Assessing Risks for Cardiovascular Disease: Blood Pressure Measurement and Lipid Profile Screenings

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Evidence-Based Medicine

- Use established guidelines to support you clinical decisions…
- Hypertension
  - JNC VII
- Hyperlipidemia
  - NCEP ATP-III

What is Hypertension?

Table 1. Classification and management of blood pressure for adults*

BP Classification	SBP* mm Hg	DBP* mm Hg	Lifestyle Modification	Initial drug therapy: Without Compelling Indication	Initial drug therapy: With Compelling Indications (See Table 8)
Normal	<120	and <80	Encourage		
Prehypertension	120–139	or 80–89	Yes	No antihypertensive drug indicated.	Drug(s) for compelling indications.‡
Stage 1 Hypertension	140–159	or 90–99	Yes	Thiazide-type diuretics for most. May consider ACEI, ARB, BB, CCB, or combination.	Drug(s) for the compelling indications.‡ Other antihypertensive drugs (diuretics, ACEI, ARB, BB, CCB) as needed.
Stage 2 Hypertension	≥160	or ≥100	Yes	Two-drug combination for most† (usually thiazide-type diuretic and ACEI or ARB or BB or CCB).	

DBP, diastolic blood pressure; SBP, systolic blood pressure.
Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BB, beta-blocker; CCB, calcium channel blocker.

* Treatment determined by highest BP category.
† Initial combined therapy should be used cautiously in those at risk for orthostatic hypotension.
‡ Treat patients with chronic kidney disease or diabetes to BP goal of <130/80 mmHg.

Benefits of Lowering Blood Pressure

- Antihypertensive therapy has been associated with reductions in incidence of:
  - Stroke 35–40%;
  - Myocardial infarction 20–25%;
  - Heart failure > 50%.
- In patients with Stage 1 Hypertension + CVD risk factors, a sustained 12 mmHg reduction in SBP over 10 years will prevent 1 death for every 11 patients treated.

Screenings vs. Diagnosis

- Pharmacists should remind patients that these BP measurements are SCREENINGS not diagnosis.
- Diagnosis of hypertension includes multiple BP readings on different days and physical examination.
- The physical examination should include:
  - An appropriate measurement of BP, with verification in the contralateral arm;
  - Examination of the optic fundi;
  - Calculation of body mass index (BMI) (measurement of waist circumference also may be useful);
  - Auscultation for carotid, abdominal, and femoral bruits; palpation of the thyroid gland;
  - Thorough examination of the heart and lungs;
  - Examination of the abdomen for enlarged kidneys, masses, and abnormal aortic pulsation;
  - Palpation of the lower extremities for edema and pulses; and neurological assessment.
- Pharmacists usually aren't performing this level of physical examination
- However, screenings identify the need for further examination.

Accurate blood pressure measurement

- Healthcare providers should use the auscultatory method with a properly calibrated and validated instrument.
- Patients should be:
  - Seated quietly, relaxed for at least 5 minutes in a chair (rather than on an exam table), and should not have smoked or ingested caffeine within 30 minutes prior to measurement.
  - With feet on the floor
  - Arm supported at heart level usually on a table.
  - Measurement of BP in the standing may be indicated periodically.
- Locate the brachial artery along the upper inner arm by palpation.

Accurate blood pressure measurement

- Wrap the deflated cuff of appropriate size snugly and firmly around the arm about 2.5 cm above the antecubital space.
  - Cuff bladder should encircle at least 80 percent of the arm.
  - The arrow on the cuff should point to the area where the brachial artery is palpable.
- Ask the patient what their SBP usually is to determine the level for maximal inflation.
  - If they are unaware of their SBP, observe the pressure at which the radial pulse is no longer palpable as the cuff is rapidly inflated and adding 30mm Hg. Then rapidly and steadily deflate the cuff. Wait at least 15-30 seconds before reinflating.
- Position the head of the stethoscope over the palpated brachial artery below the cuff at the antecubital fossa.
  - The stethoscope head should be applied with light pressure, ensuring skin contact at all points.
  - Heavy pressure may distort sounds.
  - Use the bell head to enhance sound detection as the sound generated over the vessels is relatively low in frequency.

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- Rapidly and steadily inflate the cuff.
- Release the air in the cuff so that the pressure falls at a rate of 2 to 3 mm per second.
- SBP = point at which the first of two or more sounds is heard (phase 1),
- DBP = point before the disappearance of sounds (phase 5).
- At least two measurements should be made.
- Clinicians should provide to patients, verbally and in writing, their specific BP numbers AND BP goals.

JNC VII

- Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- This work was supported entirely by the National Heart, Lung, and Blood Institute.
- Express version (34 pages) http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf

The report's key messages

- If >50 yo, a SBP > 140 mmHg is a MUCH more important CVD risk factor than DBP.
- The risk of CVD doubles with each increment of 20/10 mmHg (beginning at 115/75 mmHg)
- "Prehypertensive" = SBP 120–139 mmHg OR DBP 80–89 mmHg
  - requires lifestyle modifications to prevent CVD.
- Use thiazide diuretics for most patients with uncomplicated hypertension, either alone or in combination.

The report's key messages (continued)

- MOST patients will require **two or more** antihypertensive medications to achieve goal blood pressure
- If blood pressure is >20/10 mmHg above goal blood pressure, initiate therapy with two agents, one of which should be a thiazide diuretic.
- For therapy to work, patients must be MOTIVATED. Empathy builds trust and is a potent motivator.

Addition of PreHypertension

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Major Cardiovascular Risk Factors

- Hypertension*
- Cigarette smoking
- Obesity* (body mass index ≥30 kg/m2)
- Physical inactivity
- Dyslipidemia*
- Diabetes mellitus*
- Microalbuminuria or estimated GFR <60 mL/min
- Age (older than 55 for men, 65 for women)
- Family history of premature cardiovascular disease (men under age 55 or women under age 65)

GFR= glomerular filtration rate.

* Components of the metabolic syndrome.

Identifiable Causes of Hypertension

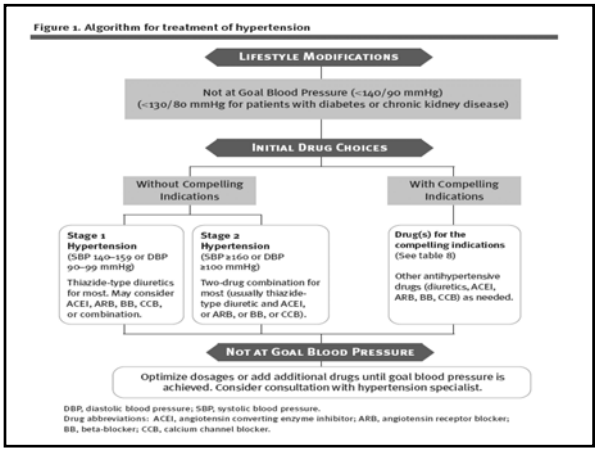
- Sleep apnea
- Drug-induced causes
- Chronic kidney disease
- Primary aldosteronism
- Renovascular disease
- Chronic steroid therapy and Cushing's syndrome
- Pheochromocytoma
- Coarctation of the aorta
- Thyroid or parathyroid disease

Target Organ Damage

- Heart
  - Left ventricular hypertrophy
  - Angina or prior myocardial infarction
  - Prior coronary revascularization
  - Heart failure
- Brain
  - Stroke or transient ischemic attack
- Chronic kidney disease
- Peripheral arterial disease
- Retinopathy

Goals of Antihypertensive Therapy

- **Ultimate goal**: reduction of cardiovascular and renal morbidity and mortality.
- **Primary focus is achieving the SBP goal**, since most patients will reach the DBP goal once SBP is at goal.
- Achieving <140/90 mmHg is associated with a decrease in CVD complications.
- In patients with hypertension and diabetes or renal disease, the BP goal is <130/80 mmHg.



Lifestyle Modifications

- Adoption of healthy lifestyles by ALL persons is critical.
  - Reduce BP
  - Enhance antihypertensive drug efficacy
  - Decrease cardiovascular risk.
- Major lifestyle modifications shown to lower BP include:
  - weight reduction in overweight or obese individuals,
  - adoption of the Dietary Approaches to Stop Hypertension (DASH) eating plan which is rich in potassium and calcium,
  - dietary sodium reduction,
  - physical activity,
  - and moderation of alcohol consumption.
- Combinations of two lifestyle modifications can achieve even better results.
  - For example, a 1,600 mg sodium DASH eating plan has effects similar to single drug therapy.

Table 5. Lifestyle modifications to manage hypertension*†

Modification	Recommendation	Approximate SBP Reduction (Range)
Weight reduction	Maintain normal body weight (body mass index 18.5–24.9 kg/m²).	5–20 mmHg/10 kg weight loss[23,24]
Adopt DASH eating plan	Consume a diet rich in fruits, vegetables, and lowfat dairy products with a reduced content of saturated and total fat.	8–14 mmHg[25,26]
Dietary sodium reduction	Reduce dietary sodium intake to no more than 100 mmol per day (2.4 g sodium or 6 g sodium chloride).	2–8 mmHg[25–27]
Physical activity	Engage in regular aerobic physical activity such as brisk walking (at least 30 min per day, most days of the week).	4–9 mmHg[28,29]
Moderation of alcohol consumption	Limit consumption to no more than 2 drinks (1 oz or 30 mL ethanol; e.g., 24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men and to no more than 1 drink per day in women and lighter weight persons.	2–4 mmHg[30]

DASH, Dietary Approaches to Stop Hypertension.
* For overall cardiovascular risk reduction, stop smoking.
† The effects of implementing these modifications are dose and time dependent, and could be greater for some individuals.

Table 6. Oral antihypertensive drugs*

Class	Drug (Trade Name)	Usual dose range in mg/day (Daily Frequency)
Thiazide diuretics	chlorothiazide (Diuril)	125–500 (1)
	chlorthalidone (generic)	12.5–25 (1)
	hydrochlorothiazide (Microzide, HydroDIURIL†)	12.5–50 (1)
	polythiazide (Renese)	2–4 (1)
	indapamide (Lozol†)	1.25–2.5 (1)
	metolazone (Mykrox)	0.5–1.0 (1)
	metolazone (Zaroxolyn)	2.5–5 (1)
Loop diuretics	bumetanide (Bumex†)	0.5–2 (2)
	furosemide (Lasix†)	20–80 (2)
	torsemide (Demadex†)	2.5–10 (1)
Potassium-sparing diuretics	amiloride (Midamor†)	5–10 (1–2)
	triamterene (Dyrenium)	50–100 (1–2)
Aldosterone receptor blockers	eplerenone (Inspra)	50–100 (1–2)
	spironolactone (Aldactone†)	25–50 (1–2)
Beta-blockers	atenolol (Tenormin†)	25–100 (1)
	betaxolol (Kerlone†)	5–20 (1)
	bisoprolol (Zebeta†)	2.5–10 (1)
	metoprolol (Lopressor†)	50–100 (1–2)
	metoprolol extended release (Toprol XL)	50–100 (1)
	nadolol (Corgard†)	40–120 (1)
	propranolol (Inderal†)	40–160 (2)
	propranolol long-acting (Inderal LA†)	60–180 (1)
	timolol (Blocadren†)	20–40 (2)
Beta-blockers with intrinsic sympathomimetic activity	acebutolol (Sectral†)	200–800 (2)
	penbutolol (Levatol)	10–40 (1)
	pindolol (generic)	10–40 (2)
Combined alpha- and beta-blockers	carvedilol (Coreg)	12.5–50 (2)
	labetalol (Normodyne, Trandate†)	200–800 (2)

Table 6. Oral antihypertensive drugs* (continued)

Class	Drug (Trade Name)	Usual dose range in mg/day (Daily Frequency)
ACE inhibitors	benazepril (Lotensin†)	10–40 (1–2)
	captopril (Capoten†)	25–100 (2)
	enalapril (Vasotec†)	2.5–40 (1–2)
	fosinopril (Monopril)	10–40 (1)
	lisinopril (Prinivil, Zestril†)	10–40 (1)
	moexipril (Univasc)	7.5–30 (1)
	perindopril (Aceon)	4–8 (1–2)
	quinapril (Accupril)	10–40 (1)
	ramipril (Altace)	2.5–20 (1)
	trandolapril (Mavik)	1–4 (1)
Angiotensin II antagonists	candesartan (Atacand)	8–32 (1)
	eprosartan (Teveten)	400–800 (1–2)
	irbesartan (Avapro)	150–300 (1)
	losartan (Cozaar)	25–100 (1–2)
	olmesartan (Benicar)	20–40 (1)
	telmisartan (Micardis)	20–80 (1)
	valsartan (Diovan)	80–320 (1)
Calcium channel blockers—non-Dihydropyridines	diltiazem extended release (Cardizem CD, Dilacor XR, Tiazac†)	180–420 (1)
	diltiazem extended release (Cardizem LA)	120–540 (1)
	verapamil immediate release (Calan, Isoptin†)	80–320 (2)
	verapamil long acting (Calan SR, Isoptin SR†)	120–360 (1–2)
	verapamil—Coer (Covera HS, Verelan PM)	120–360 (1)
Calcium channel blockers—Dihydropyridines	amlodipine (Norvasc)	2.5–10 (1)
	felodipine (Plendil)	2.5–20 (1)
	isradipine (Dynacirc CR)	2.5–10 (2)
	nicardipine sustained release (Cardene SR)	60–120 (2)
	nifedipine long-acting (Adalat CC, Procardia XL)	30–60 (1)
	nisoldipine (Sular)	10–40 (1)

Table 6. Oral antihypertensive drugs* (CONTINUED)

CLASS	DRUG (TRADE NAME)	USUAL DOSE RANGE IN MG/DAY (DAILY FREQUENCY)
Alpha$_1$-blockers	doxazosin (Cardura)	1–16 (1)
	prazosin (Minipress†)	2–20 (2–3)
	terazosin (Hytrin)	1–20 (1–2)
Central alpha$_2$-agonists and other centrally acting drugs	clonidine (Catapres†)	0.1–0.8 (2)
	clonidine patch (Catapres-TTS)	0.1–0.3 (1wkly)
	methyldopa (Aldomet†)	250–1,000 (2)
	reserpine (generic)	0.05‡–0.25 (1)
	guanfacine (generic)	0.5–2 (1)
Direct vasodilators	hydralazine (Apresoline†)	25–100 (2)
	minoxidil (Loniten†)	2.5–80 (1–2)

* These dosages may vary from those listed in the "Physicians' Desk Reference."[3]
† Are now or will soon become available in generic preparations.
‡ A 0.1 mg dose may be given every other day to achieve this dosage.

Table 7. Combination drugs for hypertension

COMBINATION TYPE*	FIXED-DOSE COMBINATION, MG†	TRADE NAME
ACEIs and CCBs	Amlodipine/benazepril hydrochloride (2.5/10, 5/10, 5/20, 10/20)	Lotrel
	Enalapril maleate/felodipine (5/5)	Lexxel
	Trandolapril/verapamil (2/180, 1/240, 2/240, 4/240)	Tarka
ACEIs and diuretics	Benazepril/hydrochlorothiazide (5/6.25, 10/12.5, 20/12.5, 20/25)	Lotensin HCT
	Captopril/hydrochlorothiazide (25/15, 25/25, 50/15, 50/25)	Capozide
	Enalapril maleate/hydrochlorothiazide (5/12.5, 10/25)	Vaseretic
	Lisinopril/hydrochlorothiazide (10/12.5, 20/12.5, 20/25)	Prinzide
	Moexipril HCl/hydrochlorothiazide (7.5/12.5, 15/25)	Uniretic
	Quinapril HCl/hydrochlorothiazide (10/12.5, 20/12.5, 20/25)	Accuretic
ARBs and diuretics	Candesartan cilexetil/hydrochlorothiazide (16/12.5, 32/12.5)	Atacand HCT
	Eprosartan mesylate/hydrochlorothiazide (600/12.5, 600/25)	Teveten/HCT
	Irbesartan/hydrochlorothiazide (150/12.5, 300/12.5)	Avalide
	Losartan potassium/hydrochlorothiazide (50/12.5, 100/25)	Hyzaar
	Telmisartan/hydrochlorothiazide (40/12.5, 80/12.5)	Micardis/HCT
	Valsartan/hydrochlorothiazide (80/12.5, 160/12.5)	Diovan/HCT
BBs and diuretics	Atenolol/chlorthalidone (50/25, 100/25)	Tenoretic
	Bisoprolol fumarate/hydrochlorothiazide (2.5/6.25, 5/6.25, 10/6.25)	Ziac
	Propranolol LA/hydrochlorothiazide (40/25, 80/25)	Inderide
	Metoprolol tartrate/hydrochlorothiazide (50/25, 100/25)	Lopressor HCT
	Nadolol/bendroflufhiazide (40/5, 80/5)	Corzide
	Timolol maleate/hydrochlorothiazide (10/25)	Timolide
Centrally acting drug and diuretic	Methyldopa/hydrochlorothiazide (250/15, 250/25, 500/30, 500/50)	Aldoril
	Reserpine/chlorothiazide (0.125/250, 0.25/500)	Diupres
	Reserpine/hydrochlorothiazide (0.125/25, 0.125/50)	Hydropres
Diuretic and diuretic	Amiloride HCl/hydrochlorothiazide (5/50)	Moduretic
	Spironolactone/hydrochlorothiazide (25/25, 50/50)	Aldactone
	Triamterene/hydrochlorothiazide (37.5/25, 50/25, 75/50)	Dyazide, Maxzide

* Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BB, beta-blocker; CCB, calcium channel blocker.
† Some drug combinations are available in multiple fixed doses. Each drug dose is reported in milligrams.

Follow-up and Monitoring

- Once drug therapy is initiated, most patients should return for monthly follow-ups until the BP goal is reached.
  - More frequent visits will be necessary for patients with stage 2 hypertension or with complicating comorbid conditions.
- Serum potassium and creatinine should be monitored 1–2 times/year.
- After BP is at goal and stable, follow-up visits can usually be every 3-6 months.
- Tobacco avoidance should be promoted vigorously.
- Low-dose aspirin therapy should be considered only when BP is controlled, because the risk of hemorrhagic stroke is increased in patients with uncontrolled hypertension

Table 8. Clinical trial and guideline basis for compelling indications for individual drug classes

Compelling Indication*	Recommended Drugs†						Clinical Trial Basis‡
	Diuretic	BB	ACEI	ARB	CCB	Aldo ANT	
Heart failure	•	•	•	•		•	ACC/AHA Heart Failure Guideline,[47] MERIT-HF,[48] COPERNICUS,[49] CIBIS,[50] SOLVD,[46] AIRE,[51] TRACE,[47] ValHEFT,[47] RALES[49]
Postmyocardial infarction		•	•			•	ACC/AHA Post-MI Guideline,[46] BHAT,[52] SAVE,[53] Capricorn,[54] EPHESUS[55]
High coronary disease risk	•	•	•		•		ALLHAT,[33] HOPE,[56] ANBP2,[57] LIFE,[58] CONVINCE[59]
Diabetes	•	•	•	•	•		NKF-ADA Guideline,[60,61] UKPDS,[62] ALLHAT[33]
Chronic kidney disease			•	•			NKF Guideline,[63] Captopril Trial,[65] RENAAL,[66] IDNT,[67] REIN,[68] AASK[69]
Recurrent stroke prevention	•		•				PROGRESS[70]

* Compelling indications for antihypertensive drugs are based on benefits from outcome studies or existing clinical guidelines; the compelling indication is managed in parallel with the BP.

† Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; Aldo ANT, aldosterone antagonist; BB, beta-blocker; CCB, calcium channel blocker.

‡ Conditions for which clinical trials demonstrate benefit of specific classes of antihypertensive drugs.

Antihypertensive Drug Choice Pearls

Potential favorable effects

- Thiazide diuretics are useful in slowing demineralization in osteoporosis.
- Beta Blockers can be useful in the treatment of:
  - atrial tachyarrhythmias/fibrillation,
  - migraine,
  - thyrotoxicosis (short term),
  - essential tremor, or
  - perioperative hypertension.
- CCBs may be useful in Raynaud's syndrome and certain arrhythmias,
- Alpha-blockers may be useful in prostatism.

Antihypertensive Drug Choice Pearls
continued

Potential unfavorable effects

- Thiazide diuretics should be used cautiously in patients with gout or a history of hyponatremia.
- Beta Blockers should generally be avoided in patients with asthma, reactive airways disease, or 2nd or 3rd degree heart block.
- ACE-I's and ARB's are contraindicated during pregnancy.
- ACE-I's should not be used in individuals with a history of angioedema.
- Aldosterone antagonists and potassium-sparing diuretics can cause hyperkalemia and should be avoided in patients with serum potassium values > 5.0 mEq/L while not taking medications.

What Do Cholesterol Numbers Mean?

- **Total cholesterol**
  - includes High-density lipoprotiens (HDL), Low-density lipoproteins (LDL), Very low-density lipoproteins (VLDL) and Intermediate-density lipoproteins (IDL)
- **LDL (bad) cholesterol**
  - the main source of cholesterol buildup and blockage in the arteries
- **HDL (good) cholesterol**
  - helps keep cholesterol from building up in the arteries. HDL protects against heart disease, so for HDL, higher numbers are better. A level less that 40 mg/dL is low and it increases your risk for heart disease.
- **Triglycerides**
  - another form of fat in your blood. Triglycerides can also raise the risk of heart disease. Levels that are borderline high (150-199 mg/dL) or high (200 mg/dL or more) may need treatment in some people.
- **Non-HDL Cholesterol**
  - Includes Low-density lipoproteins (LDL), Very low-density lipoproteins (VLDL) and Intermediate-density lipoproteins (IDL)

National Cholesterol Education Program (NCEP) ATP-III Guidelines

- Released in 2001 and Updated April 2004
- Recommending more aggressive treatment for people at risk.
  - A complete lipid profile as the initial test
  - More aggressive treatment for high cholesterol through cholesterol-lowering drugs and therapeutic lifestyle changes
  - Higher recommended levels of HDL cholesterol (>40 mg/dL)
  - Lower recommended levels of LDL cholesterol (<130 mg/dL) depending upon major risk factors
  - Increased focus on treating high triglycerides
  - An assessment of risk status using Framingham risk scoring

ATP III Guidelines At-A-Glance Quick Desk Reference

- *National Cholesterol Education Program*
- http://rover.nhlbi.nih.gov/guidelines/cholesterol/
- 2004 Update
  - http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm

Determine lipoprotein levels–
Obtain complete lipoprotein profile after 9 to 12 hour fast.

ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

LDL Cholesterol – Primary Target of Therapy	
<100	Optimal
100-129	Near optimal/above optimal
130-159	Borderline high
160-189	High
≥190	Very high
Total Cholesterol	
<200	Desirable
200-239	Borderline high
≥240	High
HDL Cholesterol	
<40	Low
≥60	High

Identify presence of clinical atherosclerotic disease that confers high risk for coronary heart disease (CHD) events (CHD risk equivalent):

- Clinical CHD
- Symptomatic carotid artery disease
- Peripheral arterial disease
- Abdominal aortic aneurysm.

Note: in ATP III, diabetes is regarded as a CHD risk equivalent.

Determine presence of major risk factors (other than LDL):

- Cigarette smoking
- Hypertension (BP >140/90 mmHg or on antihypertensive medication)
- Low HDL cholesterol (<40 mg/dL)*
- Family history of premature CHD (CHD in male first degree relative <55 years;
- CHD in female first degree relative <65 years)
- Age (men >45 years; women >55 years)

** HDL cholesterol > 60 mg/dL counts as a "negative" risk factor; its presence removes one risk factor from the total count.*

Determine risk category:

- 0-1 CVD Risk Factors
- 2+ CVD Risk Factors with 10 yr risk for CHD≤ 20%
- "High Risk"
  - All Persons with CHD and CHD Risk Equivalents (noncoronary forms of clinical atherosclerotic disease, diabetes and 2+ CHD risk factors with 10 yr risk for CHD>20%)
- Very High Risk (2004 Update)
  - Established CVD and:
    - Multiple major risk factors (i.e. diabetes)
    - Severe or poorly controlled risk factors (i.e. smoking)
    - Multiple risk factors of Metabolic Syndrome
    - Acute Coronary Syndrome

LDL Goals and Treatment in Different Risk Categories.

LDL Cholesterol Goals and Cutpoints for Therapeutic Lifestyle Changes (TLC) and Drug Therapy in Different Risk Categories.

Risk Category	LDL Goal	LDL Level at Which to Initiate Therapeutic Lifestyle Changes (TLC)	LDL Level at Which to Consider Drug Therapy
CHD or CHD Risk Equivalents (10-year risk >20%)	<100 mg/dL	≥100 mg/dL	≥130 mg/dL (100-129 mg/dL: drug optional)*
2+ Risk Factors (10-year risk ≤20%)	<130 mg/dL	≥130 mg/dL	10-year risk 10-20%: ≥130 mg/dL 10-year risk <10%: ≥160 mg/dL
0-1 Risk Factor†	<160 mg/dL	≥160 mg/dL	≥190 mg/dL (160-189 mg/dL: LDL-lowering drug optional)

* *Some authorities recommend use of LDL-lowering drugs in this category if an LDL cholesterol <100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL, e.g., nicotinic acid or fibrate. Clinical judgment also may call for deferring drug therapy in this subcategory.*

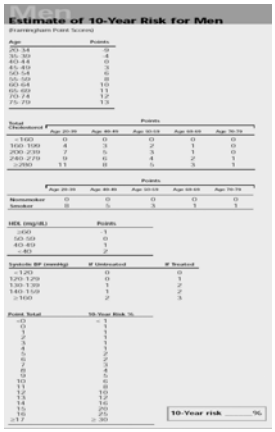
† *Almost all people with 0-1 risk factor have a 10-year risk <10%, thus 10-year risk assessment in people with 0-1 risk factor is not necessary.*

If 2+ risk factors (other than LDL) are present without CHD or CHD risk equivalent, assess 10-year CHD risk (see Framingham tables).

- **Three levels of 10-year risk:**
  - >20% — CHD risk equivalent
  - 10-20%
  - <10%

Framingham Risk Assessment

- 10 year Risk Percentage
- Point System
- Gender Specific
- Age
- Total Cholesterol
- Systolic Blood Pressure
- HDL Cholesterol
- Smoking Status



Men

Estimate of 10-Year Risk for Men

(Framingham Point Score)

Age	Points
20-34	-9
35-39	-4
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	11
70-74	12
75-79	13

Total Cholesterol	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	1
200-239	7	5	3	1	0
240-279	9	6	4	2	1
≥280	11	8	5	3	1

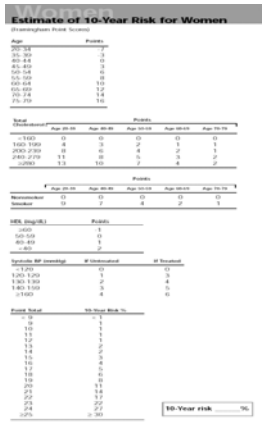
	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0	0	0	0	0
Smoker	8	5	3	1	1

HDL (mg/dL)	Points
≥60	-1
50-59	0
40-49	1
<40	2

Systolic BP (mmHg)	If Untreated	If Treated
<120	0	0
120-129	0	1
130-139	1	2
140-159	1	2
≥160	2	3

Point Total	10-Year Risk %
<0	<1
0	1
1	1
2	1
3	1
4	1
5	2
6	2
7	3
8	4
9	5
10	6
11	8
12	10
13	12
14	16
15	20
16	25
≥17	≥30

10-Year risk _____%



Women

Estimate of 10-Year Risk for Women

(Framingham Point Score)

Age	Points
20-34	-7
35-39	-3
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	12
70-74	14
75-79	16

Total Cholesterol	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	1
200-239	8	6	4	2	1
240-279	11	8	5	3	2
≥280	13	10	7	4	2

	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0	0	0	0	0
Smoker	9	7	4	2	1

HDL (mg/dL)	Points
≥60	1
50-59	0
40-49	1
<40	2

Systolic BP (mmHg)	If Untreated	If Treated
<120	0	0
120-129	2	4
130-139	3	5
≥160	4	6

Point Total	10-Year Risk %
<9	<1
9	1
10	1
11	1
12	1
13	2
14	2
15	3
16	4
17	5
18	6
19	8
20	11
21	14
22	17
23	22
24	27
≥25	≥30

10-Year risk _____%

Initiate therapeutic lifestyle changes (TLC) if LDL is above goal.

- TLC Diet:
  - Saturated fat <7% of calories, cholesterol <200 mg/day
  - Consider increased viscous (soluble) fiber (10-25 g/day) and plant stanols/sterols
- (2g/day) as therapeutic options to enhance LDL lowering
- Weight management
- Increased physical activity.

Drug Therapy for Hyperlipidemia

Drugs Affecting Lipoprotein Metabolism

Drug Class	Agents and Daily Doses	Lipid/Lipoprotein Effects		Side Effects	Contraindications
HMG CoA reductase inhibitors (statins)	Lovastatin (20-80 mg) Pravastatin (20-40 mg) Simvastatin (20-80 mg) Fluvastatin (20-80 mg) Atorvastatin (10-80 mg) Cerivastatin (0.4-0.8 mg)	LDL HDL TG	↓18-55% ↑5-15% ↓7-30%	Myopathy Increased liver enzymes	Absolute: • Active or chronic liver disease Relative: • Concomitant use of certain drugs*
Bile acid sequestrants	Cholestyramine (4-16 g) Colestipol (5-20 g) Colesevelam (2.6-3.8 g)	LDL HDL TG	↓15-30% ↑3-5% No change or increase	Gastrointestinal distress Constipation Decreased absorption of other drugs	Absolute: • dysbeta-lipoproteinemia • TG >400 mg/dL Relative: • TG >200 mg/dL
Nicotinic acid	Immediate release (crystalline) nicotinic acid (1.5-3 gm), extended release nicotinic acid (Niaspan®) (1-2 g), sustained release nicotinic acid (1-2 g)	LDL HDL TG	↓5-25% ↑15-35% ↓20-50%	Flushing Hyperglycemia Hyperuricemia (or gout) Upper GI distress Hepatotoxicity	Absolute: • Chronic liver disease • Severe gout Relative: • Diabetes • Hyperuricemia • Peptic ulcer disease
Fibric acids	Gemfibrozil (600 mg BID) Fenofibrate (200 mg) Clofibrate (1000 mg BID)	LDL *(may be increased in patients with high TG)* HDL TG	↓5-20% ↑10-20% ↓20-50%	Dyspepsia Gallstones Myopathy	Absolute: • Severe renal disease • Severe hepatic disease

* *Cyclosporine, macrolide antibiotics, various anti-fungal agents, and cytochrome P-450 inhibitors (fibrates and niacin should be used with appropriate caution).*

New HMG-CoA Reductase Inhibitor

- Rosuvastatin (Crestor)
- AstraZeneca
- STELLAR Study-Head to Head comparing all "Statins"

Drug	Cholesterol (TC)	LDL	HDL	TG
Atorvastatin 10mg	-29	-39	6	-19
Fluvastatin 40mg	-19	-25	4	-14
Lovastatin 20mg	-17	-24	7	-10
Pravastatin 40mg	-25	-34	12	-24
Simvastatin 20mg	-28	-38	8	-15
Rosuvastatin 10mg	-36	-56	14	-10

- **Table:** Percent changes in TC, LDL, HDL, and TG as witnessed in the STELLAR Study
- Jones PH, et al., for the STELLAR Study Group. Comparison of the efficacy and safety of rosuvastatin versus atorvastatin, simvastatin, and pravastatin across doses (STELLAR trial). Am J Cardiol July 15, 2003; 92:152-160.

Identify metabolic syndrome and treat, if present, after 3 months of TLC.

Clinical Identification of the Metabolic Syndrome – Any 3 of the Following:

Risk Factor	Defining Level
Abdominal obesity*	Waist circumference†
Men	>102 cm (>40 in)
Women	>88 cm (>35 in)
Triglycerides	≥150 mg/dL
HDL cholesterol	
Men	<40 mg/dL
Women	<50 mg/dL
Blood pressure	≥130/≥85 mmHg
Fasting glucose	≥110 mg/dL

* *Overweight and obesity are associated with insulin resistance and the metabolic syndrome. However, the presence of abdominal obesity is more highly correlated with the metabolic risk factors than is an elevated body mass index (BMI). Therefore, the simple measure of waist circumference is recommended to identify the body weight component of the metabolic syndrome.*

† *Some male patients can develop multiple metabolic risk factors when the waist circumference is only marginally increased, e.g., 94-102 cm (37-39 in). Such patients may have a strong genetic contribution to insulin resistance. They should benefit from changes in life habits, similarly to men with categorical increases in waist circumference.*

Treatment of Metabolic Syndrome

Treatment of the metabolic syndrome

- Treat underlying causes (overweight/obesity and physical inactivity):
  - Intensify weight management
  - Increase physical activity.
- Treat lipid and non-lipid risk factors if they persist despite these lifestyle therapies:
  - Treat hypertension
  - Use aspirin for CHD patients to reduce prothrombotic state
  - Treat elevated triglycerides and/or low HDL (as shown in Step 9)..

Treat elevated triglycerides.

ATP III Classification of Serum Triglycerides (mg/dL)

<150	Normal
150-199	Borderline high
200-499	High
≥500	Very high

Treatment of elevated triglycerides (≥150 mg/dL)

- Primary aim of therapy is to reach LDL goal
- Intensify weight management
- Increase physical activity
- If triglycerides are ≥200 mg/dL after LDL goal is reached, set secondary goal for non-HDL cholesterol (total – HDL) 30 mg/dL higher than LDL goal.

Comparison of LDL Cholesterol and Non-HDL Cholesterol Goals for Three Risk Categories

Risk Category	LDL Goal (mg/dL)	Non-HDL Goal (mg/dL)
CHD and CHD Risk Equivalent (10-year risk for CHD >20%)	<100	<130
Multiple (2+) Risk Factors and 10-year risk ≤20%	<130	<160
0-1 Risk Factor	<160	<190

If triglycerides 200-499 mg/dL after LDL goal is reached, consider adding drug if needed to reach non-HDL goal:

- intensify therapy with LDL-lowering drug, or
- add nicotinic acid or fibrate to further lower VLDL.

If triglycerides ≥500 mg/dL, first lower triglycerides to prevent pancreatitis:

- very low-fat diet (≤15% of calories from fat)
- weight management and physical activity
- fibrate or nicotinic acid
- when triglycerides <500 mg/dL, turn to LDL-lowering therapy.

Treatment of Low HDL

Treatment of low HDL cholesterol (<40 mg/dL)

- First reach LDL goal, then:
- Intensify weight management and increase physical activity
- If triglycerides 200-499 mg/dL, achieve non-HDL goal
- If triglycerides <200 mg/dL (isolated low HDL) in CHD or CHD equivalent consider nicotinic acid or fibrate.

2004 Update ATP III

- Five Major Trials since the ATP III was originally published in May 2001
  - HPS
  - PROSPER
  - ALLHAT
  - ASCOT-LLA
  - PROVE IT

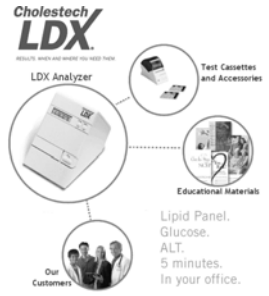
ATPIII Update Summary

- In high risk persons, the recommended LDL-C goal is <100mg/dL but when risk in very high, an LDL-C of <70mg/dL is a therapeutic option.
- When a high risk patient has high TG or low HDL-C, consideration should be given to combining a fibrate or nicotinic acid with a LDL-lowering drug
- In moderately-high risk persons (2+ risk factors and 10 yr risk 10-20%), the recommended LDL-C goal is <130mg/dL but when risk in very high, an LDL-C of <100mg/dL is a therapeutic option.

Identify and Manage Patients at Risk of Heart Disease

- Pharmacists are uniquely positioned to help combat heart disease through early identification and on-going disease management.
- Project ImPACT: Hyperlipidemia, pharmacists doubled compliance rates and helped patients to achieve target lipid levels as a result of the value-added service.
  - 93% of patients were in compliance with drug therapy as compared to previous studies where only 40% of patients remained in compliance.
  - Over 62% of these patients have reached National Cholesterol Education Panel (NCEP) goals as compared to other studies where treatment to goal was as low as 8%.

The Cholestech LDX® System



The Cholestech LDX® System

- Measures a complete lipid profile plus glucose in only 5 minutes from a simple fingerstick.
- ALT now available in 5 minutes

Key Features

- Small, lightweight, and portable
- Includes printer that provides duplicate copies of test-results
- Factory calibrated
- Fast and simple procedure saves time, enhances productivity
- Requires only a single drop of blood from a simple fingerstick and eliminates the anxiety of venipuncture.
- Provides quick feedback for on-the-spot adjustment of therapy and improved patient compliance
- CLIA-waived system and meets all relevant National Cholesterol Education Program (NCEP) guidelines for precision and accuracy

Test Cassettes

- Large variety of testing options
  - Total Cholesterol
  - Total Cholesterol and Glucose
  - Total Cholesterol and HDL Panel
  - Total Cholesterol, HDL, and Glucose Panel
  - Total Cholesterol, HDL, Triglycerides, TC/HDL ratio, estimate of LDL and VLDL
  - Total Cholesterol, HDL, Triglycerides, Glucose, TC/HDL ratio, estimate of LDL and VLDL
  - ALT (Alanine Aminotransferase)
- GDX machine

Supplies

- Lancets
- Capillary Tubes
- Capillary Plungers
- Accessory Tray
- Band-aids
- Gauze
- Alcohol swabs

Testing with Cholestech LDX

- Stick
- Click
- Done

Testing with Cholestech LDX cont

- Stick
  - Before taking the fingerstick sample, prepare your testing place
    - Make sure cassette is room temperature (allow 10 minutes)
    - Run Self Test on Analyzer by pressing RUN
    - Remove from packaging and arrange on a clean surface the following: cassettes, lancets, capillary tubes and plungers, alcohol swabs, gauze/cotton balls, band-aids
    - Insure the sharps container and garbage cans are in close proximity

Testing with Cholestech LDX cont

- Use Lancet device to pierce the skin on the finger tip
  - Make sure patients hands are warm and clean (free of soap and lotion residue)
  - Gently massage finger from base to tip to increase blood flow
  - Wipe site with alcohol swab
  - Firmly place lancet flush against the finger tip preferably outside surface of the ring finger on the right hand
  - Perform a deep and firm puncture –GOOD BLOOD FLOW IN THE KEY
  - Wipe off first drop of blood with cotton ball or gauze because it contains tissue fliud
  - Squeeze the finger with a "Pulse" the finger until a large drop of blood has accumulated do not "milk" the finger.

Testing with Cholestech LDX cont

- Collect blood sample from fingerstick in capillary tube
  - Once the fingerstick occurs, move quickly to prevent clotting.
    - Collect sample in capillary tube in less than 10 seconds
    - Use plunger to add sample to test cassette in less than 5 minutes
  - Keep the patient's hand below the level of the heart
  - Easiest to hold the capillary tube and plunger horizontally (or at a slight descending angle if necessary) to the drop of blood.
  - Touch the end of the capillary tube to the drop of blood and fill capillary tube to the black mark
  - If blood flow stops, wipe finger firmly with gauze to reopen the puncture.
- Dispense the sample toward the white material in the Cassette sample well

Testing with Cholestech LDX cont

- Click
  - Load cassette immediately into the Cholestech
  - Hold cassette horizontally and don't touch the black bar or magnetic strip
  - Black Reaction must face the Analyzer and brown magnetic stripe must be on the right.
  - Press RUN to close drawer and start test

Testing with Cholestech LDX cont

- Done
  - Results are ready to discuss with patient in 5 minutes
  - When test is complete, the LDX will beep, and results will appear on the screen
  - Press DATA button for more results.
  - Press DATA again for the Framingham Risk. Press RUN to calculate or STOP to skip and print the results

Testing with Cholestech LDX cont.

- If you decide to run the Framingham Risk, you can calculate it on the Cholestech.
- Collect the necessary patient information:
  - Gender Diabetes
  - Smoking Status
  - Age (>30 years old)
  - ECG-LVH
  - Systolic BP
  - Year to Run the Risk Prediction (4-12 yrs)
- Press STOP to close panel and end test
- Press DATA again to recall the last tests result. Only the last test can be recalled

Quality Assurance

- Optics Check Cassette
  - Checks the optical system on the Analyzer
  - Run once daily before patient samples are tested
  - Run after the Cholestech LDX System has been moved or serviced
- Quality Controls
  - Gently turn control bottles 6-7 times to mix them
  - Run QC on each
    - new shipment of cassettes
    - new lot of cassettes
    - Run of patient samples

Educational materials

- Training video for staff
- Educational pamphlets
  - Download at www.cholestech.com
  - Order 800-733-0404

Payment for services

- Screenings are predominantly a cash pay service
  - Ranging from $30-$40
- Identify who benefits from the services
  - Some employers-healthy employees mean less sick days
  - Drug manufacturers-increase compliance
  - Patients who want to see if the co-pays are worth the money

Where can you do screenings?

- **Hospital-Based Testing**
  - Outpatient Lipid and Diabetes Clinics
  - Occupational Health/Corporate Wellness
  - Cardiac Rehabilitation units
- **Employee Wellness Programs**
- **Managed Care Programs**
- **Community Screening and Health Education**
  - Community Outreach, Point-of-Care Testing (POCT)
  - Community pharmacy based services
  - Smoking Cessation programs