

HIGH BLOOD PRESSURE TREATMENT PROTOCOL FOR PATIENTS IN HAITI, INCLUDING WHEN LABORATORY MONITORING IS NOT AVAILABLE

There are a number of ways to approach the treatment of the patient with high blood pressure when laboratory testing is not available. The following is one approach.

Naturally, the particular circumstances of the individual patient and the experience and clinical judgment of the individual medical practitioner will lead to modifications of this protocol or even a different treatment protocol altogether. However, in the hope of providing concrete and usable information to the volunteer medical health care provider working in Haiti, the following treatment protocol is offered as a potential starting point.

The medications that are used in this protocol are very cost effective in order to increase the feasibility of making a sustained effort to treat hypertension in this setting.

(At wholesale prices, the cost of a 3 drug regimen is 10 cents/day.)

PLEASE READ CAREFULLY:

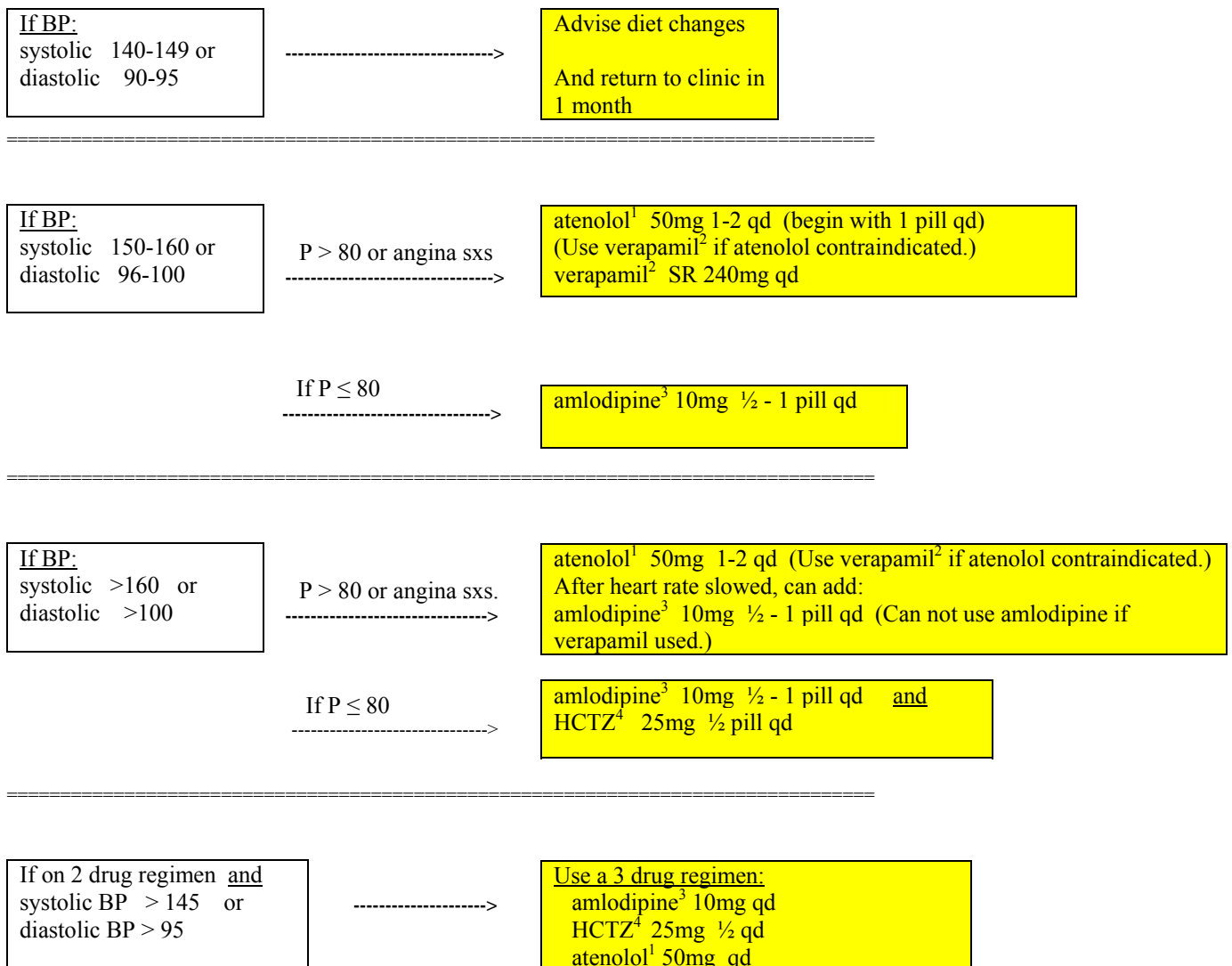
Prior to the use of any treatment protocol for hypertension, the medical practitioner should be personally knowledgeable of the complete side effect profile of every medication that is prescribed.

The following protocol is simply an approach to consider, with the final treatment decision to be made by the medical care provider seeing the individual patient while taking into account the particular clinical conditions that exist.

HIGH BLOOD PRESSURE TREATMENT PROTOCOL WHEN LAB MONITORING IS NOT AVAILABLE

- If a patient has a contraindication or develops a significant side effect with a medication, delete that medication from the protocol.
- The prescribing health care provider must be personally knowledgeable about the complete side effect profile of every medication prescribed. Final treatment decisions are to be made by the health care provider in the context of the particular conditions that exist for the individual patient.
- All patients treated for hypertension should be advised to decrease salt intake and increase fruit and vegetable intake.
- *If the patient develops profuse diarrhea or sustained nausea and vomiting, hold both the diuretic (HCTZ) and the ACE inhibitor therapy (lisinopril) until gastroenteritis resolves. (It may be necessary to hold other blood pressure medications as well.)*

BP TREATMENT FLOW CHART- IF NO LAB AVAILABLE:



HIGH BLOOD PRESSURE TREATMENT PROTOCOL WHEN LAB MONITORING IS NOT AVAILABLE (continued)

If on 3 drug regimen and
systolic \geq 150 or
diastolic \geq 100

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Have patient seen by a practioner experienced in the treatment of hypertension in order to consider adding lisinopril⁵ 20mg ½ - 1 pill qd

Special situation:

*If prior to the earthquake, the Haitian patient was **recently** on an ACE inhibitor (usually enalapril) in a laboratory monitored situation and was doing fine, the protocol can be adjusted.* (Similar situation applies, if patient had recently been on an angiotensin receptor blocker in a lab monitored setting.) In that case lisinopril 20mg ½-1 qd can be considered earlier in protocol if no newly developed contraindications such as dehydration have developed.

Footnotes to medications:

Atenolol¹ use can be limited by the development of bronchospasm or excessive slowing of heart rate, particularly if accompanied by lightheadness. (Atenolol always slows heart rate.)

Beta blockers can also cause impotence.

Beta blockers can be less effective for the treatment of hypertension in blacks.

However, there is so much mixed ancestry in Haiti, that it is unclear whether this concern has significant general applicability to Haiti.

Verapamil² can not routinely be combined with atenolol (a beta blocker) or amlodipine.

The slow release formulation of verapamil which is needed for hypertension is relatively much more expensive than the other medications in this protocol.

Verapamil can cause excessive slowing of heart rate, constipation, and GI upset.

Amlodipine³ can at times cause the development of increased heart rate and angina.

HCTZ⁴ (**hydrochlorothiazide**) use in the unmonitored lab setting should be limited to a maximum dose of 25mg ½ pill qd. In the lab monitored setting, HCTZ can be used at a dose of 12.5- 50mg. The higher the dose, the greater the tendency for potassium loss. Using a dose of 12.5 mg minimizes potassium loss and side effects. HCTZ use should be accompanied by the advice to eat 1 additional piece of fruit daily (banana, tomato, or citrus fruit) to minimize potassium loss.

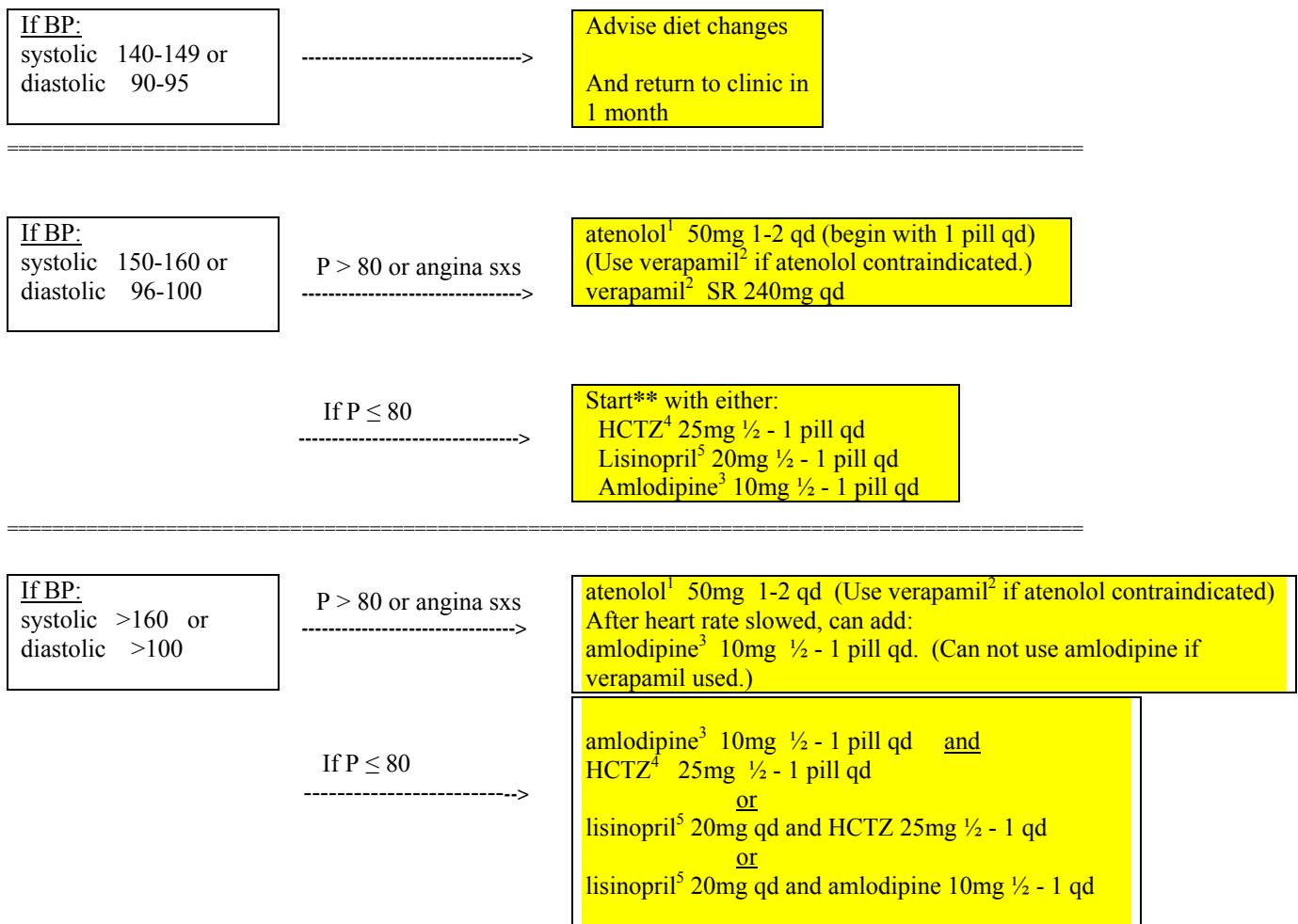
Lisinopril⁵ in this setting should not be used in patients with dehydration because of the increased risk of renal dysfunction. Lisinopril tends to increase potassium levels.

Lisinopril (as well as any other ACE inhibitor) is not to be used during pregnancy.

HIGH BLOOD PRESSURE TREATMENT PROTOCOL WHEN LAB MONITORING IS AVAILABLE

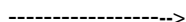
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BP TREATMENT FLOW CHART- LAB MONITORING AVAILABLE:



HIGH BLOOD PRESSURE TREATMENT PROTOCOL WHEN LAB MONITORING IS AVAILABLE (continued)

If on 2 drug regimen and
systolic BP > 145 or
diastolic BP > 95



Use a 3 drug regimen for difficult to control HTN:
amlodipine³ 10mg qd
lisinopril⁵ 20mg qd
HCTZ⁴ 25mg qd

A 4th medication can subsequently be added if needed:
atenolol¹ 50mg 1-2 pills qd

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**** Concerning the initial treatment of hypertension**

Many advocate routinely using HCTZ as the initial drug of choice in the treatment of hypertension on the basis of the ALLHAT trial and that trial's effect on subsequent meta analyses. However, this appears to be an inappropriate overgeneralization of the ALLHAT trial results. The ALLHAT trial had particular requirements for treatment protocols that do not mimic routine clinical practice. These include the prohibition of using lisinopril (an ACE inhibitor) with a diuretic as a second agent, the prohibition of using amlodipine with a diuretic as a second agent, and the prohibition from using amlodipine in combination with lisinopril which is a synergistic combination frequently used in clinical practice. For further details see:

<http://www.improvingmedicalstatistics.com/ALLHAT%20Trial%20Critique.htm>

In fact, the subsequent ACCOMPLISH trial found that the combination of an ACE inhibitor with amlodipine compared favorably with HCTZ for the initial treatment of hypertension.

For details: <http://content.nejm.org/cgi/content/short/359/23/2417>

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Why were verapamil, diltiazem, and clonidine not recommended as primary drugs in this treatment protocol for hypertension?

They were not included for reasons of cost, compliance, and compatibility with other agents. It is worthy to note that short acting generic drugs that require a long acting formulation are almost always significantly more expensive than generic drugs in the same class of medication with an intrinsically long half life.

VERAPAMIL and DILTIAZEM are both calcium channel blockers, but affect the body so differently compared to amlodipine or nifedipine, that it is best to consider these drugs as being functionally a completely different type of medication. The reasons for not including these medications as primary medications in this protocol will be detailed with verapamil.

Verapamil is an option for treatment of a patient in a setting without laboratory monitoring. **VERAPAMIL is useful for the treatment of the patient with hypertension with an elevated heart rate or in the presence of angina when beta blockers can not be used.** Verapamil can also be useful for patients with hypertension and palpitations resulting from SVT or atrial ectopy.

However, it is not used more widely in this protocol for the following reasons:

1. Verapamil slows heart rate, though less than a beta blocker. Verapamil should not be used in combination with a beta blocker for the treatment of hypertension in this setting (Verapamil can be used in combination with a beta blocker in a closely monitored situation by an experienced clinician for a condition such as angina.)
2. Verapamil can not routinely be used with amlodipine or nifedipine because they are in the same class of medications (even though they have different effects).
3. Verapamil formulations which are not long acting need to be given as a bid or tid dosage which decreases compliance. Long acting formulations are preferable for the treatment of hypertension, having better documentation in the literature of benefit.
4. Long acting verapamil is much more expensive than amlodipine.

DILTIAZEM is not useful as a primary drug in this protocol for similar reasons. In addition, long acting verapamil has much better evidence from clinical trials compared to diltiazem that it favorably affects clinical endpoints when used for hypertension.

CLONIDINE:

Clonidine is potentially useful as a drug for hypertension in the unmonitored setting. Side effects of dry mouth, fatigue, and postural hypotension can all be assessed without any laboratory monitoring which is a beneficial feature. **A reasonable case can be made for including this medication for the treatment of hypertension with or without laboratory monitoring.**

However, clonidine was not included as an initial drug of choice in this protocol because of the following:

1. The bothersome side effects of postural hypotension, dry mouth, and fatigue are common with this medication. If side effects occur early on in treatment, the patient will be less likely to continue with any blood pressure treatment or even return for follow up, particularly when there is not a broad public campaign to increase the awareness of the need for maintaining a good blood pressure.
2. Clonidine is short acting and optimally given on a bid or tid schedule. This dosing frequency will lead to decreased patient compliance.
3. Long acting transdermal formulations of clonidine are available which significantly decrease the frequency of annoying side effects to the patient, but these are much more expensive and not suitable in this setting for that reason.
4. **For resistant, hypertension not responsive to other agents, a trial of clonidine 0.1-0.2mg qhs or clonidine 0.1mg bid added to other medications is a reasonable option.**

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I hope this information is helpful in the care of the Haitian population.

Eric Roehm, M.D. 04/2/2010

(Fellow of the American College of Cardiology)