth, and newborn's gender on all four inserts.

C. The primary nurse will verify with a second staff member that all information was accurately written on ID band inserts. Staff members will confirm that all four (4) ID band numbers match.

D. The two verifying staff members will confirm the correct ID band numbers are recorded into the electronic medical record (EMR) and electronically sign as the witness.

E. ID band(s) must be placed on the newborn and parent(s) and or designated caretaker prior to leaving the delivery area. The delivery area may include a Labor and Delivery room, OB Operating Room, Main Operating Room or Emergency Department.

F. The receiving registered nurse (RN) who receives the infant from the delivery room will verify the ID bands and record the ID band number is documented in the EMR.

G. The receiving Postpartum nurse will place a security tag on the newborn at the time of admission to the postpartum unit. The infant will be admitted to the Centrak system. The security tag number will be documented in the EMR with a second staff member as a witness.

H. Each time the care of the infant is assumed by any staff member, the infant ID band and security tag will be verified, including the numbers.

I. At shift change or when assuming care the RN must verify ID band and security tag.

J. Each newborn must wear two ID bands and a security tag at all time

K. If ID band or Infant Security tag is found to be off baby, confirm correct information and replace securely. Document changes if necessary in EMR. Clear alarms in Centrak system as needed.

L. If ID band(s) are lost or unable to be re-secured, a complete new set of four ID bands is made following the initial banding procedure.

M. ID bands, and security tag, will remain intact when transferring to a different unit. Exception will be transferring to PICU. The security tag will be removed , and a new one placed when admitted to the PICU.

N. At the time of discharge ID bands will be verified with primary parents ID band. ID bands maybe removed at this time per parent(s) request.

O. When a newborn is discharged, the primary nurse will remove the infant security tag and discharge the patient from the Centrak system.

II. Neonatal Intensive Care Unit (NICU)

A. Upon admission to the NICU, the admitting RN will verify the ID bands and record the ID band number in the EMR

B. The admitting RN will place a security tag on the newborn at the time of admission. The infant will be admitted into the Centrak system. The security tag number will be documented in the EMR.

C. Only infants in an open crib and that weigh more than ~~1500~~2500gm will be required to wear security tag.

D. The admitting RN will place a soft band with the patient label securely attached.

E. Each time the care of the newborn is assumed by any staff member, the ID band and the security band will be verified, and the numbers documented in the EMR. The staff member will also verify the patient's name and DOB on the soft band. In the case of multiples, the patient MRN can also be used.

F. If ID band or security tag or soft band is found to be off the baby, confirm correct information and replace securely document changes, if necessary, in the EMR. Clear alarms in Centrak system as needed.

G. If ID bands are lost or unable to be re-secured, a complete new set of four ID bands is made and documented in the medical record.

H. At the time of discharge ID bands will be verified with primary parent's ID band. ID bands maybe removed

at this time per parent(s) request.

I. At the time of discharge. The primary nurse will remove the infant security tag and discharge the patient from the Centrak system

J. When a newborn is transferred to PICU, the primary nurse will remove the infant security tag and discharge the patient from the Centrak system in the NICU. IF the patient is transferred to PEDS or Post-Partum, the infant can keep the same security tag.

III. Pediatrics/Pediatric Intensive Care Unit (PICU)

A. All patients admitted to the Pediatric Units will receive an ID band and a security tag upon admission. It must be worn at all times

B. The patient will be admitted to the Centrak System. The security tag number will be documented in the EMR

C. Each time the care of the patient is assumed by any staff member, the RN must verify the ID band and security tag, including the numbers, and document the ID band and security tag numbers on shift assessment

D. If ID band or Infant Security tag is found to be off the patient, confirm correct information and replace securely. Document changes if necessary in EMR. Clear alarms in Centrak system as needed

E. Only when a patient is transferred to or from the PICU will the primary nurse remove the infant security tag and discharge their patient from the Centrak system. A new security tag will be placed on the patient upon completion of transfer to the new unit. The infant security tag will remain in place upon transfer to or from any other unit (Post-Partum or NICU). All existing ID bands will remain intact upon any transfer.

F. At time of discharge, the primary nurse will remove the infant security tag and discharge the patient from the Centrak system.

KEY POINTS:

Alarm Responses

a. Refer to Policy *106.002 Code Pink/Purple-Know/suspected infant/child abduction*

b. Hospital Paging Staff will call code pink/purple overhead on unauthorized egress alarm or when notified by Maternal Child Health Staff member. Call 7666 for known or suspected abduction.

c. Security to respond to reported location to:

- Clear alarms
- Confirm patient safety
- Close doors if needed
- Enter code 3291# into keypad
- Staff member to clear alarms in Centak system.

e. Information Technology (IT) Support

- Notify IT and place work order to add users
- Centrak system to be tested every 30 days by IT support team
- For technical support or to report technical support issues please call 1-800-932-2555. AMI technical support is available 24/7

REFERENCES:

All revision dates:	8/24/2023, 8/19/2021, 2/1/2014, 8/1/2012, 6/1/2010, 3/1/2010, 5/1/2006, 5/1/2004, 12/1/2001, 5/1/1999, 3/1/1999, 12/1/1992

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/24/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/24/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	8/24/2023

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

MCH.25 Care of the Infant with Hyperbilirubinemia

POLICY:

To describe Neonatal Intensive Care Unit (NICU), Obstetrics (OB) and Pediatrics (PEDS) 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 ~~Neonatal Nurse Practitioner (NNP)/~~physician.

A ~~NNP/~~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 0, 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 ~~NNP~~

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

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/~~NNP~~ 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 ± 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~~/NNP~~ regarding the need for phototherapy if Total Bili is >6 mg/dL in the first 12-24 hours or > 12-15 mg/dL any time after 24-48 hours. Physician~~/NNP~~ 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~~/NNP~~ 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 ≥ 30 μw/cm² per nm (per AAP guidelines)

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

H. **Collaborate** with the physician~~/NNP~~ 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~~/NNP~~:
   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 transfusion is indicated when bilirubin levels are approaching levels commonly associated with Bilirubin encephalopathy despite phototherapy or when there is evidence of Hemolytic Disease of the Newborn (HDN). Coordinate with ~~NNP/~~physician and blood bank for exchange transfusion. Red cells and plasm are combined to make "reconstituted whole blood." Blood products for neonates are O packed red blood cells that is CMV negative and irradiated and AB plasma without any requirements. These blood types avoid any additional hemolysis.

The following criteria are used to help determine the need and timing of 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 < 11.5g/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. Any evidence of acute bilirubin encephalopathy, per the Neonatologist evaluation.

PRE-TRANSFUSION PREPARATION/ASSESSMENT:

A. **Coordinate with** ~~NNP/~~the physician and blood bank with total volume of reconstituted product and hematocrit

1. Verify ~~NNP/~~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 patients 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.

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.
2. Place the infant on a cardiorespiratory monitor and a pulse oximeter with the alarms set appropriately.
3. Restrain the infant for the procedure with four limb restraints, as needed Attempt to maintain a position of physiological flexion, if possible.

C. Gather equipment:

1. Exchange Transfusion Tray
2. Umbilical Catheterization Tray
3. Umbilical Catheters (per ~~NNP/~~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 ABG's)
8. Exchange transfusion log

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 available (for example Albumin 5% and Normal Saline 0.9%).
3. Have prepared syringes or 2 vials of Calcium Gluconate 10% at bedside. Dilute Calcium Gluconate 10% to 50mg/ml.

E. **Double check** the blood product with another RN or physician as outlined in the Blood transfusions and Blood Bank regulations Administrative policy.

1. Utilize the blood warmer per the equipment product manual. 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 ~~NNP/~~physician
3. Notify the ~~NNP/~~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_2 , and any lab work done on the Exchange Transfusion Log during procedure.

1. The blood volume infused and phlebotomized
2. The vital signs and Sp02
3. Lab work sent
4. Lab results
5. Medications given

D. **Collaborate** with the ~~NNP/~~physician every 30 minutes during the exchange regarding the need for blood glucose, electrolytes or ABG sampling.

E. Provide pacifier and oral sucrose for comfort and pain management.

EMERGENCY MANAGEMENT:

A. **Administer** Calcium Gluconate 10% 100 mg/kg diluted to 50mg/ml, slow IVP as ordered for

hypocalcemia while monitoring the infant's heart rate and ECG.

B. 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. Maintain the infant NPO for 4 hours minimum and as ordered by ~~practioner~~physician.

B. Remove restraints, reposition and comfort infant.

C. **Monitor** the vital signs, SpO_2 , ECG, blood glucose, and urine output every hour for a minimum of four hours post Exchange Transfusion.

D. **Monitor** the blood gases, Hgb, Total and Direct Bilirubin as ordered by the ~~NNP/~~physician.

E. **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.

F. **Document** all response to care delivered as mentioned previously.

G. **Place** discard blood bag in a red biohazard bag and discard in appropriate waste receptacle.

H. **Complete** Crossmatch Tranfusion Tag form, and make a copy. Return original form to the Blood Bank with signatures.

Documentation

A. Record all assessment data

B. Record all implementation of phototherapy

C. 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.

REFERENCES:

Atlas of Procedures in Neonatology, 6th Ed., MacDonald and Ramasethu, 2019.
Handbook of Neonatal Intensive Care, 9th Ed., Merenstein and Gardner, 2017.
Essentials of Pediatric Nursing, 10th Ed., Whaley and Wong, CR 2017.
American Academy of Pediatrics ***Management of hyperbilirubinemia in the newborn 35 or more weeks of gestation, 2004;114;297.***

All revision dates: 8/29/2023, 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

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/24/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/24/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	8/24/2023

VENTURA COUNTY
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Owner:	*Minako Watabe: Chief Medical Officer, VCMC & SPH*
Policy Area:	*Administration - Medical Staff*
References:	

MS.102.023 Family Medicine Obstetrical Risk Stratification

POLICY:

To establish a risk stratification for obstetrical patients at Ventura County Medical Center/Santa Paula Hospital (VCMC/SPH).

PROCEDURE:

It is expected that physician consultation will be obtained whenever appropriate for significantly ill patients and in difficult diagnostic or therapeutic situations where additional expertise might be helpful in resolving the problem.

IA	Moderate Risk – consider consultation with a physician with privileges to manage high risk pregnancy. (Consultation determined by the physician's experience, training, and hospital privileges.)
IB	Moderately High Risk – At least one in-person consultation indicated with a physician with privileges to manage high risk pregnancy.
II	High Risk – these patients will be referred to and managed by a physician with privileges to manage high risk pregnancy.

"Moderate and Moderately High Risk"

Initial prenatal factors:

1.	Drug dependency	IA
*2.	Previous cesarean section (see requirements)	IA
3.	Grand multiparity (greater than 5)	IA
4.	History of Class A gestational diabetes	IA
5.	Pelvic or hip anatomical abnormality which may affect vaginal delivery	IB
6.	Previous fetal or neonatal demise greater than 20 weeks gestational age	IB
7.	History of preterm delivery before 37 weeks gestational age	IB
8.	Hypothyroidism	IB

9.	Hyperthyroidism	IB
10.	Heart disease class I	IB
11.	Severe anemia, unresponsive to iron therapy	IB
12.	Pelvic mass or neoplasm	IB
**13.	Previous Cesarean section desiring trial of labor after cesarean (TOLAC) (see requirements)	IB
14.	Autoimmune disorder	IB
15.	History of venous thromboembolism (VTE) or thrombophilia	IB

Subsequent prenatal and intrapartum factors:

1.	Class A_1 gestational diabetes (diet controlled)	IA
2.	Pregnancy at 42 weeks or greater	IA
3.	Estimated fetal weight less than 6 pounds at term	IA
4.	Suspected fetal macrosomia	IA
5.	Vaginal bleeding in the second or third trimester	IA
6.	Induction of labor	IA
7.	3rd or 4th degree perineal laceration	IA
8.	Vacuum extraction	IA
9.	Manual extraction of placenta	IA
10.	Ruptured membranes beyond 18 hours	IA
11.	Second stage beyond 2 hours	IA
12.	Arrest of normal labor curve	IA
13.	Category II fetal heart rate (FHR) tracing with either: a. Minimal or absent variability b. Recurrent variable or late deceleration	IA
14.	Outlet forceps (this procedure is privileged through the Obstetrics & Gynecology Department)	IA
15.	Preeclampsia without hemolysis, elevated liver enzymes, low platelets (HELLP) or disseminated intravascular coagulation (DIC)	IB
16.	Fetal malformation by alpha-fetoprotein (AFP) screening, ultrasound, or amniocentesis	IB
17	Intrauterine growth retardation (Symmetric)	IB
18.	Hydramnios	IB
19.	Preterm labor (pregnancy less than 36 weeks)	IB
20.	Abnormal antenatal testing (non-stress test (NST), contraction stress test (CST), Biophysical Profile, others)	IB
*21.	Vacuum extraction failure x 2	IB
***22.	Class A_2 gestational diabetes requiring oral medication or insulin (see requirements)	IB
23.	Cholestasis of pregnancy	IB

24.	Maternal fever intrapartum	IB

"High Risk"

Patients presenting with the following prenatal or intrapartum risk factors will be referred to and managed by a VCMC physician with privileges to manage high risk pregnancy. (Resident physicians will manage these patients in conjunction with a physician with privileges to manage high risk pregnancy):

Initial prenatal factors

1. Multiple pregnancy
2. Pre-gestational diabetes
3. Chronic hypertension
4. Renal failure
5. Heart disease, class II or greater
6. Rh isoimmunization
7. Chronic or active hepatitis
8. Convulsive disorder, poorly controlled
9. Isoimmune thrombocytopenia
10. Asymmetric intrauterine growth retardation
11. Pre-term premature rupture of membranes

Subsequent prenatal and intrapartum factors

1. Eclampsia
2. Preeclampsia with either HELLP or DIC
3. Mid-forceps delivery
4. Persistent abnormal presentation at 34 weeks
5. Placenta previa
6. Abruptio placenta
7. *Active genital herpes in labor (see requirements)
8. *Cord prolapse (see requirements)
9. *Abnormal presentation at term (see requirements)
10. *Category III FHR tracing (see requirements)

Requirements:

* If the managing family physician has cesarean section privileges, consultation with an obstetrician may not be necessary and is not required.

** Requires consultation with an obstetrician.

*** Patient will be referred for consultation to a physician with privileges to manage high risk pregnancy. Referring physician may request that care be assumed by the consultant, or may request to co-manage the patient with the consultant.

All revision dates:	5/12/2020, 4/1/2017

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: FM & OB	Tracy Chapman: VCMC - Med Staff	pending
Policy Owner	Minako Watabe: Chief Medical Officer, VCMC & SPH	5/17/2023

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

OB.13 Admission and Assessment of the Post-Partum Patient

~~POLICY:~~

~~To admit a delivered mother to the Mother-Infant Unit and make an initial assessment of her condition for planning and implementing of nursing care. Each patient has individual needs depending on her physical condition.~~

~~PROCEDURE:~~

Purpose:

To establish criteria for the admission and care of patients admitted for postpartum maternal and well newborn care.

~~After the~~Following the immediate recovery period ~~immediately~~ after delivery, the Labor and Delivery (L&D) nurse will assess the patient to ensure she is stable for transfer to Post Partum which will consist of, but is not limited to, a normal amount of vaginal bleeding, alert and oriented and stable vital signs. Report will be given by the Labor and Delivery nurse to the nurse receiving the patient in the ~~Mother-Infant Unit regarding patient's history and events of her labor and delivery as well as recovery~~postpartum unit.

~~EQUIPMENT~~

~~A. OB Pack with Peri-pads, peri-bottle, chux, elastic brief panties, and toiletries.~~

~~B. BP apparatus, Stethoscope, thermometer.~~

~~C. Bed-position~~

~~1. For vaginal delivery at low position since the patient is transferred via wheelchair.~~

~~2. At high position for mothers that delivered via C-Section, since these patients are transferred via gurney. With these patients, have an IV pole ready at the bedside.~~

~~GUIDELINES~~

~~A. Welcome the patient and introduce yourself to the patient.~~

~~B. Assist patient with peri-care and emptying her bladder.~~

C. ~~Explain operation of call lights, telephone, TV control and visiting policies.~~

D. ~~Transfer the patient's personal effects to the closet and bedside table.~~

E. ~~Check vital signs.~~

F. ~~Palpate Fundus – assess for size, firmness and height.~~

G. ~~Check peri-pads for amount of lochia.~~

H. ~~Check perineum e.g. condition of episiotomy, changes in perineum, etc.~~

I. ~~Check IV (if present) for patency and solution of oxytoxic drug present.~~

J. ~~Proceed with physician's orders.~~

K. ~~Assess breasts for presence of colostrum.~~

L. ~~Assist patient with feedings of the baby.~~

M. ~~For C-Section patient, check indwelling foley catheter for patency.~~

N. ~~Check abdominal dressing for any bleeding.~~

O. ~~Check patient ID band and baby ID band: two ID bands on the baby and one ID band on the mother with all having the same number.~~

Policy:

A. Patients will be admitted to the postpartum unit after delivery as a transfer or direct admission as a postpartum patient or well baby. A physician order for transfer or direct admission is required

B. Patients who may have delivered prior to admission, are in the immediate postpartum period, or infants transferred from the neonatal intensive care unit (NICU) may also be care for on the postpartum unit based on the LCP clinical judgment.

C. Patients placing their newborn for adoption or who have experienced perinatal loss can be given the option to be transferred to a different unit.

D. Using the nursing process as its framework, comprehensive care will be achieved through a collaborative interdisciplinary team approach including the medical and clinical care team, patient, family,guardian and support person(s).

E. Physical examinations should be explained appropriately and only undertaken with the patient's consent.

F. Check patient Identification (ID) band and baby ID band: two ID bands on the baby and one ID band on the mother with all having the same number.Upon admission to postpartum, a security tag will be placed on the newborns ankle which will activate the infant security system. This process should be explained to parent(s).

G. The following standards will be adhered to for all postpartum patients and newborns unless otherwise ordered by a LCP. The LCP will be notified of all major changes in the patient's condition and documentation of each notification will be made.

PROCEDURE:

I. Admission Criteria
A. Delivered maternal patient after initial recovery period, stable; delivered in-hospital or prior to arrival
B. Well newborn after initial transition period; delivered in-hospital or prior to arrival
C. Well newborn transferred from NICU

D. Maternal patient in the immediate postpartum period requiring obstetrical-focused care.

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II. Maternal-Admision Assessment

A. An admission assessment of the postpartum patient will be completed upon arrival to the postpartum department.

B. Upon admission to postpartum, care will be provided as ordered by LCP until discharge. Assessment will include, but not limited to:

1. Vital Signs (pulse, respiration, blood pressure, oxygen saturation)
2. Fundal tone, height
3. Lochia amount, color, consistency
4. Perineal laceration or incision, if applicable
5. Abdominal incision and dressing, if applicable
6 .IV Sites
7. Pain Level
8. Infant Bonding
9. Edinburgh Post Partum Depression Screening

C. Ongoing assessments are performed every shift and as indicated when the mother's condition changes

D. Skin to skin and breastfeeding on demand for stable mother and infant is encouraged.

E. Patients are encouraged to ambulate early in the recovery process per LCP orders with Registered Nurse (RN) assistance and then regularly and independently when gait is steady. Sequential compression devices (SCD's) if present, should remain in place as ordered.

F. For abnormal assessment findings, notify resident or attending physician and if needed, the Rapid Response Nurse.

III. Newborn-Admission Assessment and Routine Care *(see OB 65 Ongoing Admission and Care of the Newborn)*

DOCUMENTATION

A. All assessments and patient care notes are done in patient's ~~EHR~~Electronic Health Record (HR).

B. Vital signs in EHR.

C. Care plan for vaginal delivery or C-Section delivery.

D. Document medications in EHR.

REFERENCES:

~~AWHONN: Perinatal Nursing, 4th edition, 2013~~

AWHONN: Perinatal Nursing, 5th edition, 2021

American Academy of Pediatrics and the American College of Obstetrician and Gynecologist Guidelines for Perinatal Care (8th Ed.) Elk Grove, IL: American Academy of Pediatrics; Washington, DC: The American College of Obstetrician and Gynecologists

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OB.31 Cervical Ripening

POLICY:

To ripen the cervix of women 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. Women 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. Women with prior cesarean delivery

Essential Steps:

A. Determine vertex presentation with ultrasound.

B. Perform sterile vaginal exam to determine Bishop score. In case of a low (≤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 (LIP). 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) or hypertonus (contraction lasting greater than 120 seconds). The restrictions may be overridden at the discretion of the LIP 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 LIP and approved prior to re-dosing.
5. Category III tracing.

Misoprostol:

~~Equipment: 25 or 50 mcg misoprostol tablet, sterile gloves.~~

A. ~~Dose is~~Equipment: 25 or 50 mcg ~~inserted intravaginally every four (4) hours by LIP or registered nurse or 50 mcg orally every four (4) to six (6) hours~~misoprostol tablet, sterile gloves. Dosing can include the following.

1. 25 mcg inserted intravaginally every four (4) hours by LIP 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 LIP and risk factors.

D. Maximum number of doses is six (6).

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 LIP 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).

B. Pass catheter through cervix.

C. Inflate with 30-60 mL of sterile saline.

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 LIP's orders.

F. Continuous traction may be applied to the catheter. Patient may experience a vasovagal response; discontinue traction if this occurs.

G. Notify LIP 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 LIP's orders.

Cervical Ripening Balloon Out-Patient:

Procedure is to be performed by a LIP 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. LIP 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. LIP 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 LIP 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. LIP 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 LIP 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_2.

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. 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 LIP or registered nurse. Misoprostol may be inserted by LIP 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 4-6 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, 4TH edition, 2013

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Step Description	Approver	Date
Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
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Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	6/9/2023
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OB.47 Magnesium Sulfate for Pre-Eclampsia and Tocolytic Therapy

POLICY:

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

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

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

~~To prevent eclamptic seizures.~~

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

Definitions:

1. Preeclampsia: The new onset of hypertension with blood pressure ≥ 140 mm Hg systolic or ≥ 90 mm Hg diastolic on two occasions at least 4 hours apart after 20 weeks 0 days gestation in a previously normotensive women and proteinuria. However, proteinuria is not required to be present for the diagnosis to be made.
2. Eclampsia: New onset tonic-clonic, focal or multifocal seizures in absence of other causative conditions, such as epilepsy, cerebral arterial ischemia, intracranial hemorrhage, or drug use.

PROCEDURE:

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

GUIDELINES:

A. Identify patient in preterm labor or ~~pre-eclampsia/eclampsia~~hypertensive emergency as quickly as possible.

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

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

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

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

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

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

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

H. Insert foley catheter as ordered by physician.

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

1. ~~As anti-seizure therapy:~~

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

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

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

Magnesium is a calcium antagonist. The action as a anticonvulsant.

a. Blocks neuromuscular transmission and decreases acetylcholine excretion.

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

c. Depresses the vasomotor center and thereby depressing central nervous system irritability.

2. As treatment of Preterm Labor (no longer first line therapy):
    a. Blocks neuromuscular transmission by decreasing levels of acetylcholine and norepinephrine. Communication from nerves to muscles does not occur and muscle depression occurs.
    b. The heart, lungs, uterus and intestines contain smooth muscle that responds to acetylcholine – enriched stimulus. Depression and cessation of function occur at much higher magnesium levels in the heart and lung tissue then in the uterine muscle.
3. Laboratory Data:
    a. Serum magnesium level will be drawn every 6 hours after bolus dose is infused.
    b. Therapeutic levels range from 4 – 7 mEq/L
    c. Only 0.3% of the body's total magnesium content is located in the serum, therefore, clinical manifestations are important indicators of physiological response.
    d. Electrolytes initially per PHYSICIAN order, repeat if indicated
    e. Calcium levels should be kept above 7mg/100ml
4. Monitoring, assess patient for signs of toxicity every 2 hours or as ordered by physician:
    a. Visual changes
    b. Somnolence
    c. Flushing
    d. Muscle paralysis (respiratory depression: O2 sat less than 95%)
    e. Loss of Deep Tendon Reflexes (DTRs) or pulmonary edema
    f. Lab values of magnesium levels
    g. Urine output
5. Maternal effects:
    a. Sense of heat (facial flushing due to vasodilatation)
    b. Complaining of nasal congestion
    c. Nausea and vomiting, headache
    d. Dizziness
    e. Lethargy
    f. Inability to sense full bladder
    g. Pulmonary edema can occur, causing shortness of breath
    h. Respiratory depression
6. Notify physician:
    a. Levels below 5mEq/L or greater than 6mEq/dl
    b. DTRs decreased or absent
    c. Urine output less than 120 ml/4hours
    d. Respirations less than 14 breaths/min or greater than 24

e. Changes in breath sounds suggestive of pulmonary edema

f. Changes in LOC

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

7. Fetal/Neonatal effects:

   a. Decreased muscle tone

   b. Respiratory depression

   c. Drowsiness

   d. Low apgar scores when prolonged maternal treatment is used

8. Toxic effects:

   a. DTR depression, followed absence.

   b. Respiratory depression followed by arrest.

   c. Cardiac arrest, arrhythmia, bradycardia, heart block

   d. Death

9. Antidote: Calcium gluconate 1 gram IVP over 3 minutes per physician order

10. For seizures due to eclampsia:

    a. Use prepared ~~2—4~~4-6* gm IV loading dose of Magnesium Sulfate. Run in over ~~20~~20-30 minutes. ~~Or per physician discretion, use~~If using 6 gm bolus ~~and~~ run in over 30 minutes. Follow by a 1-2 gm/hour maintenance dose if renal function is normal.

    b. *If patient weighs ≥113 kg or 250 lbs a 6 gram loading dose is required, followed by 2 gm/hour mainteance dose.

    c. One or two minutes after ~~client~~patient should maintain respiratory function and show evidence of muscle relaxation. Should seizure activity continue, ~~Valium may be given IVP per physician~~give additional 2-4 grams of magnesium sulfate over 5 minutes.

    d. If patient has recurrent seizure after 2nd loading dose of magnesium sulfate, notify physician.

11. Maternal assessment:

    a. When initiating therapy, take temperature, blood pressure, pulse rate, respiratory rate, DTRs and chest assessment prior to initiation of drug.

    b. When giving a bolus, take vital signs every 5 minutes X 15 minutes; remain at the beside to continuously monitor and record vital signs q 15 minutes for the remainder of the first hour. For the second hour, record every 30 minutes and then hourly monitoring

    c. DTRs should be checked every 2 hours or per physician order and as needed, based on maternal signs and symptoms.

    d. Monitor uterine activity continuously.

    e. Measure intake and output every ~~hour~~hours by Foley catheter with urometer. If output < 30 ml/ hour, reassess Magnesium Sulfate dosage and notify physician.

    f. Auscultate chest every 2 hours to R/O lung fluid.

    g. Oxygen saturation should be assessed once per hour.

12. Fetal assessment:

a. Continuous fetal monitoring and UC activity if drug is being used for preterm labor.

b. If continuous FHR recording is not done, check FHT with each set of vital signs.

DOCUMENTATION

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

~~CONTRAINDICATIONS~~

~~A. Significant vaginal bleeding~~

~~B. Intrauterine infection~~

~~C. Fetal malformations incompatible with life~~

~~D. Fetal death~~

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

REFERENCES:

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

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

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OB.48 Testing for Prenatal Drug Exposure

POLICY:

The following applies to infants born to mothers with suspected or known substance abuse. Neonatal drug/ alcohol exposure evaluations protect the neonate from possible neglect and child abuse. The birth of a baby to a family with questioned ability to provide appropriate care **must** be reported under the Child Abuse and Neglect Reporting Act (Penal Code, 11164 et seq.). Whenever a toxicology screen is ordered, the physician must document the reason in the patient's medical record, unless provided for under a facility's policy.

PROCEDURE:

A. Neonatal Staff Responsibilities

1. Health care team members should consider notifying the social worker of neonates exposed to potentially harmful drugs.
2. Each case shall be evaluated and the necessary recommendations made, based on input from health care team members. When indicated, additional consultation or follow up should be obtained when child endangerment is suspected.
3. Member of the health care team shall report by:
    a. Making a telephone report of the situation to the Department of Child Family Services (DCFS) as soon as possible by calling 1-805-654-3200 and/or
    b. Completing the California Department of Justice DOJ Form 11166PC, Suspected Child Abuse Report. Fax to 1-805-654-5597.

B. Prenatal Responsibilities

1. When a prenatal patient presents with an acknowledged history of drug/alcohol abuse:
    a. A toxicology screen shall be ordered at the discretion of the physician. (Whenever a toxicology screen is ordered for the mother, the physician must clearly document the reason in the patient's medical record, or comply with facility policy.) Consent must also be obtained per hospital policy.
    b. Confirm that Human Immunodeficiency Virus (HIV) and Hepatitis C screening, counseling, education, and referral have been offered.
    c. Offer the patient a referral for a public health nurse.
2. If the screen is positive for:

a. Alcohol, cannabis, or illegal drugs: Refer the patient to social worker for comprehensive evaluation.

b. Legally available prescribed medications:

i. Prescribed and appropriate use: no further action needs to be taken. Note: some "over the counter" drugs result in a false positive urine toxicology screening and further testing should be sent.

ii. Prescribed but inappropriate: refer patient to social worker.

iii. Illegal use: refer patient to social worker.

3. When the father of the unborn child or the significant other of the pregnant patient is suspected of drug/alcohol abuse, refer the case to a social worker for comprehensive evaluation.

4. Despite positive drug/alcohol screens, only extreme and dangerous situations are reported to DCFS and/or police during the prenatal period.

a. Efforts are directed at counseling the family and making appropriate referrals for treatment.

b. DCFS should be notified if there are children in the home who may be endangered.

c. Public health nurse referral should also be utilized in these situations or when DCFS is not involved but the health care team may have some concern.

C. Intrapartum Responsibilities

1. When a pregnant woman presents with signs and/or symptoms of drug/alcohol abuse:

a. The physician shall consent the patient and order a urine toxicology screen. If clinically indicated consider blood alcohol and blood toxicology.

b. If a pregnant patient presents with an altered mental state, or signs of recent drug and/or alcohol abuse, a urine and/or blood toxicology test can be obtained without a consent to aid in medical decision making, and to provide appropriate medical care.

c. A team member should refer the patient to a social worker.

2. Strong consideration should be given to ordering a toxicology screen if one or more of the following factors are present (if not already done):

a. Clinical evidence of IVDU-track marks.

b. Inappropriate, disruptive behavior.

c. No prenatal care.

d. Preterm labor and/or preterm rupture of membranes.

e. Rule out (R/O) pre-eclampsia/eclampsia.

f. Abruptio placentae.

g. Fetal demise.

h. Patient choice to deliver outside of normal catchment areas without adequate explanation.

i. History of ongoing drug/alcohol abuse.

3. Obtain results of the following screens ASAP: Hepatitis B surface antigen (HBsAG), HIV, and Hepatitis C antibody and syphilis titers. If these have not been done during this pregnancy or there are new risk factors (IV drug use, new sexual partner) these should be repeated.

NEONATAL EVALUATION

The following is meant to serve as a guideline to assist physicians in deciding when to screen neonates for drugs. Health care professionals shall use sound clinical judgment. This guide should not replace training, experience or studying the latest literature and information. It is believed that families of neonates who have been exposed to maternal substance abuse in utero can be helped with identification and appropriate intervention. Parental consent is required for treatment provided to the neonate. An exception should be made if the neonate is exhibiting signs of drug exposure described below.

A. A neonatal sample should be considered if any of the following criteria are met:
    1. All infants born to mothers using illicit drugs or habitual alcohol use during this pregnancy will need:
        a. Cord tissue and urine toxicology sent.
        b. If unable to send tissue then:
            i. Collection of meconium.
        c. Consultation with social worker.
        d. Inform DCFS soon after discovery (do not wait until discharge day).
    2. If mother is on a Methadone or Buprenorphine treatment program or using illicit drug, or if there is a suspicion of ongoing drug abuse:
        a. The infant needs to be evaluated by a qualified provider for neonatal abstinance syndrome (NAS) within 24 hours.
        b. The infant should not breast feed until clarifying the status of use of other drugs, like cocaine, amphetamines, and HIV/Hep C status. In the meantime, assist mom with pumping to maintain breast milk supply.
        c. Some infants may not show signs of withdrawal until 2-3 weeks of age, therefore if the infant is asymptomatic and discharged home, it needs to be closely monitored by the primary care physician for possible late onset signs of withdrawal.
        d. Consider a public health nurse referral to assist with symptom monitoring.
    3. Mothers who have a history of ongoing illicit drug use.
    4. Babies whose mothers have a history of a drug-exposed infant in a previous pregnancy.
    5. Maternal or paternal HIV, gonococcal, chlamydia, hepatitis C, trichomonas, hepatitis B, or syphilitic infection.
    6. Inadequate prenatal care (defined as less than three visits or initiation of care in third trimester).
    7. Abruptio of the placenta.
    8. Unexplained gestational age of less than 37 weeks or birth weight below the tenth percentile for gestational age.
    9. Any one of the following neonatal symptoms, if of unknown cause: jitteriness, seizures, or lethargy.
    10. Neonatal abstinence syndrome.
    11. Vascular disruption syndromes, including (but not limited to) microcephaly, limb deformities, prune belly syndrome, bowel atresia, stroke or urinary tract anomalies.

12. If other risk factors are present, such as meconium in the amniotic fluid, precipitous labor, subarachnoid hemorrhage, or a history of stillbirth or sudden neonate death syndrome (SIDS) in a sibling.

B. Order a drug screen as soon as possible on any neonate demonstrating signs consistent with drug withdrawal. Signs of drug withdrawal can include:

1. High-pitched cry
2. Sleeps less than one (1) hour after feeding
3. Hyperactive Moro Reflex
4. Tremors (when disturbed or undisturbed)
5. Increased muscle tone
6. Generalized seizure
7. Frantic sucking of fists
8. Poor feeding, uncoordinated suck/swallow
9. Regurgitation
10. Projectile vomiting
11. Loose and/or watery stools
12. Dehydration
13. Frequent yawning
14. Sneezing
15. Nasal stuffiness
16. Sweating
17. Mottling
18. Hyperthermia
19. Tachypnea
20. Excoriation of nose, knees, toes and/or chin.

C. The neonatal sample should include umbilical cord tissue as the preferred method. If cord tissue cannot be obtained, meconium can be sent. In addition, a urine toxicology should be ordered for ALL newborns suspected of exposure to drugs in utero.

1. Procedure for cord tissue (preferred testing method)
    a. Cut a 6 to 8 inch segment of umbilical cord in the delivery room.
    b. Rinse the exterior/outside of the specimen with normal saline or sterile water. Important: Prevent the umbilical cord and specimen from coming in contact with ethanol-based liquids or vapors previous to and during the collection process. This includes ethanol-based hand sanitizer and alcohol prep pads.
    c. Squeegee/strip the cord to remove blood and mucous from cord segment.
    d. Pat the specimen dry and place it in the specimen container. The specimen must be dry.
    e. Place the newborn's ID sticker on the specimen container. Place the date, time of collection and

employee ID or Cerner Code on the label.

f. If the newborn sticker is unavailable, write the newborn's name, date of birth and collection time on the specimen cup. Once the sticker is available, place the date, time of collection and the employee ID or Cerner ID on the sticker. Label the specimen cup with the sticker.

g. The nurse who collected the specimen will take it to the Lab in the plastic bag or formally hand off the sample to another nurse or designated staff member and follow standard chain of custody protocol.

h. The nurse or designated staff member will hand carry the sample to the Lab per standard chain of custody protocol.

i. The sample must be handed directly to a licensed clinical laboratory scientist or designee (do not leave the specimen unattended) per standard chain of custody protocol.

j. Every change of custody must be documented on the specimen tracking form. Use the Chain of Custody Form.

k. Physician or nurse will place the following send-out order in Cerner

   i. Name: CordStat 13

   ii. Code: 900924

2. Procedure for meconium testing

If cord testing was not performed, the provider may order a toxicology test on meconium as follows:

a. Obtain 1 to 5 grams of meconium from the baby's diaper.

b. Place the meconium in a specimen cup and label following same steps listed above. Follow standard chain of custody requirements.

DOCUMENTATION

Documentation supporting DCFS referral and/or hold is placed in newborn's medical record. (If a newborn is placed on hold, the hospital should record the name and phone number of the DCFS worker taking custody in the mother's and the newborn's medical records.)

REFERENCES:

A. AWHONN: Perinatal Nursing, 4th edition, 2013.

B. Substance Abuse. Perinatal Guidelines of Care, Seventh Edition, 2012 American Academy of Pediatrics and the American College of Obstetricians & Gynecologists, PP 266-264.

C. PAC-LAC Prenatal and Intrapartum Guidelines of Care, 2009

D. PAC-LAC Neonatal Guidelines of Care, 2013

All revision dates: 10/14/2020, 10/12/2018, 9/27/2018, 1/1/2016, 11/1/2013, 8/1/2010, 10/1/2004, 12/1/1992

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No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Committees: Family Medicine, OB, Pediatrics Committee	Tracy Chapman: VCMC - Med Staff	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	8/24/2023
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	8/24/2023
Policy Owner	Kristina Swaim: Clinical Nurse Manager, OB	8/24/2023

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PH.26.00 Sterile Compounding Overview

Purpose:

The Department of Pharmacy Services is responsible for preparation and compounding of sterile drug preparations 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 sterile drug preparations 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 sterile drug preparations under high-risk conditions, which includes compounding sterile drug preparations 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: 11/5/2019, 10/3/2017, 7/1/2016, 4/1/2016, 2/1/2014

Attachments

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Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/3/2023
Infection Prevention	Magdy Asaad: Infection Prevention Manager	8/3/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	8/3/2023

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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 and compounding of sterile drug preparations. 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.~~

This policy promotes the safe, efficient and uniform performance of all Pharmacy staff involved in the preparation and compounding of sterile drug preparations.

- 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 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.

~~Master formula~~

~~Sterile compounding documentation.~~

4. Documentation of compounding processes (e.g., master formula and compounding records)
5. Quality assurance procedures.

   ~~Aseptic preparation procedures.~~

6. Proper hand hygiene~~, gowning and gloving technique~~ and garbing.
7. General conduct ~~in the controlled~~within the compounding area.
8. Cleaning, disinfection and maintaining of the equipment and the controlled area.
9. ~~Container, equipment and closure system selection.~~Use of equipment.

B. ~~All sterile compounding staff working with hazardous drugs shall also complete the following:~~

   ~~1. Acknowledge notification about the risks of handling hazardous drugs.~~

   ~~2. Demonstrate competence in handling and compounding hazardous drugs.~~

      ~~a. Participate in the chemotherapy preparation orientation program.~~

      ~~b. Demonstrate negative pressure technique when utilizing a biological safety cabinet or compounding aseptic containment isolator.~~

      ~~c. Demonstrate containment, cleanup and disposal procedures for hazardous drug spills.~~

      ~~d. Demonstrate competence in obtaining and using a safety data sheets (SDS).~~

      ~~e. Demonstrate competence in the use of medication boxed warnings.~~

      ~~f. Demonstrate competence in safe disposal of hazardous drugs.~~

      ~~g. Participate in other training programs as assigned by the Pharmacy Supervisor.~~

   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.

   ~~Process Validation~~

   ~~1. Medium risk media fill test shall be successfully completed.~~

      ~~a. Completed medium samples shall be incubated in a manner consistent with the manufacturers recommendations.~~

      ~~b. Manufacturer, lot number and expiration date of the media fill test shall be documented.~~

   ~~2. Gloved fingertip testing shall be successfully completed at least three times before initially being allowed to compound sterile drug preparations. Subsequent gloved fingertip testing shall be successfully completed at least once a year.~~

      ~~a. Completed samples shall be incubated at 30-35ºC for 48-72 hours.~~

   ~~3. Process validation shall be repeated at least every twelve months for each individual involved in sterile compounding.~~

   ~~Evaluation~~

   ~~1. Training exams are considered passed if 80% of questions are answered correctly. Any results less than 80% shall require additional review and discussion. The failed exams shall be retaken until 80% of questions are answered correctly.~~

2. ~~Medium risk media fill test~~
    a. ~~A clear solution denotes a pass.~~
    b. ~~A turbid solution or presence of precipitate denotes a failure.~~
3. ~~Gloved fingertip test~~
    a. ~~Initial Validation~~
        i. ~~No growth (0 colony-forming units (CFU)) denotes a pass.~~
        ii. ~~Any growth (≥1 CFU) denotes a failure.~~
    b. ~~Annual Validation~~
        i. ~~No growth or growth of ≤3 CFU for both gloves (not per hand) denotes a pass.~~
        ii. ~~Growth of >3 CFU for both gloves (not per hand) denotes a failure.~~
4. ~~Pharmacy staff who fail to pass any training exam or validation process test shall be prohibited from performing any sterile compounding until all training exams and validation process tests are successfully completed.~~

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 sterile drug preparations.
        b. Subsequent gloved fingertip testing shall be successfully completed at least once every 6 months.
        c. Completed samples shall be incubated at 30-35ºC for no less than 48 hours and then at 20-25ºC for no less than 5 additional days.
            i. No growth (0 colony-forming unit or CFU) denotes a pass.
            ii. Any growth (>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 20-25ºC and 30-35ºC 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 30-35ºC for no less than 48 hours and then at 20-25ºC for no less than 5 additional days.
                a. No growth or growth of <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 <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.

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.

2. For surface sampling growth failures, an attempt must be made to identify any microorganism recovered to the genus level.

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

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Attachments

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Approval Signatures

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Medical Executive Committee	Tracy Chapman: VCMC - Med Staff	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/3/2023
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PH.26.02 Facility and Equipment - Sterile Compounding

POLICY:

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

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 sterile drug preparations. 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. Room temperature shall be maintained at 20 to 25 °C.

   1. Sterile compounding area should be maintained at a temperature of 20 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. ~~Cleanrooms~~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. ~~Cleanrooms, clean areas or buffer areas used for hazardous compounding shall have at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01- to 0.03-inches of 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. ~~During this time, 12 hour beyond use dating shall be applied to compounded sterile products.~~
   2. During this time, a more conservative beyond use dating shall be applied to compounded sterile products.
      a. 12 hour room temperature or refrigerated (USP 797 - 2012 version)
      b. 12 hour room temperature or 24 hour refrigerated (*USP 797 - 2022 version)
         i. *Note: Pending USP 797 - 2022 version adaptation into California Board of Pharmacy Law
   3. Unclassified segregated compounding areas (SCAs) are exempt from air exchange requirements.

~~Cleaning of PECs and ISO class environments shall be done using a ready to use germicidal detergent.~~

~~Cleaning shall occur from the cleanest area to the dirtiest area of the sterile compounding area to avoid contamination.~~

F. ~~All PECs, work table surfaces, carts, counters, pass-throughs, sinks and floors shall be cleaned daily with germicidal detergent and monthly with a sporicidal agent.~~ Cleaning ~~shall be documented on the corresponding cleaning log. Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.~~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. ~~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.~~Daily Cleaning
    a. All PECs, work table surfaces, carts, counters, pass-throughs, sinks and floors shall be cleaned daily with a ready to use (RTU) disinfectant cleaner.
    b. PEC cleaning agent must be 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 PEC including exterior, work table surfaces, carts, counters, pass-throughs, sinks, floors, walls, ceilings, storage shelving, and stools shall be cleaned monthly with a RTU sporicidal agent.
    b. PEC sporicidal agent must be sterile.
    c. Monthly cleaning must be documented on the corresponding cleaning log.

~~Active work surfaces and counter tops shall be disinfected with sterile 70% isopropyl alcohol throughout each shift.~~

~~Floors shall be cleaned daily with a germicidal detergent and monthly with a sporicidal agent.~~

~~Walls, ceilings, storage shelving, tables, and stools in the sterile compounding areas shall be cleaned at least monthly with a sporicidal agent and documented on the corresponding cleaning log.~~

~~1. Note: VCMC Infusion Pharmacy staff will clean the HEPA filter diffusers (cover) monthly using an oxidizer/sporicidal agent. Staff will utilize a ladder and an isolator cleaning tool with cover to manually clean the recess between the HEPA fixture/enclosure and the HEPA filter diffuser. Great care will be taken not to touch or wet the HEPA filter. Staff will also manually clean the acorn nuts that hold the diffuser in place.~~

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 ~~drug preparations~~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 ~~and~~, ISO environment certifications, refrigerator and freezer temperature logs shall be stored for a period of three years.

~~Documentation of refrigerator and freezer temperatures shall be stored for a period of three years.~~

Equipment

A. Any equipment used to compound sterile drug preparations 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)

   ~~Baker SS600 (VCMC Satellite 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 ~~shall be kept~~must remain on ~~during pharmacy hours of operations. BSC 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 ~~daily~~ with an approved cleaning agent. ~~An alternate sporicidal agent shall be used for cleaning at least once a month.~~

1. Approved cleaning agent include:
   ~~i. PreEMPT RTU~~
   i. PreEMPT RTU
   ii. Contec TB1-3300 (sterile) or Cyquanol (sterile)
2. Approved cleaning agents with sporicidal activity include:
   i. Periodox~~-~~ RTU (sterile)
   ii. Bleach

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. ~~At the beginning of each shift.~~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.

~~The CAI isolator gloves shall be sterile.~~

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.

~~The exterior surfaces of the PEC shall be cleaned at least monthly with a sporicidal agent.~~

~~Cytotoxic and other hazardous sterile drug preparations shall be prepared in a negative pressure biological safety cabinet (BSC).~~

~~Cleaning supplies and equipment used to clean hazardous PECs shall not be used to clean non-hazardous PECs to avoid cross-contamination of hazardous material. Cleaning supplies and equipment used to clean hazardous PECs shall be identified with a "Hazardous Drug" label.~~

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 ~~once every six months~~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 ~~sites for viable airborne particle~~site testing ~~shall~~should include locations within each ISO Class 5 environment, ISO 7 and 8 areas, and in the segregated compounding areas (SCA) ~~at greatest risk of contamination (i.e. work areas near the ISO Class 5 environment). A minimum of 400 liters of air shall be tested at each location. Selected air sampling sites shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning and cleaning.~~
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	>~~100~~50 CFU

4. Any growth of a highly pathogenic microorganism shall also be considered actionable. Highly pathogenic microorganisms may include, but are not limited to, gram-negative rods, coagulase positive staphylococcus, molds and yeasts.
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 ~~nurse~~Preventionist.
    b. Development of an action plan in consultation with the Infection Control ~~nurse~~Preventionist which shall address assignment of appropriate beyond use dating, remediation, and training.
        i. ~~Beyond Use Dating shall be one of the following: USP <797> BUDs, 12 hour BUDs, or one-hour BUDs.~~Beyond Use Dating shall be one of the following
            a. SEC associated finding:

i. 12 hours room temperature or refrigerated BUD (USP 797 - 2012 version)

ii. 12 hours room temperature or 24 hour refrigerated BUD (*USP 797 - 2022 version)

b. PEC associated finding:

i. 1 hour immediate use BUD (USP 797 - 2012 version)

ii. 4 hour immediate use BUD (*USP 797 - 2022 version) for CSP prepared by pharmacy department

ii. Remediation shall include cleaning and disinfection of the affected PEC(s) and/or SEC(s).

iii. ~~Training~~Response shall include retraining of pertinent staff on cleaning and disinfection of affected PEC(s) and/or SEC(s).

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 ~~requirements~~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. Problems with equipment shall immediately be reported to the Designated Person (DP) or the Director of Pharmacy ~~Supervisor or the Director of Pharmacy~~ Services.

L. Refer to PEC operational manual(s) for further details.

Transport of drugs and supplies into the sterile compounding area

A. All cartoned supplies are decontaminated prior to being introduced into the sterile compounding area by removing them from shipping cartons and wiping them with a ~~non~~EPA-~~residue-generating disinfecting agent~~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. 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 ~~or corrugated cardboard~~.

References

A. California Code of Regulations, Division 17, Title 16, Section 1751
B. USP Chapter 797, Pharmaceutical Compounding – Sterile Preparations; 2012, 2022
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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Owner:	*Sul Jung: Associate Director of Pharmacy Services*
Policy Area:	*Pharmacy Services*
References:	

PH.26.03 Sterile Compounding Attire

Policy:

Personnel engaged in sterile compounding 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 shall be excluded from the International Organization for Standardization (ISO) Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

B. No chewing gum, candy or food items may be brought 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 breakroom.

   1. Eyeglasses are permitted but must be cleaned prior to donning any sterile compounding attire.

C. Hand ~~washing~~ hygiene is required routinely throughout the day. 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, ~~non~~low-~~shedding~~lint towel. ~~Use towel to turn off faucet.~~

D. Personnel working in a Secondary Engineering Control (SEC) shall properly put on clean, non-shedding uniform components in the following order: ~~shoe covers, scalp hair and facial hair covers/face masks, washing of hands and forearms up to the elbows for 30 seconds with soap and water, then gown. Prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless persistent alcohol-based cleanser. Sterile powder-free gloves shall be donned as the final piece of garb and gloved hands shall be washed using waterless alcohol-based cleanser in the admixture area.~~

   ~~Compounding personnel working in a compounding aseptic isolator (CAI) within a segregated compounding area shall garb as follows:~~

   ~~a. Put on clean, non-shedding uniform components in the following order: shoe covers, scalp hair cover and facial hair covers/face masks as personnel enters the segregated compounding area.~~

   ~~b. Wash hands and forearms up to the elbows for 30 seconds with soap and water.~~

c. ~~Antiseptic hand cleansing shall be performed using a waterless persistent alcohol based cleanser.~~

d. ~~Don a non-shedding gown.~~

e. ~~Don gloves. Gloved hands shall be washed using waterless alcohol based cleanser.~~

f. ~~The CAI shall have sterile gloves mounted to the sleeve (gauntlet).~~

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

1. Put on clean, non-shedding uniform components in the following order: face mask, scalp hair and facial hair covers, shoe covers as personnel enters the SEC.
2. Wash hands and forearms up to the elbows for 30 seconds with soap and water.
3. Don a non-shedding gown.
4. Hand sanitizing shall be performed using a waterless, persistent, alcohol-based cleanser.
5. Don gloves. Gloved hands shall be sanitized using sterile 70% IPA.
6. For the Segregated Compounding Area (SCA) only
   a. The Compounding Aseptic Isolator (CAI) shall have sterile gloves mounted to the sleeve (gauntlet).
   b. In the CAI, a pair of sterile gloves shall be donned over the sterile gauntlet gloves.

~~For preparation of hazardous drugs and/or work in any segregated compounding containment area or hazardous drug compounding room, gowns shall be chemo impervious, gloves shall be sterile (except as listed in Procedure D.1.) and ASTM D6978-05 rated, and double shoe covers shall be worn.~~

1. ~~The process to enter the negative pressure hazardous compounding room in the clean room suite is as follows in order:~~
   a. ~~A chemo impervious gown shall be worn on top of the regular gown.~~
   b. ~~Double shoe covers shall be donned as personnel enters the negative pressure hazardous compounding room from the ante room.~~
   c. ~~Gloved hands shall be washed using waterless alcohol based cleanser.~~
   d. ~~A second pair of sterile, ASTM D6978-05 rated gloves shall be donned.~~
2. ~~The process to exit the negative pressure hazardous compounding room in the clean room suite is as follows in order:~~
   a. ~~Remove the outer pair of sterile, ASTM D6978-05 rated gloves and discard in the hazardous waste container.~~
   b. ~~Remove the chemo impervious gown and discard in the hazardous waste container.~~
   c. ~~Remove the outer shoe covers as personnel exits the negative pressure hazardous compounding room and into the ante room. Discard in the hazardous waste container.~~
   d. ~~Hands must be washed with soap and water after removing gloves.~~

E. Sterile gloves ~~that have been tested for compatibility~~are to be routinely disinfected with ~~disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of~~ sterile ~~gloves may occur within the ante or cleanroom. Sterile gloves are to be routinely disinfected with sterile~~ 70% ~~isopropyl alcohol~~IPA before entering or re-entering the primary engineering control and after contact with non-sterile objects. ~~Sterile gloves shall also be routinely inspected for holes,~~

~~punctures, or tears and replaced immediately if such are detected.~~

F. ~~All personnel working less than a full shift (i.e. lunch coverage and/or assistance) must also comply with this policy.~~Sterile gloves shall also be routinely inspected for holes, punctures, or tears, and replaced immediately if such are detected.

All revision dates: 7/25/2023, 9/13/2022, 3/4/2020, 11/5/2019, 5/15/2019, 11/26/2018, 7/19/2018, 7/1/2016, 1/1/2014

Attachments

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Approval Signatures

Step Description	Approver	Date
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VENTURA COUNTY
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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:

Sterile Drug Preparation

A. Sterile drug preparations 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 sterile drug preparation. Each master formula shall include:

1. Active ingredients to be used.
2. Equipment to be used.
3. The maximum allowable beyond use date 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. This may include final description of completed Compounded Sterile Product (CSP).
7. Post-compounding processor procedures required, if any.
8. Instructions for storage and handling of the compounded drug preparation.

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 removed from the outer cartons and decontaminated by wiping ~~or spraying~~ the outer surface with sterile 70% isopropyl alcohol.

E. Containers shall be checked for cracks, punctures, and clarity before the sterile drug preparation process begins.

F. Ingredients used for sterile product preparation 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 sterile products.

   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 (~~i.~~e.g., labels, calculators, pens, pencils, etc.) shall not be placed inside the PEC.

H. Mathematical calculations shall be performed prior to initiating the sterile product preparation process.

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 sterile product preparation 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, ~~ampoules~~ampules, containers, and transfer sets.

L. The surfaces of ampules, vials, and container closures (~~i.~~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 (~~i.~~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. Single-dose vials used in the compounding aseptic isolator (CAI) may be used for up to six hours after initial needle puncture. Date and time vial was initially used and beyond use date (and time, when applicable) shall be documented on the vial.

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. Hazardous drugs, pediatric doses and total parenteral nutrition (TPN) solutions are the exception. 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 ~~any other patient identification (~~idate of birth.~~e. location, identification numbers). For batch-prepared products, control or lot number and expiration date.~~
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 ~~or resident, respectively,~~ with their initial.
9. Device-specific instructions, when appropriate.

   ~~Telephone number of the pharmacy.~~
10. Name of compounding, dispensing pharmacy
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 particulate matter, precipitate, or haziness in the solution.
5. Double-check calculations
6. Auxiliary labels
7. Beyond use date
8. Storage conditions

B. The pharmacist 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. ~~Beyond~~Date and time of preparation and beyond use date of final product.
3. Manufacturer, lot number and expiration date of each component.
4. Initials of the compounding staff.
5. Initials of the pharmacist performing end product evaluation.

   ~~Equipment used during the sterile compounding process.~~
6. Results of quality control (e.g., visual inspection)
7. Santa Paula Hospital Pharmacy only: CAI purge time.

B. Documentation for sterile batch preparations shall include the above and the following:

   ~~The date of preparation.~~

   ~~Manufacturer, lot number and expiration date of each component.~~

1. Pharmacy-assigned batch identification number of the finished product.

   ~~The beyond use date of the finished product.~~
2. The package size and the number of units prepared.

   ~~The signature or initials of the compounding staff.~~

   ~~The signature or initials of the pharmacist performing end product evaluation.~~

C. 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

All revision dates: 7/21/2023, 8/16/2022, 9/10/2020, 11/5/2019, 7/1/2016, 5/1/2014, 1/1/2014

Attachments

No Attachments

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Step Description	Approver	Date
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	8/3/2023
Infection Prevention	Magdy Asaad: Infection Prevention Manager	8/1/2023
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	7/21/2023

VENTURA COUNTY
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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 compounded sterile preparations shall read this policy and comply with its requirements.

Beyond Use Dates - USP 797 2012

A. The beyond use date shall not exceed the shortest expiration date or beyond use date 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 beyond-use dates 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 Conditions	Room Temperature (15 to 30° C)	Refrigeration (2 to 8° C)	Frozen (-25° to -10° C)
Low Risk Conditions	≤ 48 hours	≤ 14 days	≤ 45 days

Medium Risk Conditions	≤ 30 hours	≤ 9 days	≤ 45 days
High Risk Conditions	~~Compounding under High Risk conditions is not performed.~~Compounding under High Risk conditions is not performed.		

C. Compounded sterile drug preparations prepared under all of the following conditions are at a **LOW RISK** of contamination:

1. Sterile drug preprations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations with not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag or vial) of sterile product or administration container or device to prepare the sterile drug preparation.
3. Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.
4. Examples of LOW RISK conditions include:
    a. Single-volume transfers of sterile dosage forms from ampules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules should be passed through a sterile filter to remove any particles.
    b. Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

D. Compounded sterile preparations prepared under all of the following conditions are at a **MEDIUM RISK** of contamination:

1. Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile drug preparation that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single volume transfer.
3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.
4. Examples of MEDIUM RISK conditions include:
    a. TPN using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.
    b. Filling reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.
    c. Transfer of volumes from multiple ampules or vials into one or more final sterile containers.

E. Compounded sterile drug preparations shall **NOT** be prepared under HIGH RISK conditions.

Beyond Use Dates - *USP 797 2022

*Note: Pending USP 797 - 2022 version adaptation into California Board of Pharmacy Law

A. The beyond use date shall not exceed the shortest expiration date or beyond use date 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 beyond-use dates 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 components	4 days	10 days

C. Category 1 and Category 2 compounded sterile preparations 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, Section 1751.

B. USP Chapter 797, Pharmaceutical Compounding -- Sterile Preparations.

All revision dates: 7/21/2023, 7/10/2019, 7/1/2016, 4/1/2016, 10/1/2015, 1/1/2014

Attachments

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Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	7/21/2023

VENTURA COUNTY
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References:	

PH.26.06 Sterile Compounding Quality Assurance Program

Purpose:

This policy defines the quality assurance program for sterile compounding.

Definitions:

Integrity: 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 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.

Strength: amount of active ingredient per unit of a compounded drug preparation.

Policy:

A. Random samples of compounded sterile ~~products~~preparations (CSPs) shall be assessed on a quarterly basis 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 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:

A. Integrity of the selected compounded sterile product (CSP) shall be assessed by measuring the potency of the selected ~~CSP~~CSPs on the date of expiration.

B. Potency of the selected CSP shall be assessed by submitting a sample to a lab for analysis.

1. The resulting value shall be within ±10% the listed amount of active ingredient.

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

~~Strength of the selected CSP shall be calculated from the results of the potency assessment. The concentration of the CSP shall be multiplied by the total of the volume of the selected CSP. The resulting value shall be within ±10% the listed amount of active ingredient.~~

D. 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.

E. Complete Quality Assurance Sampling Action Report (Attachment A)

F. Any unacceptable result relating to the potency, labeled strength, quality or sterility of the CSP shall result in the following:

1. Designated Person or Pharmacist in charge shall start an investigation and review~~:~~

   ~~a. compounding logs~~

   ~~b. active ingredients used~~

   ~~c. master formula~~

2. The action plan shall include any procedural changes, educational needs, mitigation plan, and monitoring.

3. ~~For unacceptable results relating to potency and labeled strength, staff shall review of pharmaceutical calculations and syringe measurements.~~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.**

   ~~For unacceptable result relating to the quality and sterility, staff shall complete a revalidation process on aseptic technique and aseptic area practices.~~

G. Any unacceptable result shall result in a recall of the ~~sterile compounded product~~CSP.

1. 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.

All revision dates: 7/21/2023, 9/13/2022, 12/8/2020, 7/10/2019, 7/19/2018, 11/20/2017, 10/3/2017, 7/1/2016, 2/1/2014

Attachments

Ph.26.06 Quality Assurance Sampling Action Report

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Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	7/21/2023

VENTURA COUNTY MEDICAL CENTER

QUALITY ASSURANCE PROGRAM REMEDIATION ACTION PLAN

VENTURA COUNTY MEDICAL CENTER / SANTA PAULA HOSPITAL
DEPARTMENT OF PHARMACY SERVICES

Location: _____

Date Sampled: _____ **Date Action began:** _____

Type of Environmental Sample:

☐ **Viable Air Sample** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ Non-ISO Classified; ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Dynamic

Describe specific location/s: _____

☐ **Surface Sampling (SS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ Non-ISO Classified; ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Dynamic

Describe specific location: _____ Date sampled: _____

Type of Aseptic Technique Sample

☐ **Glove Fingertip Sampling (GFTS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 (Post compounding) ☐ ISO 7 (Post garbing) ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Dynamic

Name of staff: _____ Date sampled: _____

☐ **Media Fill Test (MFT) – ISO 5** ➡ ☐ CSP Category 1 ☐ CSP Category 2 ☐ Multiple samples

Check all that apply: ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Dynamic

Name of staff: _____ Date sampled: _____

☐ **Qualify Assurance Product Sampling (CSP, CNSP)** ➡ ☐ CSP or ☐ CNSP

Check all that apply: ☐ Potency ☐ Sterility ☐ Integrity ☐ Negative space ☐ Positive space ☐ Neutral space;

Describe specific medication: _____ Date sampled: _____

Name of staff: _____

When the quality assurance monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐ **Alert Level:** If positive for growth but below Action Level, then perform an evaluation of appropriate facility engineering controls, personnel; work practice changes and environmental factors that could be causing this environmental finding in an effort to regain microbial control. Document review, conclusions, and actions taken.

☐ **Below Action Level AND a pathogenic organism of concern:** Investigate as you would if action level exceeded.

☐ **Action Level Exceeded:** Complete all sections of this form and develop Root Cause Analysis and Corrective Action Plan.

Samples for Microbial Identification: When the environmental monitoring action levels are exceeded, the laboratory shall identify the CFUs at least to the genus level.

☐ Name and contact info for Laboratory performing ID: _____

_____

Microbiological Results:

☐ Results attached Date results received: _____

What is the typical reservoir for the microbe or microbes identified? _____

Was the location of the excursion near the location of the typical reservoir? ☐ Yes ☐ No

Has this organism/s been found at this location previously? ☐ Yes ☐ No

Potency Results:

☐ Results attached Date results received: _____

Date of completion of competency (Sterile or Non-sterile compounding)? _____

Last date worked by compounder involved in CSP/CNSP: _____

Initiate Recall:

Recall initiated due to potency results (> ± 10%) for batched products dispensed to patient(s)? ☐ Yes ☐ No

- ☐ Report to DoP Date/Time reported: _____
- ☐ Patient(s) Date/Time reported: _____
- ☐ Prescriber Date/Time reported: _____
- ☐ CA BoP Date/Time reported: _____

Investigation Actions Taken

Perform investigation of relevant elements and document in attempt to identify possible cause.

1. **Was Certification documentation of SEC/PEC associated with samples reviewed?** ☐ Yes ☐ No

   Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

   _____

2. **Were logs of relevant work practices associated with the finding reviewed?** ☐ Yes ☐ No

   Based on review **documentation** of documentations and staff observation, was correct procedure followed? Investigate if something unusual happened during initial sampling thru staff interviews.

   b. Check all that apply: ☐ Cleaning Logs ☐ Pressure Logs ☐ Temperature Records
   ☐ Garbing Competency ☐ Cleaning and Disinfection Competency ☐ Direct Observation

   c. Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

   _____

3. **Was the area recleaned after receiving this microbiological identification?** ☐ N/A ☐ Yes ☐ No

   What agent/s was the area treated with? _____

   When was the area recleaned (include date and time): _____

4. **Was the area taken out of service (compounding suspended)?** ☐ N/A ☐ Yes ☐ No

   Explain what was done: _____

5. **Was the SEC/PEC checked or repaired by authorized personnel?** ☐ N/A ☐ Yes ☐ No

   What was the date and company and attach documentation: _____

   If work done inside a PEC and/or SEC, was area triple cleaned? ☐ N/A ☐ Yes ☐ No

6. **Were assigned BUDs shortened for any period of time?** ☐ N/A ☐ Yes ☐ No

   If yes, explain what was done: _____

7. ***Environmental* findings only:** ☐ VAS ☐ SS (other than that taken during compounding)

   a. Was historical trend of sample location reviewed? ☐ Yes ☐ No

   b. Has this location/s had other positive findings within the last 6 months? ☐ Yes ☐ No

   c. Are there multiple excursions found in the room? ☐ Yes ☐ No

   d. Was the area/s retested? Date of retest: _____ ☐ N/A ☐ Yes ☐ No

   f. Microbiological Results of Retest: Date results received: _____ ☐ Number pages attached: _____

   g. Comparison of results to initial finding: ☐ Below Alert Level on repeat ☐ Below Alert Level on repeat

   (Check all that apply): ☐ Exceeds Alert Level on repeat ☐ Exceeds Action Level on repeat

   Discussion of Findings: _____

   _____

8. **Was any personnel retraining conducted?** ☐ N/A ☐ Yes ☐ No

   Describe what was done (include date performed):

   _____

   _____

   _____

   _____

   _____

9. **Based on the investigation, were work practices changed?** ☐ N/A ☐ Yes ☐ No

   If yes, which SOPs and/or Forms were changed:

   _____

   _____

   _____

   _____

VENTURA COUNTY MEDICAL CENTER

QUALITY ASSURANCE PROGRAM REMEDIATION ACTION PLAN

VENTURA COUNTY MEDICAL CENTER / SANTA PAULA HOSPITAL
DEPARTMENT OF PHARMACY SERVICES

Resampling and Results

Type of Environmental Resample:

☐ **Viable Air Sampling (VAS)** ➡ ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Dynamic

Describe specific location/s from ESP: _____ Date sampled: _____

☐ **Surface Sampling (SS)** ➡ ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Dynamic

Describe unit/s location based on ESP: _____ Date sampled: _____

Type of Aseptic Technique Sample

☐ **Glove Fingertip Sampling (GFTS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 (Post compounding) ☐ ISO 7 (Post garbing) ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Static ☐ Dynamic

Name of staff: _____ Date sampled: _____

☐ **Media Fill Test (MFT) – ISO 5** ➡ ☐ CSP Category 1 ☐ CSP Category 2 ☐ Multiple samples

Check all that apply: ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Dynamic

Name of staff: _____ Date sampled: _____

☐ **Qualify Assurance product sampling (CSP, CNSP)** ➡ ☐ CSP or ☐ CNSP

Check all that apply: ☐ Potency ☐ Sterility ☐ Integrity ☐ Negative space ☐ Positive space ☐ Neutral space;

Describe specific medication: _____ Date sampled: _____

Name of staff: _____

Results:

☐ **No Excursion. Close investigation.**

☐ **Excursion. Continue investigation.**

_____ _____

Signature of Pharmacy Supervisor or Designee | Date Investigation and Remediation Closed

VENTURA COUNTY MEDICAL CENTER

QUALITY ASSURANCE PROGRAM REMEDIATION ACTION PLAN

VENTURA COUNTY MEDICAL CENTER / SANTA PAULA HOSPITAL
DEPARTMENT OF PHARMACY SERVICES

Root Cause Analysis:

Corrective Action Plan:

Document specific plan, actions taken, outcomes and follow up. (Attach)

Notification:

Policy PH.26.02 Facility and Equipment – Sterile Compounding (excerpt)

Viable air and viable surface sampling shall be done at least once every six months 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 sites for viable airborne particle testing shall include locations within each ISO Class 5 environment, ISO 7 and 8 areas and in the segregated compounding areas (SCA) at greatest risk of contamination (i.e. work areas near the ISO Class 5 environment). A minimum of 400 liters of air shall be tested at each location. Selected air sampling sites shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning and cleaning.
2. 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

3. Any growth of a highly pathogenic microorganism shall also be considered actionable. Highly pathogenic microorganisms include, but are not limited to, gram-negative rods, coagulase positive staphylococcus, molds and yeasts.
4. Any actionable finding shall result in the following:
    a. Immediate reassessment of the conditions of the engineering controls in consultation with the Infection Control nurse.
    b. Development of an action plan in consultation with the Infection Control nurse which shall address assignment of appropriate beyond use dating, remediation and training.
        i. Beyond Use Dating shall be one of the following: USP <797> BUDs, 12 hour BUDs, or one-hour BUDs. Four-hour BUD for CSP prepared by pharmacy department (USP 797 – 2022 version)
        ii. Remediation shall include cleaning and disinfection of the affected PEC(s) and/or SEC(s).
        iii. Training shall include retraining of pertinent staff on cleaning and disinfection of affected PEC(s) and/or SEC(s).
    c. Once remediation is completed, viable air and surface sampling shall be repeated to confirm results are below actionable levels.

Policy PH.26.06

A. Strength of the selected CSP shall be calculated from the results of the potency assessment. The concentration of the CSP shall be multiplied by the total of the volume of the selected CSP. The resulting value shall be within ±10% the listed amount of active ingredient.