HOUSTON Methodist
WILLOWBROOK HOSPITAL

Houston Methodist Willowbrook Hospital

Medical/AHP Staff Orientation Manual

HOUSTON Methodist
WILLOWBROOK HOSPITAL

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HOUSTON Methodist WILLOWBROOK HOSPITAL

Dear Practitioner:

Thank you for choosing to practice at Houston Methodist Willowbrook Hospital.

As part of the orientation process for Houston Methodist Willowbrook Hospital, please review the following information including use of restraints, emergency preparedness, fire safety, infection control and HIPAA security responsibilities.

After you have reviewed the information, please sign the Orientation Attestation, which is included in the packet, and return to the Medical Staff Office.

You may also access this information online at the Medical Staff Services intranet site (http://www.tmh.tmc.edu/willowbrook/MedStaff/Orientation/attestation.htm), which can be located on the left hand side of the Houston Methodist Willowbrook Hospital intranet site.

If you should need assistance finding this information, please contact us at (281) 737-1005.

Sincerely,

Colleen M. Hutson, CPMSM, CPCS
Director, Medical Staff Services

HOUSTON Methodist
WILLOWBROOK HOSPITAL

I have read and reviewed the attached Houston Methodist Willowbrook Hospital's Medical/AHP Staff Orientation Manual. I understand where I can locate the information via the intranet site.

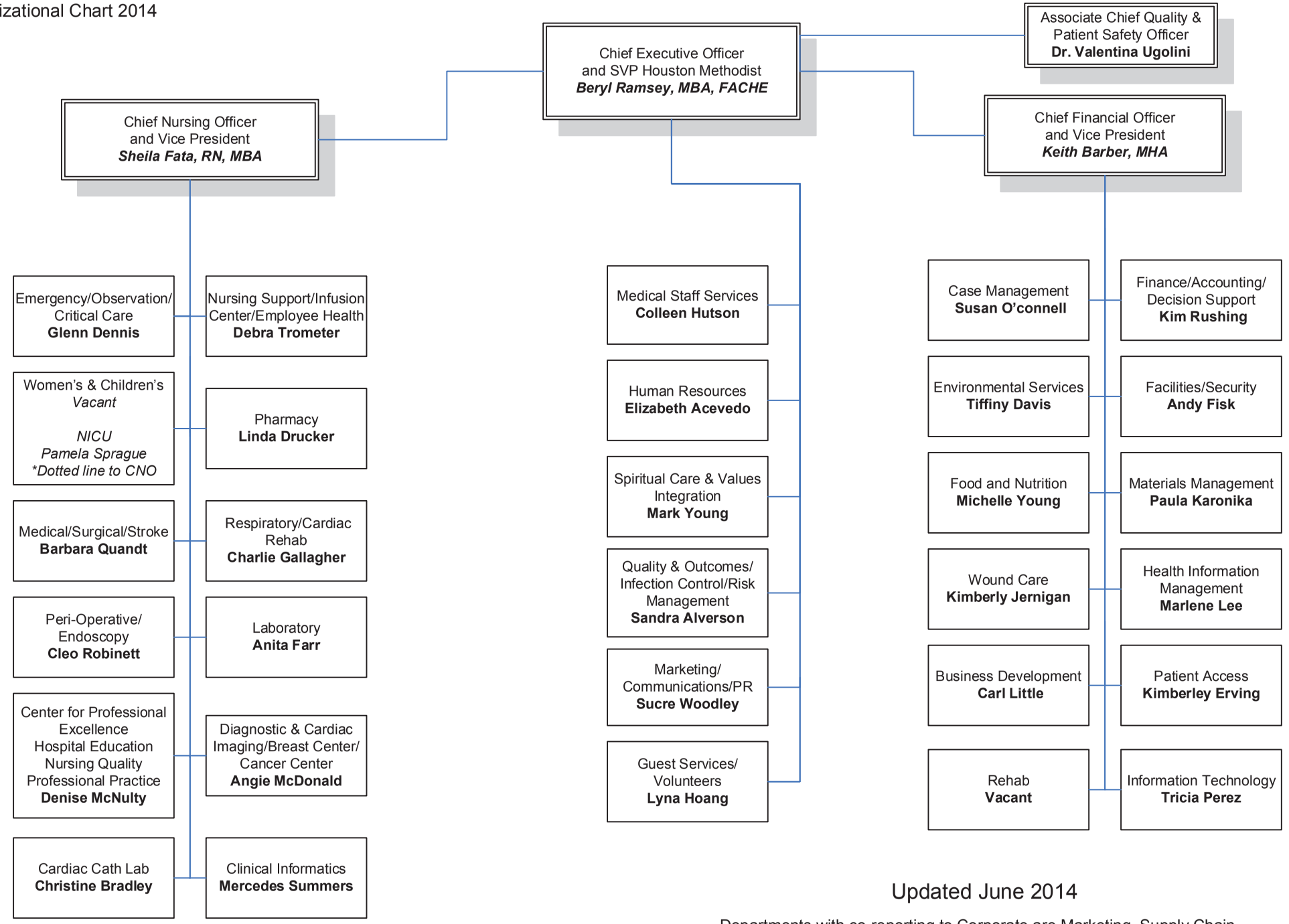
_____

Practitioner Name (please print)

_____ _____

Practitioner Signature Date

Houston Methodist Willowbrook Hospital
Organizational Chart 2014



All RNs in the organization have a dotted line reporting to the CNO

Updated June 2014

Departments with co-reporting to Corporate are Marketing, Supply Chain, Guest Services, Quality, HIM, EVS, Food and Nutrition, and Information Technology.

HOUSTON Methodist WILLOWBROOK HOSPITAL

POLICY AND PROCEDURE PC/PS026

Subject: Restraints

Applies to:
Houston Methodist Hospital

Scope:
All areas where restraints and/or seclusion are used

Originating Area:
Nursing

Effective Date:
12/1/2000

Date Revised/Reviewed:
7/23/2013

Target Review Date:
10/1/2014

I. POLICY AND GENERAL STATEMENT

Methodist Willowbrook Hospital (MWH) staff is seeking to provide a patient care environment which limits the use of restraints.

Restraint is used only to protect patients, staff or others from harm and only after less restrictive measures were deemed ineffective. MWH does not permit restraint or seclusion for purposes such as coercion, discipline, convenience or retaliation. Staffing levels and assignments are set to minimize circumstances that give rise to restraint or seclusion use and to maximize safety when restraint and seclusion are used.

Hospital leadership routinely evaluates restraint use within the organization. Measurement and assessment of restraint and seclusion use allows MWH to target causal factors of restraint use and the potential need for process improvement which can be incorporated into the organization's plans and priorities. MWH explores opportunities to limit restraint or seclusion or eliminate their use through consideration of preventive strategies or alternatives.

All deaths that occur while a patient is in restraint or seclusion, within 24 hrs after removal of restraint or seclusion, or within one week that is reasonable to assume that the use of the restraint or seclusion contributed directly or indirectly to the patient's death will be reported to the Administrative Coordinator (AC). The AC will immediately e-mail the Quality and Outcomes Management Department, specifically the Risk Management Liaison and the Accreditation Coordinator. All Hospital employees must immediately report the following circumstances, to the Administrative Coordinator and complete the questions regarding restraints and seclusion in the electronic Care of Death document in the patient's record:

- Each death that occurs while a patient is in restraint or seclusion.
- Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

- Each death that occurs within one week after restraint or seclusion where it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient's death.

II. **DEFINITIONS**

A. Restraint: A restraint is any manual method, physical or mechanical device, material or equipment attached or adjacent to the participant's body that restricts movement or immobilizes/reduces the ability of a patient to move his or her arms, legs, body, or head freely.

B. Exclusions: medical devices, such as orthopedically prescribed devices, surgical dressings, bandages, protective helmets or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or equipment used to protect the patient from falling out of bed, or equipment which permits the patient to participate in activities without the risk of physical harm. Recovery from the anesthesia that occurs when a patient is in a critical care setting or post-anesthesia care unit is considered part of the surgical procedure. Therefore medically necessary use of devices to restrict movement is this setting does not meet the definition of restraint use. However, if the intervention is maintained when the patient is transferred to another unit or recovers from the effects of anesthesia (whichever comes first), an order for restraint use is necessary.

C. Non-Violent Restraint: a physical restraint used to prevent interference with medical treatments and to support medical healing.

D. Violent Restraint: a restraint that is used to protect the patient against serious injury to self or others because of an emergency or crisis situation where the patient's behavior becomes severely aggressive, destructive, violent, or suicidal.

E. Seclusion: is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff, or others.

F. Chemical Restraint: A restraint also is a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. Exclusions: Drugs or medications that are used as part of the patient's standard medical or psychiatric treatment and are administered within the standard dosage for the patient's condition; appropriate doses of sleeping medication prescribed for patients with insomnia; anti-anxiety medication prescribed to calm a patient who is anxious; and analgesics prescribed for pain management. The use of the drug to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the provider's knowledge of that patient's expected response to the medication.

G. Physical Holds: Are limited to emergencies in which there is eminent risk of a patient physically harming him or herself, staff, or others and when non-physical interventions are not effective. When used, it shall be employed for the least amount of time necessary in order that the individual may resume cooperative

behavior or other restraint is employed to prevent harm to themselves or others. Physical holds are done in a manner that preserves the individual's health, safety, rights, dignity, and well-being.

The following shall not be used in physical holds under any circumstance:

a. Face down restraint with back pressure;
b. Any technique that obstructs the airways or impairs breathing;
c. Any technique that obstructs the vision
d. Any technique that restricts the recipients ability to communicate

The use of physical holds will be subject to the following requirements:

a. The weight of the staff shall be placed to the side, rather than on top of the individual
b. No hold shall allow staff to straddle or bear weight on the individuals torso
c. No hold shall allow the individuals hands or arms to under or behind his/her head or body. The arms must be at the individual's side.
d. No soft devices such as a pillow, blanket, or other items shall be used to cushion the patient's head.
e. All staff involved must constantly observe the individual's respiration, coloring, and other signs of distress, listen for the individual's complaints of breathing problems, and immediately respond to assure safety.

H. Qualified Staff: A registered nurse, nurse practitioner, patient care assistant, mental health technician, or any other staff member who has successfully completed the hospital's restraint competency training and is operating within the discipline's scope of practice.

III. **STAFF/PROVIDER/PROVIDER EDUCATION**

Staff is trained and demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion. Individuals providing staff training are qualified as evidenced by education, training, and experience in techniques used to address patient's behaviors.

A. Staff members who are authorized to perform two hour assessments of patients who are in restraint receive initial and ongoing training and demonstrate competence in:

1. Taking vital signs and interpreting their relevance to the physical safety of the patient in restraint
2. Recognizing nutritional/hydration needs
3. Checking hygiene and elimination.
4. Addressing physical and psychological status and comfort
5. Recognizing readiness for the discontinuation of restraint
6. Recognizing when to contact the Provider (Provider)acting on behalf of the provider to evaluate and/or treat the patient's physical status

B. Staff receives initial and ongoing training and demonstrates competence in the assessment of the patient's readiness for discontinuation of restraints or establishing the need to secure a new restraint order.

C. The role delineation for restraint use is defined as follows:

1. Restraint assessment: RN
2. Restraint monitoring: RN or PCA as appropriate
3. Restraint application, release and re-application: PCA (under the direction of an RN), Physical/Occupational Therapist, Respiratory Therapist, Radiological Technologists and Emergency Department Technicians
4. Restraint minimization, use of less restrictive measures: all health care providers

D. Administrative Coordinators,Security, Charge Nurses and Emergency Department staff receives De-Escalation Training to provide the skills necessary to de-escalate a situation annually.

E. Providers have a working knowledge of hospital policy regarding the use of restraint and seclusion.

IV. **PROCEDURE FOR NON-VIOLENT RESTRAINTS**

A. Prior to Initiation of Non-violent Restraint

1. Prior to the initiation of a restraint, including emergent restraints, less restrictive alternative measures, and evaluation of underlying conditions to protect the patient will be used according to the Restraint Decision Algorithm. See Attachment A.
2. Examples of non-physical interventions/less restrictive measures may include but are not limited to:
   a. Increase observation (possibly move closer to the nurse station) by staff, family, or other approved individuals
   b. Decrease environmental stimuli, e.g. quite room, soft light, “time out”
   c. Relaxation/deep breathing techniques
   d. Music
   e. Medication review
   f. Reality Orientation
   g. Daily activity schedule modification
   h. Feasible suggestions to maintain control offered by patient
3. Other disciplines, e.g., Social Worker, Pharmacist, Dietitian, Physical Therapist and/or Chaplains may be consulted to evaluate alternative measures to restraint.
4. A Registered Nurse (RN) will perform a clinical assessment of the patient and will include information obtained from the patient’s initial assessment to determine the need for restraints.
5. The initial assessment should identify any pre-existing medical conditions or physical disabilities and/or limitations that would place the patient at greater risk during restraint.

B. Initiation of non-violent restraint

1. In the case of emergent restraint application, an RN must perform a clinical assessment of the patient prior to the initiation of a restraint.
2. An RN may initiate the application of a restraint only if less restrictive measures are ineffective, and if the clinical assessment supports the use of a non-violent restraint.
3. The type of non-violent restraint will be individualized to the patient’s situation and the least restrictive intervention that assists in continuing medical interventions will be used.

4. Within one hour of restraint application, staff will notify and obtain an order either via telephone or verbal order from the provider(Providers)who is responsible for the patient or from the Nurse Practitioner (NP) acting on behalf of the provider.
5. The provider will enter an order for Restraint usage in the medical record which is based on the examination of the patient. The provider order is entered into the patient's medical record within 24 hours of the initiation of restraint.
6. If the order is received from a provider other than the responsible providerprovider, the responsible provider is notified as soon as possible.
7. Standing orders or "as-needed/PRN" restraint orders will not be accepted.
8. As early as feasible in the non-violent restraint process, the patient is made aware of the rationale for restraint and the behavior criteria for its discontinuation.
9. In cases in which the patient has consented to have the family kept informed about his/her care, treatment, and services and the family has agreed to be notified, staff will attempt to contact the family to notify them of the restraint or seclusion episode. The family will be made aware of the rationale for restraint or seclusion and the behavior criteria for its discontinuation.
10. Restraint care plan is included within the restraint module in the EMR.

C. Order renewal for non-violent restraint
   1. Renewal of the original order is required for each calendar day if continuation of the restraint is justified.
   2. The renewal restraint order may be a telephone verbal order.

D. Monitoring Patients with non-violent restraints
   1. Patient monitoring will promote the patient's safety, dignity and comfort needs.
   2. Monitoring of the patient is performed every 2 hours and includes as appropriate:
      a. reason to continue restraints
      b. skin condition
      c. nutrition/hydration
      d. elimination
      e. peripheral circulation of restrained extremity
      f. restraint released and range of motion performed
      g. vital signs dependent on the patient's physical/hemodynamic status
   3. The every two (2) hour removal and reapplication does not require a new order.

Restraint orders are to be discontinued before transporting a patient to a procedure area., unless the RN will stay with the patient through the procedure and return with the patient to the home unit.

E. Discontinuation of non-violent restraint:
   1. An RN may discontinue non-violent restraints when less restrictive measures are effective or the patient no longer meets the criteria clinically justifying the use of restraints and document goal met in care plan.
   2. A new order is required to reapply restraints once they have been discontinued.

F. Documentation of non-violent restraint:
   Revisions are made to the plan of care to reflect the use of restraints and the criteria to be met for removal. The plan of care is reviewed daily and revised as

necessary. Restraint documentation reflects the monitoring of the patient and is performed every two (2) hours:

1. Is the restraint properly secured
2. reason to continue restraints
3. skin condition
4. nutrition/hydration
5. elimination
6. extremity restrained
7. peripheral circulation of restrained extremity
8. restraint released and range of motion performed
9. removal of restraint and reapplication
10. A newly applied restraint requires patient's condition pre-application and the rationale for the restraint explained to patient and family.
11. Vital signs dependent on the patient's physical and hemodynamic status.

G. Documentation of Physical Hold

1. Start/Stop time of the physical hold
2. Minutes of length of the physical hold
3. If injuries occurred during the physical hold – to whom, patient, staff, or no injuries occurred
4. Description of the injuries, if any are noted.

V. **PROCEDURE FOR VIOLENT RESTRAINTS AND SECLUSION**

See Attachment A, "Frequently Asked Questions About Restraints/Seclusion" and Attachment C, "Restraint Standards."

A. Prior to Initiation of Violent Restraints and/or Seclusion. See attachment B

1. The patient is assessed and less restrictive interventions attempted. A violent restraint and/or seclusion are used only if the less restrictive interventions have been ineffective to protect the patient or others from harm.
2. Unit Staff may collaborate with the psychiatric staff to promote appropriate evaluation and care.
3. Security may be contacted for immediate assistance.

B. Initiation of Violent Restraints and/or Seclusion

1. Restraint or seclusion should not be based on a patient's violent restraint or seclusion history or solely on a history of dangerous behavior.
2. An RN may initiate and/or authorize the emergent application of a violent restraint and/or seclusion in advance of a provider's order if less restrictive interventions were unsuccessful.
3. The RN will make the patient aware of the rationale for violent restraint and or seclusion and the behavior necessary for discontinuation.
4. The RN will obtain a telephone or written order from a provider acting on behalf of the provider within one hour after initiation of restraint or seclusion. If the order is received from a provider other than the responsible primary provider, the responsible primary provider is notified as soon as possible.
5. An RN who has completed training and demonstrated competency in the assessment of behaviorally compromised patients will perform an in-person,

face-to-face assessment of the patient within one (1) hour after violent restraints and/or seclusion are initiated. The following should be documented:
   a. Description of the patient's behavior and the intervention used
   b. Less restrictive or alternative interventions attempted
   c. The patient's condition or symptom that warranted the use of violent restraint or seclusion
   d. The patient's response to the intervention used
   e. The need to continue or terminate the violent restraint or seclusion
6. The RN/NP will report the results of the assessment to the responsible provider as soon as possible after the completion of the one (1) hour face-to-face assessment.
7. In cases in which the patient has consented to have the family kept informed about his/her care, treatment, and services and the family has agreed to be notified, staff will attempt to contact family to notify them of the restraint or seclusion episode.
8. The restraint order form or the electronic medical record entry is used to order violent restraints and or seclusion. Orders for violent restraint and/or seclusion may not exceed:
   a. Ages 18 and older: four (4) hours
   b. Ages 9-17: two (2) hours
   c. Ages under 9 years: one (1) hour
9. The RN will amend the patient's treatment plan to address current interventions and future plan of care.

C. Provider Order Renewal for Violent Restraint and/or Seclusion
1. The patient is evaluated face-to-face prior to the order expiring.
2. The evaluation may be performed by
   a. a provider
   b. an RN who has completed training and demonstrated competency in the assessment of behaviorally compromised patients
3. Violent restraints and/or seclusion may be renewed via telephone or written order in accordance with the following limits:
   a. Four (4) hour for adults 18 years of age or older;
   b. Two (2) hour for children and adolescents 9 to 17 years of age; or
   c. One (1) hour for children under 9 years of age.
4. Upon reorder of restraints the following should occur:
   a. Review treatment plan
   b. Collaborate to identify ways to help the patient regain control
   c. Evaluate the patient every four (4) hours for adults ages 18 years and older, every two (2) hours for ages 9 to 17 and every one (1) hour for children under 9 years of age.
5. Notify the Unit Director or designee regarding:
   a. Any reapplication of a violent restraint within 12 hours after discontinuation.
   b. Two or more episodes within twelve hours and then every 24 hours thereafter while the patient remains in a restraint.
6. The provider conducts an in-person reevaluation at least every 8 hours for patients 18 years and older and every 4 hours for patients 17 and younger.

D. Patient Monitoring during violent restraint or seclusion
1. Qualified staff will monitor the patient through continuous in-person observation. (One-to-one staff to patient ratio)

2. Qualified staff will assess the patient at the initiation of violent restraint and/or seclusion and every 15 minutes until the restraint or seclusion is discontinued.
3. The assessment may include, as appropriate, the following:
    a. Is the restraint properly secured
    b. Signs of any injury associated with applying restraint or seclusion
    c. Nutrition and hydration
    d. Circulation and range of motion in the extremities
    e. Vital signs
    f. Hygiene and elimination
    g. Physical and psychological status and comfort
    h. Readiness for discontinuation of restraint or seclusion
4. Should the patient's behavior or refusal prevent hands-on assessment, the RN will perform a visual assessment.

E. Discontinuation of violent restraints and/or seclusion
1. Violent restraints and/or seclusion are discontinued as soon as it is indicated by the patient's behavior.
2. An RN authorizes discontinuation of restraints when less restrictive measures are effective or the patient no longer meets the criteria clinically justifying the use of restraints.
3. Other qualified staff may remove a restraint when authorized by an RN.

F. Interdisciplinary Debriefing Conferences
1. The staff members involved with the patient, the patient, and if appropriate family members, will hold a debriefing session.
2. The debriefing will occur as soon as possible, but no longer than 24 hours after the episode.
3. The debriefing will focus on:
    a. Identifying what led to the incident and possible causes of behavior
    b. Ascertaining whether the patient's physical well-being, psychological comfort, and right to privacy were addressed; and
    c. Determining the need to modify the patient's treatment plan.

G. Documentation of violent restraint and or seclusion.
1. Patient and/or family were instructed about the policy on restraint
2. Pre-existing medical conditions or physical disabilities that would place the patient at greater risk during restraint and or seclusion
3. History of sexual or physical abuse that would place the patient at greater psychological risk during restraint or seclusion.
4. Circumstances that led to restraint or seclusion
5. Consideration or failure of nonphysical interventions
6. Rationale for the type of physical interventions selected
7. Notification of the patient's family as appropriate
8. Criteria for discontinuing restraint or seclusion
9. Informing the patient of criteria for discontinuing restraint or seclusion
10. The 15 minute assessment, as appropriate to the type of restraint or seclusion, the following:
    a. Patients behavior;
    b. Signs of any injury associated with applying restraint or seclusion and treatment of injuries;
    c. Nutrition and dehydration;
    d. Circulation and range of motion in the extremities;
    e. Vital signs;
    f. Hygiene and elimination;

g. Physical and psychological status and comfort;
h. Readiness for discontinuation of restraint or seclusion;
i. Assistance provided to the patient to meet the criteria for discontinuing violent restraint and/or seclusion; and
j. Continuous monitoring

11. Results of visual assessment if patient's behavior prevented hands-on assessment.
12. Debriefing of the patient and/or family with staff

VI. **COUNCILS OR COMMITTEES REVIEWING OR APPROVING PROCEDURE AND REVIEW OR APPROVAL DATES**

Nursing Leadership July 2013

VI. **AUTHORITATIVE REFERENCES**

Centers for Medicaid and Medicare Services (CMS) Conditions of Participation
DNV NIAHO ® Accreditation Requirements, Interpretive Guidelines & Surveyor Guidance, Version 10, Effective July 16, 2012,

VII. **NAME OF APPROVING EXECUTIVE:** Sheila Fata, MBA, RN, NEA-BC
TITLE: Chief Nursing Officer/Vice President

_____ _____
Signature of Approving Executive Date Signed

Revision History As required by ISO9001, document the

Revision	Date	Changed by	Revision Summary
1	6/27/2013	Nursing Leadership & Restraint Taskforce/Mona Cockerham	1. Definitions Section: G. Physical Holds removed generalized information (first two sentences and kept remaining statements) 2. Allow for telephone renewal q 24 hours/ changed to calendar day for non-violent (failures with getting orders within 24 hours per log review) 3. Violent restraint renewels must be in person by a provider within a calendar day 4. Therapeutic hold – 5. Training program for assessment for need of restraints (pg4 #7) – we do not have this. 6. No new order is needed for restraints, if restraints are removed for a patient transport for a test and a RN accompanies the patient. The RN serves as the restraint. 7. Where MD/NP is noted; provider is added in (provider). Definition of provider is added. 8. CPI training is changed to reflect a non-specific provider. The education program

			will be defined as "De-escelation Training" 9. Section IV A. 1. Added word "alternative" 10. Section IV B. 10. Restraint care plan is included within the restraint module in the EMR is added. 11. Section IV C. 1. Change 24 hours to Calendar Day. 12. Section IV C. 2. Removed sentence to refer to 24 hour renewal order 13. Section IV C. 3. Removed sentence to not allow time to lapse more than 24 hours. 14. Section IV C. Added "telephone/" before verbal order. **15.** Section IV D. Added 4. Restraint removal for patient care does not require a new order for reapplication as the staff member remains with the patient and serves as the restraint. Example: Transport to tests where patient is occupied by a RN at all times. 16. Section IV D 4. Restraint orders are to be discontinued before transporting a patient to a procedure area where the originating unit RN will not stay with the patient for the entire procedure and return with the patient to the home unit. 17. Section IV G. 1. Removed "Was a physical hold done" 18. Section IV G 5. Added, "if any are noted." 19. Page 13 of Attachment B – "Remove Interdisciplinary Conference ASAP within 24 hours" removed. Patient are evaluated for restraint usage daily. (To be in next revision due to flow diagram being a picture, needs to be changed to Viseo flow diagram). 20. Attachment C – Changed references to 24 hours to calendar day. 21. Where physician, NP, or PA are note, (provider) is added.

Attachment A: FAQ about Restraints/Seclusion

Attachment B: Restraint Decision Algorithm

Attachment C: Summary of Required Time Frames

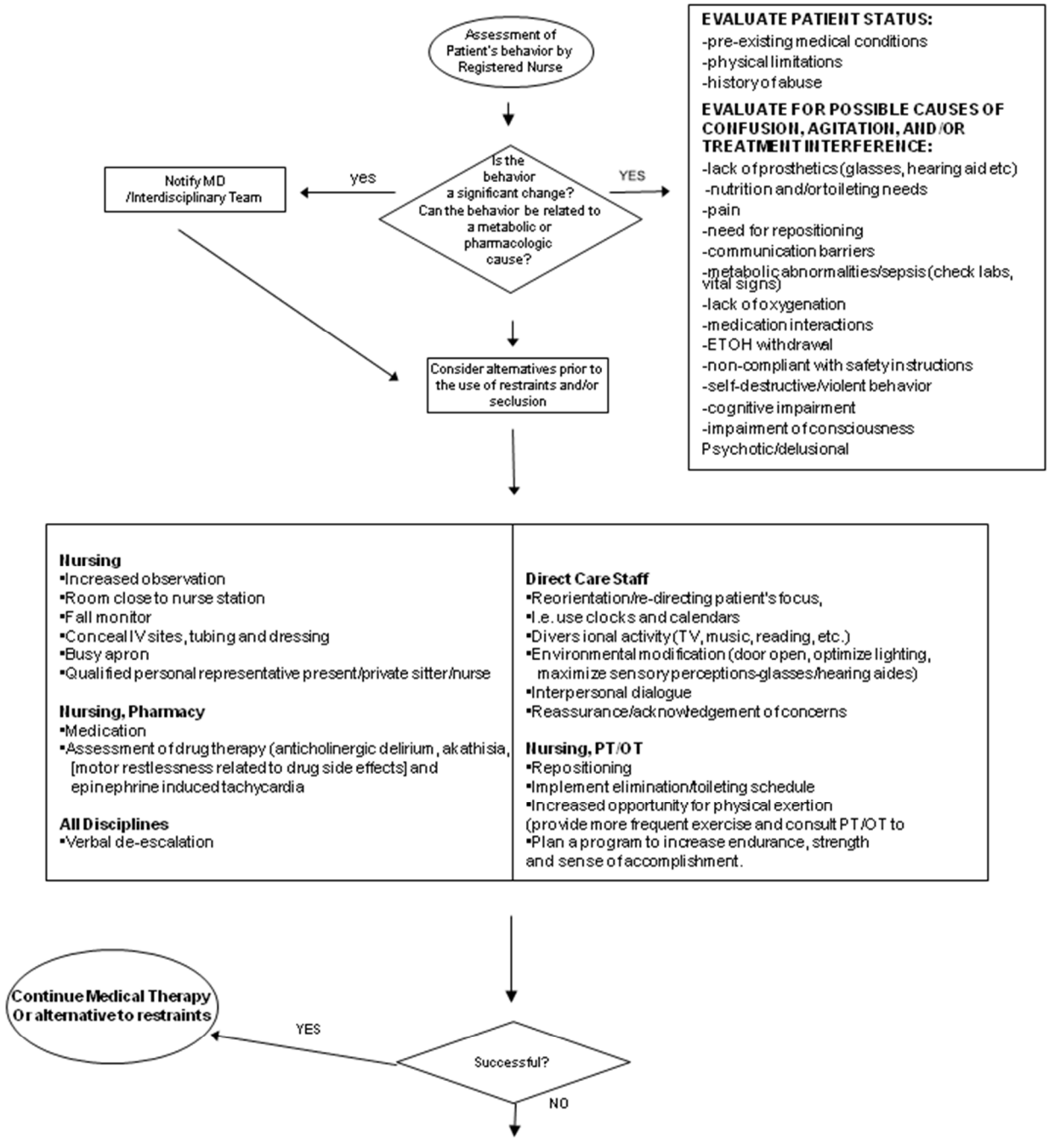
ATTACHMENT A

Frequently Asked Questions About Restraints/Seclusion

QUESTION	ANSWER
1. What is the difference between non-violent and violent restraint?	Non violent restraint is a physical restraint used to prevent interference with medical treatments and to support medical healing. Violent restraint is a restraint that is used to protect the patient against serious injury to self or others because of an emergency or crisis situation where the patient's behavior becomes severely aggressive, destructive, violent, or suicidal.
2. What are the types of restraints used at MWH?	Wrist, ankle, mittens, and side rail. Evaluation of new/improved products occurs on an ongoing basis, therefore this list may change.
3. Is a side rail a restraint?	Yes, if the patient does not have the freedom to exit the bed when desired, for example when all four side rails are raised and the patient cannot lower them. If the side rail is used to restrict patient movement, it is a restraint. No, if the side rail is used to protect the patient from falling during bed mobility.
4. What does "appropriate for patient's physical/emotional condition" mean when removing and reapplying violent restraints in Attachment C?	The frequency of removing and reapplying violent restraints will be on a case by case basis dependent on the patient's physical condition and behavior. It should be done frequent enough to check for skin condition and assess for injury. The standard is 1 hour. If the patient continues to demonstrate aggressive attempts to self-harm or inflict injury to others, document the behavior and observation of the patient's physical status.
5. Should we equate a ventilator with a restraint?	A restraint is not equated with any type of equipment or procedure. Each patient is assessed and the least restrictive measure is implemented for the patient's condition.
6. Who can apply and who can remove a restraint?	Registered nurse, nurse practitioner, patient care assistant, mental health technician, respiratory therapist, or any other staff member who has successfully completed the hospital's restraint competency training may remove a restraint after the patient is assessed.

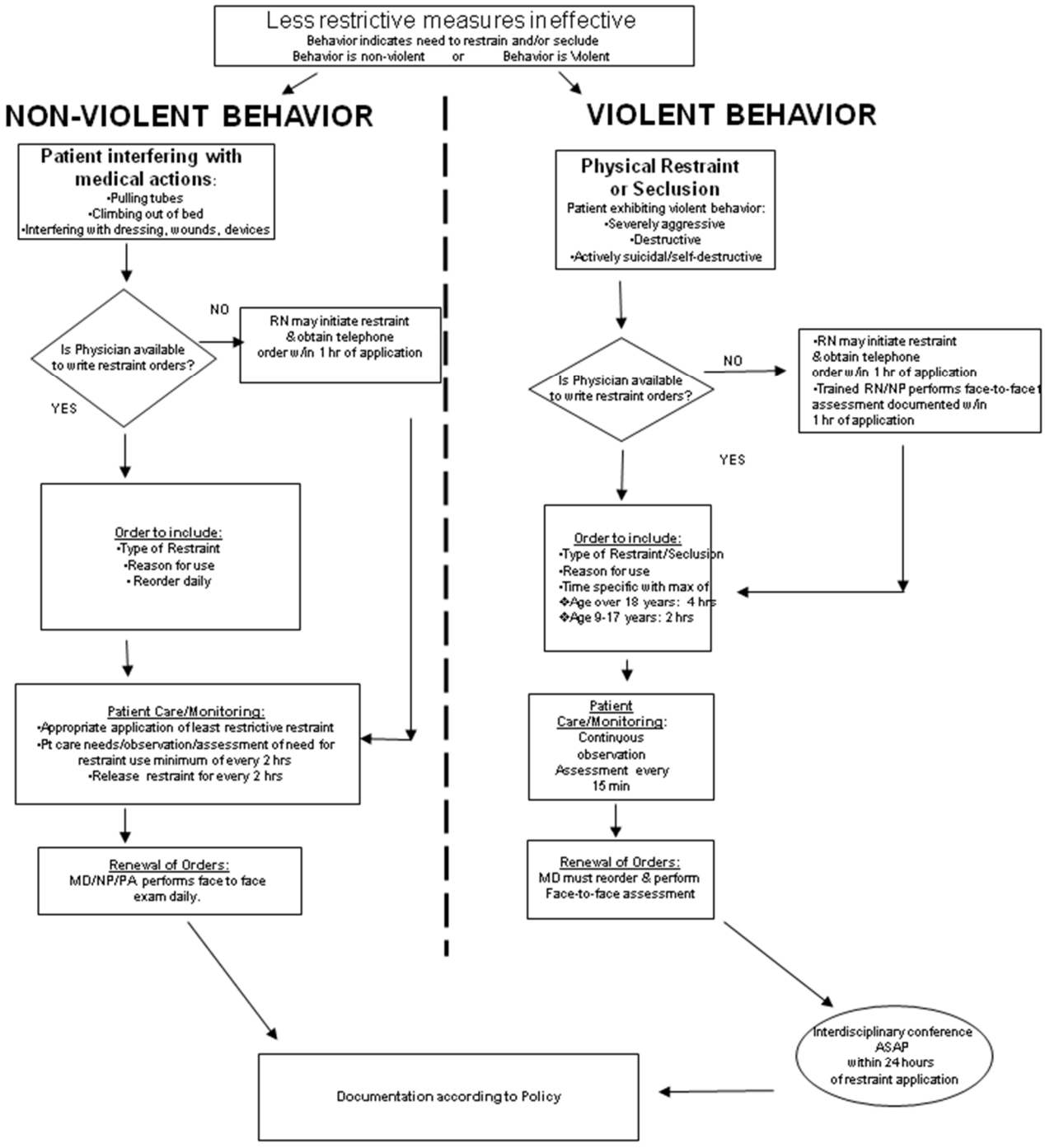
7. Where do we tie/secure a restraint?	The restraint is tied to a non-movable part of the bed.
8. What is a quick release knot?	A quick release knot is a bow or a knot that can be released in a single step.
9. When can a nurse take a telephone order for a restraint?	A telephone order may be obtained for the initial placement of non-violent restraints and violent restraint or seclusion.
10. Who can give a restraint order?	A providerprovider or Nurse Practitioner or ProviderProvider Assistant (Provider) acting on behalf of the providerprovider may give a telephone or written restraint order.
11. Mr. Jones was restrained on Tuesday and then dies 6 days later. What does the nurse need to do?	Complete the restraint section in the Care After Death screen in MethOD. The questions **must** be answered.

Restraint Decision Algorithm



7/2011

ATTACHMENT B
(continued)



Attachment C – Summary of Required Time Frames

	Non-Violent Restraints	**Violent Restraints and Seclusion**
Time frame for obtaining initial order (telephone or written)	1 hour	1 hour
Consultation with responsible providerprovider(Provider) if order not written by responsible providerprovider (Provider)	As soon as possible	As soon as possible
Length of time for which initial order may be written	Calendar Day	Age 18 & older – 4 hours Age 9 -17 yrs – hours Age 9 yrs and under – 1 hour
Time frame for providerprovider (Provider) to see, evaluate patient and sign initial order	Calendar day	1 hour
Time frame for renewal of initial restraint order	Calendar Day	MD may authorize RN renewal of the initial order once with RN face-to-face assessment of the continued need as follows: Age 18 & older- 4 hours (maximum 8 hours total from initial order) Age 9-17 yrs – 2 hours (maximum 4 hours from initial order) Age under 9 years – 1 hour (maximum 2 hours from initial order)
Time frame for providerprovider (Provider) to see and re-evaluate patient who requires continuing restraint following initial order	Calendar Day	Age 18 & older – 8 hours Age 17 and under – 4 hours
Monitoring frequency:		
Physical restraint - Verify restraint properly secured - skin integrity - remove and reapply restraint	 q 2 hours q 2 hours q 2 hours, and as appropriate	Continuous face-to-face observation required (1:1 staffing ratio) q 15 minutes q 15 minutes q 1 hour, while awake and as appropriate
Psychological status (reason for continuation/discontinuation) -restless, agitated, rational, cooperative, etc.	q 2 hours	q 1 hour
Extremity Restraints - peripheral circulation -range of motion for extremity Restraints	q 2 hours q 2 hours, while awake	q 15 min q 1 hour, while awake
Needs Addressed - hydration, nutrition and elimination	q 2 hours	q 2 hours
Vital Signs	Appropriate to the patient's condition **(Evaluate the relevance to the patient's physical safety)**	Appropriate to the patient's condition **(Evaluate the relevance to the patient's physical safety)**

Emergency Management

Methodist Willowbrook Hospital's (MWH) Emergency Management activities provide a framework that ensures the safety of employees, physicians, patients and visitors through effective mitigation, preparation, response and recovery to disasters or emergencies affecting the environment of care. MWH follows the National Incident Management System (NIMS) and qualification through NIMS 100, 200, 700 and 800 are annually reviewed.

Objective
The objective of the Emergency Management Plan is to effectively anticipate, prevent where possible, prepare for and manage an emergency, and to return the facility to normal operation. In addition, the Emergency Management Plan provides a framework for the hospital's participation in the both NIMS and the National Disaster Medical System (NDMS).

Environment of Care/Patient Safety Committee Oversight
The Environment of Care Committee/ Patients Safety (EoC/PS) is responsible for all aspects and final approval of the Emergency Management Plan. Responsibilities under the Plan are as follows. The Committee delegates hazard vulnerability analysis, plan and exercise development, training of leaders and staff, plan and exercise performance review, and other specific tasks to an Emergency Preparedness Subcommittee.

Emergency Code – Code Yellow
All Methodist Hospitals use Code Yellow for activation of their disaster/emergency management plan.

Employee Responsibilities
1. Know and understand the location of department's disaster plan. The plans should be online and/or in a central location in each department.
2. Know the location and function of the Labor Pool that the employee is assigned to.
3. Wear hospital photo identification badge at all times while on hospital premises:
    a. Persons who cannot produce a valid employee photo identification badge may be denied access to the facility
    b. Photo identification badges should not be left at work:
        i. Badges will be used by most local law enforcement agencies to allow entry to the area or hospital during emergency
        ii. Badge necessary for access to hospital
4. Return to primary work area for a "Code Yellow" event and follow departmental plan
5. May not be assigned to their regular duties
6. See Emergency Management Labor Pool Policy and Emergency Management Medical Staff Assignments Policy.

Management Responsibilities
1. Planning
    a. Develop, review and update departmental disaster/severe weather/hurricane plans
    b. Provide staff training on the departmental and hospital disaster plans at least annually
2. Notify staff of Emergency Management Plan activation
3. Staffing during an event
    a. Assess ability to provide care in their own areas and determine how many

employees can be provided to the labor pools
4. Maintain a current employee contact phone list
5. Hurricane/Severe Weather Preparedness
    a. Determine staffing needs and enter in Management Toolbox (see System Procedure HR 94 for more details of this process).
    b. Allow employees expected to be on-site during the peak of the event (rideout employees) to go home 24 hours before expected landfall and attend to their dependents and belongings
    c. Instruct employees to return at least 12 hours prior to projected landfall and to bring 3 days worth of non-perishable food, drinking water, clothing, bedding, medication and personal hygiene articles
    d. Instruct employees NOT on site during landfall (recovery employees) to return to work as soon as roads are passable or as directed by their departmental management
6. Evaluate departmental & hospital response and provide feedback

Executive Responsibilities

1. Be familiar with the general function and design of the Hospital's Incident Command System
2. Be prepared to:
    a. Make the decision to activate the Hospital's Emergency Management Plan
    b. Make decision to modify or discontinue some hospital services
    c. Serve as Incident Commander, Section Chief or other Incident Command role
    d. Activate the Emergency Operations Command Center in the Conference Center or other appropriate location

Hazard Vulnerability Analysis (HVA)

Methodist Willowbrook Hospital will perform an annual hazard vulnerability analysis to identify areas of vulnerability or opportunities for improvement. The goal of this exercise is to prioritize activities to lessen the severity and/or impact of a disaster or emergency that could affect the services provided by the hospital

Internally and in collaboration with community emergency management planning, the hospital prioritizes potential emergencies identified in its hazard vulnerability analysis. The internal evaluation will occur at the end of each calendar year, the external interaction & feedback sessions will occur in the spring and the results will be presented to the EoC/PS Committee during the first quarter.

Hospital Role in Community-wide Emergency Management and Planning

Methodist Willowbrook Hospital cooperates with local, county and state emergency management drills. The hospital is represented at both the Houston Area Hospitals Emergency Management Collaborative (conducts planning for the Houston Metropolitan Medical Response System and coordinates with other agencies for any large-scale drills) and the Regional Hospital Preparedness Collaborative North Corridor Group which facilitates emergency planning in northern Harris & Montgomery counties.

Command Structure

The command structure utilized by MWH in coordination with the community-wide command structure is the Incident Command System (ICS). The Hospital's ICS is modeled on and interfaces with the ICS used by the Texas Medical Center and the City of Houston Office of Emergency Management through the Catastrophic Medical Operations Command (CMOC). The

hospital links to the Harris County Office of Emergency Management (through TRANSTAR – the County Emergency Management Center), the Texas Department of Public Safety and the Federal Emergency Management Agency (through the CMOC).

Incident Commander (IC)

1. Activates Emergency Management Plan
2. Manages on-scene emergency operations
3. Determines which Incident Command **Staff Officer** positions to fill
4. Appoints Incident Command **Section Chiefs**
5. Will make the determination as to when the disaster is contained
6. Issues the 'all clear'

Emergency Activation - Code Yellow

The ICS should be activated for any unplanned or potential event that can cause deaths or significant injuries to patients, staff or the public or the disruption / shutdown of hospital operations.

Notification of Emergency

When the facility is notified of an emergency, the person receiving notification will immediately notify the Administrative Coordinator (AC) and the Administrator on Call (AoC) whether it is an internal or external emergency.

The AC and/or AoC will evaluate and determine whether the Emergency Management Plan will be activated. If the plan is activated, the Administrative Coordinator, Administrator on Call (AoC) or ED charge nurse will notify Security to page "Code Yellow" at one of the three levels defined below:

1. "Code Yellow – Standby" alerts Executives and management through the Management Alert Text Paging system
2. "Code Yellow – External Activation" for events centered in the Emergency Department. This code activates:
    a. ICS Staff and Section Officers as requested
    b. The Emergency Department
    c. The ED Staging Unit
3. "Code Yellow – Internal '**location'" a**ctivates all departments of the hospital for events requiring an immediate, hospital-wide response. For all internal disasters, the AC will immediately notify AoC and Senior Leadership. The AC will function as the Incident Commander until relieved by AoC or Senior Leadership.
    a. Incident Commander will:
        i. Activate the Incident Command System
        ii. Assemble the Command Staff and necessary Section Chiefs, who will assemble necessary Section Leaders
        iii. Notify Liason Officer or Security of additional outside agencies that may be needed to assist the hospital in the event of an internal emergency, i.e., fire department, flood or gas leak
        iv. Initiate the recovery phase of the plan

Labor Pool

If a labor pool (personnel staging units) is required for a specific incident, the Planning Section will coordinate communication regarding activation, staffing and direction of these resources through the Incident Commander. The labor pool will be located in the Aspen/Alder Conference Center rooms.

Outside Communication
The Hospital normally communicates with external authorities and agencies through the telephone system. If the premise-based VoIP telephone system fails, analog telephones on each unit/department, department-based emergency cellular telephones, 800 mhz County Emergency radios, and Amateur Radio equipment will be used to communicate with other hospitals, the CMOC and others.

Management of Patients during Emergencies
At the direction of the Incident Commander, the Hospital may suspend normal admission requirements, outpatient services may be restricted or suspended, elective admissions and procedures may be canceled including elective surgery and non-emergent outpatient procedures, and stable patients may be transferred to other facilities to accommodate the admission of unstable or critical emergency victims

Hospital Evacuation
Total facility evacuation will be ordered by Senior Leadership, or designee. See the Appendix I, Hospital Evacuation Plan for additional information.

Orientation & Education
At least during orientation and annual (on their focal point review schedule) staff will receive basic information on the emergency management plan. Each spring staff will participate in rideout/recovery staffing conversations with their department and both personal and hospital emergency management will be discussed. As changes to specific elements of the plans change, they will be communicated through various means.

Annual Evaluation
The annual evaluation of the Emergency Management Program will include a review of the programs' mitigation, preparation, response and recovery effectiveness. This also includes response to the HVA priorities and direction on future emergency management activities.

Fire Safety and Evacuation

Fire Response - You see the fire or smell smoke

Employees are expected to respond to the discovery of a fire by implementing the **R.A.C.E**.

Rescue anyone in immediate danger from the fire and move him or her to a safer location
Alarm- Activate a fire pull station and call the appropriate telephone number to report the fire
Contain the fire by closing the door to the room
Extinguish the fire if you can safely do so

Fire Alarm Response – You hear the alarm but do not see fire or smell smoke

1. If you hear a fire alarm, you should check your work area.
2. If you discover fire or smoke, implement **RACE**
3. If fire conditions are not found, stand by for an all-clear announcement.
4. If no all clear is announced, you can call Security (**281.737.1002**) and ask if the alarm is clear.
5. Stay alert until alarm is clear.

Code Red

1. When a fire is reported to the hospital fire operator (7-7777), the fire operator begins a Public Address Announcement to inform personnel. In order to prevent the panic that might ensue among patients and visitors if a fire was announced over the Public Address system, the Hospital uses a code word in place of a "fire" announcement. The code word to announce a fire is " **Code Red**".
2. The fire operator will page "**Code Red all clear**" when the fire emergency is over.

Use of Fire Extinguishers

Pull the pin
Aim the discharge device (hose or nozzle)
Squeeze the handle
Sweep the discharge device slowly back and forth at the base of the fire

Defend In Place

1. The hospital uses a "defend in place" strategy to protect patients, visitors, employees, medical staff, students and volunteers (hereafter referred to as patients) from fire.
2. In most cases, patients in the Hospital are safer from fire in their room with the door closed than they would be if they were evacuated through a smoke filled corridor.
3. Staff should inspect all rooms on their unit and close the door. If fire is discovered, **RACE** should be implemented. If not, closing the door isolates areas from the fire and smoke.
4. During room search and subsequent door closing, staff should inform patients that there is a fire alarm and they are closing their door until the alarm is clear.
5. Once the alarm is clear, staff should go back to each room and inform patient that all is clear.

Managers/Directors Duties

Ensure that all employees are trained on departmental specific fire safety information such as:

1. Departmental program
2. Fire alarm pull station locations
3. Fire extinguisher locations
4. Use of other fire equipment
5. Patient evacuation equipment specific to the department

Employee Duties

1. Responsible for safety of patient and visitors
2. Know hospital fire safety and evacuation program
3. Know departmental fire safety and evacuation program
4. Know location and use of fire extinguishers
5. Know fire alarm system as well as other fire equipment
6. Be aware of patient evacuation equipment specific to areas

Building Fire Protection Features

1. The cross-corridor smoke/fire doors on the floor of alarm close automatically to prevent fire spread.
2. The air conditioning system on the floor of alarm shuts down and prevents smoke from spreading to the safe areas.
3. Smoke or heat detectors, pull stations, fire sprinklers, fire hoses, or fixed fire extinguishing systems can activate fire alarms.

Oxygen and Fire

1. Oxygen is not flammable itself, but supports and accelerates fire. Items that are normally fire resistive may burn in oxygen enriched atmosphere.
2. Shutting off oxygen zone valves could affect many patients. All employees working in patient care areas where oxygen is administered should be familiar with the procedure for discontinuing oxygen during a fire.
3. Oxygen Zone Valve Shutoff will occur only under the direction of the Administrative Coordinator (AC) on patient care units, Anesthesia in the OR's, or the Fire Department.

Fire Prevention

1. In order to maintain a facility that is safe from fire, it is imperative that employees practice fire prevention.
2. Questions about fire prevention and fire safety should be directed to the Safety Officer at 281-737-2137.
3. Some common fire prevention rules are listed below:
    - Store all combustible materials at least 18-inches below sprinkler heads and/or light fixtures.
    - Remove unnecessary combustible materials such as excess paper, cardboard, and trash from the work area.
    - Do not use extension cords in lieu of permanent wiring.
    - Use only U.L. or F.M. approved three prong multi-outlet strips with current limiting protection.
    - Never store combustible materials near heat sources.
    - The use of toasters, toaster ovens, and other food preparation equipment with open heating elements, is prohibited outside of authorized Food and Nutrition areas of the Hospital.

- Space heaters with open heating elements are very dangerous and are not allowed for use within the Hospital.

Evacuation Level A (Horizontal)

1. In some cases, it may be necessary to move patients away from the fire area instead of "defending in place", in order to insure their safety.
2. Patients can be moved **horizontally** through the nearest set of fire/smoke doors to the next smoke compartment on the same floor.
3. Any employee can make the decision to move patients horizontally.
4. Fire/smoke doors should remain closed to restrict movement of smoke and fire except when patients or personnel are evacuating.

Evacuation Level B (Vertical)

In severe fire or disasters, even moving patients to another smoke compartment on the floor may not be enough to protect them.

1. Vertical evacuation (using the exit stairwells) may become necessary and will be used as a last resort.
2. Vertical evacuation will be done only under the direction of the Houston Fire Department, Administrator-On-Call, their designee, or the Administrative Coordinator.
3. If vertical evacuation is necessary, determine the destination prior to beginning the evacuation (e.g. North Pavilion (NP) 7 West will relocated to NP5 West.)
4. The stair on the unit, or if not on the unit then immediately adjacent to the unit (e.g. Women's & Children's Pavilion Stair 4), is the primary stair for vertical evacuation.
5. The North Pavilion center stair (Stair NE) should be avoided for vertical evacuation if possible.
6. Do not use elevators for evacuation unless instructed to do so by the Fire Department.

Evacuation Level C (Total Building)

1. In severe fires or disasters that may damage the facility to the point where it is not functional, it may be necessary to transfer patients to another hospital.
2. Senior Leadership authorizes this type of evacuation.
3. Patient Access will contact the receiving hospital to coordinate the transfer of patients.
4. Patients will be staged on the ground floor prior to their departure. All patients leaving the hospital must be entered in EMTrack (regional patient tracking system) prior to their departure.
5. Nursing and/or other professionals would accompany patients to the receiving hospital to assist in-patient care there.
6. When the damaged facility is repaired and functional, patients will be returned.

Maintain Exits

1. It is important that all exits and corridors be maintained free of obstructions so all building occupants can move safely during an emergency.
2. Nothing should be stored in any corridor or exit stairwell.
3. Any portable equipment in use in the corridors should be kept on one side of the corridor.
4. All portable equipment in the corridors must be attended by its user and in case of a fire alarm, removed from the corridor. Equipment cannot be stored in a hallway.
5. No normally closed doors (such as stairwell or corridor doors) may be propped or wedged open.

Fire Drills

1. Conducted randomly throughout the year to evaluate employee knowledge of the Fire Safety Program.
2. All employees are expected to participate to the fullest extent possible.
3. A primary unit will be selected and personnel there will be asked to participate in the drill.
4. Other units throughout the hospital will also be evaluated.
5. Respond as you would to a real fire (RACE – PASS) with the exception of actual patient movement and discharging the fire extinguisher.

Fire Wall Penetration Permits

1. Any work that involves penetrating a rated wall will require a Fire Wall Penetration Permit
2. The Permit may be obtained from Facility Management Services (FMS).
3. Examples of firewall penetrations include installing low voltage cables, piping, conduit, etc.
4. The person performing the work must supply FMS with the route that the cable, piping, etc. will be run and information about the approved firestop system to be used.
5. No work may begin until a permit is issued.
6. After the work is complete, the FMS employee who issued the permit must inspect and approve the job to ensure that it is properly fire stopped.
7. Supply Chain will not pay vendors who do not have a properly executed cable permit.

Hot Work Permits

1. Before the start of any temporary operation or work that involves open flames and/or sparks, a Hot Work Permit is required. The following operations that are included are:
    - Brazing
    - Cutting/Grinding
    - Open flame soldering
    - Welding
    - Torch applied roofing
2. Hot Work Permit must be obtained from the FMS
3. The work site shall be inspected to confirm that precautions have been taken to prevent a fire and the site is in accordance with NFPA 51B.

Interim Life Safety Measures (ILSM)

1. Measures implemented to protect the safety of occupants when existing life safety or equipment systems are not in place.
2. FMS and contractors (where involved) have the responsibility for implementation and oversight of the ILSM process.
3. Additionally, FMS and Infection Control provide oversight for infection control measures during renovation and construction.
4. These activities are reported to the Environment of Care/Patient Safety Committee monthly.

Environment of Care Committee Oversight

The Life Safety Management program is overseen and reviewed by the Environment of Care/Patient Safety Committee. Incidents, performance data and issue resolution is reported to this committee, and where required, other Hospital Committees and the Board of Trustees.

HOUSTON Methodist WILLOWBROOK HOSPITAL

POLICY IC 319

Subject:
Isolation Policy
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Applies to:
Methodist Willow brook Hospital

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Originating Area:
Infection Prevention and Control

Effective Date: 2000

Date Revised/Reviewed:
9/2000, 9/2009, 6/2013

Target Review Date:
6/2016

I. POLICY STATEMENT:

Methodist Willow brook Hospital will comply with the CDC Guidelines for Isolation Precautions.

II. PURPOSE:

To prevent the transmission of infection, among patients, staff and visitors.

III. PROCEDURE:

Isolation precautions will be initiated by the RN, attending physician, the infection Prevention and Control Practitioner or the Chairman of the Infection Prevention and Control Committee. Isolation can be discontinued by the aforementioned.

a) Room placement for Isolation will be determined by using the disease or infection in Appendix A of CDC Isolation Guidelines located on the Hospital Intranet under Isolation Quick Guide. The Infection Prevention and Control Practitioner or Administrative coordinator or designee will be available as a resource for any decisions regarding isolation or room placement.
b) Nursing department will be responsible for implementation of Isolation procedures and for instruction of personnel and visitors as appropriate.
c) Patient Isolation Quick Guide is available on Hospital Intranet under Infection Control tab/ Isolation Quick Guide.

IV. STANDARD PRECAUTIONS:

Standard Precautions combine the major features of Universal Precautions and Body Substance Isolation and are based on the principle that all blood, body fluids, secretions, excretions except sweat, nonintact skin, and mucous membrane may contain transmissible infectious agents. Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infections status, in any setting in which healthcare is delivered.

Standard Precautions are also intended to protect patients by ensuring that healthcare personnel do not carry infectious agents to patients on their hands or via equipment used during patient care.

Barrier precautions:

- Wear gloves (clean non-sterile gloves are adequate) for anticipated hand contact with blood, secretions, excretions, mucous membrane, contaminated items, non intact skin, and any moist body substance of all patients.
- Wash hands after removing gown and gloves.
- Wear gowns, plastic aprons, masks and goggles or face shield when secretions, excretions, blood or other body fluids are likely to soil or splash on clothing, skin or the face.
- Change gloves between tasks and procedures on the same patient, after contact with body fluids. Remove gloves promptly after use and discard them in the patient's room.

V. TRANSMISSION BASED PRECAUTIONS:

There are three categories of Transmission Based Precautions: Contact Precautions, Droplet Precautions, and Airborne Precautions.

1. Contact Precautions:

- Contact Precautions are intended to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct or indirect contact with the patient or the patient's environment. The specific agents and the circumstances for which Contact Precautions are indicated are found in Appendix A, and the Isolation Quick Guide on the Hospital Intranet.
- Contact Precautions also apply where the presence of excessive wound drainage, fecal incontinence, or other discharges from the body suggest an increased potential for extensive environmental

contamination and risk of transmission. A single patient room is preferred for patients who require Contact Precautions.

- Donning PPE upon room entry and discarding before exiting the patient room is done to contain pathogens, especially those that have been implicated in transmission through environmental contamination (VRE, C.difficile, Norovirus and other intestinal tract pathogens, or RSV)

2. Droplet Precautions:

- Droplet Precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.
- Infectious agents for which Droplet Precautions are indicated are found in Appendix A and Isolation Quick Guide under Hospital Intranet, and include Influenza virus, Adeno virus, Rhino virus, N. meningitides and group A streptococcus (for the first 24 hours of antimicrobial therapy)
- A single patient room is preferred for patients who require Droplet Precautions.
- Healthcare personnel wear a surgical mask upon entry to patient's room.
- Patients on Droplet Precautions who must be transported outside of the room should wear a mask if tolerated and follow Respiratory Hygiene /Cough Etiquette.

3. Airborne Precautions:

- Airborne Precautions prevent transmission of infectious agents that remain infectious over long distances when suspended in the air e.g. Rubella virus (Measles), Varicella Virus (Chicken Pox), M. Tuberculosis, and possibly SARS-CoV.
- The preferred placement for patients who require Airborne Precautions is, in an Airborne infection isolation room (AIIR)
- Health care personnel caring for patients on Airborne Precautions wear a NIOSH approved respirator that is fit tested and donned prior to room entry.
- Whenever possible non –immune HCWs should not care for patients with vaccine preventable airborne diseases (eg. Measles, chickenpox, and small pox.)

APPENDICES

Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007

VI. COUNCILS OR COMMITTEES REVIEWING OR APPROVING POLICY

Pharmacy, Therapeutics and Infection Control Committee. June 2013

VII. AUTHORITATIVE REFERENCES;

1. **Association of Professionals in Infection Control and Epidemiology (2008)**
2. **CDC Isolation Guidelines 2007**

VIII. NAME OF APPROVING DIRECTOR:

Susan Lindsay, RN

_____ _____

Signature of Approving Director **Date Signed**

HOUSTON Methodist WILLOWBROOK HOSPITAL

IC620 Occupational Exposure to Blood or Body Fluid

Subject:
Occupational Exposure
To Blood or Body Fluid

Effective Date:
December 2000

Applies to:
Methodist Willowbrook Healthcare Workers

Date Revised/Reviewed:
November 2009; August 2012; Sept 2013

Originating Area:
Infection Control

Target Review Date:
September 2016

I. POLICY AND GENERAL STATEMENT

To provide guidelines for the evaluation of health care workers after an exposure to blood or body fluids.

A. Methodist Willowbrook Hospital will follow guidelines published by the Centers for Disease Control and Prevention.

B. Post Exposure Prophylaxis (PEP) will be offered to employees after occupational exposures to blood and body fluids, based on assessment of the incident and the likelihood of bloodborne pathogen transmission using most updated recommendations:

Updated US Public Health Service Guidelines for Management of Occupational Exposures to HIV & Recommendations for Postexposure Prophylaxis; Laurie Barclay, MD, Aug 9, 2013 Infection Control & Hospital Epidemiology; Vol 34, No. 9 pp. 875 – 892 (Sept. 2013) and

New York State Department of Health Recommendations, October 2012

C. Post Exposure Prophylaxis (PEP) for HIV should be initiated promptly, preferably within 2 hours post exposure.

II. PROCEDURE

A. Procedure for Exposed Healthcare Worker:

1. Wash or irrigate the involved area immediately. Flush mucous membranes with water.
2. Exposed employees are to report to the charge nurse/supervisor immediately. All exposures involving needles or sharps, blood or body fluid and known communicable disease, must be immediately reported to the Employee Health Office (281- 737- 1410) and (after business hours) to the Administrative Coordinator on duty (281) 737- 4747.
3. Employees are to follow the directions contained in the Needlestick or Blood and Body Fluid Exposure Packet Instructions for Employees. Non-hospital employees are to follow the directions contained in the Needlestick or Blood and Body Fluid Exposure Packet Instructions for Non-Employees.

4. If the source is known or likely to be HIV positive, report ASAP (preferably within 2 hours) to the Emergency Department for consultation with a physician regarding the use of PEP for significant exposure, including a risk assessment of the incident.
5. Employees will be notified by Employee Health or (after business hours) the Administrative Coordinator with results of the rapid HIV test. Employee Health will notify the healthcare worker of additional lab results related to the exposure. Any follow up monitoring required will be conducted by the Employee Health Nurse or Physician through the Employee Health Clinic.

B. Evaluate Incident:

1. Type of exposure
   - Percutaneous injury
   - Mucous membrane exposure
   - Nonintact skin exposure
   - Bites resulting in blood exposure to either person involved
2. Type and amount of fluid
   - Blood
   - Fluids containing blood
   - Potentially infectious fluid or tissue (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids)
   - Direct contact with concentrated virus
3. Infectious status of source
   - Presence of HbsAg (See Table 1, page 6)
   - Presence of HCV Antibody
   - Presence of HIV Antibody
4. Susceptibility of exposed person as indicated
   - Hepatitis B vaccine and vaccine response status
   - HBV, HCV and HIV status

C. Assess Source:

1. Source Known
   a. Test known source for HBsAg, anti-HCV and test for HIV antibody if HIV status is unknown
      - Assess whether there is blood on hand to perform the tests or draw the patient's blood and send with the Employee Health lab requisition forms to the lab.
   b. HIV test results will be called to Employee Health (71410) during business hours and to the Administrative Coordinator 74747 or pager 281 735 9890 after Employee Health Clinic hours or on the weekends and/or holidays. Recommendations for follow up will be made based on the source patient's lab and or clinical presentation

   .

   DO NOT ENTER THE SOURCE PATIENT'S LABS IN THE COMPUTER OR PUT IN THE CHART. NO SOURCE PATIENT CONSENT IS REQUIRED.

   c. Employee Health and/or the Administrative Coordinator will obtain the source results from the lab. Non-employees are to contact their employer or agency for instructions and follow-up.
   d. For known source whose infection status remains unknown, consider medical diagnoses, clinical symptoms and history of risk behaviors.
2. Source Unknown: Evaluate the likelihood of exposure to a source at high risk for infection; Consider likelihood of bloodborne pathogen infection among patients in that exposure setting. Refer to Employee Health for follow up.

D. Evaluate Exposed Person: For known exposures to Blood & Body Fluids or the source is unknown, exposed employee's baseline labs will be drawn the day of exposure or the next

Employee Health business day. Ongoing monitoring of the employee will occur through the Employee Health Clinic (EHC).

E. Give PEP for exposures posing risk of infection transmission

1. Hepatitis C (HCV):
   No prophylaxis is indicated, Immune globulin (IG) and/or antiretroviral drugs are not recommended. EHC will offer HCW testing for anti-HCV: baseline and follow-up at 4-6 months. Counsel exposed person to refrain from donating blood, plasma, organs, tissue or semen. The exposed person does not need to modify sexual practices or refrain from becoming pregnant.
2. Hepatitis B (HBV):
   See Table 1 (p. 6) for interventions. Counsel as in HCV exposure above.
   Pregnancy: No apparent risk from vaccination for developing fetuses. The vaccine contains non-infectious HbsAg particles and should pose no risk for adverse effects. Neither pregnancy nor lactation is a contraindication to HBV vaccination or administration of HBIG.
3. HIV:
   See Tables A1 (p. 7) for PEP regimens and Table B1 3 (pg. 8 - 11) for PEP meds.
   Pregnancy: Data are limited on the potential effects of antiretroviral drugs on the developing fetus. Expert consultation should be sought with consideration of the risks of therapy versus the benefits.

F. Follow Up after Exposure

1. Instruct exposed persons to notify Employee Health for any acute illness occurring during follow-up period.
2. HBV exposures
   - Test for anti-HBs 1-2 months after last dose of HBV vaccine.
   - Anti-HBs response cannot be ascertained if HBIG was given in the previous 3-4 months
3. HCV exposures
   · Perform baseline and follow-up testing for anti-HCV 4-6 months after exposure
   · Consider testing for ALT (alanine amino-transferase).
4. HIV exposures
   · Perform HIV-antibody testing for at least 3 months postexposure (baseline, 1 month,) and 3 months). Obtain employee consent for HIV testing (p.14).
   · Perform HIV antibody testing if illness compatible with acute retroviral syndrome occurs.
   · If HIV prophylaxis is initiated in the Emergency Department, a prescription will be provided for three days only.
   · Exposed persons taking PEP must report to the EHC within 72 hours after exposure for continued monitoring and evaluation.
   · The duration of therapy for HIV prophylaxis is a maximum of four weeks for any regimen initiated.
5. Employee Health will provide a Written Medical Opinion to the employee within 15 working days of the completion of the evaluation.

G. Counseling HCW exposed to HIV:

1. An employee exposed to known HIV source will be counseled. Should an employee terminate with Methodist Willowbrook Hospital, the hospital will continue post-exposure follow-up, however, it will be the responsibility of the employee to maintain contact for instructions.
2. All employees exposed to HIV must sign the top portion of Appendix C, “Information Given”. If HIV prophylaxis is offered, the employee must either accept or decline by signing the bottom of Appendix C. (p. 13). Copy signed form and place original in the employee’s health file. If prophylaxis initiated in the Emergency Dept. (ED) signed form will be forwarded to the Employee Health Clinic.

3. Employees who choose to take HIV prophylaxis must sign Appendix B "Recommended Practices for Personnel Exposed to HIV" (p. 12) and Appendix C "Employee Consent for Antiretroviral Therapy." (p. 13). Copy signed forms and place originals in the employee's health file. If prophylaxis is initiated in the Emergency Dept. (ED) signed forms will be forwarded to the Employee Health Clinic. PEP prescriptions dispensed in the ED will be for three days only. To continue, the employee must report to the EHC within 72 hours
4. If HIV PEP is offered, the HCW should be informed about possible drug toxicities, the need for monitoring, and possible drug interactions. Discuss information and give information sheets to the employee. (See drug information sheets Appendix E pp. 15-21, Appendix F, p. 22, Appendix G, p. 23, & Appendix H, p. 24)
5. HIV exposed HCW should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6-12 weeks after exposure when most HIV infected persons are expected to seroconvert: See Appendix A. (p. 11)
6. Follow-up after initial counseling will be done through the Employee Health Clinic.

H. Situations for which expert consultation* for HIV post-exposure prophylaxis is advised**:**

Delayed exposure report: (i.e., later than 24 – 36 hours)

Unknown source:

- Decide use of PEP on case-by-case basis.
- Consider severity of exposure and the epidemiological likelihood of HIV.
- Do not test needles or other sharps for HIV.

Known or suspected pregnancy in the exposed person**:**

- Does not preclude the use of optimal PEP regimens.
- Do not deny PEP solely on the basis of pregnancy.

Resistance of the source virus to antiretroviral agents:

- Influence of drug resistance on transmission is unknown.
- Selection of drugs to which the source person's virus is unlikely to be resistant is recommended, if the source person's virus is known or suspected to be resistant to 1 of the drugs considered for the PEP regimen.
- Resistance testing of the source person's virus at the time of exposure is not recommended.

Toxicity of the initial PEP regimen**:**

- Adverse symptoms such as nausea and diarrhea are common with PEP.
- Symptoms often can be managed without changing the PEP regimen by prescribing antimotility or antiemetic agents.

Serious medical illness in the exposed person:

- Significant underlying illness (ie, renal disease) or an exposed provider already taking multiple medications may increase the risk of drug toxicity and drug-drug interatctions

*Expert consultation can be made with local experts and/or the National Clinician's Post-Exposure Hotline:

PEPline 1-888-448- 4911 or http://www.nccc.ucsf.edu/about_nccc/pepline

III. COUNCILS OR COMMITTEES REVIEWING OR APPROVING POLICY

Infection Control Committee August ~~2007~~ 2012
Policy & Procedure Committee August ~~2007~~ 2012

IV. AUTHORITATIVE REFERENCES

CDC: Guideline for Infection Control in Health Care Personnel, AJIC, Vol 26.3, 1998.

CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post exposure Prophylaxis, MMWR, June 29, 2001/50 (RR11) Prohttp://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm

Morbidity and Mortality Weekly Report, September 30, 2005 /Vol.54 /No. RR-9
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HIV/AIDS Clinicians' Consultation Center http://www.nccc.ucsf.edu/

Name of Approving Executive
Title: Shelia Fata, CNO

_____
Signature of Approving Executive

Revision	Date	Changed By	Summary
1	8/24/2012	Linda Payton	Updated references and approvals after review
2	9/20/2013	Linda Payton	Updated new recommended medication regimens and references after review & approval from P&T and IC

Table 1. Recommended Post Exposure Prophylaxis for exposure to Hepatitis B virus

Vaccination and antibody response status of exposed workers[1]	Treatment		
	Source HbsAg[2] positive	Source HbsAg[2] negative	Source unknown or not available for testing
Unvaccinated	HBIG[3] x 1 and initiate vaccine series[4]	Initiate HB vaccine series[4]	Initiate HB vaccine series[4]
Previously vaccinated			
Known responder5	No treatment	No treatment	No treatment
Known nonresponder6	HBIG x 1 and initiate revaccination[7] OR HBIG baseline & 1 month	No treatment	If known high risk source, treat as if source were HbsAg positive
Antibody response unknown	Test exposed person for Anti-HBs[8] 1. If adequate [5], no treatment is necessary 2. If inadequate, administer HBIG x 1 and HB vaccine booster	No treatment	Test exposed person for Anti-HBs[8] 1. If adequate [5], no treatment is necessary 2. If inadequate, administer vaccine booster and recheck titer in 1-2 months

1 Persons who have previously been infected with HBV are immune to re-infection and do not require post exposure prophylaxis.
2 Hepatitis B surface antigen
3 Hepatitis B immune globulin; dose is 0.06 ml/kg intramuscularly
4 Hepatitis B vaccine
5 A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs reported as positive)
6 A non-responder is a person with inadequate response to vaccination (i.e., anti-HBs reported as negative)
7 The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.
8 Antibody to HBsAg.

Table A1. Human Immunodeficiency Virus (HIV) Postexposure Prophylaxis (PEP) Regimens

Preferred HIV PEP Regimen
Raltegravir (Isentress; RAL) 400 mg PO twice daily
Plus
Truvada, 1 PO once daily
(Tenofovir DF [Viread; TDF] 300 mg + emtricitabine [Emtriva; FTC] 200 mg)

Alternative Regimens

(May combine 1 drug or drug pair from the left column with 1 pair of nucleoside/nucleotide reverse-transcriptase inhibitors from the right column; prescribers unfamiliar with these agents/regimens should consult physicians familiar with the agents and their toxicities)[a,b]

Raltegravir (Isentress; RAL)	Tenofovir DF (Viread; TDF) + emtricitabine (Emtriva; FTC); available as Truvada
Darunavir (Prezista; DRV) + ritonavir (Norvir; RTV)	Tenofovir DF (Viread; TDF) + lamivudine (Epivir; 3TC)
Etravirine (Intelence; ETR)	Zidovudine (Retrovir; ZDV; AZT) + lamivudine (Epivir; 3TC); available as Combivir
Rilpivirine (Edurant; RPV)	
Atazanavir (Reyataz; ATV) + ritonavir (Norvir; RTV)	Zidovudine (Retrovir; ZDV; AZT) + emtricitabine (Emtriva; FTC)
Lopinavir/ritonavir (Kaletra; LPV/RTV)	

The following alternative is a complete fixed-dose combination regimen, and no additional antiretrovirals are needed: Stribild (elvitegravir, cobicistat, tenofovir DF, emtricitabine)

Alternative Antiretroviral Agents for Use as PEP Only with Expert Consultation[b]

Abacavir (Ziagen; ABC)
Efavirenz (Sustiva; EFV)
Enfuvirtide (Fuzeon; T20)
Fosamprenavir (Lexiva; FOSAPV)
Maraviroc (Selzentry; MVC)
Saquinavir (Invirase; SQV)
Stavudine (Zerit; d4T)

Antiretroviral Agents Generally Not Recommended for Use as PEP

Didanosine (Videx EC; ddI)
Nelfinavir (Viracept; NFV)
Tipranavir (Aptivus; TPV)

Antiretroviral Agents Contraindicated as PEP

Nevirapine (Viramune; NVP)

Note For consultation or assistance with HIV PEP, contact the National Clinicians' Post-Exposure Prophylaxis Hotline at telephone number 888-448-4911 or visit its website at http://www.nccc.ucsf.edu/about_nccc/pepline/. DF, disoproxil fumarate; PO, per os.

a The alternatives regimens are listed in order of preference; however, other alternatives may be reasonable based on patient and clinician preference.

Table B1. Information on Human Immunodeficiency Virus (HIV) Postexposure Prophylaxis (PEP) Medications

Drug name	Drug class	Dosing (dosage form)	Advantages	Disadvantages
Abacavir (Ziagen; ABC)	Nucleoside reverse-transcriptase inhibitor (NRTI)	ABC: 300 mg daily; available as 300-mg tablet Also available as component of fixed-dose combination Epzicom, dosed daily (300 mg of 3TC + 600 mg of ABC) Trizivir, dosed twice daily (150 mg of 3TC + 300 mg of ABC + 300 mg of AZT)	Take without regard for food	Potential for life-threatening ABC hypersensitivity reaction (rash, fever, nausea, vomiting, diarrhea, abdominal pain, malaise, respiratory symptoms) in patients with HLA-B*5701; requires patient testing prior to use, which may not be available or practical prior to initiating PEP
Atazanavir (Reyataz; ATV)	Protease inhibitor (PI)	ATV: 300 mg + RTV: 100 mg once daily (preferred dosing for PEP[a]) ATV: 400 mg once daily without RTV (alternative dosing—may not be used in combination with TDF) Available as 100-, 150-, 200-, and 300-mg capsules	Well tolerated	Indirect hyperbilirubinemia and jaundice common Rash Nephrolithiasis Potential for serious or life-threatening drug interactions that may affect dosing Absorption depends on low pH; caution when coadministered with H_2 antagonists, antacids, and proton pump inhibitors PR interval prolongation Caution in patients with underlying conduction defects or on concomitant medications that can cause PR prolongation Must be given with food
Darunavir (Prezista; DRV)	PI	DRV: 800 mg once daily + RTV: 100 mg once daily (preferred dosing for PEP[a]) DRV: 600 mg twice daily + RTV: 100 mg twice daily (alternative dosing) Available as 75-, 150-, 400-, and 600-mg tablets	Well tolerated	Rash (DRV has sulfonamide moiety) Diarrhea, nausea, headache Hepatotoxicity Potential for serious or life-threatening drug interactions that may affect dosing Must be given with food and with RTV
Efavirenz (Sustiva; EFV)	Nonnucleoside reverse-transcriptase inhibitor (NNRTI)	EFV: 600 mg daily; available as 50- and 200-mg capsules and 600-mg tablets Also available as component of fixed-dose combination Atripla, dosed daily (200 mg of FTC + 300 mg of TDF + 600 mg of EFV)	Available as a complete regimen dosed once per day	Rash Neuropsychiatric side effects (eg, dizziness, somnolence, insomnia, abnormal dreaming) common; severe psychiatric symptoms possible (dosing before bedtime might minimize these side effects); use with caution in shift workers Do not use during pregnancy; teratogen in nonhuman primates Potential for serious or life-threatening drug interactions that may affect dosing May cause false-positive results with some cannabinoid and benzodiazepine screening assays Take on an empty stomach
Elvitegravir (EVG)	Integrase strand transfer inhibitor (INSTI)	Available as a component of fixed-dose combination Stribild, dosed daily (150 mg of EVG + 150 mg of cobicistat + 300 mg of TDF + 200 mg of FTC)	Well tolerated Available as a complete regimen dosed once per day	Diarrhea, nausea, headache Nephrotoxicity; should not be administered to individuals with acute or chronic kidney injury or those with eGFR <70 Cobicistat is a pharmacokinetic enhancer to increase EVG exposures and has no antiviral activity but is a potent CYP3A inhibitor Potential for serious or life-threatening drug interactions Must be given with food

Drug name	Drug class	Dosing (dosage form)	Advantages	Disadvantages
Emtricitabine (Emtriva; FTC)	NRTI	200 mg once daily; available as 200-mg capsule Also available as component of fixed-dose combination Atripla, dosed daily (200 mg of FTC + 300 mg of TDF + 600 mg of EFV) Complera, dosed daily (25 mg of RPV + 300 mg of TDF + 200 mg of FTC) Stribild, dosed daily (150 mg of EVG + 150 mg of cobicistat + 300 mg of TDF + 200 mg of FTC) Truvada, dosed daily (200 mg of FTC + 300 mg of TDF)	Well tolerated Minimal toxicity Minimal drug interactions Take without regard for food	Rash perhaps more frequent than with 3TC Hyperpigmentation/skin discoloration If the PEP recipient has chronic hepatitis B, withdrawal of this drug may cause an acute hepatitis exacerbation
Enfuvirtide (Fuzeon; T20)	Fusion inhibitor (FI)	T20: 90 mg (1 mL) twice daily by subcutaneous injection; available as single-dose vial, reconstituted to 90 mg/mL	…	Local injection-site reactions occur in almost 100% of patients Never studied among antiretroviral-naive or HIV-negative patients False-positive EIA HIV antibody tests might result from formation of anti-T20 antibodies that cross-react with anti-gp41 antibodies Twice-daily injection
Etravirine (Intelence; ETR)	NNRTI	200 mg twice daily; available as 100- and 200-mg tablets	Well tolerated and has not had the same frequency of CNS side effects reported as EFV	Rash (including SJS) and hypersensitivity (sometimes with organ dysfunction, including hepatic failure) Nausea Potential for serious or life-threatening drug interactions that may affect dosing Must be given with food
Fosamprenavir (Lexiva; FOSAPV)	PI	FOSAPV: 1,400 mg daily + RTV: 100 mg once daily (preferred dosing for PEP) FOSAPV: 1,400 mg twice daily without RTV (alternative dosing) Available as 700-mg tablet	Well tolerated	Diarrhea, nausea, vomiting, headache, rash (FOSAPV has sulfonamide moiety) Potential for serious or life-threatening drug interactions that may affect dosing Oral contraceptives decrease FOSAPV concentrations Take with food if given with RTV
Lamivudine (Epivir; 3TC)	NRTI	3TC: 300 mg once daily (preferred dosing for PEP) 3TC: 150 mg twice daily (alternative dosing) Available as 150- and 300-mg tablets Also available as component of fixed-dose combination generic lamivudine/zidovudine, dosed twice daily (150 mg of 3TC + 300 mg of AZT) Combivir, dosed twice daily (150 mg of 3TC + 300 mg of AZT) Epzicom, dosed daily (300 mg of 3TC + 600 mg of ABC) Trizivir, dosed twice daily (150 mg of 3TC + 300 mg of ABC + 300 mg of AZT)	Well tolerated Minimal toxicity Minimal drug interactions Take without regard for food	If the PEP recipient has chronic hepatitis B, withdrawal of this drug may cause an acute hepatitis exacerbation
Lopinavir/ritonavir (Kaletra; LPV/RTV)	PI	Kaletra: 400/100 mg = 2 tablets twice daily (preferred dosing for PEP) Kaletra: 800/200 mg = 4	Take without regard for food	GI intolerance, nausea, vomiting, diarrhea are common PR and QT interval prolongation have been reported; use with caution in

Drug name	Drug class	Dosing (dosage form)	Advantages	Disadvantages
		tablets once daily (alternative dosing) Available as 200/50-mg tablets		patients at risk of cardiac conduction abnormalities or receiving other drugs with similar effect Potential for serious or life-threatening drug interactions that may affect dosing
Maraviroc (Selzentry; MVC)	CCR5 coreceptor antagonist	MVC: 300 mg twice daily (if on concomitant CYP3A inducers, dose may need adjustment by expert consultant); available as 150- and 300-mg tablets	Well tolerated	Abdominal pain, cough, dizziness, musculoskeletal symptoms, pyrexia, rash, orthostatic hypotension Hepatotoxicity that may present with an allergic reaction, including rash Requires HIV tropism testing of source virus before treatment to ensure CCR5-tropic virus and efficacy, which may not be available or practical prior to initiating PEP Potential for serious or life-threatening drug interactions that may affect dosing Dose adjustments for MVC required when given with potent CYP3A inhibitors or inducers
Raltegravir (Isentress; RAL)	INSTI	400 mg twice daily; available as 400-mg tablet	Well tolerated Minimal drug interactions Take without regard for food	Insomnia, nausea, fatigue, headache, and severe skin and hypersensitivity reactions have been reported
Rilpivirine (Edurant; RPV)	NNRTI	25 mg once daily; available as 25-mg tablet Also available as component of fixed-dose combination Complera, dosed daily (25 mg of RPV + 300 mg of TDF + 300 mg of FTC)	Well tolerated and fewer rashes and discontinuations for CNS adverse effects compared with EFV Available as a complete regimen dosed once per day	Depression, insomnia, rash, hypersensitivity, headache Potential for serious or life-threatening drug interactions that may affect dosing Caution when coadministered with H_2 antagonists and antacids Coadministration with proton pump inhibitors is contraindicated Use RPV with caution when coadministered with a drug having a known risk of torsades de pointes Must be given with food
Saquinavir (Invirase; SQV)	PI	SQV: 1,000 mg + RTV: 100 mg twice daily (preferred dosing for PEP); available as 500 mg tablet	Well tolerated, although GI events common	GI intolerance, nausea, diarrhea, headache Pretreatment ECG recommended SQV/r is not recommended for patients with any of the following: (1) congenital or acquired QT prolongation, (2) pretreatment ECG >450 msec, (3) receiving concomitant therapy with other drugs that prolong QT interval, (4) complete AV block without implanted pacemakers, and (5) risk of complete AV block PR and QT interval prolongations, torsades de pointes has been reported Potential for serious or life-threatening drug interactions that may affect dosing Must be given with food
Stavudine (Zerit; d4T)	NRTI	d4T: 40 mg twice daily if body weight is >60 kg d4T: 30 mg twice daily if body weight is <60 kg Available as 15-, 20-, 30-, and 40-mg tablets	Take without regard for food	GI side effects include diarrhea and nausea Hepatotoxicity, neurologic symptoms (eg, peripheral neuropathy), pancreatitis
Tenofovir DF (Viread; TDF)	NRTI	300 mg once daily; available as 300-mg tablet Also available as component of fixed-dose	Well tolerated Take without regard for food	Asthenia, headache, diarrhea, nausea, vomiting Nephrotoxicity; should not be administered to individuals with acute or

Drug name	Drug class	Dosing (dosage form)	Advantages	Disadvantages
		combination Atripla, dosed daily (200 mg of FTC + 300 mg of TDF + 600 mg of EFV) Complera, dosed daily (25 mg of RPV + 300 mg of TDF + 200 mg of FTC) Stribild, dosed daily (150 mg of EVG + 150 mg of cobicistat + 300 mg of TDF + 200 mg of FTC) Truvada, dosed daily (200 mg of FTC + 300 mg of TDF)		**chronic kidney injury or those with eGFR <60 If the PEP recipient has chronic hepatitis B, withdrawal of this drug may cause an acute hepatitis exacerbation Drug interactions**
Zidovudine (Retrovir; ZDV; AZT)	**NRTI**	**AZT: 300 mg twice daily; available as 100-mg capsule or 300-mg tablet Also available as component of fixed-dose combination generic lamivudine/zidovudine, dosed twice daily (150 mg of 3TC + 300 mg of AZT) Combivir, dosed twice daily (150 mg of 3TC + 300 mg of AZT) Trizivir, dosed twice daily (150 mg of 3TC + 300 mg of ABC + 300 mg of AZT)**	**Take without regard for food**	**Side effects (especially nausea, vomiting, headache, insomnia, and fatigue) common and might result in low adherence Anemia and neutropenia**

Note This appendix does not provide comprehensive information on each individual drug. For detailed information, please refer to individual drug package inserts. AV, atrioventricular; CNS, central nervous system; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; EIA, enzyme immunoassay; GI, gastrointestinal; SJS, Stevens-Johnson syndrome.

a Certain antiretroviral agents, such as PIs, have the option of once- or twice-daily dosing depending on treatment history and use with ritonavir. For PEP, the selection of dosing and schedule is to optimize adherence while minimizing side effects where possible. This table includes the preferred dosing schedule for each agent, and in all cases with the exception of Kaletra the once-daily regimen option is preferred for PEP. Twice-daily administration of Kaletra is better tolerated with respect to GI toxicities compared with the once-daily regimen. Alternative dosing and schedules may be appropriate for PEP in certain circumstances and should preferably be prescribed by individuals experienced in the use of antiretroviral medications.

Exposure Management and Pregnancy:

HBV:

No apparent risk exists for the developing fetus if Hepatitis B vaccine is administered to a pregnant woman. The vaccine is comprised of non-infectious HbsAg particles. HBV disease in pregnancy could result in severe disease for mother and/or child. Therefore, neither HBV vaccine nor HBIG is contraindicated in either pregnancy or lactation.

HIV:

Evaluation of risk and the need for PEP should be approached as with any person who has been exposed. However, the final decision to administer HIV PEP should be discussed with both the woman's healthcare provider and a physician with expertise in antiretroviral medication.

APPENDIX A

Antiretroviral Counseling

If anti-retroviral prophylaxis is being considered, the worker should be counseled regarding:

a. The theoretical rationale for postexposure prophylaxis and the risk of occupational acquired HIV infection due to exposure.
b. The limitations of current knowledge of anti-retroviral therapy when used as post-exposure prophylaxis. Current knowledge of the toxicity of such drugs and the limitations of this knowledge in predicting toxicity in uninfected individuals who take the drug after occupational exposures, and
c. The need for post-exposure follow-up (including HIV serologic testing), regardless of whether an anti-retroviral drug is taken.

The worker should also be informed that there are diverse opinions among physicians regarding the use of anti-retroviral therapy for postexposure prophylaxis, and that the Public Health Service cannot make a recommendation for or against the use of anti-retroviral agents because of the limitations of current knowledge. The duration of follow-up needed to detect evidence of HIV transmission or delayed toxicity among workers who undergo prophylaxis is presently unknown. Workers taking anti-retroviral postexposure may require follow-up to detect HIV seroconversion for a longer period than that recommended for workers who do not do so. Regardless of the length of follow-up, employee needs to make sure that the Employee Health Clinic has phone numbers and/or an address to contact the employee.

Counseling HCW exposed to HIV:

1. HIV exposed HCW should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6-12 weeks after exposure when most HIV exposed persons may seroconvert:

- Exercise sexual abstinence or use condoms to prevent sexual transmission and to avoid pregnancy. Refrain from donating blood, plasma, organs, tissue, or semen.
- If exposed woman is breastfeeding, she should be counseled about the risk of HIV transmission through breast milk and discontinuing breast-feeding should be considered, especially for high-risk exposures. Additionally, nucleoside reverse transcriptase inhibitors are known to pass into breast milk, as is NVP (Nevirapine); whether this is true for other approved antiretroviral drugs is unknown. (See Appendix F p. 15))

2. Seek medical evaluation for any acute illness that occurs during the follow-up period. Such an illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, might be indicative of acute HIV infection but also might be indicative of a drug reaction or another medical condition.

3. For exposures for which PEP is prescribed, HCW should be informed about possible drug toxicities and the need for monitoring and possible drug interactions

APPENDIX B

Recommended Practices For Personnel Exposed To HIV

The average risk of Human Immunodeficiency Virus (HIV) transmission from an HIV antibody positive patient has been estimated to be 0.3% after percutaneous exposure, 0.09% after mucous membrane exposure and less than this for non-intact skin. Even with this low risk, however, it is recommended that health care workers with such exposure be offered baseline and follow-up blood test for HIV antibody. If infection occurs, the test may be positive by 3 months after the exposure. Since an individual could become infectious after one negative test, but before the subsequent tests are done, it is recommended that the exposed person take certain precautions until the likelihood of the infection has been ruled out. These recommendations, for the time period until testing is complete, are as follows:

1. Refrain from donating blood, plasma, body organs, other tissue, or sperm.
2. Avoid exposure of others through exchange of body fluids and sexual intercourse unless condoms are used. The efficacy of condoms in preventing infection with HIV is unproven, but the consistent use of them may reduce transmission.
3. Toothbrushes, razors, needles, or other implements that could become contaminated with blood should not be shared.
4. Since pregnant women who are infected may transmit infection to the fetus, health care workers who have been exposed should avoid becoming pregnant until the tests are known to be negative.
5. After accidents resulting in bleeding, contaminated surfaces should be cleaned with household bleach freshly diluted 1:10 in water (1 part bleach to 10 parts water - wear gloves).
6. Devices that have punctured the skin, such as hypodermic and acupuncture needles, should be safely discarded or sterilized by autoclave before reuse. Whenever possible, disposable needles and equipment should be used.
7. If you see your doctor or dentist for a routine check-up, or for any other reason, you should inform those responsible for your care that you have been exposed so that the appropriate evaluation can be undertaken and precautions taken to prevent potential transmission to others.
8. During the period when HIV follow-up is performed all illness should be reported to Employee Health. Employee Health personnel will determine if special testing is required. I have read the above precautions. I have been informed that my risk of acquiring HIV infection following this exposure is very low, and I understand the recommendations to follow until the blood tests are known to be negative for HIV

_____ _____

Signature Date

**File this form in employee health file/Copy to employee*

APPENDIX C

Employee Consent for Antiretroviral Therapy

I. INFORMATION GIVEN

I have been informed of the possible advantages, disadvantages, and risks associated with antiretroviral therapy.

Signature _____ Date _____

Print Name _____ Witness _____

II. ANTIRETROVIRAL THERAPY: SIGN A OR B

A. ACCEPTANCE OF ANTIRETROVIRAL THERAPY

I have been informed of the possible side effects of antiretroviral therapy and understand that there is no guarantee of prevention of HIV infection. Knowing the above information, I request that such therapy be prescribed to me. If antiretroviral therapy initiated in the ED, I agree to report to the Employee Health Clinic within 72 hours for monitoring and evaluation to determine continued therapy.

_____ _____
Signature Date

_____ _____
Print Name Witness

B. DECLINATION OF ANTIRETROVIRAL THERAPY

Having considered the above and being fully informed, I do not want the antiretroviral therapy.

_____ _____
Signature Date

_____ _____
Print Name Witness

**File this form in employee health file/Copy to employee*

APPENDIX D

CONSENT TO HIV TESTING

1. I authorize and consent to testing of a sample of my blood to see if I have been exposed to the human immunodeficiency virus, the virus associated with Acquired Immune Deficiency Syndrome (AIDS).

2. Human immunodeficiency virus or HIV may be the cause of AIDS, a viral disease. The virus may be transmitted to others who come in contact with the blood or body fluids of an infected person. Although a positive HIV test does not necessarily mean a person has AIDS, testing can assist health care personnel in medical management.

3. I understand that I should rely on the physician or designated healthcare professional for information regarding the nature and purpose of the HIV test and the meaning and significance of the results of the test.

4. I understand that HIV testing is not always 100% accurate and that results may be "false negative" (negative results when the virus is actually present) or "false positive" (positive results when the virus is not present). If a positive result is obtained, additional tests will be done to attempt to confirm the test results.

5. I understand the results of the test will be confidential and will not be disclosed unless required by law.

6. I certify that this form has been fully explained to me, that I have read it or had it read to me,* and that I understand its contents. I have been given an opportunity to ask questions about the test and I believe that I have sufficient information to give this informed consent.

_____	_____
Patient/Exposed Person	Witness
_____	_____
Print Name	Print Name
_____	_____
Date	Date

*Translated into _____Read to patient by: _____
Signature

_____ _____
Print Name Date

**File this form in employee health file/Copy to employee*

Appendix F

Table 3. Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent

Class and agent	Side effect and toxicity
Nucleoside Reverse Transcriptase Inhibitors (NRTI)	**Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis**
Zidovudine (Retrovir®; ZDV, AZT) Lamivudine(Epivir®, 3TC)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Stavudine (Zerit™; d4T)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Didanosine (Videx®; ddl) Emtricitabine(Emtriva, FTC)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver functions tests (LFTs), anemia, and neutropenia
	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
	Headache, nausea, vomiting, diarrhea, and rash
	Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
Nucleotide Analogue Reverse Transcriptase Inhibitor (NtRTI) Tenofovir (Viread®; TDF)	**Class warning: all NtRTIs have the potential to cause lactic acidosis with hepatic steatosis** Nausea, diarrhea, vomiting, flatulence, and headache
Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs) Efavirenz(Sustiva®; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
Protease Inhibitor	Nausea, abdominal pain, nephrolithiasis, and indirect Hyperbilirubinemia
Indinarvir (Crixivan®, IDV) Nelfinavir(Viracept®; NFV) Ritonavir (Norvir®; RTV)	Diarrhea, nausea, abdominal pain, weakness, and rash Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (Invirase®; SQR) Fosamprenavir (Lexiva®; FOSAPV) Atazanavir (Reyataz®; ATV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Lopinavir/ritonavir (Kaletra®; LPV/RTV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides
Fusion Inhibitor Enfuvirtide (Fuzeon®	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy and cough

Appendix G
Prescription and over-the-counter drugs that should not be administered with protease inhibitors (PIs)

Antimycobacterial: rifampin	Decreases plasma concentrations and area under plasma concentration curve of the majority of PIs by approximately 90%, which might result in loss of therapeutic effect and development of resistance
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or lifethreatening events (e.g., prolonged or increased sedation or respiratory depression
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or lifethreatening events (e.g., acute ergot to characterized by peripheral vasospasm and ischemia of the extremities and other tissues
Gastrointestinal motility agent cisapride	Contraindicated because of potential for serious or lifethreatening events (e.g.; cardiac arrhythmias)
HMG-CoA reductase inhibitors (statins: lovastatin, simvastatin	Potential for serious reactions (e.g., myopathy, including rhabdomyolysis); atorvastatin may be used cautiously, beginning with lowest possible starting dose, and monitoring for adverse events
Neuroleptic: pimozide	Contraindicated because of potential for serious or lifethreatening events (e.g., cardiac arrhythmias)
Inhaled steroids: fluticasone	Coadministration of fluticasone and ritonavir-boosted protease inhibitors are not recommended unless the potential benefit to the patient outweighs the risk for systemic corticosteroid side effect
Herbal products: St. John's wort (hypericum perforatum), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance

This table does not list all products that should not be administered with PIs (atazanavir, lopeinavir/ritonavir, fasamprenavir, indinavir, nelfinavir, saquinavir)
Product labels should be consulted for additional information regarding drug interactions.
Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at http://hivinsite.ucsf.edu/InSite?page=ar-00-02.

Appendix H
Prescription and over-the-counter drugs that should not be administered with Efavirenz because of drug interactions

Antifungal: voriconazole	Contraindicated because Efavirenz substantially decreases voriconazole plasma concentration
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or lifethreatening events (e.g., prolonged or increased sedation or respiratory depression
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or lifethreatening events (e.g., acute ergot to characterized by peripheral vasospasm and ischemia of the extremities and other tissues
Gastrointestinal motility agent cisapride	Contraindicated because of potential for serious or lifethreatening events (e.g.; cardiac arrhythmias)
Herbal products: St. John's wort (hypericum perforatum), garlic	Co-administration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir level

This table does not list all products that should not be coadministered with Efavirenz. Efavirenz product labeling should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at Box 1:

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
A HIPAA Primer

I. OBJECTIVES OF HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) was enacted into law on August 21, 1996 with the following objectives:

- Ensure health insurance portability;
- Reduce health care fraud and abuse;
- Improve the efficiency of health care delivery by standardizing the electronic exchange of certain administrative and financial data; and
- Provide security and privacy of health care information.

II. ADMINISTRATIVE SIMPLIFICATION STANDARDS

Provisions to meet the last two objectives above are contained in HIPAA's Administrative Simplification Standards for Privacy, Security and Electronic Transactions.

The **Privacy and Transaction** Standards apply to health plans, health care clearinghouses, and any health care provider who transmit health information electronically in connection with a **HIPAA covered transaction** and the Privacy Standard's protections extend to all health information pertaining to an individual, not just when this information is in an electronic form.

The **Security** Standard applies to health plans, health care clearinghouses, and health care providers who **electronically** maintain or transmit health information pertaining to an individual and extends protections to only the electronic format of this information.

A. PRIVACY STANDARD (Compliance Date: April 14, 2003 and April 14, 2004 for small health plans)

The Privacy Standard establishes:

- Universal rights for individuals regarding their health information;
- Requirements for health plans, clearinghouses, and health care providers to protect health information;
- Boundaries for the use and disclosure of health information; and
- Accountability for misuse of health information.

1. Protected Health Information (PHI)

The Privacy Standard specifically protects health information (including demographic data) transmitted or maintained in any form, that:

- Relates to an individual's:
  - Past, present, or future physical or mental health, or condition;
  - Provision of health care to an individual; or
  - Past, present or future payment for the provision of health care to an individual; and
- Could be used (or reasonably used) to identify the individual.

2. Notice of Privacy Practices

Each Health Care Provider is required to have a notice which informs individuals of:

- Their health information rights;
- The entity's uses and disclosures of health information; and
- The entity's legal duties.

A Health Care Provider must provide the Notice to individuals at the time of their first service and obtain acknowledgment of its receipt. If an attempt is made but is not successful, this "good faith" effort must be documented. The Notice must also be posted publicly and electronically at the provider's web site, and must be available in hard copy for anyone, upon request.

3. **Rights of Individuals**
   The Privacy Standard provides individuals with rights to:
   - Obtain a copy of the Notice of Privacy Practices;
   - Inspect and obtain a copy of their health information;
   - Request amendment or correction of their health information;
   - Request restrictions of the uses and disclosures of their health information;
   - Receive communications regarding their health information at an alternative address or by alternative means; and
   - Obtain an accounting or list of disclosures of their health information.

4. **Authorization**
   Written patient authorization is required prior to the use or disclosure of a patient's health information for any purpose not otherwise permitted or required by law. Patient authorization is not required for treatment, payment or health care operations.

5. **Minimum Necessary**
   This requirement is a limitation placed on uses and disclosures of health information. Reasonable efforts must be made to limit the use or disclosure of health information to the minimum necessary to accomplish the intended purpose of the use or disclosure. Exceptions to this requirement are:
   - Uses or disclosures of health information for treatment purposes;
   - Disclosure to the patient; and
   - Uses or disclosures with a patient's authorization.

B. SECURITY STANDARD (Compliance Date: April 21, 2005)

The Security Standard establishes the following requirements to ensure the confidentiality, integrity, and availability of all electronic protected health information.

1. **Administrative Safeguards**
   Each health care provider and health plan must conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (risk analysis) and implement security measures to reduce risks and vulnerabilities to a reasonable and appropriate level (risk management.)

   Security management processes must include:
   - Assignment of a security official;
   - Implementation of a security training program and sanctions policy;
   - Implementation of policies and procedures, which include:
     - Regular review of records of information system activity
     - Granting different levels of access to information;
     - Contingency plans for responding to an emergency; and
     - Prevention, detection, containment and detection of security incidents.
   - Written contracts for business associates to safeguard electronic protected health information they create, receive, maintain or transmit.

2. **Physical Safeguards**
   Implementation of policies and procedures for:
   - Facility access controls for limiting physical access to electronic information systems;
   - Disposal and re-use of hardware and electronic media containing electronic protected health information; and
   - Work station use and security.

3. **Technical Safeguards**
   - Measures and mechanisms to:
     - Guard against unauthorized access to electronic protected health information;

- Corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner;
- Record and examine activities in information systems that contain or use electronic protected health information; and
- Guard against unauthorized access to electronic protected health information transmitted over an electronic communications network;

- Policies and procedures to prevent improper alteration or destruction of electronic protected health health information and to verify a person or entity seeking access to such information.

C. ELECTRONIC TRANSACTION STANDARDS (Compliance Date: October 16, 2003)

1. Transactions and Transaction Formats

The Electronic Transaction Standards cover these common billing and administrative transactions between health plans and health care providers:

- Health care claim (837);
- Coordination of benefits (837);
- Health plan eligibility inquiry and response (270/271);
- Health care claim status inquiry and response (276/277);
- Claim payment and remittance advice (835);
- Referral certifications and authorizations (278);
- Health plan enrollment (834); and
- Health plan premium payments (820).

ASCX12N formats, developed by ANSI, the American National Standards Institute were selected as the national standard for the transactions listed above. With the exception of Medicare claim submission, health care providers are not required to use electronic transmission. Health plans must accept electronic transactions from health care providers if submitted in the proper X12N format.

2. Code Sets

Health organizations also must adopt standard code sets for health transactions. Many of these code sets are in use today for coding of diseases, injuries, health problems and conditions, procedures, services, and supplies.

3. Unique Identifiers

Standards for unique identifiers for health care providers, employers, health plans, and individuals were not included in the Transaction Standards and will be issued separately. Compliance for the final rule for **Standard Unique Employer Identifiers** will be required by **July 30, 2004.**

III. COMPLIANCE WITH HIPAA

Compliance brings potential business opportunities and benefits such as reduction of manual processes in claims processing and claims errors, streamlining of business processes, and encouragement of e-health opportunities.

Non-compliance with HIPAA can result in civil penalties for failure to comply with the standards, and criminal penalties if personally identifiable data is wrongfully disclosed.

IV. RESOURCES

Internal

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Privacy Specialist
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External

Centers for Medicare and Medicaid Services (CMS)
http://www.cms.gov/hipaa/

Office for Civil Rights (OCR)
http://www.hhs.gov/ocr/hipaa/