

Appendix A: The patient workup process

Clinical Drug Monitoring

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1. Identify issues that need to be discussed with the patient.....	1
2. Interview the patient.....	2
3. Collect objective data.	4
4. Define current medical problems.	4
5. Determine the goals for the therapy of each of the patient's medical problems.....	4
6. Analyze the subjective and objective data to determine your patient's drug-related problems.....	5
7. For each drug-related problem, identify all reasonable therapeutic alternatives.....	6
8. Choose and individualize the best therapeutic option.	6
9. Design a monitoring plan for efficacy and toxicity.....	6
10. Document your decision-making process.	6
An Example	7

It's your first clerkship. You followed the rules in the first chapter: contacted your pharmacist preceptor and set up the time and place to meet. You put on your cleanest lab coat, made sure your student name tag was pinned right side up, arrived at your site early, and received your orientation. Your preceptor has just assigned you a patient and has left you on your own. What do you do now?

1. Identify issues that need to be discussed with the patient.

You absolutely must talk with the patient. You will feel more comfortable interviewing the patient, however, if you can determine some discussion issues. To do this, you will first want to scan the patient's chart or profile. Consider:

- The current medication list. You will find this on the patient profile or most recent medication administration record (MAR). What medications has the patient been prescribed? What likely disease states does he/she have?
- Compliance/Adherence (patient profile or most recent MAR). How often does the patient get his or her chronic medications refilled? In an institutional setting you will want to glance at the MAR to see if the patient has been receiving or refusing his or her medications.
- Disease state control (recent progress notes). Monitoring notes written previously by health care providers will be useful in an institutional or clinic ambulatory setting. If you are at a community pharmacy setting, however, you may not have extensive documentation of previous disease state control available. Look for disease state monitoring data obtained through interview, physical examination, and laboratory values. Well-written progress notes will include this information.
- Cost (patient profile will contain costs; most recent MAR will not). Are any chronic medications high cost? Is there any indication that lower-cost agents have not worked? The physician's sample cabinet facilitates initiation of high-cost brand name products without preceding trials of low-cost agents.
- Adverse drug effects (recent progress notes). Are there any medications which may have been prescribed to treat side effects from other medications? When thinking about adverse drug reactions, you will find the "prn" portion of an MAR useful, since prn medications are often given to combat side effects from routinely scheduled medications. For instance, if the patient begins asking for a laxative shortly after beginning opiate therapy for pain, you will suspect opiate-induced constipation.

To summarize: prior to interview you will want to look at the patient's medication list in the chart or profile in any setting, the MAR in an institutional setting, and any previous care notes which would tell you how well the patient's disease states are controlled.

Note: You will notice that the first step is to quickly identify discussion issues, *not* to read the patient's chart from one end to the other. This is because the most important source of information that will generate your patient's problem list is not the chart: it is your patient. If you have not seen very many patient charts, it will be exceedingly easy for you to spend hours (literally) reading the chart, aimlessly writing down everything you see, and not identifying what information in the chart is important and what is not. Only after the patient interview can you use the chart information efficiently.

2. Interview the patient.

Now you need to obtain subjective information from the patient. This is the single most important step in the database-building process. You need to make it a priority to interview every single patient assigned to you, unless the patient is intubated or comatose.

Before beginning the interview, you will need to introduce yourself and explain your role on the health care team (which is to optimize the patient's drug therapy). Tell the patient you would like to ask him or her some questions about his or her medication use. Ask if this is a good time (you can expect that your first few interviews will probably take at least 10 minutes if patient's drug regimen is simple, and longer if regimen is complicated. Don't worry about the time involved at this point! You will get faster with practice.) If it is not a good time (e.g., the patient is in a hurry, has visitors, or is going for a diagnostic test), schedule another time with the patient.

What information do you need to obtain? How can you make sure you gather that information completely and consistently? Experienced clinicians use the Standard Organization for Patient History and Physical Database (see Figure 1) as a mental "nudge" for directing the interview. You may choose to design your own data collection form. Regardless of the data collection method you select, your pharmaceutical care database must include detailed information about medication use:

Prescription Medications. Review all prescription medications that the patient is currently taking. For each drug, note:

- Drug, dose, route, frequency, indication (this is the *patient's* version of the indication).
- Efficacy ("Tell me how you know that this medication is working for you.")
- Toxicity ("Are there any problems that you are having which you think may be caused by this medication?"). If the patient says "no", then probe with a few of the most common side effects.
- Compliance ("How often do you actually take this medication?" or "Tell me what interferes with your ability to take the medication regularly.") What does the patient do if a dose is missed? Try to verify if cost, dosing frequency, adverse effects, or personal beliefs may be an obstacle to patient compliance. If your patient is able to state clearly how s/he ensures that all drugs and doses are taken on time and as prescribed, then you will feel more comfortable trusting their compliance self-assessment.
- Medication management issues. How does the patient store his or her medications? Is the patient able to administer the medication easily (e.g., tablet size can sometimes be a problem)? How many physicians does the patient see? What is the name and number of the pharmacy(ies) at which the patient gets his or her prescription filled? How does the patient remind him/herself to obtain refills? Is transportation to physician or pharmacy a problem? Inquire about technique and maintenance of devices (such as spacers, peak-flow meters, blood pressure or blood glucose monitors) used to facilitate drug delivery or monitor drug therapy. Have the patient demonstrate their inhaler use technique to you.

Non-prescription Agents. These include over-the-counter (OTC) medications, herbal and other natural remedies, vitamins and minerals, and non-drug therapy. Inquire about non-prescription agents used by the patient using the "head to toe" Review of Systems approach as follows. In addition to gaining valuable information about non-prescription agents the patient uses routinely or infrequently, you will also often

identify disease states which you may not have identified through your prescription medication portion of the interview.

- HEENT: nose, ear, or eye drops; nasal inhalers; analgesics used for headache or sinus pain; dental products.
- Respiratory tract: antihistamines, decongestants, OTC inhalers.
- GI: antacids, antiflatulants, antidiarrheals, laxatives, hemorrhoidal preparations.
- GU: urinary antibacterials; vaginal antiinfectives; usual amount of fluid consumed daily, what kind of fluid (e.g., soda pop versus water versus lite beer).
- Musculoskeletal: aspirin, anti-inflammatory agents, acetaminophen, or combination pain medications
- Dermatological: psoriatic, seborrheic, antiinfective, or analgesic topical preparations; corn/callus pads or other foot care.
- Hematological: consider iron, B12, folate.
- Overall/system-wide: insomnia or motion sickness medications; vitamins; herbal, homeopathic or other alternative healthcare products. Ask about tobacco and alcohol use, noting favored product, quantity, frequency, and duration of use. Ask the patient in a straightforward manner ask if he or she ever uses non-prescribed drugs for recreational purposes. The patient may not be honest with you about use, but they are more likely to be honest if you ask in a matter-of-fact manner.

Establish how often the medical problem occurs, if the non-prescription therapy works, and if it causes any side effects. Inquire where your patient usually buys non-prescription products (i.e., is there a pharmacist or other health care professional available there to answer questions about the products?) and how he or she obtains answers to questions about non-prescription products.

After you have finished going over both prescription and OTC medications and non-drug therapy for problems the patient may note, review with the patient the list of disease states that the patient appears to have. Ask them what disease states or medical problems you have missed.

Inquire about allergies and adverse drug reactions (ADRs). For each drug that the patient states, obtain as much of the following information as possible.

- Name of drug to which reaction occurred. Occurrence of similar reaction when drugs in same class taken. Number of times the same drug was used prior to reaction, without adverse sequelae.
- Reason patient took drug. Likelihood of viral infection preceding drug use.
- Complete description of physical symptoms of reaction. Conduct physical assessment if ADR currently in progress. Differentiate between hives and maculopapular rash.
- Timing of reaction versus administration of drug (e.g., "How soon after you took the drug did this reaction happen?" "How many days or doses into therapy were you when this reaction occurred?"). Any information you can obtain about other medications that were started around the same time that the reaction occurred may also be useful.

Level of general disease state knowledge. Ask the patient if s/he can describe the disease (e.g., "Just to give me an idea of your understanding of congestive heart failure, please describe what is happening."). Probe for understanding of the effects of overtreatment, undertreatment, or sporadic treatment of the disease (e.g., "Tell me what long-term complications you may avoid if your blood pressure is lowered."). Ask about therapies used previously for each disease state. Note drug names, doses, frequencies, duration of use, efficacy, toxicity, and compliance for each medication previously used.

Overall attitude about medications and disease states. (e.g., "Tell me how you feel about medication use, in general." "How do you feel your medications impact your quality of life?") These questions could give you some important tips about cultural and personal beliefs that might affect current or future drug therapy.

Patient height and weight. Obtain this verbally if you cannot measure the patient yourself or do not have access to recent weight and height determinations made by other health care professionals.

3. Collect objective data.
 - Conduct any physical examination necessary to test your drug-related problem hypotheses.
 - Check current and past laboratory data. Have there been any changes which might support drug efficacy or toxicity?
 - Review diagnostic tests to determine if any support drug efficacy or toxicity. These will also give you an idea of the severity of the patient's medical problems.
 - Call the patient's pharmacy if you have any questions about current prescription drug doses. You can also ask about refill patterns to confirm compliance.

If you would like to obtain information from an objective parameter that has not previously been ordered, you will need to be able to explain to your preceptor why the objective information you wish to obtain will be helpful and cost-justified in confirming your tentative pharmaceutical diagnoses. Be able to justify which of the tests or procedures must be done immediately and which ones can be delayed until the most emergent problem(s) is/are addressed.

4. Define current medical problems.

After you have collected both the subjective and objective data, you will need to make a list of all the patient's *current* medical problems—those problems that the patient is experiencing or being treated for at this time. These medical problems should be numbered and placed in order of importance starting with the medical problems needing the most immediate attention (you will need to justify to your preceptor *why* they need immediate attention) and ending with the problems that can be addressed later. When you have done this, you can move on to step #4.

5. Determine the goals for the therapy of each of the patient's medical problems.

You must determine a goal for each medical problem for which the patient will receive drug or non-drug therapy. Trying to solve a problem without first setting a therapeutic goal is similar to getting into a car and starting to drive before you decide where you want to go: you will waste a lot more time and fuel than if you plan your destination and check the route before getting into the car. The four primary goals for therapy include:

- Cure a disease (e.g., infection)
- Eliminate or reduce a patient's symptoms (e.g., pain control, congestive heart failure)
- Arrest or slow a disease process (e.g., diabetes, cholesterol reduction to reduce risk of coronary heart disease)
- Prevent a disease or other unwanted condition (e.g., immunization, contraception)

There are other secondary goals that you (and the patient!) will have. Attaining these secondary goals will maximize your ability to attain the patient's primary goals. Secondary goals include:

- Avoidance of adverse effects
- Convenience
- Cost-effectiveness
- Education of the patient

For each goal, you will need to determine a measurable, patient-specific endpoint. The endpoint can be objective (e.g., measuring the blood pressure of a patient with hypertension) or subjective (e.g., patient self-rating of their cancer pain using a pain scale). You must use the same method of endpoint measurement each time you test for goal attainment in order to ensure comparability of the measurement with past measurements. As you tailor your goal to your patient, remember that the goal must be reasonable. For example, it is probably not reasonable to set a goal of "no pain" for a patient with severe rheumatoid arthritis. Instead, you will try to decrease the pain to a level where the patient can perform most of the necessary activities of daily living.

You have now collected and organized the patient's subjective and objective data, and determined the patient's medical problems and the goals for those problems. You are now ready to determine and address your patient's drug-related problems.

6. Analyze the subjective and objective data to determine your patient's drug-related problems.

You will have learned about drug-related problems (DRPs) in your pharmacy school curriculum (*Figure 2* contains one example). To help identify whether or not your patient has any actual or potential drug-related problems, ask yourself the following questions about each of the medications:

- Is the treatment working? If the answer is "no," there could be several explanations: undercompliance, drug ineffectiveness, a dose that is too low, or a drug interaction that has led to a lower than desired serum drug concentration.
- Is the treatment causing toxicity? Could any of the medical problems be drug-induced? Are any abnormal laboratory values drug-induced?
- Are the doses correct? Consider the patient's age (especially pediatrics and geriatrics), weight, renal and hepatic functions, dosing schedule, and dosage form (regimen convenience, possible need for sustained release products, cost effectiveness).
- Is the patient taking the medications as prescribed? Is there evidence of non-compliance, overuse or underuse by the refill patterns as indicated by your computer? If "yes", try to find out why (confusing regimen? cost? side effects? personal or cultural beliefs about the medication or disease states? presence of interacting drugs?).
- Is the regimen cost-effective? Is there any medication that the patient is taking for which there is a lower-cost alternative? If so, has that alternative been tried already? If the alternative has been previously used, was the dose maximized? Are all medications covered by the patient's insurance company? Is there any evidence of therapeutic duplication? Could more than one of the patient's medical problems be treated with one drug?
- Are there any contraindications to be considered? If the profile indicates prior allergies, the current regimen should be screened for possible cross-reacting drugs. If the patient is receiving a potential cross-reacting drug without deleterious effect, this needs to be noted for future therapeutic consideration. Consider and inquire about the possibility of pregnancy in women of child-bearing age who are not using oral contraceptives and who are to receive a medication that could adversely affect a fetus.
- Are there any drugs prescribed for the patient with no apparent indication? If the answer is "yes", either you have failed to identify one of the patient's medical problems, you have overlooked an unusual use of a drug specific to this patient, or you have identified a possible inappropriately prescribed drug. You should investigate further and make necessary interventions.
- Are there any medical problems (diagnoses) identified by the prescriber or you for which no drug therapy has been prescribed? If the answer is "yes," it may be appropriate (e.g., a patient with Type II diabetes who has been able to achieve acceptable blood glucose control with diet alone). On the other hand, perhaps you failed to identify a drug that was prescribed for the patient, you misunderstood the indications for a drug that you thought was being used for something else or the prescriber has inadvertently forgotten to order something for that patient. You should investigate further and develop a plan for any necessary interventions.

Using the questions above, you should develop a list of drug-related problems. Each drug-related problem should correspond to one of the medical problems. It is helpful to write the lists alongside each other.

In addition to determining the drug-related problems, you must also be able to justify why you think they exist. What signs and/or symptoms led you to suspect the drug-related problem? Be able to defend the existence of problems you detect.

7. For each drug-related problem, identify all reasonable therapeutic alternatives.

Consider various drug classes and non-drug therapy as you think about the different ways you could go about solving each drug-related problem. For each therapeutic option, determine:

- the evidence for efficacy
- the likelihood and severity of adverse medication effects
- the number of daily doses
- the impact (either positive or negative) of the option on the patient's other diseases
- the cost relative to the other agents.

You will have learned much of this information in your therapeutics series, but you may have forgotten some of it, so you must plan to do a lot of re-reading during your clerkships. Additionally, you should make it a practice to search the primary literature regularly to determine the most effective treatments. The ability to clearly summarize the most recent evidence supporting (or disputing) each treatment option will allow you to provide the best care possible for your patient. Your preceptor will query you extensively about the therapeutic alternatives for your patient, so do not neglect this important step!

8. Choose and individualize the best therapeutic option.

If you have done a good job collecting and evaluating the benefits and hazards of each of your therapeutic options, then choosing the most reasonable therapeutic option should be easy. You must then individualize that option to fit the characteristics of your patient. This is where knowledge about height and weight (for pharmacokinetic dose considerations), concomitant diseases and medications (for drug-disease and drug-drug interactions), and compliance history (to determine frequency of doses) will be vital. If your plan includes drug therapy you will need to specify the drug, dose, route, frequency, and duration of therapy. All drug and non-drug plans should include some degree of patient education.

9. Design a monitoring plan for efficacy and toxicity.

After choosing a therapeutic regimen, you will need to design a plan that will allow you to see if the drug or non-drug therapy works, and if it causes any problems. Your plan should be specific. You need to think about exactly *what* will be measured, *who* will do the measuring, *how often* it will be done, *when* you will worry, and what your backup plan will be. You will need to be able to defend to your preceptor your choice of what you measure and how often you measure it. This will be easy if the monitoring parameter is cheap, quick, and noninvasive, but more difficult for expensive, lengthy, or invasive measures.

10. Document your decision-making process.

It is professionally unacceptable and legally dangerous to provide care for a patient and not record your care decisions and the reasoning behind those decisions. Your clerkship experiences will be valuable because you will have enough time to gain the practice you need to produce a brief yet informative note in a short amount of time.

An Example

Scenario: you are a pharmacy student on your first day of practicum at a community pharmacy. Mr. Smith, a 68 year-old gentleman who has been a patient this pharmacy for several years, enters the store and presents a prescription for Coumadin 2mg #30, i po qd. Your preceptor asks you to take care of Mr. Smith. You have available to you Mr. Smith, his pharmacy profile, and a sheet of his laboratory values, which your preceptor has trained him to bring every time he comes to the pharmacy. The following information is the history and physical data you are able to obtain, your assessment of Mr. Smith's situation, and your chart note.

Patient history and physical database:

ID: 68 year-old male

CC: needs increase in warfarin dose due to decreased efficacy of past dose

HPI: Takes warfarin daily for DVT prevention. INR today was 1.5 and so physician has decided to increase his warfarin dose from 5mg po qd to 7mg po qd.

PMH:

DVT, 2 months ago

hip replacement surgery, 3 months ago

atrial fibrillation, single episode 4 years ago; currently in NSR

CHF, diagnosed 7 years ago

COPD, diagnosed 5 years ago

Anterior MI, 14 years ago; no current chest pain

DH:

warfarin 5mg po qd x 2 months (DVT; same dose since discharge from hospital 2 months ago)

digoxin 0.25mg po qd x 7 years (CHF)

ipratropium 2 puffs QID x 9 years (COPD)

albuterol 2 puffs QID x 9 years (COPD)

OTC medications:

multivitamin with iron and minerals, i po qd x 7 months

psyllium i scoop in glass of water for constipation, daily x 4 years

bismuth salicylate 4 tablespoonfuls prn diarrhea (took 1 dose twice in the past year for stomach flu)

alfalfa tabs 2-3 qd for health; friend recommended this to him about a month ago

garlic capsules 1-2 qd for "flu prevention;" friend recommended this to him about a month ago

medication refill records indicate that he obtains refills on time; he obtains all prescription and OTC medications from this pharmacy; he bought alfalfa tabs and garlic capsules at health food store

recreational drug use:

40-pack year smoking history: quit 2 years ago

occasional alcohol use: 1-2 drinks/week; no recent change in that amount

allergies: denies history of medication or environmental allergies

FH: father died of AMI at age 54

SH: retired; lives with spouse who assists with medication management at home; denies any changes in ingestion of vitamin K containing foods

ROS: no current complaints

lungs: clear sputum, no spells of coughing recently; denies shortness of breath (SOB), dyspnea on exertion (DOE), paroxysmal nocturnal dyspnea (PND), sleeps with one pillow; is comfortable walking short distances (no change from 3 months ago)

CV: denies chest pain

skin: denies bleeding or bruising

GI/GU: stools dark brown; urine clear, yellow, denies blood

PE:

5'10", 80 kg today (usual weight)

HR: 85, regular rhythm BP: 135/82 RR: 20 temp 37.2

No bruising found on arms, legs, or face.

Pertinent Labs:

Today	2 weeks ago	4 weeks ago	6 weeks ago	8 weeks ago (at discharge)	8 weeks ago
INR: 1.5	INR: 1.9	INR: 2.4	INR: 2.6	INR: 2.3	Alb: 4.5

Current medical problems	Goal of therapy	Measurable endpoint
1. Recent DVT	prevent recurrent thromboembolism	therapeutic INR
2. CAD	prevent angina and MI	no anginal episodes
3. CHF	symptom control	no episodes SOB, edema, PND
4. COPD	symptom control	no DOE, SOB, PND

Current drug-related problems	Justification	Therapeutic alternatives
1a. underanticoagulation (wrong dose? drug interaction?)	Subtherapeutic INR Possible causes: Diet (no recent change) EtOH (patient denies) Underlying disease state change (no evidence to support) Drug interaction (recent addition of natural product which contains varying amounts of Vitamin K) Compliance (no evidence of noncompliance)	increase warfarin dose (problematic considering inconsistent amount of vitamin K in alfalfa tablets) discontinue (D/C) alfalfa heparin (prolonged heparin use would be more expensive than warfarin; short-term LMW heparin use might save cost of ultrasound to check for clot formation)
2a. inadequate MI prophylaxis (needs drug?)	Current AHCPR guidelines recommend aspirin and beta-blocker for all patients post-MI unless contraindicated	ASA 81mg po qd (lower dose will minimize risk of bleeding) ASA 325mg po qd beta-blocker (contraindicated secondary to CHF + COPD)
3a. inadequate CHF and post-MI mortality benefit (needs drug?)	Current ACC/AHA guidelines recommend ACEI for all patients with CHF; SAVE, AIRE, and TRACE trials support use post-MI to reduce mortality	ACE inhibitor angiotensin receptor antagonist
4a. COPD overmedicated (wrong drug?)	1995 study conducted in the Netherlands showed increased costs and no additional benefit of two bronchodilators over one alone	D/C albuterol (preferred due to CHF) D/C ipratropium

Recommendation	Monitoring Plan
<p>1. anticoagulation D/C alfalfa tablets. Start enoxaparin 80mg (1mg/kg) SQ q12h. D/C when INR \geq 2.0. Continue warfarin at current dose. Instruct patient to self-administer SQ medication.</p>	<p>Return for INR check in 5 days Patient to self monitor for signs/symptoms (S/S) of DVT: calf warmth, tenderness or pain. Patient to call provider immediately if experiences chest pain or SOB. Patient to self-monitor for S/S minor, moderate, and major bleed: visual check for gum, urine, stool, skin bruising, epistaxis.</p>
<p>2. MI prophylaxis ASA 81mg po qd</p>	<p>Patient to self-check for bleeding as noted above. Stool guaiac in 3 months.</p>
<p>3. CHF/post-MI mortality benefit lisinopril 5mg po qd; first dose at bedtime; titrate dose upward weekly to maximal doses (20mg po q12h) as tolerated per BP and serum creatinine (SCr).</p>	<p>Check BP in one week (goal SBP 100-120) Check SCr now for baseline and again in one week. Patient to self monitor for and report dizziness/lightheadedness and any increase in coughing frequency.</p>
<p>4. COPD D/C albuterol</p>	<p>Patient to self-monitor for and report any increased incidence of SOB, DOE, PND</p>

Today's date and time

Pharmacy note regarding anticoagulation and other drug therapy for 68-year old white male.

S:

- Pertinent medical history: DVT, 2 mos ago; CHF x 7 yrs; COPD x 5 yrs; anterior MI, 14 yrs ago
- ROS: denies coughing, SOB, DOE, PND, chest pain, bleeding or bruising, blood in stool or urine
- occasional alcohol use: 1-2 drinks/week; no recent change in that amount
- denies any changes in ingestion of vitamin K containing foods; has taken alfalfa tabs 2-3 qd x ~1 mo per friend's advice (for general health)

O:

1. 5'10", 80 kg today (usual weight) HR: 85, regular rhythm BP: 135/82 RR: 20
2. No bruising found on arms, legs, or face.
3. INR: 1.5, today; 1.9, two weeks ago; 2.4, four weeks ago; 2.6, six weeks ago; 2.3, at discharge eight weeks ago
4. Pertinent prescription medications: warfarin 5mg po qd (same dose x last 2 mos), ipratropium 2 puffs QID, albuterol 2 puffs QID

A:

1. INR \leq 2.0 associated with \uparrow risk of recurrent DVT. Addition of alfalfa coincides with \downarrow INR control. D/C of alfalfa preferable to increasing warfarin dose since varying vit K tablet amount confounds dose titration. Since patient shows no signs/symptoms of acute DVT, addition of outpatient enoxaparin for a few days until INR in therapeutic range would be more cost-effective than admission to hospital to watch for recurrent DVT.
2. Suboptimal CHF and post-MI mortality benefit. Addition of aspirin for CAD and ACE inhibitor for CHF and post-MI associated with \downarrow mortality. Beta-blocker use also associated with \downarrow risk of subsequent MI but is relatively contraindicated in this patient because of CHF and COPD.
3. Dual bronchodilator therapy not superior to single-bronchodilator therapy for COPD (Am J Resp Crit Care Med 1995;151:975). Ipratropium preferred over albuterol in this patient due to CHF.

R:

1. D/C alfalfa tabs. Start enoxaparin 80mg SQ q12h. D/C when INR \geq 2.0. Continue warfarin at current dose. Teach patient how to self-administer SQ medication. Return for INR check in 5 days. Instruct patient to self monitor and report: calf warmth, tenderness or pain; chest pain or SOB; excessive blood in gums, urine, stool, nose, dermis.
2. Start: ASA 81mg po qd; lisinopril 5mg po qd; first dose at bedtime; titrate dose up by 5mg qweek to max 20mg po qd as tolerated per BP (\sqrt in 1 wk; goal: SBP 100-120) and SCr (\sqrt today and in 1 wk). Patient to report any dizziness or \uparrow coughing.
3. D/C albuterol. Patient to report any \uparrow in SOB, DOE, PND.

Pharmacist signature