SECTION XV

PHARMACIST PARTICIPATION IN CLINICAL MONITORING PROGRAMS

FOOD DRUG INTERACTION MANAGEMENT

ADVERSE DRUG REACTION REPORTING

DOSAGE MONITORING OF RENALLY CLEARED MEDICATIONS

CONNECTICUT VALLEY HOSPITAL
PHARMACY POLICY AND PROCEDURE MANUAL

SECTION XV: CLINICAL PROGRAM PARTICIPATION
CHAPTER 15.1: FOOD DRUG INTERACTIONS

POLICY: 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. Patients are educated as deemed appropriate by the physician regarding food-drug interactions.

PROCEDURE:

1. A list of medications that has the potential to interact with foods is developed and maintained by the Pharmacy Nutrition and Therapeutics Committee (PNT).
2. The Food Drug Interaction List is maintained in the Drug Therapy Guidelines
3. The medications that have the potential for food-drug interactions are flagged in the pharmacy computer system in the clinical reporting portion of the drug database. This will cause the message Drug-Food Interaction to appear during the routine order entry process. The Pharmacy Unit Supervisor or designee is responsible for maintaining the computer message codes as the PNT modifies the list of drugs that interact with foods.
4. When the message Drug-Food Interaction appears during routine order entry of new/changed medication orders the pharmacist completes the Food Drug Interaction Communication Form and faxes it to the dietary department as instructed on the form.
5. Once received by dietary the clinical dietician follows the Dietary Department policy and procedure regarding food-drug interactions.

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Connecticut Valley Hospital Food Drug Communication Form
Complete form and fax to the Clinical Dietician at 262-5002

Patient Name _____ Location_____

Date Therapy Started _____ Drug Name (Please check all that apply):

- o Amiloride
- o Antidiabetic agent: Drug Name _____
- o Ciprofloxacin
- o Isoniazid
- o Lithium
- o Lurasidone
- o Lipid lowering drug: Drug Name _____
- o Minocycline
- o Monoamine-oxidase inhibitor
- o Orlistat
- o Phenytoin
- o Potassium-depleting diuretics: Drug Name _____
- o Tetracycline
- o Verapamil
- o Warfarin
- o Ziprasidone
- o Other: Drug Name _____

Drug Strength _____ Dosage Form _____ Regimen _____

Pharmacist _____ Date _____

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CHAPTER 15.2: **AVAILABLE**

POLICY:

PROCEDURE:

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SECTION XV: CLINICAL PROGRAM PARTICIPATION
CHAPTER 15.3: SUSPECTED ADVERSE DRUG REACTION REPORTING PROGRAM

PURPOSE:

1) Provide a mechanism for the collection and evaluation of suspected adverse drug reaction (ADR) data in order to improve patient safety.
2) Review aggregate data for opportunities for improving patient safety.
3) Ensure proper reporting of ADRs to the FDA and manufacturer when indicated.

POLICY:

Definition (ASHP)1: An ADR is "any, unintended, undesired, or excessive response to a medication."

Adverse reactions due to administration of established drugs and diagnostics, investigational drugs and biological agents should be reported.

An ADR is not the same as a "medication error."

All potential ADRs should be reported; there is no need for certainty of cause and effect.

Reactions observed in both inpatients and outpatients are reportable.

Adverse drug reactions should be reported if, in the view of the reporter, it will affect the patient's current and future medical therapy.

Minor temporary or reversible side effects normally associated with a drug in question need not be reported.

The definition of a non-reportable side effect is:

> ***An expected, well known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth due to administration of certain antihistamines or nausea associated with the use of antineoplastics.)***

1 American Society of Health System Pharmacists

The definition of a significant ADR is unintended, undesired, or excessive response to a medication that:

Requires discontinuing the drug (therapeutic or diagnostic),

Requires changing the drug therapy (adding a new agent to treat the ADR),

Requires modifying the dose (except for minor dosage adjustments),

Necessitates evaluation at an Emergency Department (ED),

Prolongs stay in at this hospital,

Necessitates supportive treatment,

Significantly complicates diagnosis,

Negatively affects prognosis, or

Results in temporary or permanent harm, disability, or death."

ADRs at Connecticut Valley Hospital are ranked by severity as:

LEVEL 1	A reaction that resulted in the need for increased patient monitoring or observation but no other treatment or intervention was required.
LEVEL 2	A reaction that resulted in the discontinuation of the medication or the need for treatment with another medication and/or intervention(s) in addition to monitoring,
LEVEL 3	A reaction that resulted in the need for evaluation/treatment in a hospital emergency room or different level of care.
LEVEL 4	A reaction that resulted in the need for acute care hospital admission but was not life threatening and resulted in no permanent patient harm.
LEVEL 5	A reaction that was life threatening or resulted in permanent patient harm.
LEVEL 6	A reaction that resulted in patient death.

ADRs at Connecticut Valley Hospital are ranked by causal relationship as: Remote, Possible, Probable, or Highly Probable based upon completion of the ADR probability algorithm of the ADR reporting form

PROCEDURE:

1. Initiation of the ADR reporting process is the responsibility of the medical staff[2], nurses, and pharmacists. The person reporting the suspected ADR informs the prescribing and attending physician. All medical staff, nursing staff, and pharmacy staff are requested to report all observed ADRs by calling the ADR hotline (ADRS – x2377).

2. The unit pharmacist is responsible for completing the adverse drug reaction reporting form. The pharmacist will also complete the probability and severity ratings on the back of the form. Clinical activity is documented in the clinical section of the pharmacy computer system. The pharmacist will verify that the prescribing and/or attending physician have been notified.

3. After assessing the ADR, the attending physician should make an entry in the progress notes to document the occurrence of a possible ADR and to document patient counseling concerning the ADR as indicated. (This documentation is not needed for those ADRs classified as "remote").

4. Significant ADRs will be initially reviewed by the Pharmacy Supervisor, or designee, for submission to the FDA based on the criteria outlined in: ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. See CHAPTER 15.3.1 of Pharmacy Policy and Procedure Manual.

5. All ADRs shall be reported to and reviewed by the PNT Committee. The PNT Committee will conduct an Intensive Case Analysis (ICA) on ADRs rated a level 3 or greater or when an ICA is otherwise indicated to improve care.

6. The PNT Committee receives from the Pharmacy Supervisor (or designee), a report of ADR trends and recommendations quarterly

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2 per Article VI – Medication of the Medical Staff Rules & Regulations

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SECTION XV: CLINICAL PROGRAM PARTICIPATION
CHAPTER 15.3.1: INSTRUCTIONS FOR FDA FORM 3500

POLICY:

All ADRs will be reviewed by the Pharmacy Nutrition and Therapeutics Committee for possible submission to the FDA.

PROCEDURE:

Form FDA 3500 may be used by health professionals for voluntary reporting of adverse events, product use errors, product quality problems, and therapeutic failures for:

- drugs (prescription and over-the-counter)
- biologics, (including blood components, blood derivatives, allergenics, human cells, tissues, and cellular and tissue-based products (HCT/Ps)
- medical devices (including in vitro diagnostic products)
- combination products
- special nutritional products (dietary supplements, infant formulas, medical foods)

Adverse events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS), http://vaers.hhs.gov/index. For additional information or assistance with filing a VAERS report, call: 1-800-822-7967.

Adverse events involving investigational (study) drugs, such as those relating to Investigational New Drug (IND) applications, including those for cellular products administered under IND, should be reported as required in the study protocol and sent to the address and contact person listed in the study protocol. They should generally not be submitted to FDA MedWatch as voluntary reports.

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SECTION XV: CLINICAL PROGRAM PARTICIPATION
CHAPTER 15.4: DOSAGE ADJUSTMENT ASSESSMENT FOR RENALLY CLEARED MEDICATIONS

POLICY:

All patients 65 years of age or older ***and*** patients who have a SrCr greater than the upper limit of normal are routinely monitored for appropriate dosing of renally cleared medications. The Pharmacy Services Unit and Medical Staff work collaboratively to identify drugs to be monitored, and implement and maintain a monitoring process.

PROCEDURE:

1) The Pharmacy Nutrition and Therapeutics Committee (PNT) formulate a list of drugs that require monitoring in renally impaired patients.

2) The list includes the usual dosage range for each medication and a recommended dosing adjustment based on calculated CrCl.

3) CrCl is calculated using SrCr and the formulas noted below.

    a. MALES: CrCl (ml/min) = (140-age in yrs)(wgt in kg)/SrCr(72)
    b. FEMALES: (Use above formula) X (0.85)

4) Patients' drug therapy is assessed using the dosing guidelines found in the Drug Therapy Guidelines.

5) Recommendations for dosing adjustments will be made as appropriate.

6) The estimated CrCl will be updated quarterly.

7) If a significant change has occurred in a patient's renal function, the procedure outlined above will be followed.

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