University of New Mexico Health Sciences Center
University of New Mexico Hospital
Pharmacist Clinician Protocol
Cardiovascular Pharmacotherapy

Pharmacist Clinician: _____, PharmD, RPh, PhC
Address
City, State

Supervising Physician: _____, MD
Address
City, State

Alternate Physician(s): _____, MD
Address
City, State

_____, MD
Address
City, State

PURPOSE:

1. To provide pharmaceutical care to University of New Mexico Hospital patients with cardiovascular (CV) disease. These will include patients with: coronary artery disease (CAD), risk for CV disease, heart failure, mechanical heart valves, dysrhythmia, angina, or other CV disorders not otherwise specified.
2. To provide and review a comprehensive patient medical profile, assuring that patient care is compliant with current treatment guidelines and University Hospital prescribing practices. These practices will be continuously updated as dictated by emerging literature.
3. To provide appropriate therapeutic monitoring.
4. To provide the most effective drug regime, in a cost-effective fashion.
5. To obtain pertinent medical and medication histories.
6. To conduct research in the therapy of cardiovascular disease.
7. To provide clinical pharmacy services for CV research studies.
8. Serve as an educational site for pharmacy students, pharmacy practice residents, pharmacy specialty residents, medical students, medical residents and nursing students.

DEFINITIONS:

Pharmacist Clinician (PhC): a pharmacist with additional training required by regulations adopted by the New Mexico Board of Pharmacy in consultation with the New Mexico Board of Medical Examiners and the New Mexico Academy of Physician Assistants, who exercises prescriptive authority in accordance with guidelines or protocol. {16 NMAC 19.4.23.2.7}

Pharmaceutical Care: is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

Cardiovascular Risk Factors: Risk factors (often times modifiable) as defined by the American Heart Association known to increase the chance of a CV event. These include, but are not limited to: hypertension, cigarette smoking, obesity (BMI $\geq$ 30,) dyslipidemia, diabetes mellitus, sedentary lifestyle, microalbuminuria or estimated GFR < 60ml/min, age (men > 55 y.o. and women > 65 y.o.) or family history of premature CV disease (men < 55 y.o. and women < 65 y.o.).

Heart Failure: Also referred to as Congestive Heart Failure or Chronic Heart Failure, encompasses systolic and diastolic cardiac dysfunction, congenital heart disease, and dilated cardiomyopathy resulting in decreased cardiac output.

Dysrhythmia: Decribes any of a large and heterogeneous group of conditions in which there is abnormal electrical activity in the heart.

POLICY:

1. Measuring/reviewing vital signs: Vital signs will be taken by the nurse aide or medical assistant prior to the appointment for the pharmacist clinician. Measurements outside of the following will be called to the supervising and/or the alternate supervising physician:
    - Blood pressure: SBP > than 200 mmHg or DBP > 110 mmHg; SBP < 80 mmHg and/or DBP < 50 mmHg or any blood pressure that results in symptoms of hypotension.
    - Heart rate < 50 bpm or symptomatic bradycardia. Heart rate > 120 bpm or symptomatic tachycardia.
    - Temperature greater than 98.6 °F.
    - Blood glucose < 60mg/dL (If unable to correct with food items on-hand in clinic.)
    - Fasting > 400 mg/dL, or random blood glucose > 500mg/dL
    - Suspected diabetic ketoacidosis
    - Chest pain consistent with unstable angina
    - Shortness of breath at rest (New York Heart Association Functional Class IV) that is either of new onset or refractory to treatment.

2. A Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will assess the patient with CV disease and provide recommendations and/or a therapeutic plan for the initiation of therapeutic lifestyle changes (TLC) and/or medications where appropriate.

3. The Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will assess and monitor patient response to therapy (lifestyle and/or pharmacotherapeutic) and maintain a comprehensive patient medication and goals profile to promote a rational, safe and effective therapeutic regimen.

4. Patients will be provided education materials and counseling concerning their risk factors, therapeutic lifestyle change recommendations, medication regimens, and monitoring parameters.

5. A Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will provide other health care professionals with drug information.

6. The Pharmacist Clinician in charge will supervise pharmacy students.

PROCEDURE:

Responsible staff: Pharmacist Clinicians, post-Pharm. D Residents, and pharmacy students. Final responsibility is with the Pharmacist Clinician in charge.

Procedural Steps:

1. Referral from provider: Providers may refer patients to the pharmacist clinician for assessment, evaluation, recommendations, and/or management of cardiovascular conditions included in this protocol. Therapeutic recommendations and/or changes will be communicated to the referring provider and the patient's primary care provider if they are not also the referring provider.

2. Physical assessment of the patient will be conducted and laboratory and diagnostic tests ordered as clinically necessary.

3. A SOAP note will be written and/or dictated to address some or all of the following:
   - Assessment of the cardiovascular condition.
   - Medication history including drug allergies, intolerances, and adherence problems.
   - Medication dosing, anticipated duration, potential adverse effects, drug interactions, and treatment goals as per current clinical guidelines.

- Use of most cost-effective medications.
- Appropriate communication to the referring provider and primary care provider if they are not the referring provider.
- Patient education regarding medication self-administration and disease state monitoring.
- Referrals to cardiac rehabilitation, smoking cessation, diabetic education classes, or other patient education programs as deemed clinically necessary.

4. The treatment of CV disease can be complicated by many other co-morbidities; therefore, treatment of the patient with CV disease is not restricted to the treatment of the CV system alone. Other factors that can potentially worsen CV disease include but is not limited to the following:
   - CV factors:
     - Ischemia or infarction
     - Uncontrolled hypertension
     - Valvular disease
     - New onset or uncontrolled dysrhythmia (eg. Atrial fibrillation)
   - Systemic factors:
     - Inappropriate medications
     - Infection
     - Anemia
     - Uncontrolled diabetes
     - Thyroid dysfunction
     - Mental illness (eg. Anxiety, depression)
     - Electrolyte disorders
     - Gastrointestinal disorders (eg. GERD, peptic ulcer disease)
     - Pulmonary disease (eg. Asthma, COPD)
     - Pregnancy
   - Patient related factors:
     - Medication non-compliance
     - Dietary indiscretions
     - Alcohol, tobacco, or other substance abuse

5. The following medications may be ordered, adjusted, or administered with appropriate communication to the referring provider and/or primary care provider (PCP) as part of the CV PhC consult. Therapeutic management will be based on both professional guidelines and the most recent evidence-based research for each of the following areas:

   - Antihyperlipidemic medications: HMG Co-A reductase inhibitors (statins), bile acid sequestrants, fibric acid derivatives, niacin and nicotinic acid, cholesterol uptake inhibitors, fish oil (including omega 3 ethyl esters), as well as plant stanols and other OTC products where appropriate. Treatment will be in accordance with current NCEP guidelines.[1,2]

- Antihypertensive agents: diuretics, beta-blockers, calcium channel blockers, ace inhibitors, alpha blockers, angiotensin II antagonists, renin inhibitors, vasodilators, and centrally acting alpha adrenergic agonists where appropriate**.** Treatment will be in accordance with current Joint National Committee (JNC) on Prevention, Detection, Evaluation, and Treatment of high blood pressure guidelines.[3]

- Antiplatelets/Anticoagulants: Antiplatelet drugs (both Rx and OTC), initiation of Coumadin (with referral to UH Coumadin Clinic for therapeutic drug monitoring/management), and low molecular weight heparins (LMWH) or anti-Xa medications for bridging purposes. In accordance with ACC/AHA and American College of Chest Physicians (ACCP) guidelines for primary and secondary prevention of CAD, guidelines for the management of patients with valvular disease, prevention of stroke in patients with atrial fibrillation, the AHA/ASA guidelines for the prevention of stroke, and AHA/ACC guidelines for the management of patients with peripheral arterial disease.[4-13]

- Diabetes agents: sulfonylureas, α- glucosidase inhibitors, meglitinides, metformin, thiazolidinediones (TZD), glucagon-like peptide 1 agonists (GLP-1 agonists), dipeptidyl peptidase 4 inhibitors (DPP-4 inhibitors), amylin agonists (pramlintide), glucagon, and insulin (including syringes) where appropriate. This would also include self monitoring blood glucose (SMBG) supplies including monitors, test strips, and lancets/lancet devices. Treatment will be in accordance with current American Diabetes Association Standards of Care.[14,15]

- Vaccinations: Vaccines will be ordered by the pharmacist clinician and given by the pharmacist clinician or another authorized healthcare provider in the clinic in accordance with the Centers for Disease Control Guidelines (available at: http://www.cdc.gov/vaccines/recs/default.htm) and as listed in the New Mexico Board of Pharmacy prescriptive authority protocol.

- Thyroid medications: T3 and T4. Hypothyroidism has been linked to elevated LDL and triglyceride values, both of which are risk factors for cardiovascular disease. TSH levels should be drawn at baseline and then 4-6 weeks after the initiation of therapy or dosage adjustment. Treatment will be in accordance with the American Association of Clinical Endocrinologist (AACE) guidelines for the treatment of hyper- and hypothyroidism. [16,17] Elderly patients and those with CHF or CAD will be started at low doses and monitored closely.

- Hormone replacement therapy (HRT): Conjugated estrogens, progesterones, estrogen/progesterone combinations, and estradiol.

HRT may be continued for menopause symptom control or may need to be refilled in order to taper the patient off of the medications. A risk/benefit assessment will be performed for every patient receiving or requesting HRT therapy. Should the need for HRT treatment outweigh the risk in an individual patient, dosage forms may need to be changed (i.e.: oral estrogen replacement to topical replacement) in the treatment of dyslipidemia. The Recommendations for estrogen and progestogen use in peri- and postmenopausal women: March 2007 position statement of The North American Menopause Society or the most recent evidence-based literature will be used as guidance to treat and monitor patients with HRT.[18]

- Gastrointestinal medications: H_2 blockers, metoclopramide, sucralfate, and proton pump inhibitors for the treatment of gastroesophageal reflux (GERD). Often times in patients with chronic heart failure, it may be difficult to ascertain whether pain has a cardiac or non-cardiac etiology. Based on information from the patient (i.e.: temporal relationship of pain with meals or symptoms in relationship to foods known to exacerbate GERD), an empiric trial of H_2 blockers or PPI's may be attempted to rule out worsening cardiac disease. Patients with documented esophageal dysfunction or gastroparesis secondary to diabetes mellitus may also present with non-cardiac related chest pain or discomfort. H2 blockers and PPIs may also be used for GI protection in patients using anti-inflammatory/antiplatelet drugs.[19-22]

- Anti-inflammatories: NSAIDS, COX-2 inhibitors, and salicylates for refill and dosage modification purposes only. All new disease state findings will be discussed with supervising physician.[23]

- Metered dose inhalers/dry powder inhalers for the treatment of COPD/asthma. Additionally peak flow monitors, pulse oximetry, and pulmonary function tests may be ordered. All new disease state findings will be discussed with supervising physician.[24,25]

- Electrolyte replacement/dietary supplements. This would include agents used in the treatment of electrolyte abnormalities (i.e.: potassium and magnesium,) and anemia (i.e.: B12, folic acid, iron, or multivitamins).

- Antidepressants: Serotonin reuptake inhibitors, tricyclic antidepressants (TCA's,), and other antidepressants as indicated. Due to the high prevalence of cardiac and diabetes related depression, patients will be assessed and monitored for depression as clinically indicated using a validated tool such as the Geriatric Depression Scale or the Becks Depression Inventory.[26-29]

- Smoking cessation: Nicotine gum, patches, lozenges, inhalers, or nasal sprays; buproprion as deemed clinically appropriate per patient or referral to a smoking cessation program. Choice of product will need to each patient's needs. PhC's will follow the recommendations based on the U.S. Department of Health and Human Services Clinical Practice Guidelines and and as listed in the New Mexico Board of Pharmacy prescriptive authority protocol.[30]

- Weight loss: Gastrointestinal lipase inhibitors (i.e.: orlistat.) Obesity is a risk factor for cardiac disease. Therapeutic life style modifications are the first line treatment (i.e.: diet and exercise) for weight loss, however not all patients are able to obtain their goal body weight (within 10% of their ideal body weight.) Should it be deemed necessary for a patient to receive a prescription for such medications, it would only be done in conjunction with referral for nutritional counseling.[31]

- Anti-arrhythmics: Class I-III anti-arrhythmics, digoxin, or calcium channel blockers (for refill and dosage modification purposes only). All new disease state findings will be discussed with supervising physician.[8,32]

- Anti-anginals: Beta-blockers, calcium channel blockers, ranolazine, and nitrates as indicated. Treatment will be in accordance with recent AHA/ACC guidelines for the management of patients with stable chronic angina.[33,34]

- Diuretics: Thiazides, loop diuretics, aldosterone inhibitors, potassium sparing diuretics, vasopressin antagonists, and nesiritide. These medications will be used in combination as clinically necessary to treat CHF and its associated symptoms of edema. Choice of medications and dose regimen will be individualized to each patient as clinically tolerated. The supervising physician will be notified should the patient become unresponsive to the prescribed diuretic regimen. Treatment will be in accordance with the ACC/AHA guidelines for the treatment of heart failure.[35]

- Congestive Heart Failure: For Stages A – D Systolic Heart Failure and Diastolic Heart Failure, therapeutic lifestyle modifications and medications will be managed according to the AHA/ACC Guidelines for heart failure.[35]

- Antibiotics: Amoxicillin, cephalexin, clindamycin, azithromycin, or clarithromycin for use in endocarditis prophylaxis for dental procedures as per ACC/AHA guidelines for the management of patients with valvular disease.[7]

- Medication Review: All patients' medications will be routinely reviewed for appropriateness of therapy. The review may include identification of drug-drug interactions, inappropriate dose and duration, drug-disease interactions, no necessity of the drug based on medical conditions, and therapeutic duplication. As a result of this review, medications may be adjusted, discontinued or tapered off. Refills of any non-controlled substances prescriptions may be made during this review to ensure adherence with maintenance therapy.

- Medications deemed appropriate per consultation with PCP or supervising physician.

6. Laboratory and diagnostic tests to be ordered where appropriate (including, but not limited to):

   - Liver function tests—sequential testing will be performed at specified intervals to monitor for potential toxicity.
   - Fasting complete lipoprotein profiles (Total cholesterol, LDL, HDL and triglycerides), or individual lipoprotein elements where appropriate.
   - Thyroid function tests.
   - Hemoglobin/Hematocrit or complete blood count (CBC)
   - Glycosylated hemoglobin (HbA1c), blood glucose, C-peptide, and OGTT.
   - Renal function tests
   - Urinalysis
   - Electrolytes
   - hs-C-reactive protein (CRP)
   - B-type natriuretic peptide (BNP)
   - Coagulation panel
   - Iron studies, B-12, folate
   - Homocysteine
   - Therapeutic drug monitoring
   - Labs and/or diagnostics deemed appropriate for assessment and evaluation by the PCP
   - ECG and echocardiograms.
   - Treadmill, nuclear stress tests, and cardiac catheterization upon consultation with the supervising physician.
   - Pulmonary function tests (PFT's)
   - Sleep study
   - Chest X-ray
   - Ankle-brachial index (ABI)

7. Clinical pharmacy services for cardiovascular research studies will be those services required by the clinical research protocol to be provided by either the principal investigator or co-investigator.
    - Performing required physical examination procedures.
    - Ordering and interpretation of required diagnostics, such as laboratory tests, electrocardiograms, chest radiographs, echocardiograms, etc.
    - Initiating and titrating study medication per research protocol and writing medical orders for research studies.
    - Initiating and adjusting concomitant medication as necessary per research protocol.
    - Providing patient education regarding the research protocol.
    - Administration of research-related medications.
    - Submission of consult requests for other medical services when appropriate.

8. All clinic notes will be scanned, typed and/or dictated into the patient's electronic medical record at UNMH.

9. Quality Assurance: The supervising physician will review at least 20% of the PhC charts and meet with the PhC periodically (at least once every 3 months) to review cases.

10. Patients will be referred back to their PCP or urgent care for any new signs or symptoms of illness regardless of etiology for appropriate assessment. If the new symptoms are deemed urgent, the PCP and/or supervising physician will be immediately consulted for further instructions.

Pharmacist Clinician:

Pharmacist Clinician Name (printed): _____

Pharmacist Clinician (signature) _____
_____, R.Ph., Pharm.D., PhC

Supervising Practitioner:

Physician Name (printed): _____

Physician (signature): _____
_____, MD

Alternate Supervising Practitioner(s):

Physician Name (printed): _____

Physician (signature): _____
_____, MD

Physician Name (printed): _____

Physician (signature): _____
_____, MD

Physician Name (printed): _____

Physician (signature): _____
_____, MD

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