SECTION XI

GUIDELINES FOR ORDERING MEDICATIONS

STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE

SECTION XI: GUIDELINES FOR ORDERING MEDICATION AND SPECIAL CONSIDERATIONS IN DRUG USE. CHAPTER 11.1: CLOZAPINE USE

POLICY:

The CVH Pharmacy bases its Clozapine Policy and Procedures on established FDA Regulations including the Clozapine Risk Evaluation and Mitigation Strategy (REMS), the CVH Drug Therapy Guidelines, and information provided by the manufacturer's package insert.

1. Clozapine REMS

The Pharmacy Supervisor is responsible for the registration of the hospital and maintenance of a current roster of physicians as provided by the Chief of Professional Services with the Clozapine REMS. With every modification of the privileged medical staff that occurs at CVH, the Chief of Professional Services will send the Pharmacy Supervisor an updated medical roster.

2. PHARMACIST KNOWLEDGE BASE

A. The pharmacists understand and demonstrate knowledge of the information provided in the Drug Therapy Guidelines, including but not limited to, the package insert, black box warnings, indications for use, dosing, laboratory assessments, contraindications and precautions, and drug interactions. The pharmacist understands that death can occur as a result of agranulocytosis or myocarditis and oversees the dispensing of all clozapine preparations.

B. The pharmacists demonstrate an appreciation of the requirements of the Clozapine REMS, including the need for physician's registration and patient registration, verification of re-challenge status, and on-going patient monitoring.

3. REQUIRED FDA REPORTING OF WBC AND ANC FOR CLOZAPINE PATIENTS The pharmacist provides the registry with up-to-date information and necessary documentation to register, maintain, change therapy, or discontinue therapy for all clozapine patients.

PROCEDURE:

A. Initiation of Treatment

- 1. Clozapine therapy may be initiated when the assigned pharmacist can register the patient in the Clozapine REMS program.
- 2. The pharmacist will review the written clozapine order. This will occur prior to initiation of clozapine therapy.
- 3. When reviewing the physician's order, the pharmacist will check to insure that they include the following:
 - a. Acceptable lab values of White Blood Count (WBC) not less than 3500/mm³ and Absolute Neutrophil Count (ANC) not less than 1500/mm³
 - b. The WBC and ANC have been obtained within 30 days of initiation of treatment.
- 4. The pharmacist will then review the medical record to insure the necessary baseline studies, as per the Clozapine Drug Therapy Guidelines, have been implemented per physician's order and documented accordingly.
- 5. After reviewing the order, the pharmacist will register the patient in Clozapine REMS program. The registry must be notified for newly admitted patients who were on clozapine prior to admission, as well as those patients who have been hospitalized at CVH for any length of time, and who are being started on clozapine.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

B. Continuation of Treatment for Patients Being Admitted

1. When a patient on clozapine is admitted to CVH and the prescriber would like to continue the drug, the assigned pharmacist must follow the same steps as above. Because the system of care has changed, the pharmacist must re-register the patient with the appropriate registry.

SECTION XI: GUIDELINES FOR ORDERING MEDICATION AND SUBSTANTIAL RISK IN DRUG USE CHAPTER 11.2 ANTICOAGULATION THERAPY

Policy: Connecticut Valley Hospital provides individualized quality anticoagulation management, monitoring, and education for the patients at Connecticut Valley Hospital, and works to reduce the likelihood of patient harm associated with the use of anticoagulation therapy.

Procedure:

- 1. CVH uses approved protocols for the initiation and maintenance of anticoagulation therapy.
 - a. Warfarin is a narrow therapeutic index medication affected by many factors including age, diet and other medications. The Oral Anticoagulation Protocol (appendix 1.) is intended to guide oral anticoagulation therapy in the hospitalized patient and is based on the recommendations from the American College of Chest Physicians.
 - b. The Enoxaparin Protocol (appendix 2.) is intended to guide low molecular weight heparin therapy in the hospitalized patient and is based on manufacturer recommendations for the specific condition(s) being treated.
- 2. Before starting a patient on warfarin, the patient's baseline coagulation status assessed; for all patients receiving warfarin therapy, a current INR is used to adjust this therapy. The baseline status and current INR are documented in the medical record.
- 3. Patients at CVH have their diet and/or drug therapy adjusted appropriately taking into account potential food-drug interactions. A list of drugs that have the potential for significant interaction with food is developed jointly by the Pharmacy Services Unit, Dietary Department, and the Medical Staff.
- 4. CVH has a policy that addresses baseline and ongoing laboratory tests that are required for anticoagulants.
- 5. The safety of medication management is monitored on an ongoing basis via the Adverse Drug Reaction and Medication Event Reporting processes. Additionally, a quality improvement indicator is included in the Pharmacy Department QI plan.

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APPENDIX 1. WARFARIN PROTOCOL

A. Warfarin Anticoagulation Management

1. The Appropriate Dose for Initiation of Warfarin

- a. The initiation of oral anticoagulation therapy with doses between 5 and 10mg for the first 1 or 2 days is suggested for most individuals.
- b. Subsequent dosing should be based on INR response.

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Following the administration of warfarin, an initial effect on PT usually occurs within the first 2 or 3 days, depending on the dose administered, and an antithrombic effect occurs within the next several days.
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A loading dose of warfarin (i.e. >20mg) is not recommended.

2. Anticoagulation in the Elderly

a. In the elderly, for patients who are debilitated, malnourished, have congestive heart failure, or have liver disease a starting dose of 5mg or less is suggested.

3. Frequency of Monitoring Oral Anticoagulation Therapy

- a. A baseline INR should be available and INR monitoring should begin after the initial 2 or 3 doses of oral anticoagulation therapy.
- b. For patients who are receiving a stable dose of oral anticoagulants, monitoring at an interval of no longer than every 4 weeks is suggested.
- c. If INR is unstable and is determined to be the result of a vitamin K deficiency, patients may be supplemented with vitamin K orally.

4. Management of Dosing when the INR is Above the Therapeutic Range

- a. For patients with INRs above the therapeutic range but less than 5 who have no significant bleeding, lower the dose or omit the dose, monitor more frequently, and resume therapy at a lower dose when the INR is in the therapeutic range. If only minimally above the therapeutic range, no dose reduction may be required.
- b. For patients with INRs greater of equal to 5 but below 9 who have no significant bleeding, omit the next 1 or 2 doses, monitor more frequently, and resume therapy at a lower dose when the INR is in the therapeutic range. Alternatively, omit a

dose and administer vitamin K1 (1-2.5mg *orally*), particularly if the patient is at increased risk of bleeding.

- c. For patients with INRs of greater than 9 who have no significant bleeding, discontinue warfarin therapy and administer vitamin K1 (5-10mg *orally*) with the expectation that the INR will be reduced in 24-48 hours. Monitor the patient more frequently and use additional vitamin K1 if necessary. Restart warfarin therapy at a lower dose when the INR is in the therapeutic range.
- d. In patient with serious bleeding and elevated INRs, discontinue warfarin therapy. Administration of vitamin K1 10mg by slow IV infusion supplemented with fresh plasma is recommended.
- e. In patients with life-threatening bleeding and elevated INRs, discontinue warfarin. Administration of prothrombin complex concentrate or recombinant factor VIIa supplemented with vitamin K1 by slow IV infusion is recommended.
- f. In patients with mild to moderately elevated INRs who have no major bleeding, it is suggested to administer vitamin K1 orally rather than subcutaneously.

5. Management of Dosing when an Invasive Procedure is Required

- a. For patients with a low risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow INR to return to near normal values, briefly use postoperative prophylaxis (if the intervention increases the risk of thrombosis) with a prophylactic dose of LMWH and simultaneously begin warfarin therapy.
- b. For patients with an intermediate risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow the INR to fall, cover the patient beginning 2 days preoperatively with a prophylactic dose of LMWH and then commence LMWH and warfarin postoperatively.
- c. For patients with a high risk of thromboembolism, stop warfarin therapy approximately 4 days before surgery, allow the INR to return to normal at the time of surgery and begin therapy with full dose of LMWH as the INR falls (approximately 2 days preoperatively); stop therapy 12-24 hours before surgery with the expectation that the anticoagulant effect will have worn off by the time of surgery. Then commence LMWH and warfarin postoperatively.
- d. For patients with a low risk of bleeding, continue warfarin therapy at a lower dose and operate at an INR of 1.3-1.5. The dose of warfarin can be lowered 4 or 5 days before surgery. Warfarin therapy then can be restarted postoperatively, supplemented with a prophylactic dose of LMWH if necessary.

B. Baseline and Ongoing Laboratory Studies

Baseline and periodic laboratory values include: PT/INR, and CBC.

C. Therapeutic Goals		
Indication	Target INR (goal)	Duration
Prophylaxis for VTE	2.5 (2-3)	1 month
Arterial thrombosis and		
stroke prevention		
Atrial Fibrillation	2.5 (2-3)	Life
Acute Myocardial	2.5 (2-3)	Variable
Infarction [*]		
Valvular Heart Disease	2.5 (2-3)	Life
Prosthetic tissue heart	2.5 (2-3)	Variable
valve		
Prosthetic mechanical	3 (2.5-3.5)	Life
heart valve ^{**}		

* a target INR of 3 (2.5-3.6) is appropriate for patients following an acute MI to prevent recurrent cardiac events

** a target INR of 2.5 (2-3) is appropriated for patients who have a mechanical bileaflet valve in the aortic position, normal cardiac chamber size, and no other risk factors for stroke

D. Contraindications and Precautions

Contraindications

- 1. alcoholism; lack of patient cooperation
- 2. bacterial endocarditis
- 3. bleeding tendencies of the gastrointestinal, genitourinary, or respiratory tract
- 4. blood dyscrasias
- 5. gastrointestinal, genitourinary or respiratory tract ulcerations or overt bleeding
- 6. hemorrhagic tendencies
- 7. hypersensitivity to warfarin or any component of the product
- 8. pregnancy, known or suspected
- 9. psychosis; lack of patient cooperation
- 10. senility; lack of patient cooperation

Precautions

- 1. anemia; increased risk of bleeding
- 2. cerebrovascular disease; increased risk of bleeding
- 3. coronary disease, serious; increased risk of bleeding
- 4. CYP2C9 and VKORC1 genetic variation; influences patient response to initial and maintenance therapy and increase the risk of bleeding
- 5. duration of therapy, long; increased risk of bleeding
 - a. factors which influence response to warfarin including diet, medications (including herbal medications), environment and physical state

- b. dietary vitamin K; may affect prothrombin time
- c. poor nutritional state; may increase PT/INR response
- d. vitamin K deficiency; may increase PT/INR response
- e. hypertension, severe to moderate; increased risk of bleeding
- f. malignancy; increased risk of bleeding
- g. renal impairment, severe to moderate; increased risk of toxicity, and bleeding
- h. trauma which may result in internal bleeding or in large exposed raw surfaces
- i. cancer; may increase PT/INR response
- j. collagen vascular disease; may increase PT/INR response
- k. conditions that increase risk of hemorrhage, necrosis, and/or gangrene, preexisting
- 1. congestive heart failure; may exhibit increased PT/INR response to warfarin
- m. diabetes, severe
- n. diarrhea; may increase PT/INR response
- o. edema; may decrease PT/INR response
- p. elderly or debilitated; narrow therapeutic range may add to risk of hemorrhage in these patients
- q. febrile; may increase PT/INR response
- r. hemorrhage and necrosis, potentially life-threatening; have been reported
- s. hepatic impairment, severe to moderate; increased risk of toxicity
- t. hyperlipidemia; may increase PT/INR response
- u. hyperthyroidism; may increase PT/INR response
- v. hypothyroidism; may decrease PT/INR response
- w. indwelling catheters
- x. infectious diseases or disturbances of intestinal flora, such as sprue or antibiotic therapy
- y. nephrotic syndrome; may decrease PT/INR response
- z. polycythemia vera
- aa. protein C mediated anticoagulant response, known or suspected deficiency; increased risk of tissue necrosis
- bb. steatorrhea; may increase PT/INR response
- cc. thrombocytopenia, heparin-induced; potentially fatal venous limb ischemia, necrosis, and gangrene have been reported upon heparin discontinuation and warfarin initiation or continuance
- dd. thrombosis, deep venous; potentially fatal venous limb ischemia, necrosis, and gangrene have been reported upon heparin discontinuation and warfarin initiation or continuance
- ee. vasculitis
- ff. warfarin resistance, acquired or inherited; decreased therapeutic responses have been reported

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APPENDIX 2. ENOXAPARIN PROTOCOL

A. Enoxaparin Anticoagulation Management

1. The Appropriate Dose for Initiation of Enoxaparin

a. Abdominal surgery - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing abdominal surgery who are at risk for thromboembolic complications is 40 milligrams subcutaneously once daily, with first dose given 2 hours prior to surgery, and continued for 7 to 10 days.

b. Arthroplasty of total knee - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing knee replacement surgery is 30 milligrams every 12 hours beginning 12 to 24 hours after surgery and continued for 7 to 10 days.

c. Deep venous thrombosis, in combination with warfarin

Inpatient: The recommended dosage is 1 milligram/kilogram every 12 hours OR 1.5 milligrams/kilogram every 24 hours. Enoxaparin should be continued for at least 5 days and until INR of 2 to 3 has been achieved.

d. Deep venous thrombosis, in patients with restricted mobility from acute illness; Prophylaxis

The recommended dosage for medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness is 40 milligrams subcutaneously every 24 hours. The usual duration of administration is 6 to 11 days.

e. Total replacement of hip - Postoperative deep vein thrombosis; Prophylaxis

The recommended dosage for patients undergoing hip replacement surgery is 30 milligrams subcutaneously every 12 hours beginning 12 to 24 hours after surgery and continued for 7 to 10 days. Patients may begin therapy with 40 milligrams every 24 hours beginning 9 to 15 hours prior to surgery. Following the initial phase of thromboprophylaxis, extended prophylaxis with enoxaparin 40 mg subcutaneously once daily for 3 weeks is recommended for a total duration of therapy of approximately 4 weeks

2. Dosage in Renal Failure

a. Recommended Dosage Adjustments (CrCl less than 30 mL/min)

i. Prophylaxis in Abdominal Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 2 hours prior to surgery. The usual duration of administration is 7 to 10 days.

ii. Prophylaxis in Knee Replacement Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 12 to 24 hours after surgery. The usual duration of administration is approximately 7 to 10 days.

iii. Prophylaxis in Hip Replacement Surgery

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily with the initial dose given 12 to 24 hours after surgery. The usual duration of administration is 7 to 10 days.

iv. Prophylaxis Is Medical Patients during Acute Illness

The recommended dosage is enoxaparin 30 milligrams subcutaneously once daily. The usual duration of administration is 6 to 11 day.

v. Treatment of Deep Vein Thrombosis

The recommended dosage is 1 milligram/kilogram subcutaneously once daily. Enoxaparin should be continued until a therapeutic INR has been reached. The average duration of administration is 7 days.

3. Dosage in Geriatric Patients

At dosages used for prophylaxis the incidence of bleeding complications is similar between elderly and younger patients. When use for treatment of venous thromboembolism, elderly experience a greater incidence of bleeding complications. Elderly patients weighing less than 45 kg or those predisposed to renal dysfunction should be closely monitored.

B. Baseline and Ongoing Laboratory Studies:

Baseline and periodic laboratory values include and CBC.

C. Therapeutic Goals

Unlike conventional unfractionated heparin, low-molecular-weight heparins (LMWH) cause only a slight increase in PTT and thrombin. Activated clotting time (ACT) of enoxaparin is also poorly correlated to the anti-Xa levels. When LMWHs are used for treatment, monitoring plasma anti-factor Xa concentrations may be useful in select populations. These include:

Patients with renal insufficiency, Patients on long-term therapy with LMWH, Pregnant patients, Patients with extremes of body fat, Patients with a high risk of bleeding or recurrent thrombosis.

D. Contraindications and Precautions

Contraindications

- 1. active major bleeding (Prod Info LOVENOX(R) injection, 2004)
- 2. hypersensitivity to enoxaparin, heparin, pork products
- 3. hypersensitivity to benzyl alcohol (multi-dose formulation)
- 4. thrombocytopenia associated with a positive test for antiplatelet antibody in the presence of enoxaparin

Precautions

- 1. concurrent use of drugs which affect hemostasis (i.e., NSAIDs); increased risk of epidural or spinal hematoma
- 2. bacterial endocarditis; increased risk of hemorrhage
- 3. bleeding diathesis
- 4. concomitant platelet inhibitors; increased risk of hemorrhage
- 5. congenital or acquired bleeding disorders; increased risk of hemorrhage
- 6. diabetic retinopathy
- 7. elderly patients; potential for delayed elimination of enoxaparin
- 8. gastrointestinal disease, ulcerative and angiodysplastic, active or recent; Increased risk of hemorrhage
- 9. hemorrhagic stroke; increased risk of hemorrhage
- 10. heparin-induced thrombocytopenia, history of; use extreme caution
- 11. low-weight men (less than 57 kg) and women (less than 45 kg); increased exposure to enoxaparin and increased risk for bleeding
- 12. major hemorrhage (including intracranial and retroperitoneal) or bleeding at any site may occur; investigate any unexplained reduction in hematocrit or blood pressure
- 13. not adequately studied for thromboprophylaxis in patients (including pregnant women) with prosthetic heart valves
- 14. recent brain, spinal or ophthalmological surgery; increased risk of hemorrhage
- 15. renal impairment; increased exposure to enoxaparin and increased risk for bleeding, dosage adjustment recommended in patients with CrCl less than 30 mL/min
- 16. thrombocytopenia may occur; discontinue therapy if platelet count falls below 100,000/mm(3)
- 17. uncontrolled hypertension

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SECTION XI: STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE. CHAPTER 11.3: IMPROVING THE SAFETY OF USING HIGH RISK MEDICATION.

POLICY: High risk medications are those drugs involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes.

Connecticut Valley Hospital understands the importance of identification, storage, ordering, distribution, and monitoring of high-risk medications. When appropriate, individualized policies and procedures will be implemented to insure the proper handling of these medications.

PROCEDURE: 1. Once high-risk medications are identified, common risk factors will be identified and a proactive planning process will be implemented.

2. Proactive planning may include the development and implementation of specific policies and procedures, and may address such things as storage, ordering, distributing, administering, and/or monitoring of the medication.

3. All formulary addition requests will be presented to the Pharmacy Nutrition and Therapeutics Committee and will have as an element of review the potential for being a high-risk medication.

4. The Pharmacy Nutrition and Therapeutics Committee will review all High Risk Medications on an annual basis for any necessary revision or additional proactive planning.

5. Medication Events will be reviewed to determine if the medication(s) involved should be considered for inclusion into the "High Risk Medication" Policy.

6. All medications available in more than one concentration in the hospital will be considered "High Risk Medications". When more than one concentration is necessary, the numbers of concentrations are limited to the minimum required to meet patient care needs.

MEDICATIONS			
High-alert medication	Common Risk Factor	Proactive Planning	
Fluphenazine injectable	Fluphenazine injectable is available as an immediate acting and decanoate preparation.	These medications are stored as far apart as possible in the pharmacy department. At CVH these medications are in separate drawers in the PYXIS medstation. At Blue Hills these medications are in separate "high alert" labeled containers in the medication rooms.	
Insulin	No dose check system	Establish a check system in which one nurse prepares the dose and another reviews it. Refer to nursing Policy and Procedure.	
	Mix-up due to insulin and heparin vials being kept in close proximity to each other on nursing units.	Heparin is only stocked in the pharmacy.	
	"U" used as an abbreviation for "units" in orders.	"U" was added to the DO NOT USE abbreviation list. See Pharmacy Policy and Procedure.	
Haloperidol injectable	Haloperidol injectable is available as an immediate acting and decanoate	These medications are stored as far apart as possible in the pharmacy department. At CVH	

COMMON RISK FACTORS AND PROACTIVE PLANNING FOR HIGH-ALERT

Heparin	preparation. Multidose containers.	these medications are in separate drawers in the PYXIS medstation. At Blue Hills these medications are in seriate "high alert" labeled containers in the medication rooms. The pharmacy does not stock multidose containers of heparin.
	Mix-ups due to insulin and heparin vials being kept in close proximity to each other on nursing units. Greater than one concentration is available in the	Heparin vials are not stocked on the nursing units. Each different insulin is stored separately in vials. Warning labels are affixed to each vial.
	pharmacy.	
Medroxy- progesterone Injectable	Greater than one concentration is available in the pharmacy.	These medications are stored as far apart as possible in the pharmacy department. At CVH these medications are in separate drawers in the PYXIS medstation. At Blue Hills these medications are in seriate "high alert" labeled containers in the medication rooms. Warning labels are affixed to each package.
Opiates	Parenteral narcotics stored as	Parenteral narcotics are not
	'	·

floor stock in	routinely stocked
nursing areas.	on the nursing
	units. Parenteral
	narcotics are non-
	formulary and
	obtained only for
	individual patients
	following the
	completion of the
	non-formulary
	approval process.

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SECTION XI: STATEMENT ADVISING OF SPECIAL CONSIDERATION IN DRUG USE. Chapter 11.4: USING MEDICATION WITH LOOK ALIKE-SOUND LIKE NAMES

Policy: There shall be a policy in the management of medication with look alike or sound alike names.

Procedure: Strategies are developed to prevent the interchange of look alike or sound alike medications as outline in the chart below.

Identify and, at a minimum, annually review a list of look–alike sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs.

All medication orders will be written using the generic name of the medication <u>Exception</u>: combination medications (drugs having more than one ingredient) may be written using the *Brand Name* but the indication must be included in the order.

Pharmacists will verify that all medication orders are written according to the procedure before the order is accepted and dispensed; discrepancies will be brought to the attention of the prescriber so that the order can be re-written in the proper format.

Management of these medications is outlined in the chart below.

Look alike-sound-alike medication will be stored, packaged, and dispensed according to strategies listed in the chart below.

Bar coding is used when dispensing all medications to the Pyxis Medstations.

Non-formulary medications are stored in different colored bins in the pharmacy inventory.

Potential Problematic Drug Names	Generic Lower Case and Brand Names Upper Case	Potential Errors and Consequences	Specific Safety Strategies
Amiloride/Amlodipine	MIDAMOR (amiloride) NORVASC (amlodipine)	Generic names can be easily confused	"Tall Man" letters are used to differentiate these medications.
Bupropion/Buspirone	WELLBUTRIN (bupropion) BUSPAR (buspirone)	Generic names can be easily confused	Dosage must be clearly written to distinguish between drugs. "Tall Man" letters are used to differentiate these medications.
Carbamazepine/ Oxcarbazepine	TEGRETOL (carbamazepine) TRILEPTAL (OXCARBAZEPINE)	Generic names can be easily confused	Drugs stored in pharmacy alphabetically by generic name. "Tall Man" letters are used to differentiate these medications.
Celebrex/Celexa	CELEBREX (celecoxib) CELEXA (citalopram)	Both brand and generic names can be easily confused	Orders to be written using the generic name of the drug. Dosage must be clearly written to distinguish between drugs. Celecoxib is a non-formulary drug stored accordingly.
Chlordiazepoxide/ Chlorpromazine	LIBRIUM (chlordiazepoxide) THORAZINE (chlorpromazine)	Generic names can be easily confused	Chlordiazepoxide is a controlled drug and is stored in Pyxis CII safe in pharmacy.
Citalopram/ Escitalopram	CELEXA (citalopram) LEXAPRO (escitalopram)	Generic names can be easily confused.	"Tall Man" letters are used to differentiate these medications.
Clonidine/Klonopin/ Clonazepam	CATAPRES (clonidine) KLONOPIN (clonazepam)	The generic name for clonidine can be easily confused for the trade or generic name of clonazepam	Orders to be written using the generic name of the drug. Clonazepam is a controlled substance and is stored in Pharmacy in CII safe.
			On units clonazepam is stored on Pyxis Medstation in carousel drawer.

National Patient Safety Goal: A list of Look-alike/sound-alike Drugs Used in the Organization: Strategies to Prevent the Interchange of these Drugs

Gabapentin/	NEURONTIN	Generic names can be easily	Gabapentin 600mg is stored in IL pockets.
Gemfibrozil	(gabapentin)	confused, they have similar	
	LOPID	dosage strengths, these	Gemfirozil is a non-formulary medication and stored accordingly.
	(gemfibrozil)	medications can be easily	
		confused for each other.	
Glyburide/Glipizide	MICRONASE	Generic names can easily be	Glyburide is dispensed to ward in IL pocket containers and placed in
	(glyburide)	confused for each other;	Pyxis Medstation with bar codes.
	GLUCOTROL	indication of use is similar as	
	(glipizide)	well	"Tall Man" letters are used to differentiate these medications.
Guaifenesin/Guanfacine	VARIOUS BRAND	Generic names can be easily	Guafacine is non-formulary and stored accordingly.
	NAMES	confused	
	(guaifenison)		"Tall Man" letters are used to differentiate these medications.
	TENEX/INTUNIV		
	(Guanfacine)		
Hydroxyzine/	Vistaril, Atarax	Because the first 4 letters of their	Storage in the Pharmacy separates the drugs as far from each other as
Hydralazine	(hydroxyzine)	generic names are identical and	possible.
	hydralazine	they have similar dosage	
		strengths, these medications can	"Tall Man" letters are used to differentiate these medications.
		easily be confused for each other	
Ibuprofen/Gabapentin/	VARIOUS	These medications can be easily	Gabapentin 600mg is stored in IL pockets.
Gemfibrozil	(ibuprofen)	confused for each other; They	
	NEURONTIN	have similar dosage strengths,	Gemfibrozil is a non-formulary medication and stored accordingly.
	(gabapentin)	and appearances.	
	LOPID		
	(gemfibrozil)		
Insulin Products	VARIOUS	Similar names, strengths, and	Auxiliary labels are used to differentiate the different insulin products
		concentrations may contribute to	
		medication errors	A check system in which one nurse prepares the dose and another reviews
			it. Refer to nursing Policy and Procedure.
Lamisil/Lamictal	LAMISIL	Similarity in brand names can	Orders to be written using the generic name of the drug
	(terbinafine)	be easily confused	
	LAMICTAL		Drugs stored in pharmacy alphabetically by generic name
	(lamotrigine)		
			Lamotrigine is stored in IL pockets.

Metformin/	GLUCOPHAGE	Generic names can be easily	Storage in the Pharmacy separates the drugs as far from each other as
Methocarbamol	(metformin)	confused for each other, and	possible.
	ROBAXIN	both drugs have similar strengths	
	(methocarbamol)		
Metformin/	FLAGYL	Generic names can easily be	ONLY the 250mg tablet of metronidazole is on formulary, since
Metronidazole	(metronidazole)	confused for each other, and	metformin is not available in a 250mg tablet.
	GLUCOPHAGE	medications are available in	
	(metformin)	similar strengths	
MS Contin/ Oxycontin	MS CONTIN	Brand names can be easily	Orders to be written using the generic name of the drug
	(morphine)	confused and medications are	
	OXYCONTIN	used for similar indications	Drugs stored in the control drug vault/Pyxis CII safe in different
	(oxycodone)		compartments
Paroxetine/fFuoxetine	PAXIL	Generic names can be easily	Drugs stored in pharmacy alphabetically by generic name.
	(paroxetine)	confused	
	PROZAC		
	(fluoxetine)		
Paxil/Plavix	PAXIL	Brand names can be easilty	Orders to be written using the generic name of the drug.
	(paroxetine)	confused	
	PLAVIX		Drugs stored in pharmacy alphabetically by generic name.
	(clopidogrel)		
Prilosec/Prozac	PRILOSEC	Brand names can be easilty	Orders to be written using the generic name of the drug.
	(omeprazole)	confused	
	PROZAC		Drugs stored in pharmacy alphabetically by generic name.
	(fluoxetine)		
Retrovir/Ritonivir	RETROVIR	Both drugs look and sound alike	Orders to be written using the generic name of the drug
	(zidovudine)	as well as indications are similar	
	NORVIR	and strengths are the same	Ritonavir is stored in the unit dose section
	(ritonavir)		
Sertraline/Cetirizine	ZOLOFT	Generic names can be easily	Dosage must be clearly written to distinguish between drugs.
	(sertraline)	confused	
	ZYRTEC		Drugs stored in pharmacy alphabetically by generic name.
	(cetirizine)		
Terbinafine/Terbutaline	LAMISIL	Generic names can be easily	Orders to be written using the generic name of the drug
	(terbinafine)	confused	
	BRETHINE		In pharmacy drugs are stored in separate areas
	(terbutaline)		

			Terbutaline is not stocked
Topamax/Toprol XL	TOPAMX (topiramate)	Brand names can be easily confused, likely attributable to	Orders to be written using the generic name of the drug
	TOPROL XL (metoprolol)	the similarity in the names with the "X" in the XL looking like	Drugs stored in pharmacy alphabetically by generic name
		the ending of Topamax, in addition the dosage strengths are identical	
Tramadol/Trazadone	ULTRAM (Tramadol) Trazadone	Generic names can be easily confused	Tramadol is now a controlled substance and placed in Pyxis Medstation with bar codes
Zantac/Xanax	ZANTAC (ranitidine) XANAX	Both brand names sound a like	Orders to be written using the generic name of the drug Dosage must be clearly written to distinguish between drugs.
	(alprazolam)		Xanax is a controlled drug and is stored in Pyxis CII safe in pharmacy
Zyprexa/Zyrtec	ZYPREXA (olanzanino)	Brand names can be easily confused	Orders to be written using the generic name of the drug.
	(olanzapine) ZYRTEC (cetirizine)	confused	Drugs stored in pharmacy alphabetically by generic name.

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SECTION XI: STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE. CHAPTER 11.5: IMPROVING THE SAFETY OF USING HAZARDOUS MEDICATION.

POLICY: Hazardous drugs and medications are those in which studies in animals or humans indicate that exposure to them have a potential for causing cancer, developmental or reproductive toxicity, genotoxicity, or harm to organs. An example of a hazardous drug is one that contains antineoplastic agents or other ingredients that cause the aforementioned risks. Lists of hazardous drugs are available from the National Institute for Occupational Safety and Health (NIOSH).

Connecticut Valley Hospital understands the importance of identification, and handling of hazardous medications. When appropriate, individualized policies and procedures will be implemented to insure the proper managing of these medications.

PROCEDURE:

- 1. Once hazardous medications are identified, the occupational hazard and risk factors will be identified and a proactive planning process (including personal protection) will be implemented.
- 2. Proactive planning may include the development and implementation of specific policies and procedures, and may address such things as storage, ordering, distributing, administering, and/or monitoring of the medication.
- 3. Medications are received and dispensed in unit dose and/or ready to use forms whenever possible.
- 4. If a medication from the hazardous medication list requires prepacking it will be prepacked by an outside vendor.
- 5. The pharmacy does not compound medications.
- 6. If there is an outpatient prescription for a hazardous medication, the pharmacist and technician preparing the prescription will follow the PPE guidelines set forth for that medication.
- 7. All formulary addition requests will be presented to the Pharmacy Nutrition and Therapeutics Committee and will have as an element of review the potential for being a hazardous medication.
- **8.** The Pharmacy Nutrition and Therapeutics Committee will review all Hazardous Medications on an annual basis for any necessary revision or additional proactive planning.

Approved October 15, 2018

SECTION XI: GUIDELINES FOR ORDERING MEDICATIONS AND STATEMENT ADVISING OF SPECIAL CONSIDERATIONS IN DRUG USE

CHAPTER 11.6: USE OF DIETARY SUPPLEMENTS

POLICY: Dietary supplements are defined in DSHEA (Dietary Supplement and Education Act of 1994) as products "intended to supplement the diet" that contains any of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by humans to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, a constituent, extract, or combination of any ingredient mentioned above. They must be identified on the label as a dietary supplement.

Dietary supplement labels can bear health claims, nutrient content claims, and structure/function claims. Health claims can be used to characterize the relationship between a dietary ingredient and reducing the risk of a disease or health related condition. Both health claims and nutrient content claims must be approved by the FDA.

Structure/function claims are the most commonly use claims on dietary supplement labels. They can be sued to describe the effect a dietary supplement has on the structure or function of the body, the way a dietary ingredient acts to maintain a structure or function, general well-being from consumption, or a benefit related to a nutrient deficiency disease if the prevalence of the disease in the U.S. is also indicated. Structure/function claims are not pre-approved by the FDA.

DSHEA does not require FDA to review evidence or safety of dietary supplements, so manufacturers have no burden to prove that their products are effective or safe. Manufacturers that wish to carry the "USP approved" seal on their product labels have to subject their products to testing by USP. This only serves to establish GMPs (good manufacturing practices).

The decision to include any product in the CVH formulary is based on comparative data regarding efficacy, adverse effects, cost, and potential therapeutic advantages and deficiencies. The lack of definitive evidence of efficacy and safety and the demonstrated variability in product content make most dietary supplements unsuitable for inclusion on the formulary.

Dietary supplements are not routinely supplied by CVH pharmacy. CVH does not endorse the use of dietary supplements not recognized by well established medical evidence. The challenge to the hospital is to preserve patient autonomy and satisfaction without compromising high standards of care and evidence-based medicine.

The shortcomings that make most dietary supplements unsuitable for inclusion in formularies also argue strongly against their use by patients during a hospital stay. The use of "patients own medications" for dietary supplements should be avoided to the extent possible.

PROCEDURE:

- 1. If a licensed independent practitioner determines that a supplement is appropriate for a patient, the LIP must complete a non-formulary request form for all products (even if patients wish to use their own supply) and follow procedures outlined in CVH Pharmacy Policy 17.3 Orders for Non-Formulary Medications.
- 2. If the non-formulary request is approved, the pharmacy will obtain the supplement; to the greatest extent possible obtain those supplements that are USP verified.
- 3. A patient's own supply of supplements may only be taken with a physician's order in accordance with CVH Pharmacy Policy 4.5, Patients' Personal Medications brought to the Hospital, and after the non-formulary process has been carried out.
- 4. Orders for supplements will be reviewed by the pharmacist according to CVH Pharmacy Policies 4.1 Guidelines for Prescribing Medications, and 5.4 Physician Order Sheet.
- 5. If the order is for a nutrient supplement, the pharmacist will collaborate with the Supervising Dietician or designee.
- 6. Insufficient evidence to support the use of the requested supplement is considered grounds to not approve the non-formulary request.

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