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MINISTRY OF HEALTH - ETHIOPIA

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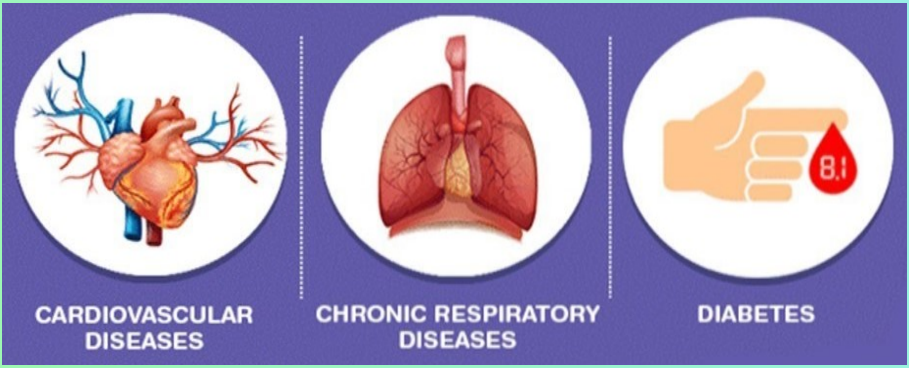
HEALTHIER CITIZENS FOR PROSPEROUS NATION

NATIONAL NONCOMMUNICABLE DISEASES MANAGEMENT PROTOCOLS



PROTOCOLS

1. Hypertension
2. CVD Risk Assessment
3. Rheumatic Heart Disease
4. Diabetes Mellitus
5. Chronic Respiratory Diseases

Addis Ababa
November 2021

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FOREWORD

Ethiopia has achieved several of the national targets on health. A lot has been done at all levels to reach these goals in maternal and child health, HIV, Tuberculosis, Malaria and NTDs.

However, the country has entered into an epidemiologic transition and is now suffering a triple burden of diseases; the unfinished agenda of communicable, maternal, neonatal and nutrition disorders; the ever emerging and looming epidemic of non-communicable diseases; and the catastrophic injuries from motor vehicle injuries, civil unrest and military conflicts.

What has been achieved over the past 3 decades is fading away unless we rebound our efforts to the control of the non-communicable diseases. To this effect the ministry of health has developed national strategic plans for control of Major NCDs (2020-2025) and mental health (2020-2025) and is in the process of revising the national cancer control plan and eye health strategic plan.

The National strategic plans stressed the need for simplified protocols for screening, diagnosis and management of common NCDs.

This is a compilation of protocols for the management of hypertension, cardiovascular disease risk assessment, rheumatic heart disease, diabetes and chronic respiratory diseases (Asthma and COPD). Protocol developments for cancer and mental health are underway.

The purpose of these protocols is standardizing care so that quality of care can be ensured, the supply management system for NCDs be simplified and the recording and reporting of these conditions be consistent and treatment outcomes be compared across sites.

It is my firm belief that all health facilities will follow these protocols and all relevant directorates and agencies will support implementation of these protocols in the forecasting and procurement of products; registration and regulation of products and strengthening of the health system to that effect.

I would like to thank all the experts and managers involved in the development of the protocols.

Dereje Duguma, MD, MPH
State Minister of Heath, Ministry of Health Ethiopia

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ACKNOWLEDGEMENTS

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Special gratitude goes to members of the national NCD technical working group, and the experts from the Society of Cardiac Professionals-Ethiopia, Ethiopian Thoracic Society, Ethiopian Diabetes Association and partners working on NCDs as listed below

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Hiwot Solomon

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SECTION 1:
NATIONAL HYPERTENSION SCREENING AND MANAGEMENT PROTOCOL

1. INTRODUCTION TO HYPERTENSION

Hypertension is a clinical condition where the arterial blood pressure is persistently elevated. It is a serious medical condition that significantly increases the risks of heart, brain, kidney and other diseases. An estimated 1.13 billion people worldwide have hypertension, most (two-thirds) living in low- and middle-income countries. According to the National WHO STEPS survey conducted in 2015 the prevalence of hypertension in Ethiopia is estimated to be 16%.

In Ethiopia and other low- and middle-income countries, there is a wide gap between evidence- based recommendations and current practice. Treatment of major CVD risk factors remains suboptimal, and only a minority of patients who are treated reach their target levels for blood pressure, blood sugar and blood cholesterol. In other areas, overtreatment can occur with the use of non-evidence-based protocols.

This treatment protocol has been developed for the management of hypertension at health centers, primary hospitals and general hospitals as part of the Ministry of Health's effort to improve and standardize the diagnosis, management and follow up of patients with hypertension. The treatment protocol is based on a number of international and national guidelines and publications.

A standardized set of simple clinical-management protocols, which are drug- and dose-specific, and include a core set of medications are developed. The core set of medications in the treatment protocol was adapted and endorsed from the WHO HEARTS: Evidence –based treatment protocols based on scientific evidence on efficacy, safety, ease of administration, cost, and local availability in Ethiopia.

The aim of using standard treatment protocols is to improve the quality of clinical care, reduce clinical variability and simplify the treatment options, particularly in primary health care.

This evidence-based protocols uses hypertension screening and treatment as an entry point to control cardiovascular risk factors, prevent target organ damage, and reduce premature morbidity and mortality.

2. HYPERTENSION DETECTION AND TREATMENT

2.1 When to measure blood pressure

Measuring blood pressure is the only way to diagnose hypertension, as most people with raised blood pressure have no symptoms.

Blood pressure measurements should be conducted on all patients during health facility visits as part of the vital sign. The Ministry of Health-Ethiopia recommends all adults are advised to check their blood pressures. But the focus will be screening all adults aged ≥ 30 years of age as the yield of getting individuals with raised blood pressure will be higher based on the National WHO Steps Survey report and pilot program in Ethiopia.

Every patient with an elevated blood pressure reading requires repeated measurements to confirm the reading and enroll into care. More frequent screening with blood pressure measurements is particularly important to rule out or rule in hypertension in adults who:

- Have had a prior heart attack or stroke
- Have diabetes
- Have chronic kidney disease (CKD)
- Are obese
- Use tobacco
- Have a family history of heart attack or stroke

2.2 How to measure blood pressure

Effective treatment algorithms for hypertension are dependent on accurate blood pressure measurement. The following advice should be followed for measuring blood pressure:

- Use the appropriate cuff size, noting the lines on the cuff to ensure that it is positioned correctly on the arm. (If the arm circumference is >32 cm, use large cuff.)
- On initial evaluation it is preferable to measure blood pressure on both arms and use the arm with the higher reading thereafter
- The patient should be sitting with back supported, legs uncrossed, empty bladder, relaxed for 5 minutes and not talking.
- It is preferable to take at least two readings on each occasion of measurement and to use the second reading.
- Blood pressure can be measured either by a conventional sphygmomanometer using a stethoscope, or by an automated electronic device. The WHO recommended calibrated electronic device is preferred because it provides more reproducible results and is not influenced by variations in technique or by the bias of the observers.

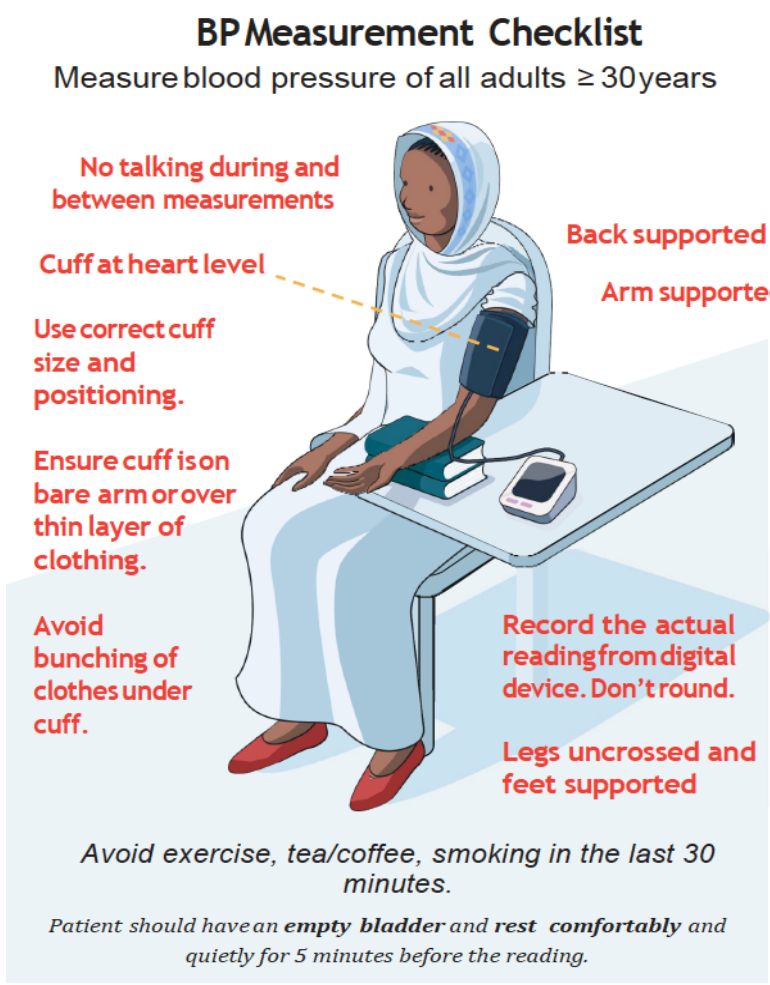


Figure: How to measure blood pressure

If the health care facility has electricity or regular access to batteries, then consider an automated validated blood pressure device with a digital reading. If the primary health care facility has no electricity or batteries, then a manual (Aneroid or Mercury) BP Apparatus will have to be used by auscultating with a stethoscope.

2.3 Diagnosis of Hypertension

The diagnosis of hypertension should be confirmed at an additional patient visit, usually with in 1 to 4 weeks after the first measurement depending on the measured values and other circumstances. In general, hypertension is diagnosed if, on two visits, on different days:

- Systolic blood pressure on both days is ≥140 mmHg, and/or
- Diastolic blood pressure on both days is ≥90 mmHg.

Clinical Condition	Office Blood Pressure Measurement			
	< 140/90	140-159/90-99	160-179/100-109	>180/110
If there is no evidence of end-organ damages (hypertension mediated organ damage)	Re-measure after 1year	Confirm within one Month	Confirm as soon as possible within one week	Diagnose HTN, initiate treatment and refer
If there is evidence of hypertension mediated organ damage (or end-organ damages)	Confirm HTN, initiate treatment and/or refer to the next level			
Hypertensive Crises (BP> 180/110 mmHg) with or without target organ damage	Confirm HTN, initiate treatment and/or refer to the next level			

Once the diagnosis of hypertension is confirmed: -

1. Look for evidence of hypertension mediated organ damage (previously called end-organ damage) based on:

a. **History:** Symptoms of heart failure (SOB, unusual fatigue and body swelling), history of sudden onset body weakness (stroke), intermittent claudication or previous diagnosis of the above problems on previous evaluation at other health institutions, severe headache and blurring of vision.

b. **Physical Examination:** Pulse rate and rhythm, signs of heart failure (edema, elevated JVP, crackles on the lungs), focal neurologic deficit, eye signs. The physical examination should be done to the maximum capacity of the health work force including fundoscopic retinal examination if possible.

c. **Laboratory and other diagnostic tests:** Health facilities should thrive to avail at least mandatory tests. Please note that waiting for laboratory tests shouldn't delay the management of hypertension as the disease do much harm than the extra benefit obtained from the tests. The tests are categorized as follows:

   i. Mandatory tests at diagnosis (do urine dipstick to check for protein, serum creatinine to check for renal function)

   ii. Optional tests at diagnosis (ECG to look for effect of blood pressure on the heart, serum electrolytes mainly potassium, thyroid function test to assess a secondary cause of hypertension)

   iii. Indication based tests (do echocardiography for heart failure patients, brain imaging for suspicion of stroke)

   iv. Comorbidity and risk factor assessment tests (do blood sugar and serum cholesterol)

2. Look for risk factors:

a) History: Smoking, excess salt intake, sedentary life, low fruit and vegetable intake, excess alcohol consumption

b) Physical Measurement: measure weight, height and abdominal circumference
Calculate BMI: Weight in kg / square of height in meter

3. Cardiovascular Risk Assessment:

More than 50% of hypertensive patients have additional CV risk factors. Most commonly: metabolic syndrome, T2DM, lipid disorders, high uric acid.

For all patients found to have raised BP, their future 10-year cardiovascular risk should be assessed by using WHO CV risk score (Refer to WHO CV risk assessment manual).
In a setting where serum cholesterol and fasting blood glucose can be determined use the laboratory-based risk assessment.

If laboratory assessment service is not available, use the WHO non-laboratory-based risk charts.

2.4 Classification of Hypertension and Recommended Management

Category	Systolic (mmHg)		Diastolic(mmHg)
Normal	<130	and	<85
High Normal	130-139	and/or	85-89
Grade 1	140-159	and/or	90-99
Grade 2	160-179	and/or	100-109
Grade 3 (Severe)	≥180	and/or	≥110
Hypertension Emergency	SBP higher than 180 mmHg and/or DBP higher than 110 mmHg with the presence of acute target organ damage (dissecting aortic aneurysm, acute pulmonary edema, acute myocardial infarction, unstable angina pectoris, acute renal failure, acute intracranial hemorrhage, acute ischemic stroke, hypertensive encephalopathy, eclampsia or pre-eclampsia)		
Hypertension Urgency	SBP higher than 180 mmHg and/or DBP higher than 110 mmHg in an otherwise stable person without clinical or laboratory evidence of acute target organ damage		

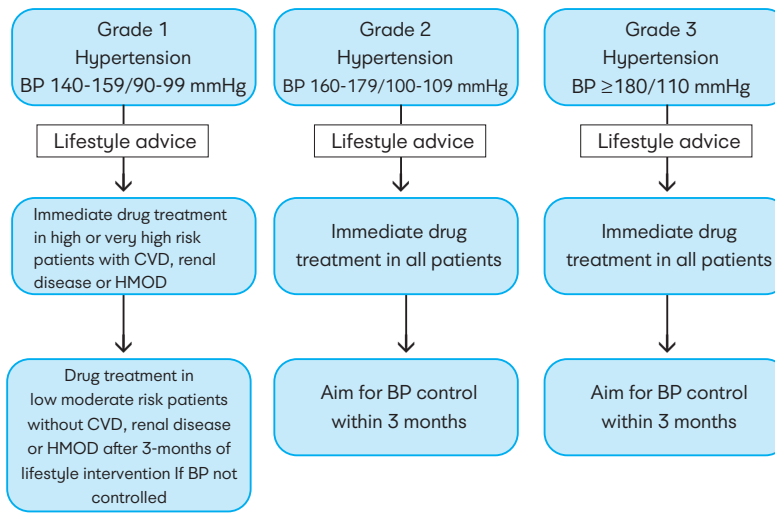


Figure: Initiation of blood pressure-lowering treatment (lifestyle changes and medication) at different initial office blood pressure levels. BP = blood pressure; CAD = coronary artery disease; CVD = cardiovascular disease; HMOD= hypertension-mediated organ damage.

2.5 Management of Hypertension

2.5.1 Lifestyle interventions

Treatment of hypertension should involve non-pharmacologic therapy (also called lifestyle modifications) alone or in concert with antihypertensive drug therapy and is a critical component of good hypertension management and should be implemented in all grades of hypertension.

Lifestyle intervention is often recommended as a first step for patients with blood pressure of SBP 130–139 mmHg and/or DBP 80–89 mmHg who do not have other CVD risk factors. Lifestyle intervention can be tried for up to three months for uncomplicated grade 1 hypertension before initiation of medications. If failed to achieve a blood pressure of less than 140/90 mmHg, then initiation of antihypertensive medication as per the algorithm below is recommended. However, in settings where people do not regularly visit the doctor, people who are recommended only lifestyle modification may not return for re-evaluation and needed treatment, resulting in uncontrolled hypertension and associated complications.

The lifestyle modifications we need to emphasize include:

1. Reduce salt consumption to less than 1 tea spoonful (5g)/day (i.e. do not add salt if you are using Ethiopian “berberie” or “Shiro”). No added salt after food is prepared. Avoid salty foods.
2. Follow Healthy Diet
    - Eat 5 servings of fruits and vegetables per day.
    - Eat nuts, legumes, whole grains, and foods rich in potassium like avocado.
    - Eat fish at least twice per week.
    - Use healthy oils like sunflower, sesame seed, niger seed, soybean, peanut and olive.
    - Limit red meat to once or twice per week.
    - Avoid added sugar. Avoid sugary beverages.
    - Limit consumption of fried foods and foods with high amounts of saturated fats.
    - Avoid chips, margarines and other processed foods containing trans-fat.
    - Moderate consumption of coffee and green tea
3. Reduce fat intake by changing how you cook:
    - Remove the fatty part of meat.
    - Boil steam or bake instead of frying.
    - Limit reuse of oil for frying.
4. Stop tobacco use, and avoid second- hand smoke and
5. Avoid harmful use of alcohol: Limit consumption to no more than 2 drinks per day in most men, and to no more than 1 drink per day in women and lighter weight persons.

6. Increase physical activity equivalent of brisk walk 150 min/week
7. If overweight or obese, lose weight.

2.5.2 Pharmacotherapy of Hypertension

Pharmacologic antihypertensive therapy, as compared with placebo, produces a nearly 50 percent relative risk reduction in the incidence of heart failure, a 30 to 40 percent relative risk reduction in stroke, and a 20 to 25 percent relative risk reduction in myocardial infarction

Who should receive hypertension drug treatment?

1. Indicated for adults diagnosed with hypertension, as defined above (SBP ≥140 mmHg and/or DBP ≥90 mmHg) who couldn't achieve target blood pressure with three months of lifestyle modification.
2. Immediate treatment may be Indicated for adults diagnosed with hypertension at initial presentation in those with:
    - Hypertension mediated organ damage (End-organ damage)
    - High WHO CVD risk (Lab based WHO cardiovascular risk >20% or non-Lab based WHO cardiovascular risk >10%)
    - Hypertensive Crises (SBP ≥180 mmHg or DBP ≥110 mmHg) (see below)

Treatment targets

- For most patients, blood pressure is considered controlled when SBP <140 mmHg and DBP <90 mmHg.

What medications should be used to treat hypertension?
Refer to the Ethiopian hypertension management algorithm below.

A. Initial monotherapy in uncomplicated hypertension:

- The amount of blood pressure reduction and the attained blood pressure target are the major determinant of reduction in cardiovascular risk in patients with hypertension, not the choice of antihypertensive drug.
- Each class of antihypertensive drugs has been equally effective in monotherapy trials if the attained blood pressure is similar.
- Some patients have an indication for a specific drug or drugs that is unrelated to essential hypertension, which will influence the choice of therapy.

In the absence of a specific indication, the World Hypertension League and the International Society of Hypertension recommend three main classes of drugs to be used for initial monotherapy:

- Long acting dihydropyridine calcium channel blockers (such as amlodipine),
- Thiazide diuretics,
- ACE inhibitors or angiotensin II receptor blockers.

B. Combination therapy: Though there is a wide inter-patient variability in drug response, each of the antihypertensive agents is roughly equally effective in lowering the blood pressure, producing a good antihypertensive response in 30 to 50 percent of patients. As the dose is increased with most antihypertensive drugs, the antihypertensive response attenuates, and side effects become more prominent with the relative exception of ACE inhibitors and ARBs in patients with normal renal function. As a result, we generally limit dose titration to one step with a given drug (e.g., 12.5 to 25 mg of hydrochlorothiazide and 5 to 10 mg of amlodipine). Eventually, most patients with hypertension will require more than one drug.

The World Hypertension League and the International Society of Hypertension recommend the following drugs in a combination therapy:

- Long acting dihydropyridine calcium channel blocker plus a thiazide diuretic,
- Long-acting dihydropyridine calcium channel blocker plus a long-acting ACE inhibitor/ARB or
- Long-acting ACE inhibitor/ARB plus a thiazide diuretic.

Amlodipine is recommended as first line drug for the treatment of uncomplicated primary (essential) hypertension in Ethiopia as it reduces the need for monitoring of electrolytes and renal function and avoids need for different treatment for women of childbearing age that may become pregnant.

Hydrochlorothiazide is recommended to be used as add on when target BP not achieved with amlodipine as it is readily available and less expensive than other hypertension medications in our setting. The use of hydrochlorothiazide as initial monotherapy should be limited because of the risk of hypokalemia and the unfavorable effects on lipid and glucose associated with the drug which necessitates laboratory monitoring.

Lisinopril (or Enalapril) is recommended as a third antihypertensive agent if target BP is still not achieved with a combination of amlodipine and hydrochlorothiazide.

Notes on specific hypertension treatment

- Screen for Secondary causes if patient has clinical clues that are suggestive of secondary hypertension like:
    - Severe or resistant hypertension as defined by the persistence of high BP despite concurrent use of adequate doses of three antihypertensive agents from different classes.
    - An acute rise in BP developing in a patient with previously stable values.

- Age less than 30 years in non-obese, non-black patients with a negative family history of and no other risk factors (eg, obesity) for hypertension.
- Malignant or accelerated hypertension (eg, patients with severe hypertension and signs of end-organ damage such as retinal hemorrhages or papilledema, heart failure, neurologic disturbance, or acute kidney injury).
- Proven age of onset before puberty.
- If there are other findings that specifically suggest renovascular or other forms of secondary hypertension

- Beta blockers should NOT be used for initial monotherapy in the absence of a specific indication, as it may have an adverse effect on some cardiovascular outcomes, particularly in older patients. If a heart attack has been diagnosed within the previous three years, or there is atrial fibrillation or heart failure, then a beta blocker should be added to the starting dose of antihypertensive medication. Patients with angina may also benefit from treatment with a beta blocker.
- Pregnant women and women of childbearing age not on effective contraception should not be given ACE inhibitors, ARBs, or thiazide/thiazide-like diuretics; CCBs should be used. If not controlled with intensification dose of medication, refer to specialist.

2.5.3 Treatment adherence

Adherence to treatment is critical for blood pressure control. If antihypertensive medication is being prescribed, the following are critical to ensuring adherence:

- Teach the patient how to take the medications at home.
- Explain the difference between medicines for long-term control (for example, of blood pressure) and medicines for quick relief (such as for headaches).
- Explain the reason for prescribing the medicine(s).
    - Explain the diagnosis of hypertension.
    - Discuss the asymptomatic nature of hypertension and explain that medications must be taken even if there are no symptoms.
    - Inform patient of the complications of untreated hypertension, including stroke, heart attack, and kidney failure.
    - Explain the disability and economic and family burden these preventable complications cause.
- Show the patient the appropriate dose.
- Explain how many times a day the patient should take the medication and at what time, and adopt the following simple steps to help them to adhere to the guidelines:
    - Label and package the tablets.
    - Check the patient's understanding before the patient leaves the health center.

- Wherever possible, use once-daily dosages of all medications, to be given at the same time each day.

- Explain how important it is for the patient to:
  - Keep an adequate supply of medications safely at home.
  - Take the medicines regularly as advised, even if there are no symptoms.
- Explain potential adverse effects of the medications and what to do if the patient experiences the adverse effects.

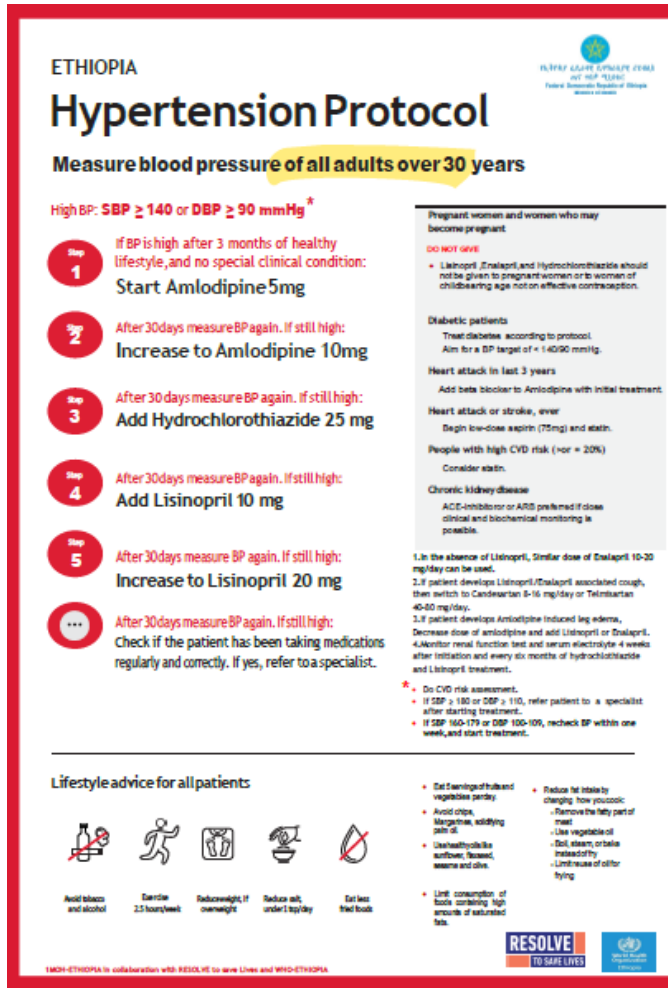


Figure: Ethiopia Hypertension Management Algorithm

3. MANAGEMENT OF HYPERTENSION IN SPECIAL CLINICAL CONDITIONS

3.1 Background

- Hypertensive patients have several comorbidities that can affect cardiovascular risk and treatment strategies.
- The number of comorbidities increases with age, with the prevalence of hypertension and other diseases.
- Common comorbidities include coronary artery disease (CAD), stroke, CKD, HF, and COPD.
- Uncommon comorbidities include rheumatic diseases and psychiatric diseases.
- Common and uncommon comorbidities should be identified and managed according to available evidence.

3.2 Ischemic Cardiovascular Disease and Heart failure (both ischemic and non-ischemic)

- Hypertension is one of the most important risk factors for CAD and stroke (ischemic or hemorrhagic stroke).
- Hypertension is also a risk factor for the development of HF with reduced ejection fraction (HFrEF), and HF with preserved ejection fraction (HFpEF). Clinical outcome is worse, and mortality is increased in hypertensive patients with HF.
- BP should be lowered if ≥140/90 mm Hg and treated to a target of <130/80 mm Hg (<140/80 in elderly patients).
- B-blockers are indicated for all HF patients with >BP 100/60, for HR >60 beats/minute and with no pulmonary edema.
- If LVEF <40 %: ACE inhibitors and spironolactone are prescribed
- If there is evidence of Heart failure furosemide should be prescribed (see heart failure for details)
- If BP is still >130/80, non-dihydropyridine calcium channel blockers are prescribed.
- Patient with ischemic stroke after acute event: Thiazide diuretic is preferred initial choice followed by ACEI and calcium channel blockers as third agent.

3.3 Diabetes

- BP should be lowered if ≥140/90 mm Hg and treated to a target <140/90 mm Hg (<130/80 if possible).

- Initial antihypertensive choice is similar to non -diabetic patient. ACEI/ARBs are preferred as second line for all diabetic patients with hydrochlorothiazide as third agent due to concern with raised blood glucose
- For proteinuric patients initial antihypertensive choice should either be single agent ACEI/ARB (if BP 130-159/80-99mmHG) or combination of ACEI/ARB and calcium channel blockers if initial BP is greater than 160/100mmHG.
- The treatment should include glucose and lipid lowering as per national guidelines. (Refer to the national diabetes protocol)

3.4 Hypertension and Chronic Kidney Disease (CKD)

- Hypertension is a major risk factor for the development and progression of albuminuria and any form of CKD.
- A lower eGFR is associated with resistant hypertension, masked hypertension, and elevated nighttime BP values.
- BP should be lowered if ≥140/90 mm Hg and treated to a target <140/90 mm Hg (<130/80 if possible).
- Furosemide or other loop diuretics are preferred first line agents if there is volume overload.
- If proteinuric and serum creatinine less than 2.5mg/dl, ACE inhibitors alone or in combination with hydrochlorothiazide or calcium channel blockers can be used. If serum creatinine increases by > 30% from baseline stop using the ACEI/ARB.
- If Serum creatinine >2.5mg/dl or patient has ESRD calcium channel blockers, loop diuretics, B blockers or methyldopa can be used.

3.5 Hypertension in Pregnancy

Hypertension in pregnancy is a condition affecting 5%–10% of pregnancies worldwide. Maternal risks include placental abruption, stroke, multiple organ failure (liver, kidney), disseminated vascular coagulation. Fetal risks include intrauterine growth retardation, preterm birth, and intrauterine death. Hypertension in pregnancy includes the following conditions:

- Preexisting hypertension: Starts before pregnancy or <20 weeks of gestation, and lasts >6 weeks postpartum with proteinuria.
- Gestational hypertension: Starts >20 weeks of gestation, and lasts <6 weeks postpartum.
- Preeclampsia: Hypertension with proteinuria (>300 mg/24 h or ACR >30 mg/mmol [265 mg/g]). Predisposing factors are preexisting hypertension, hypertensive

disease during previous pregnancy, diabetes, renal disease, first- or multiple pregnancy, autoimmune disease (SLE). Risks are fetal growth restriction, preterm birth.

- Eclampsia: Hypertension in pregnancy with seizures, severe headaches, visual disturbance, abdominal pain, nausea and vomiting, low urinary output: Immediate treatment and delivery required.
- HELLP (hemolysis, elevated liver enzymes, and low platelets) syndrome: Immediate treatment and delivery required.

Management of hypertensive disorders of pregnancy

Initiate Drug treatment if BP persistently:

- >150/95 mmHg in all women
- >140/90 mmHg if gestational hypertension or subclinical HMOD

First Line Drug Therapy Options: Methyldopa, Amlodipine, Nifedipine

If SBP ≥170mmHg or DBP ≥110mmHg (Emergency):

- Immediately hospitalize
- Initiate IV hydralazine and magnesium Sulfate
- If pulmonary edema, IV nitroglycerin

Delivery in Gestational Hypertension or Pre-Eclampsia

- At 37 weeks if asymptomatic
- Expedite delivery in women with pre-eclampsia with visual disturbances or hemostatic disorders or HELLP syndrome.

In summary, the following table summarizes the detailed considerations for prescribing antihypertensives.

Considerations for individualizing antihypertensive therapy

Indication or contraindication	Antihypertensive drugs
Compelling indications (major improvement in outcome independent of blood pressure)	
Heart failure with reduced ejection fraction	ACE inhibitor or ARB, beta blocker, diuretic, aldosterone antagonist*
Postmyocardial Infraction	ACE inhibitor or ARB, beta blocker, aldosterone antagonist
Proteinuric chronic kidney disease	ACE inhibitor or ARB
Angina pectoris	Beta blocker, calcium channel blocker
Atrial fibrillation rate control	Beta blocker, nondihydropyridine calcium channel blocker
Atrial flutter rate control	Beta blocker, nondihydropyridine calcium channel blocker
Likely to have a favorable effect on symptoms in comorbid conditions	
Benign prostatic hyperplasia	Alpha blocker
Essential tremor	Beta blocker (noncardioselective)
Hyperthyroidism	Beta blocker
Migraine	Beta blocker, calcium channel blocker
Osteoporosis	Thiazide diuretic
Raynaud phenomenon	Dihydropyridine calcium channel blocker
Contraindications	
Angioedema	Do not use an ACE inhibitor
Bronchospastic disease	Do not use a non-selective beta blocker
Liver disease	Do not use methyldopa
Pregnancy (or at risk for)	Do not use an ACE inhibitor, ARB, or renin inhibitor (eg, aliskiren)
Second- or third-degree heart block	Do not use a beta blocker, nondihydropyridine calcium channel blocker unless a functioning ventricular pacemaker
Drug classes that may have adverse effects on comorbid conditions	
Depression	Generally avoid beta blocker, central alpha-2 agonist
Gout	Generally avoid loop or thiazide diuretic
Hyperkalemia	Generally avoid aldosterone antagonist, ACE inhibitor, ARB, renin inhibitor
Hyponatremia	Generally avoid thiazide diuretic
Renovascular disease	Generally avoid ACE inhibitor, ARB, or renin inhibitor

ACE: angiotensin-converting enzyme; ARB: angiotensin receptor blocker.
* A benefit from an aldosterone antagonist has been demonstrated in patients with NYHA classIII-IV heart failure or decreased left ventricular ejection fraction after a myocardial infarction.

4. HYPERTENSIVE CRISES

4.1 Definition of hypertensive crises

Hypertensive emergencies are diagnosed if there is a systolic blood pressure higher than 180 mmHg or a diastolic blood pressure higher than 110 mmHg with the presence of acute target organ damage. The 1-year mortality incidence of hypertensive emergencies is more than 79%, and the median survival is 10.4 months if these persons are not treated with antihypertensive drug therapy.

Hypertensive urgencies are diagnosed if there is a systolic blood pressure higher than 180 mmHg or a diastolic blood pressure higher than 110 mmHg in an otherwise stable person without clinical or laboratory evidence of acute target organ damage. These persons need intensification of their antihypertensive drug therapy.

Patients with hypertensive emergencies include those who have:

- Hypertensive encephalopathy and retinopathy
- Ischemic and Hemorrhagic Stroke
- Acute Coronary Syndrome
- Acute Cardiogenic Pulmonary edema
- Acute Renal failure
- Acute Kidney Injury/Thrombotic microangiopathy (Malignant hypertension)
- Severe Preeclampsia / eclampsia
- Aortic Dissection

For hypertensive emergencies parenteral antihypertensive medication should be used for immediate BP reduction to avoid progressive organ failure. The choice of antihypertensive drugs used threshold to initiate treatment and targets BP are determined by the type of organ damage (see table below).

If there is no evidence of end organ damage mentioned above the patient is said to have hypertensive urgency and BP can be lowered more gradually with oral antihypertensive drugs.

The overall therapeutic goal in patients presenting with hypertensive emergencies is a controlled BP reduction to safer levels to prevent or limit further hypertensive damage while avoiding hypotension and related complications.

Table: Treatment timelines and BP targets as well as preferred antihypertensive drug choices for Specific Hypertensive Emergencies

Clinical Presentation	Timeline and Target BP	First Line Treatment	Alternative
Malignant hypertension with or without thrombotic microangiopathy or acute renal failure	Several hours, MAP –20% to –25%	Labetalol	Hydralazine
Hypertensive encephalopathy	Immediate, MAP –20% to –25%	Labetalol	Hydralazine
Acute ischemic stroke and SBP >220 mm Hg or DBP >120 mm Hg	1 h, MAP –15%	Labetalol	Hydralazine
Acute ischemic stroke with indication for thrombolytic therapy and SBP>185 mmHg or DBP>110mmHg	1 h, MAP –15%	Labetalol	Hydralazine
Acute hemorrhagic stroke and SBP >180 mm Hg	Immediate, 130<SBP<180 mm Hg	Labetalol	Hydralazine
Acute coronary event	Immediate, SBP <140 mm Hg	Nitroglycerine	
Acute cardiogenic pulmonary edema	Immediate, SBP <140 mm Hg	Nitroglycerine (with loop diuretic)	Loop diuretic
Acute aortic disease	Immediate, SBP <120 mm Hg and heart rate <60 bpm	Nitroglycerine and metoprolol	Labetalol or metoprolol
Eclampsia and severe preeclampsia/ HELLP	Immediate, SBP <160 mm Hg and DBP <105 mm Hg	Labetalol and magnesium sulphate	Hydralazine or short acting nifedipine

MAP=Mean Arterial Blood pressure (calculated as SBP+2DBP divided by 3)

Follow Up after hypertensive emergency

Patients who experienced a hypertensive emergency are at increased risk of cardiovascular and renal disease. Thorough investigation of potential underlying causes and assessment of Hypertensive Mediated Organ Damage (HMOD) is mandatory to avoid recurrent presentations with hypertensive emergencies.

Similarly, adjustment and simplification of antihypertensive therapy paired with advice for lifestyle modification will assist to improve adherence and long-term BP control. Regular and frequent follow-up (monthly) is recommended until target BP and ideally regression of HMOD has been achieved.

5. ROUTINE CARE FOR HYPERTENSION

Routine monitoring for hypertensive patients

Assess	When to assess	Note
Symptoms	Every visit	Manage symptoms on symptom pages. Ask about symptoms of heart failure, ischaemic heart disease, or stroke/TIA.
BP	Check 2 readings at every visit.	If BP < 140/90 (< 150/90 if ≥ 60 years), BP is controlled: continue current treatment and review 3-6 monthly. If BP ≥ 140/90 (≥ 150/90 if ≥ 60 years), BP is not controlled: decide based on algorithm. If ≥ 180/110: also check if patient needs urgent attention.
CVD risk	At diagnosis, then depending on risk	Assess CVD risk using WHO Risk Assessment Chart. Decide based on result
Eyes for retinopathy	At diagnosis, then yearly and if visual problems	If new retinopathy, visual problems or cataracts, refer.
Glucose	At diagnosis, then yearly	Check glucose. If known diabetes manage.
eGFR	At diagnosis, then yearly	If eGFR < 60mL/min/1.73m2, discuss or refer to specialist.
Urine dipstick	At diagnosis, then yearly	If blood or protein on dipstick, refer to hospital and repeat dipstick at next visit. If glucose on dipstick, screen for diabetes.
Random total cholesterol	At diagnosis, then yearly	If cholesterol ≥ 300mg/dl start simvastatin and refer for further assessment.
	3 months after starting simvastatin/ Atorvastatin	If repeat cholesterol > 190mg/dl increase simvastatin dose. If already on 40mg daily discuss with specialist.
ECG	At diagnosis, then yearly	If abnormal, discuss with doctor.

SECTION 2:
WHO RISK-BASED CVD MANAGEMENT PROTOCOL IN ETHIOPIA

Abbreviations

BMI: body mass index
CAD: coronary artery disease
CVD: cardiovascular disease
DM: diabetes mellitus
ESC: European Society of Cardiology
GBD: Global Burden of Disease
HTN: hypertension
HDL-C: high-density lipoprotein cholesterol
IHME: Institute for Health Metrics and Evaluation
IHRMS: INTERHEART Modifiable Risk Score
LMIC: low- and middle-income countries
MI: myocardial infarction
NCR-RisC: NCD Risk Factor Collaboration
PEN: Package of Essential Non-communicable Disease Interventions
SBP: systolic blood pressure
TC: total cholesterol
WHO/ISH: World Health Organization / International Society of Hypertension

1. INTRODUCTION TO CV RISK ASSESSMENT

CVDs are number one cause of death globally with estimated 17.9 million people dying from CVDs in 2016, representing 31% of all global deaths. Of CVD deaths, 85% are due to heart attack and stroke and about 80% occur in low- and middle-income countries, often in people less than 60 years of age.

Few hospital based studies and evidences from 2017 global burden of diseases have clearly demonstrated that CVDs are rising alarmingly in Ethiopia on top of already existing CVDs like Rheumatic heart diseases, cardiomyopathy and cor-pulmonale.

Cardiovascular diseases (CVD) are preceded by longtime exposure to single or combined risk factors which can be modifiable or non-modifiable. Continuing exposure to these risk factors leads to further progression of cardiovascular diseases which include one or more of the following:

- Coronary artery disease (CAD) manifested by fatal or nonfatal myocardial infarction (MI), angina pectoris, and/or heart failure
- Cerebrovascular disease manifested by fatal or nonfatal stroke and transient ischemic attack
- Peripheral artery disease manifested by intermittent claudication and critical limb ischemia
- Aortic atherosclerosis and thoracic or abdominal aortic aneurysm

Early identification, control and avoidance of the modifiable risk factors can significantly reduce or retard the progression of cardiovascular diseases. Moreover, control of the risk factors before development of CVDs is the most cost effective and applicable intervention especially for low-income countries likes Ethiopia.

Previous guidelines did not take into consideration some important facts: that multiple risk factors are responsible for cardiovascular disease, that risk factors and determinants of heart attacks and strokes are very similar, and, therefore, prevention approaches are similar. The new guidelines integrate the management of multiple risk factors e.g., raised blood pressure, raised cholesterol, and raised blood sugar and tobacco use. Current evidence show total cardiovascular risk assessment is a better strategy than single factor interventions.

2. CARDIOVASCULAR RISK ESTIMATION

The current approach for the treatment and management of individual CV risk factors such as hypertension and dyslipidemia for prevention of atherosclerosis and CVD include the following important measures:

- CV risk assessment.
- Treatment of those at high risk for disease.
- Management adjusted to patient's total CVD risk, the higher the risk, the greater the intensity of management.
- Employment of a range of interventions to address risk factors for CVD, including treatment of hypertension, treatment of dyslipidemia, smoking cessation, increased physical activity, cardio protective diet, treatment of hyperglycemia, weight management, antiplatelet/anticoagulant therapy, and psychosocial support.

There is no single absolute test, or score used to predict the future development of CVDs. While a general estimate of the relative risk for CVD can be approximated by counting the number of traditional risk factors present in a patient, the increased risk of CVD resulting from multiple risk factors is frequently greater than simply additive. Hence, we need a more precise estimation of the absolute risk for a first CVD event desirable when making treatment recommendations for a specific individual.

The total risk approach relies on risk prediction scores derived from large epidemiologic cohort studies involving diverse groups of individuals with risk factors but with no CVDs at baseline. The follow up in these studies is usually made over long period of time like over 10 years with consideration of the requirement for the risk factors to be present for extended time to result in statistically significant number of CVDs. The World Health Organization (WHO) and the International Society of Hypertension (ISH) recently developed a set of CV risk prediction charts for use in all regions of the world. The first WHO risk prediction chart was developed in 2007 and recent update was made in 2019 where the world was divided into 21 GBD regions and Ethiopia is represented by the Eastern Sub-Saharan African Region. It was suggested by the WHO working group of CV risk prediction chart that each country should adapt the risk chart to its national context. It is with this basis that the national CV working group developed this risk.

3. WHO CVD Risk Charts

3.1 Definitions of terms

It is worth to define the following terms before using WHO risk charts.

A. CV risk: in the WHO risk assessment CV risk refers to the chance of having fatal or nonfatal heart attack or stroke in the next 10 years with the current risk profile of the patient.

B. CV risk factors are any biologic or environmental conditions known to increase the inherent risk/chance of having CV event. They are classified into modifiable and non-modifiable risk factors. The following are known modifiable cardiovascular risk factors:

1. Raised Blood Pressure
2. Dyslipidemia (raised total cholesterol, low HDL, high LDL or raised TGs)
3. Diabetes Mellitus
4. Overweight/Obesity/Metabolic Syndrome
5. Low physical exercise
6. Unhealthy diet (Low fruit intake, excess salt intake, consumption of high saturated or trans-fat diet)
7. Smoking
8. Excess alcohol intake
9. Psychosocial Stress

The non-modifiable risk factors include age, gender, family history, race and other genetic factors

C. Cardiovascular disease (CVD): is manifested cardiovascular event (stroke, heart attack, peripheral arterial, or aortic disease).

D. Risk chart: is collection of tables of risk estimates with different types and levels of risk factors.

E. Primary Prevention: This is control of risk factors before cardiovascular disease develops.

F. Secondary Prevention: Prevention of further occurrence or progression of previous cardiovascular disease.

3.2 TYPES OF WHO RISK CHARTS

WHO risk charts were developed for estimation of the chance of future cardiovascular event in those individuals who never had cardiovascular diseases. It does not apply for patients who have already developed cardiovascular diseases.

There are two types of WHO risk charts based on availability of laboratory facility to measure blood glucose and cholesterol levels

A. Laboratory-based WHO CVD risk charts

These are CVD risk charts that include measurements of total cholesterol and information on diabetes mellitus. The laboratory-based CVD risk charts should be used for treatment decisions. This is the indicated risk chart in a setting where laboratory facilities and human and financial resources are accessible. These charts will facilitate health providers to initiate an intervention and treatment regimen, and to implement an appropriate follow-up plan based on the patient's total risk status.

The variables needed for using this chart are as follows:

History:

- Age: specific numbers between 40 to 74 years. The risk prediction doesn't apply for age category out of the specified range.
- Smoking: current or past history of smoking
- Sex: Male OR Female
- Diabetes: Yes OR No. If history of diabetes is not known OR there is no blood sugar determination facility; then risk assessment should be done using the other risk prediction chart (the non-laboratory based charts)

Physical Examination

Blood Pressure: measured value of the systolic blood pressure

Laboratory

1. Blood sugar: to diagnose diabetes
2. Total cholesterol: Measured values of total cholesterol in mmol/L. In most of the Ethiopian Laboratories, total cholesterol is in mg/dl units; but the risk prediction score applies values in mmol/l units. The cholesterol value in mg/dl should be multiplied by 0.02586 before applying the value for risk prediction.

B. Non-laboratory-based WHO risk charts

Many HC and Primary Hospitals have limited testing facilities or limited financial and physical capacity for biochemical measurements (e.g. blood sugar determination and cholesterol assays). WHO CVD risk (non-laboratory-based) charts can be used to predict total CVD risk without information on total cholesterol and diabetes. In most primary health care facilities of Ethiopia, laboratory facilities exist to diagnose diabetes either with fasting or random blood glucose levels. If the patient is not diabetic, the non- laboratory-based WHO risk chart correlates well with laboratory-based risk chart when a 10 % cut of point is used as high risk. The non-laboratory-based WHO CVD risk charts are aimed at stratification in low-resource communities and office settings and can be used for decisions regarding referral. Patients diagnosed to have diabetes and non-diabetic patients with non-lab-based risk level of greater than 10% should be considered high risk and managed accordingly in areas where serum cholesterol cannot be determined.

To use the non-lab based chart, the following variables should be available:

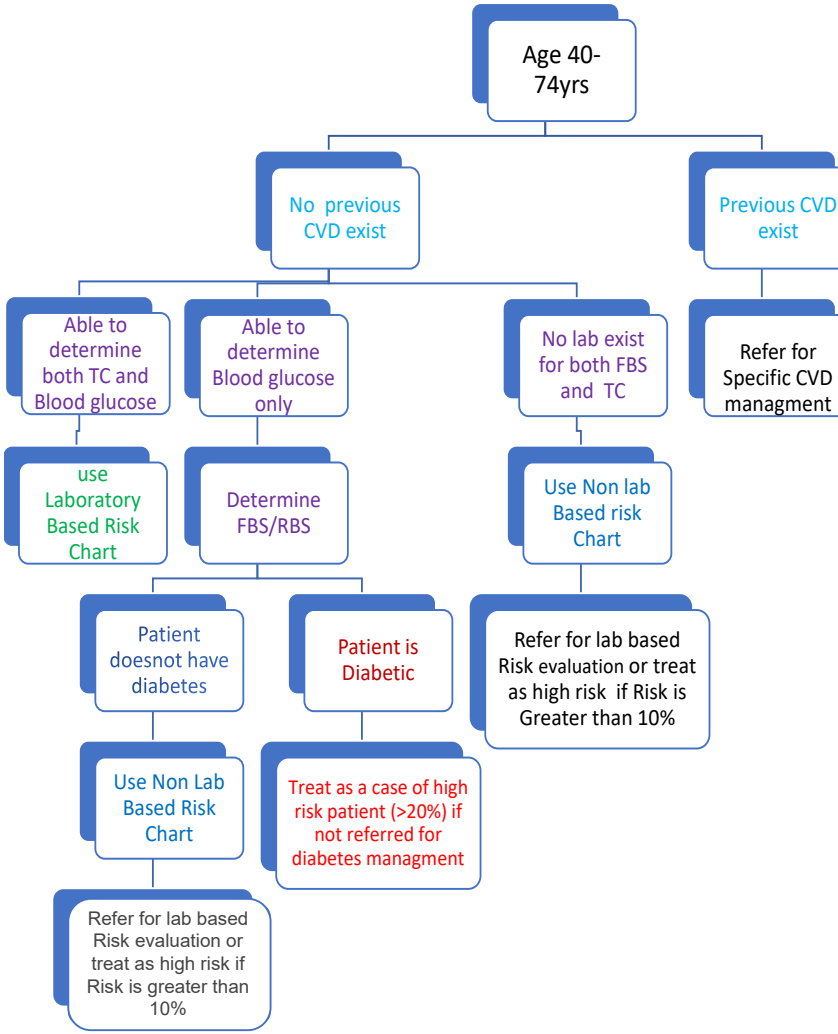
History:

1) Age: specific numbers between 40 to 74 years. The risk prediction doesn't apply for age category out of the specified range
2) Smoking: current smoking
3) Sex: Male OR Female

Physical Examination

1) Blood Pressure: measured value of the systolic blood pressure
2) BMI (Body Mass Index): Calculation of the BMI from weight and height

Figure 1: Steps in selecting appropriate Chart for WHO CV Risk Assessment



4 INSTRUCTIONS FOR USING THE WHO CVD RISK CHARTS

4.1 Laboratory- based Risk Chart

Table 1and Figure 2 presents a step-by-step guide to applying the WHO CVD (laboratory-based) risk charts. These charts are to be used only for individuals whose status regarding diabetes and total cholesterol is available. Tests for diabetes and cholesterol can be carried out at the time of assessment. If the information on diabetes and total cholesterol is not available, then refer to the instructions on use of non-laboratory-based risk charts.

Table 1: Instructions for using laboratory-based WHO risk Chart

<table>
<tr><td colspan="4">Have the following information ready:
• age
• sex
• smoker' or non-smoker
• presence or absence of diabetes!
• systolic blood pressure
• total blood cholesterol!</td></tr>
<tr><td colspan="4">Using the charts</td></tr>
<tr><td colspan="4">STEP1: Select the section of the chart as relevant for people with or without diabetes.</td></tr>
<tr><td colspan="4">STEP 2: Select the table for men or women, as appropriate.</td></tr>
<tr><td colspan="4">STEP 3: Select smoker or non-smoker column.</td></tr>
<tr><td colspan="4">STEP 4: Select age-group.</td></tr>
<tr><td colspan="4">STEP 5: Within the selected box find the cell where the person's systolic blood pressure and total blood cholesterol intersect.</td></tr>
<tr><td rowspan="5">STEP 6: The colour of the cell indicates the 10-year risk of a fatal or non-fatal CVD event The value within the cell is the risk percentage. Colour coding is based on the grouping</td><td></td><td>Green</td><td><5%</td></tr>
<tr><td></td><td>Yellow</td><td>5% to <10%</td></tr>
<tr><td></td><td>Orange</td><td>10% to <20%</td></tr>
<tr><td></td><td>Red</td><td>20% to <30%</td></tr>
<tr><td></td><td>Deep Red</td><td>≥30%</td></tr>
<tr><td colspan="4">STEP 7: Record CVD risk percentage in person's chart.</td></tr>
<tr><td colspan="4">STEP 8: Counsel, treat and refer according to risk level</td></tr>
<tr><td colspan="4">* Current smoker
† Fasting plasma ≥ glucose ≥7.0 mmol/L (126 mg/dL), or 2-h plasma glucose ≥11.1 mmol/L (200 mg/ dL), or HbA1c ≥ 6.5% or known diabetes
‡ Cholesterol values are to be entered in the chart as mmol/L(To convert mg/dL to mmol/L multiply by 0.02586. eg 200 mg/dL x 0.02586 = 5.172 mmol/L)</td></tr>
</table>

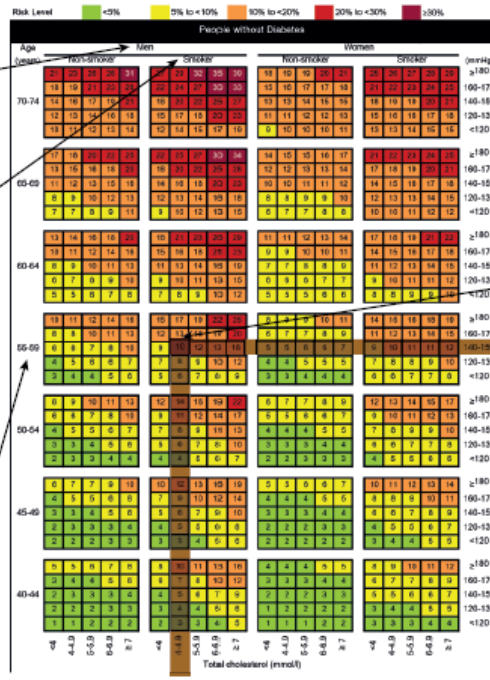
Figure 2: Step by Step Instructions for using laboratory based WHO risk Chart

STEP 1 Select the section of the chart for people with or without diabetes.

STEP 2; Select the table for men or women, as appropriate

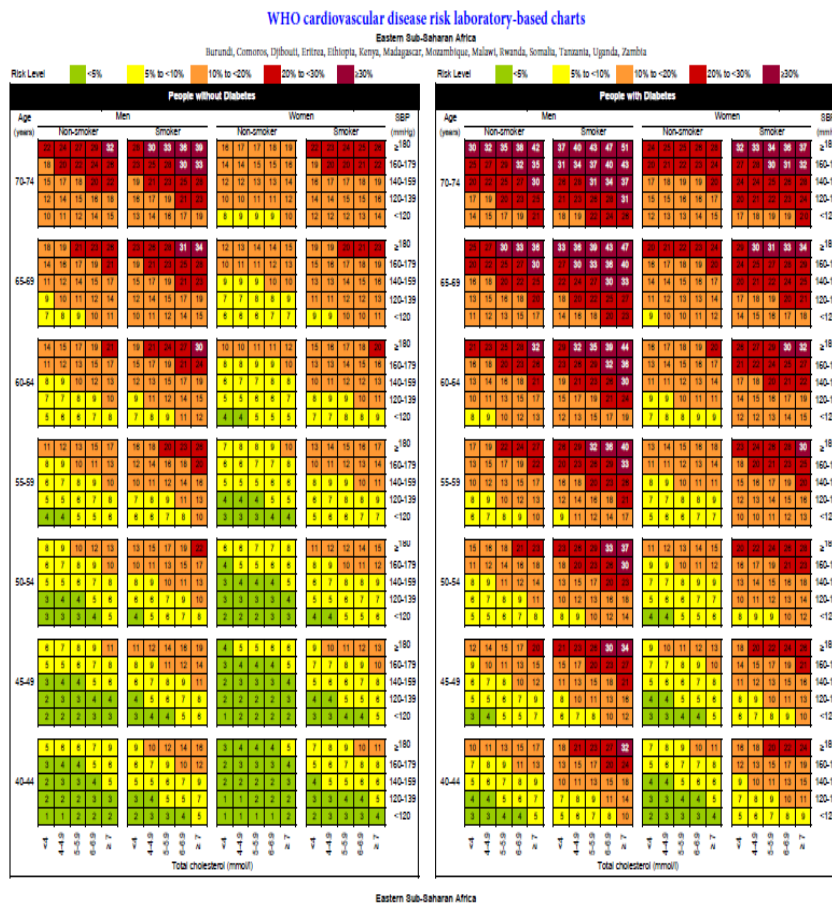
STEP 3; Select the column for non-smoker or smoker.

STEP 4; Select the relevant age group.



STEP 5; Within the selected box, find the cell where the person's systolic blood pressure and serum cholesterol intersect.

Table 2: Laboratory based WHO risk Chart



4.2 Non laboratory-based WHO CV Risk Charts

These charts are for the use in settings where blood glucose and cholesterol cannot be measured. They can also be used to identify people at high risk who can be taken up for further investigations.

Table 2 and Figure 3present the steps to apply the non-laboratory WHO CVD risk charts.

Table 4: Instructions for using Non laboratory-based WHO risk Chart

Have the following information ready: • age • sex • smoker" or non-smoker • systolic blood pressure • BMI (body mass index) = weight (kg) 4÷ height (m)2			
Using the charts			
STEP1: Select the table for men or women, as appropriate.			
STEP 2: Select smoker or non-smoker column.			
STEP 3: Select age-group.			
STEP 4: Within the selected box find the cell where the person's systolic blood pressure and body mass index (BMI) intersect.			
STEP 5: The colour of the cell indicates the 10-year risk of a fatal or non-fatal CVD event. The value within the cell is the risk percentage. Colour coding is based on the grouping		Green	<5%
		Yellow	5% to <10%
		Orange	10% to <20%
		Red	20% to <30%
		Deep Red	≥30%
STEP 6: Record CVD risk percentage in person's chart.			
STEP 7: Counsel, treat and refer according to risk level			
* Current smoker			

Figure 3: Step by Step Instructions for using Non-laboratory based WHO risk Chart

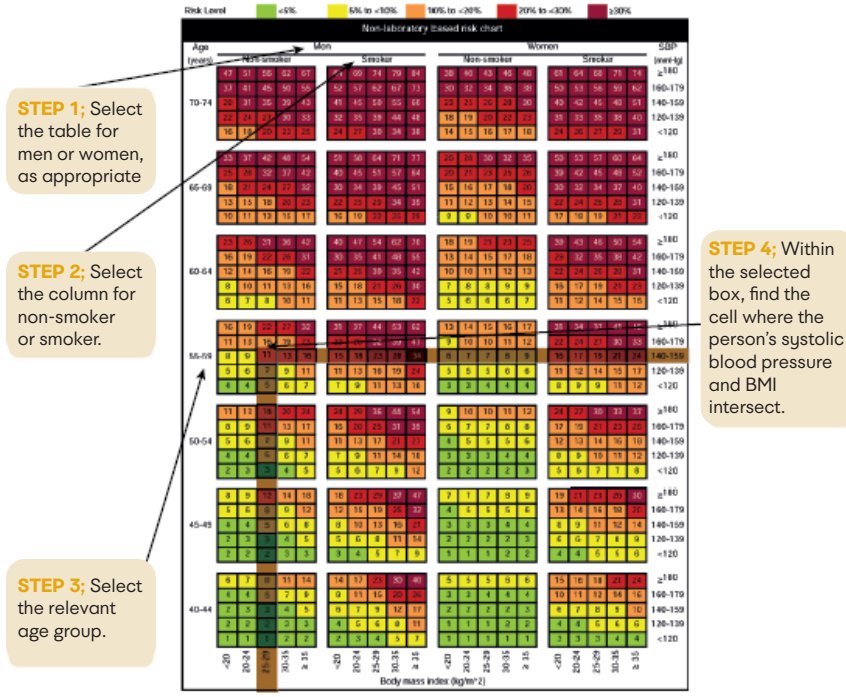
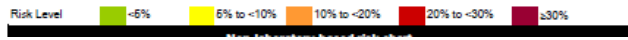


Table 5: Non-Laboratory based WHO risk Chart

WHO cardiovascular disease risk non-laboratory-based charts

Eastern Sub-Saharan Africa

Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Madagascar, Malawi, Mozambique, Rwanda, Somalia, Uganda, United Republic of Tanzania, Zambia



Non-laboratory-based risk chart

Age (years)	Men										Women										SBP (mmHg)
	Non-smoker					Smoker					Non-smoker					Smoker					
	<20	20-24	25-29	30-35	≥ 35	<20	20-24	25-29	30-35	≥ 35	<20	20-24	25-29	30-35	≥ 35	<20	20-24	25-29	30-35	≥ 35	
70-74	24	25	27	29	30	30	32	34	36	38	18	18	19	20	20	25	26	26	27	28	≥180
	20	21	22	24	25	25	26	28	30	32	15	15	16	16	17	21	22	22	23	24	160-179
	16	17	18	20	21	21	22	23	25	27	12	13	13	14	14	18	18	19	19	20	140-169
	13	14	15	16	17	17	18	19	21	22	10	11	11	11	12	15	15	16	16	17	120-139
	11	11	12	13	14	14	15	16	17	18	9	9	9	10	10	12	13	13	14	14	<120
65-69	19	20	22	23	25	25	27	29	31	34	14	14	15	16	16	21	22	23	24	24	≥180
	15	16	17	19	20	20	22	24	26	28	11	12	12	13	13	17	18	19	20	20	160-179
	12	13	14	15	16	16	18	19	21	23	9	10	10	10	11	14	15	15	16	17	140-169
	9	10	11	12	13	13	14	15	17	18	8	8	8	8	9	12	12	13	13	14	120-139
	8	8	9	10	11	10	11	12	14	15	6	6	7	7	7	10	10	10	11	11	<120
60-64	14	16	17	19	21	21	23	25	28	30	11	11	12	12	13	18	19	20	20	21	≥180
	11	12	14	15	16	17	18	20	22	24	9	9	9	10	10	15	15	16	16	17	160-179
	9	10	11	12	13	13	14	16	17	19	7	7	7	8	8	12	12	13	13	14	140-169
	7	7	8	9	10	10	11	12	14	15	5	6	6	6	6	9	10	10	11	11	120-139
	5	6	6	7	8	8	9	10	11	12	4	4	5	5	5	7	8	8	8	9	<120
55-59	11	12	14	15	17	17	19	22	24	27	9	9	9	10	10	15	16	17	18	19	≥180
	8	9	11	12	13	13	15	17	19	21	7	7	7	8	8	12	13	13	14	15	160-179
	6	7	8	9	10	10	11	13	15	16	5	5	6	6	6	9	10	10	11	11	140-169
	5	5	6	7	8	8	9	10	11	13	4	4	4	4	5	7	8	8	8	9	120-139
	4	4	5	5	6	6	7	8	9	10	3	3	3	3	4	6	6	6	7	7	<120
50-54	9	10	11	12	14	14	16	18	21	24	7	7	7	8	8	13	14	14	15	16	≥180
	6	7	8	9	11	11	12	14	16	18	5	5	5	6	6	10	10	11	12	12	160-179
	5	5	6	7	8	8	9	11	12	14	4	4	4	4	5	8	8	8	9	9	140-169
	3	4	4	5	6	6	7	8	9	10	3	3	3	3	3	6	6	6	7	7	120-139
	3	3	3	4	4	4	5	6	7	8	2	2	2	2	3	4	5	5	5	6	<120
45-49	7	8	9	10	11	12	14	16	18	21	5	5	6	6	6	11	12	12	13	14	≥180
	5	5	6	7	8	9	10	12	14	16	4	4	4	4	5	8	9	9	10	10	160-179
	3	4	5	5	6	6	7	9	10	12	3	3	3	3	3	6	6	7	7	8	140-169
	2	3	3	4	4	5	5	6	7	9	2	2	2	2	3	4	5	5	5	6	120-139
	2	2	2	3	3	3	4	5	5	6	1	2	2	2	2	3	4	4	4	4	<120
40-44	5	6	7	8	9	10	11	13	16	19	4	4	4	5	5	9	10	11	11	12	≥180
	4	4	5	6	7	7	8	10	11	14	3	3	3	3	4	7	7	8	8	9	160-179
	2	3	3	4	5	5	6	7	8	10	2	2	2	2	3	5	5	6	6	6	140-169
	2	2	2	3	3	3	4	5	6	7	1	2	2	2	2	3	4	4	4	5	120-139
	1	1	2	2	2	2	3	4	4	5	1	1	1	1	1	3	3	3	3	3	<120

Body mass index (kg/m^2)

5. APPLICATIONS OF WHO RISK ASSESSMENT CHARTS

As stated above the WHO risk chart applies for patients who haven't been diagnosed to have cardiovascular diseases like stroke, heart attack, peripheral arterial, or aortic diseases. For patients with cardiovascular diseases, management should include specific disease management and more intense risk factor management with lifestyle interventions and pharmacologic agents. Below are summaries of recommendation for management of CVD risk factors for primary prevention of CVDs. Table 4 depicts action required in different clinical situations and risk levels.

1. Hypertension (See HTN treatment protocol for details)

- Target blood pressure should be less than 140/90mmHG in all risk groups
- For patients with high WHO risk (>10%with non-lab based and >20% with lab based WHO risk), antihypertensive drug should be started to lower BP below 140/90 on top of life style interventions.
- For patients with BP of 140-159/90-99 mmHG and no end-organ damage or cardiovascular diseases, antihypertensive drug can be started after 3 months trial of life style interventions to keep BP <140/90mmHG.
- For any WHO risk level and BP >160/100mmHG drug should be started to lower BP below 140/90 on top of life style intervention

2. Dyslipidemia

- All patients with WHO risk level greater than 20% should receive statin as part of primary prevention.
- All patients with TC of 324mg/dl or serum LDL of > 190 if available should be given statin regardless of risk level.
- All diabetic patients older than 40 years should receive statin regardless of WHO risk level or serum cholesterol level.

3. Lifestyle interventions

- All individuals should be encouraged to engage in healthy lifestyle (see specific topic for details) at any risk level. If CVD risk is < 10% and no CVD risk factors, reassess CVD risk after 5 years.
- Patients with any behavioral (unhealthy diet, smoking, excess alcohol intake, sedentary life) and physiologic risk factors (obese or patients with metabolic syndrome) should be routinely evaluated for control of these risk factors and have annual CV risk assessment.

4. Patients with high CVD risks (>20% with lab-based and >10 % with non-lab based WHO risk Charts)

are managed like patients with established CVDs. Stain should be started and preferably referred to specialist center for better evaluation and initiation of treatments.

Dose: Atorvastatin 20-40mg/day if not available Simvastatin 40mg/day for primary prevention of CV events.

For patients with previous cardiovascular events or for patients with very high cholesterol levels (Total cholesterol >320mg and/or LDL cholesterol >190mg/dl) double the above doses.

5. For policy makers, Monitoring and evaluation of CVD interventions

- WHO risk can be used for baseline cardiovascular risk assessment at national, regional and facility level and to assess the impacts of CV interventions at national and subnational levels.

Table 3. Management guidance for total CVD risk

Management of total CVD risk	
Risk <10%	➢ Counsel on diet, physical activity, smoking cessation and avoiding harmful use of alcohol. ➢ If risk <5%, follow up in 12 months. ➢ If risk 5% to <10%, follow up every 3 months until targets are met, then 6–9 months thereafter.
Risk 10% to <20%	➢ Counsel on diet, physical activity, smoking cessation and avoiding harmful use of alcohol. ➢ Persistent BP ≥140/90 mmHg consider drugs (see below). ➢ Follow up every 3–6 months.
Risk >20% (or >10% with Non lab based WHO risk)	➢ Counsel on diet, physical activity, smoking cessation and avoiding harmful use of alcohol. ➢ Persistent BP ≥130/80, consider drugs (see below). ➢ Give a statin. ➢ Follow up every 3 months. If there is no reduction in cardiovascular risk after six months of follow-up refer to next level.
Important practical points	**Management of hypertension and diabetes** ➢ For management of hypertension refer National Hypertension Treatment Protocol ➢ For management of diabetes mellitus type National Diabetes Treatment Protocol
	Consider drug treatment for following categories: ➢ All patients with established DM and CVD (coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease or peripheral vascular disease), renal disease. If stable, should continue the treatment already prescribed and be considered as having risk >20%. ➢ People with albuminuria, retinopathy, left ventricular hypertrophy. ➢ All individuals with persistent raised BP ≥160/100 mmHg. ➢ Consider statin for high risk patients , diabetes, previous cardiovascular disease and very high cholesterol levels (see above)
	Follow-up visits: ➢ Ask about: new symptoms, adherence to advice on tobacco and alcohol use, physical activity, healthy diet, medications etc. ➢ Assess (physical exam). ➢ Estimate cardiovascular risk. ➢ Refer if necessary. ➢ Counsel all and treat as shown in protocol.

SECTION 3:
NATIONAL ACUTE RHEUMATIC FEVER AND RHEUMATIC HEART DISEASE DIAGNOSIS AND TREATMENT PROTOCOL

1. ACUTE TONSILLOPHARYNGITIS

1.1 Introduction

- Rheumatic fever is an inflammatory disease involving the joints, skin, heart and brain, which develops following an untreated or partially treated group A Beta-hemolytic streptococcal (GABHS) infection of the throat (streptococcal pharyngitis).
- Most episodes of acute tonsillopharyngitis are caused by viruses.
- Up to 30% of sore throats in children and young people are caused by GABHS
- GABHS pharyngitis is rare among those under the age of 3 years and highest in children 5-15 year of age, especially in young school-age children.
- About 0.3% to 3% of young people with an untreated GABHS sore throat will develop RF.
- After recovery from the initial episode of RF, up to 60% to 65% of patients develop valvular heart disease and the risk of RF recurrence following GABHS infection rises to 50%.
- Identification and treatment of bacterial sore throat is an important component of Rheumatic Fever/Rheumatic Heart Disease Prevention and Control Program.

1.2 Diagnosis of Streptococcal Tonsillopharyngitis

We follow the Clinical Decision Rule (CDR) for diagnosis of streptococcal pharyngitis

Cardinal Clinical features

Symptoms or Signs	Points
History of high fever or (objective record ≥ 38°C)	1
Absence of cough and rhinorrhea	1
Tender anterior Cervical adenopathy	1
Tonsillar swelling or exudates	1

Clinical Decision Rule (CDR)

- ≥ 2 points, treat as GABHS pharyngitis (with antibiotic),
- < 2 points, treat as viral pharyngitis (no antibiotic

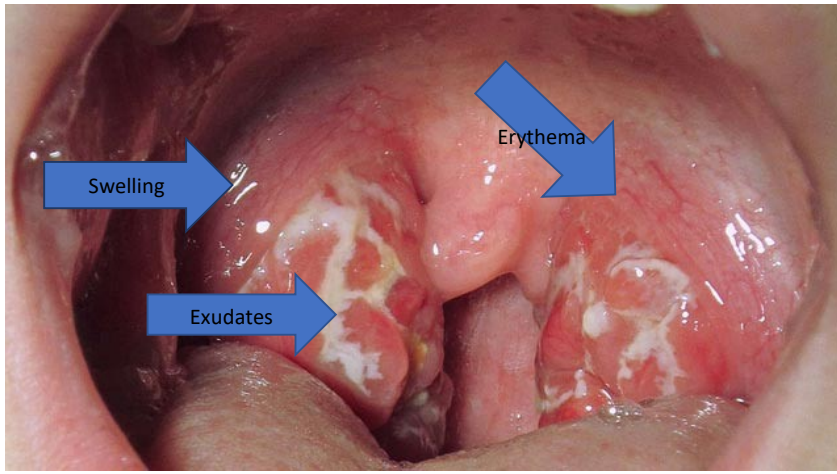


Figure. Tonsillar swelling with erythema and exudates.

1.3 Management of Bacterial Tonsillopharyngitis

Objectives of bacterial sore throat therapy

- To improve clinical symptoms and signs.
- For the prevention of supportive complications (e.g. Peritonsillar abscess)
- For the reduction of transmission of GAβHS to family members, classmates and other close contacts of the patient.
- to allow for the rapid resumption of usual activities
- for the prevention of Acute Rheumatic Fever (80% reduction of risk);

General Management

- Analgesics/Antipyretic (paracetamol) for relief of pain and fever.
- Identification and early treatment of complications
- Avoid cold drinks
- Hydration and rest may be needed.

Specific Management (Antimicrobial therapy)

First Line	Alternative	If Patient is allergic to penicillin:
Benzathine penicillin G Dose: Wt. < 30kg: 600,000 IU IM stat. Wt. > 30 kg: 1.2 million IU IM stat. **Follow Safe BPG Injection Procedures!**	**Amoxicillin** Dose: Children < 7years: 50 mg/kg per day in three divided doses for 10 days. Age ≥ 7 Years: 500mg POTID for 10 Days	**ERYTHROMYCIN** Dose: • Children < 7 years: 250 mg BD for 10 days • Age ≥ 7 years: 500 mg BD for 10 days

2. ACUTE RHEUMATIC FEVER

2.1 Introduction

- ARF is a multisystem post infectious, non-supportive sequelae of tonsillopharyngeal infection with Group A Beta Hemolytic Streptococci (Streptococcus pyogenes).
- It usually affects children and young adults.
- RHD is the only long-term sequelae of ARF or recurrent rheumatic fever.
- RHD manifests several years (5-20 years) after ARF with heart failure or complications like atrial fibrillation, stroke or infective endocarditis.
- ARF and RHD can easily be prevented by early identification and treatment of streptococcal pharyngeal infection.

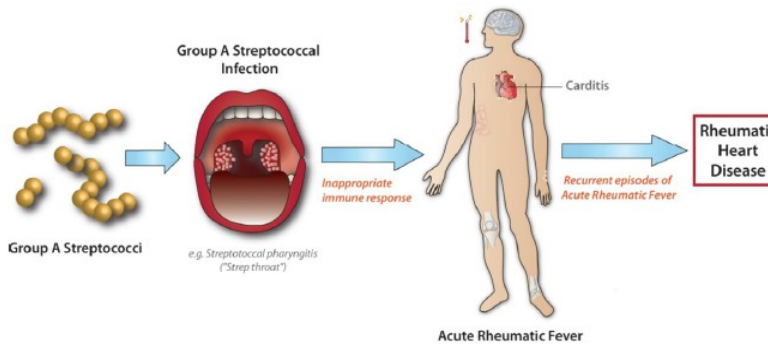


Figure: Pathogenesis of Acute Rheumatic Fever and RHD

2.2 Diagnosis of Acute Rheumatic Fever

We use the Revised Jone's Criteria for Diagnosis of Acute Rheumatic Fever for high prevalence settings.

Table: Revised Jone's Criteria for Diagnosis of Acute Rheumatic Fever for high prevalence settings

<table>
<tr><td colspan="3">Evidence of preceding group A streptococcal infection (other than chorea):
✓ Raised ASO titer OR
✓ Positive throat culture for GABHS OR
✓ Positive Rapid antigen test OR
✓ Recent history of tonsilopharyngistis *strongly consider and emphasize</td></tr>
<tr><td rowspan="2">Diagnosis:</td><td>Intial ARF</td><td>2 major or 1 major plus 2 minor manifestations PLUS evidence of recent strep infection (other than chorea)</td></tr>
<tr><td>Recurrent ARF</td><td>2 major or 1 major and 2 minor or 3 minor PLUS evidence of recent strep infection (other than chorea)</td></tr>
<tr><td colspan="3">Criteria</td></tr>
<tr><td>A. Major</td><td colspan="2">B. Minor</td></tr>
<tr><td>• Arthritis (Monoarthritis or polyarthri tis or polyarthralgia[a]
• Carditis[b] (Clinical and/or subclinical)
• Chorea
• Erythema marginatum
• Subcutaneous nodules</td><td colspan="2">• Monoarthralgia
• Fever (≥38°C)
• ESR ≥30 mm/lh and/or CRP ≥3 mg/dL[c]
• Prolonged PR on ECG (for age) (unless carditis is a major criterion</td></tr>
</table>

[a]Polyarthralgia should only be considered as a major manifestation after exclusion of other causes and in the presence of another major criterion. Joint manifestations can only be considered in either the major or minör categories but not both in the same patient.

[b]Sub-clinical carditis is pathological echocardiographic valvulitis

[c]CRP value must be greater than upper limit of normal for the laboratory. Also because ESR may evolve during the course of ARF, peak ESR values should be used.

Chorea does not require other manifestations or evidence of preceding Strep A infection, provided other causes of chorea are excluded.

Decision Based on Jone's Criteria

Definite ARF: 2 major, or 1 major plus 2 minor manifestations PLUS evidence of recent strep infection (other than chorea)

Highly Probable ARF: If an ARF diagnosis is considered highly probable (but not confirmed due to lack of evidence for recent streptococcal infection). This group may be more common in Ethiopia as there is often lack of laboratory tests to confirm recent streptococcal infections.

2.3 Management of Definite and Highly Probable Acute Rheumatic Fever

- Admit in Hospital
- Confirm diagnosis
- Investigate for complications or extent of disease
- Educate patient and family on ARF and RHD
- Register in national RHD register for chronic care

Table: Management of Acute Rheumatic Fever

ARF Condition	Management	Follow up
Treat the Infection	• A single intramuscular injection of benzathine penicillin G (BPG) to eradicate GAS from upper respiratory tract. o 600 000 IU for those < 30kg and o 1.2 million IU for those > 30kgs. • Erythromycin PO for 10 days, if allergic to penicillin.	Monthly IM Benzathine Penicillin G
Treat Arthritis and fever	**Mild to Moderate Arthralgia** • Paracetamol at doses of 60 mg/kg/day in four divided doses **For Arthritis and severe arthralgia Use:** • Start Aspirin 75 mg per kilogram per day divided 6 hourly after meals for up to 4-6 weeks, OR • Ibuprofen 30mg/kg per day 8 hourly. **If Patient is not responding or tolerating ASA or Ibuprofen** • Start Prednisolone 2mg per kilogram per day for 2 weeks; then aspirin is added at dose 60 mg per kilogram per day divided into 4 doses for another 2 weeks; then Prednisolone is tapered & discontinued	• ESR 2 weekly and taper aspirin dose by decreasing the dose of Aspirin by 2 tablets every week • Most ARF episodes subside within 6 weeks, and 90% resolve within 12 weeks.
Treat Carditis	• Bed rest if in heart failure, with mobilization as symptoms permit • Do Urgent echocardiogram • Manage heart failure (fluid restriction, diuretics, ACE inhibitors) • Consider Prednisolone for severe carditis	• Monitor vital signs should be recorded four times daily • Monitor input and output • Monitor weight
Treat Chorea	• Most mild-moderate cases do not need medication • Provide calm and supportive environment (prevent accidental self-harm) • Carbamazepine at 7–10 mg/kg day in three divided doses or Valproic acid at 15–20 mg/kg/day in three divided doses or phenobarbitone at 3-6 mg/kg/day (particularly in children) can be given for severe cases.	Monitor progress

3. SECONDARY PROPHYLAXIS IN RHEUMATIC FEVER AND RHD

3.1 Introduction

- Secondary prophylaxis is a term used to describe regular delivery of antibiotics to prevent recurrence of GABHS infection and subsequent development of ARF.
- When should secondary prophylaxis be considered?
    - ARF confirmed by the Revised Jones Criteria
    - RHD confirmed on echocardiogram
    - ARF or RHD not confirmed but considered highly 'probable'
    - RHD post-surgery
- Benefits of Secondary prevention in ARF and RHD
    - Prevent further Group A Streptococcal infection
    - Prevent recurrence ARF
    - Prevent the development of RHD
    - Reduce the severity or worsening of RHD. It is associated with regression of heart disease in approximately 50-70% of those with good adherence over a decade and reduces mortality.

3.2 Standard Secondary Prophylaxis for ARF and RHD Prevention

- Benzathine penicillin G
    - 1,200,000 units for all people ≥ 30kg
    - 600,000 units for children <30kg
- BPG should be given every 4 weeks (by deep intramuscular injection)
- If Penicillin Allergic:
    - Erythromycin 250mg PO BID for<7-year-olds and 500mg PO BID for > 7-year-olds.

3.3 Recommended Duration of Secondary Prophylaxis

Disease Classification	Duration of Secondary Prophylaxis
ARF without carditis	1. Minimum of 5 years after last ARF, or 2. Until age 21 years (whichever is longer)
ARF with carditis but no current residual carditis	1. Minimum 10 years after last ARF, or 2. Until age 25 years (whichever is longer)
RHD and following Cardiac Surgery for RHD	Continue medication for life

3.4 Concerns with BPG Injections

- Patients and health care providers are concerned about the risk of anaphylaxis from BPG injections and pain during injection.
- Life-threatening allergic reactions are very rare in patients on long-term intramuscular benzathine penicillin for secondary prevention of RF.
- Benzathine Penicillin G (BPG) is an essential medicine for prevention of ARF/RHD
- Alternatives to BPG (e.g. oral medicines) are not as effective as BPG
- Skin testing with dilute BPG will not predict the patients who are allergic, therefore it is not indicated.
- Always inform patient or guardian and obtain informed verbal consent.
- BPG injection can be given by any trained health worker following standard procedures as shown below.

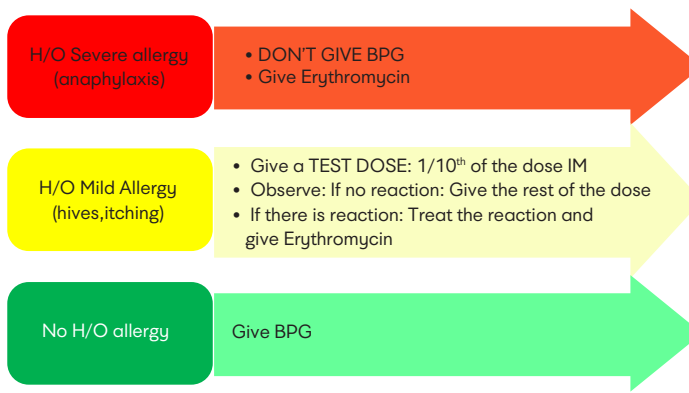
3.5 Steps in Safe Administration of Benzathine Penicillin

5 Steps for Administration of BPG

Step 1-Ask Patient or Guardian about past history of Penicillin Allergy
Step 2- Prepare the items needed to inject BPG
Step 3- Prepare the injection
Step 4- Prepare the patient and give the injection slowly
Step 5- Observe patient for 15 Minutes

3.6 Step by Step Guide for Safe BPG Injection

Step 1- Ask about the History of Penicillin Allergy and decide



Step 2- Prepare the items needed for BPG Injection

1. One 10 ml syringe
2. One 5 ml syringe
3. One BPG ampoule 1.2 million units
4. One vial of local anesthetic lidocaine 2% (or water for injection)
5. One adrenaline vial 1:1000
6. One antihistamine vial: Promethazine 50mg injection
7. Normal saline 1000ml: 1 bag (with IV Cannula)

Step 3-Prepare the injection

1. Draw appropriate amount of local anesthetic as diluents for the BPG powder or water for injection if no lidocaine (make sure it's not cold)
2. Inject the diluents into the BPG vial
3. Mix gently till dissolved by rolling in the hands
4. Draw in 5 ml syringe
5. Change the needle to a large bore (10 ml syringe) needle.

Step 4- Prepare the Patient and Give the Injection:

1. Ask the patient to lie on the abdomen
2. Mark the site of the injection on the gluteus muscle
3. To minimize pain: press with your thumb over the site for 10 seconds
4. Aspirate first to avoid veins then give the injection SLOWLY deep in the muscle.
5. Use new needle for each patient
6. Discard used needles and syringes in safety box
7. Keep the patient for 15 minutes
8. Document the date and dose on the patient chart and the patient passport

NEVER EVER GIVE BPG INTRAVENOUSLY
THIS MAY LEAD TO IMMEDIATE DEATH!!

Step 5-Observe and treat reactions

Observe the patient for at least 15 minutes.
If any reaction develops evaluate the patient and classify the reaction as follows and act accordingly:

i. Mild Reaction (Local Reaction) :

- Itching, hives or urticaria: manage with antihistamine injection. Continue observation until the patient is well.

ii. Severe Reaction (Anaphylaxis):

- sudden face/tongue swelling with difficulty breathing, BP < 90/60 or collapses over minutes to hours

iii. Vasovagal (Pain) Reaction:

- Sudden immediate collapse and transient loss of consciousness usually in a very sick patient.

3.7 Management of Penicillin reactions

I. Vasovagal Reaction

Prevention of Vasovagal Reactions:

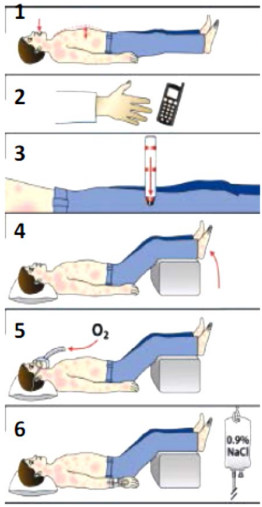
- Pain is the main factor contributing to vasovagal reactions hence injection techniques that help reduce pain will decrease vasovagal reactions.
  Management of Vasovagal reaction:
- Protect patient from falls and injuries.
- Patients should be advised to assume the supine position with legs raised at the onset of symptoms.
- Advise the patient to do Isometric Counter-pressure maneuvers:
- Educate and reassure the patient and family.
- Closely monitor vital signs

II. Anaphylaxis

Diagnosis

Anaphylaxis is highly likely when any ONE of the following three criteria is fulfilled:
1. Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (eg, generalized hives, pruritus or flushing, swollen lips-tongue-uvula)
AND AT LEAST ONE OF THE FOLLOWING
A. Respiratory compromise (eg, dyspnea, wheeze-bronchospasm, stridor, reduced PEF in older children and adults, hypoxemia)
B. Reduced BP* or associated symptoms of end-organ dysfunction (eg. hypotonia, collapse, syncope, incontinence)
2. TWO OR MORE OF THE FOLLOWING that occur rapidly after exposure to a LIKELY allergen for that patient (minutes to several hours)
A. Involvement of the skin-mucosal tissue (eg, generalized hives, itch-flush, swollen lips-tongue-uvula
B. Respiratory compromise (eg, dyspnea, wheeze-bronchospasm, stridor, reduced PEF in older children and adults, hypoxemia))
C. Reduced BP* or associated symptoms (eg, hypotonia, collapse, syncope, incontinence)
D. Persistent gastrointestinal symptoms (eg, crampy abdominal pain, vomiting)
3. Reduced BP* after exposure to a KNOWN allergen for that patient (minutes to several hours) A. Infants and children: low systolic BP (age specific) * or greater than 30 percent decrease in systolic BP B. Adults: systolic BP of less than 90 mmHg or greater than 30 percent decrease from that person's baseline

Management of Anaphylaxis:



1.Assess ABC: if needed perform CPR

DO STEPS 2,3,4 QUICKLY AT SAME TIME

2.Call for help

3.Inject adrenaline: 0.3 ml (<7 y), 0.5 ml (>7 y) of 1:1000 solution. Can be repeated in 15 minutes

4.Lie the patient with legs up

5.If distressed, give O2

6.IV line: give IV normal saline10ml /kg boluses. Can give adrenaline infusion

4. DIAGNOSIS AND MANAGEMENT OF RHD

4.1 Introduction

- RHD is inflammation of heart valves that follows infection with Group A beta hemolytic streptococcus, commonly pharyngitis.
- It is thought that 40-60% of patients with ARF will go on to developing RHD.
- Rheumatic disease (RHD) is the only long-term sequel of ARF which can lead to death or disability
- Rheumatic carditis affects mainly the heart valves.

4.2 Manifestations

- In patients with RHD permanent damage of the valve apparatus leads to scarring resulting in poor opening and closure of the valves. This results in failure of valves to close (regurgitation) or open(stenosis) or both.
- The mitral valve is the most common valve involved followed by aortic, tricuspid and very rarely pulmonary valve in that order.
- RHD could remain asymptomatic or may be detected by routine physical examination or echocardiography.

4.3 Common Murmurs in RHD

Valve affected	Description
Mitral regurgitation	A pansystolie murmur heard loudest at the apex and radiating laterally to the axilla
Mitral stenosis	A low-pitched, diastolic ramble heard best at the apex with the bell of the stethoscope and with the person lying in the left lateral position
Aortic regurgitation	A diastolic blowing decrescendo murmur best heardat the left sternal border withthe person sitting up and leaning forward in full expiration
Aortic stenosis	A loud, low pitched mid-systolic ejection murmur best heard in the aortic area, radiating to the neck

4.4 Screening for RHD

- Screening for RHD is recommended for children and young adults in Ethiopia.
- The following sequence is recommended for screening: taking a history for prior ARF, performing echocardiography in all, and then clinical cardiac evaluation of cases with abnormal echocardiography.

- Timing and frequency of screening-the evidence on the natural history of RHD suggests that at least two echocardiography-based screening tests are indicated: one before age 18 and another by 35 years of age.
- Cases of probable or possible RHD require a repeat evaluation within a year to confirm the diagnosis prior to embarking upon long-term prophylaxis.

4.5 Management of RHD

The main goal of management of RHD is to prevent disease progression and to avoid, or at least delay, valve surgery.

The key principles for effective management of RHD include:

- Effective baseline assessment, education and referral
  - Establishing the diagnosis of RHD
  - Detecting and treating Complications of RHD (Heart failure, Arrhythmia, stroke)
- Treatment of cardiac and other symptoms
- Long-term secondary prophylaxis (to prevent recurrent ARF)
- Regular medical and cardiology review including echocardiography
- Appropriate and timely surgical interventions
- Dental assessment and care
- Advise on Family planning and referral
- Management of RHD in special situations (e.g . pregnancy)

4.6 Recommended routine review and management plan for ARF and RHD

Classification	Criteria	Review and Management Plan	Frequency
High Risk (Priority level1)	Severe valvular disease or Moderate/ severe valvular lesion with symptoms or Mechanical prosthetic valves, tissue prosthetic valves and valve repairs, including balloon valvuloplasty	Secondary prophylaxis	3-4 weekly
		Doctor/HO/BSC Nurse review	3-monthly
		ECG (optional)	Yearly
		Medical or Heart specialist review	6-monthly
		Echocardiogram	Annually for surgery or post surgery valve status assessment
		Dental review	Within 3 months of diagnosis , yearly thereafter
		Endocarditis prevention	As required
		Warfarin or Aspirin	As prescribed
Medium Risk (Priority level 2)	Any moderate valve lesion in the absence of symptoms, and with normal leftventricular function	Secondary prophylaxis	4 weekly
		Doctor/HO/BSC Nurse review	6-monthly
		ECG (optional)	Yearly
		Medical or Heart specialist Review	Yearly
		Echocardiogram	Every 1 years for children Every 2 years for adults
		Dental review	Yearly
		Endocarditis prevention	As required
Low Risk (Priority level 3)	ARF with no ARF with no of RHD or Trivial to mild	Secondary prophylaxis	
		Doctor/HO/BSC Nurse review	Yearly
		Dental review	Yearly
		Medical or Heart	Every 2 years for adults

5. MANAGEMENT OF COMPLICATIONS OF RHD

5.1 Heart Failure

Heart failure is constellation of symptoms and signs arising from structural or functional cardiac disorders that impair the ability of the ventricle(s) to fill with and/or eject blood.

Abnormal filling will result in accumulation of fluid (congestion) in tissues like in lung, abdomen and extremities causing shortness of breath and edema.

Abnormality in pumping adequate blood will result in poor perfusion of tissues and cause fatigue (exercise intolerance), syncope and angina.

RHD can result in either filling abnormality or poor pumping of the heart by causing abnormal valvular function. Heart Failure is the most common presentation of RHD in Ethiopia. The initial manifestation of heart failure usually comes with some precipitating causes which put extra load on the heart. The most common precipitating causes of heart failure in RHD include fever, anemia, infective endocarditis, pregnancy, rheumatic fever recurrence and excessive salt consumption.

Clinical Manifestations of Heart Failure

Symptoms due to excess fluid accumulation	Symptoms due to a reduction in cardiac output
• cough, • wheezing, • dyspnea, • orthopnea, • paroxysmal nocturnal dyspnea, • lower extremity edema, • abdominal pain from hepatic congestion, • Ascites (abdominal distension)	• fatigue, • weakness, • decreased exercise tolerance • palpitations

Common physical findings in heart failure include increased heart rate, a third heart sound, irregular pulse, increase respiratory rate, laterally displaced apical impulse, heart murmurs, elevated jugular venous pressure, cold extremities, cyanosed lips and tongues., tender abdomen, peripheral edema and chest crepitation's.

Diagnosis of Heart failure

The diagnosis of heart failure is a complex process but for primary health care level the modified Framingham criteria is used as a diagnostic tool.

Modified Framingham Clinical Criteria for the diagnosis of Heart Failure

Major Criteria	Minor Criteria
• Paroxysmal nocturnal dyspnea	• Bilateral leg edema
• Orthopnea	• Nocturnal cough
• Elevated jugular venous pressure	• Dyspnea on ordinary exertion
• Pulmonary rales	• Hepatomegaly
• Third heart sound	• Pleural effusion
• Cardiomegaly on chest x-ray	• Tachycardia (heart rate≥120 beats/min)
• Pulmonaryedema on chest x-ray	• Weight loss ≥4.5 kg in five days
• Weight loss ≥4.5 kg in five days in response to treatment of presumed heartfailure*	
Diagnosis The diagnosis of heart failure requiresthat **2 major or 1 major and 2 minor criteria** that cannot be attributed to another medical condition.	

NB: The Framingham Heart Study criteria are 100% sensitive and 78% specific for identifying persons with definite congestive heart failure.

Heart Failure Classification-New York Heart Association for Adults and Modified Ross for Children

Class	NYHA(for Adults)	Modified Ross (for Children)
Class I	No limitations of physical activity	No limitations or symptoms
Class II	May experience fatigue, palpitations,dyspnea, or angina during moderate exercise but not during rest	**Infants:** Mild tachypnea or diaphoresis with feeding **Older children:** Mild to moderate dyspnea on exertion
Class III	Symptoms with minimal exertion that interfere with normal daily activity	**Infants:** Growth failure and marked tachypnea or diaphoresis with feeding **Older Children:** Marked dyspnea on exertion
Class IV	Unable to carry out any physical activity because they typically have symptoms of HF at rest that-worsen with any exertion	Sy mptoms at rest such as tachypnea. retractions, grunting, or diaphoresis

Management of Heart Failure

Initial management of heart failure depends on severity of symptoms and concomitant conditions. Mild and moderate HF can be managed with salt restriction and diuretics. Severe decompensation requires hospitalization. Management includes treating the congestive state, precipitating cause and the underlying cause.

Treatment to decrease the congestive state in heart failure

Decrease Preload	Increase contractility of the heart	Decrease Afterload:
• Decrease salt intake to less than 2g/day (don't add salt to foods) • Give Diuretics: o Furosemide with a initial dose of 1-2mg/kg PO escalated to a dose which can achieve a weight loss of 0.5-lkg/day for edematous/congested patient and then tapered down to lowest dose which can make the patient symptom free. Start at 40mg PO/day in adults. Escalate based on Wt., urine output, response and lab tests (to max 400mg/day in adults).	• Indicated for those with reduced contractility (Ejection fraction less than 60% in patients with Mitral regurgitation and less than 40% in all other patients. • Digoxin is the usual drug given to enhance contractility. Dose 0.125-0.25mg PO/day.	• Indicated for patients with severe acute MR or AR and patients with Chronic severe MR or AR for whom surgery is not possible. • Commonly used drug is Enalapril 2.5 mg PO BID to max of 10 mg PO BID

5.2 Atrial Fibrillation

Patients with RHD are at increased risk of developing heart rhythm abnormalities. The most common arrhythmia is atrial fibrillation. An irregularly irregular pulse is suggestive of atrial fibrillation. Atrial fibrillation is commonly seen in patients with mitral stenosis.

Patients having irregular heart rhythm should be referred to hospitals to confirm the diagnosis and initiate treatment for AF and anticoagulation.

Management of Atrial fibrillation in RHD

Management should address the atrial fibrillation and its potential complications.
There are two options for management of atrial fibrillation: rate control versus rhythm control.

We prefer rate control for RHD as there is no clear survival benefit of rhythm control over rate control and it is costly and needs higher expertise.

i. Rate control:

If patient does not have pulmonary congestion or hypotension beta blockers PO like metoprolol 25-100mg/day or atenolol 50-100mg/day can be given to keep heart rate between 60-80/min at rest and 90-115 beats/min with exercise if however, the patient has pulmonary congestion or hypotension digoxin 0.125-0.25mg/day PO can be given to control the heart rate.

Patients with heart failure and coexisting atrial fibrillation should be treated with diuretics and ACE inhibitors and this will often reduce the heart rate.

ii. Anticoagulation in RHD and Atrial Fibrillation

Anticoagulation is indicated in patients with RHD and:

- atrial fibrillation or
- history of embolization (stroke) and
- following valve replacement (Bio prosthetic or Mechanical)

Medicines and Monitoring:

- Vitamin K antagonists like warfarin are the preferred drugs.
- Usual starting dose is Warfarin 2.5mg /d and then escalated based on INR. It usually takes 3-5 days to know the effects of the new dose.
- INR Target: 2.0 -3.0
- Frequency of INR -Once baseline INR is determined, initially patients should be monitored weekly until they achieve target INR and then monthly once target INR is achieved.
- Patients should be advised on symptoms of excessive anticoagulation like epistaxis, easy bruising, delayed stopping of bleeding after needle puncture or minor trauma, reddish discoloration of urine, heavy menses or easy bruising.

5.3 Infective Endocarditis

Infective endocarditis (IE) is an important complication of heart disease in general and valvular heart disease in particular. This is infection of the damaged valves by microbial agents which have got access to the blood stream In RHD, endocarditis most commonly occurs in the mitral or aortic valves. The most common organisms causing IE arise from normal flora like from gingival tissue. The most common focus of such infection is the periodontal region.

As RHD constitutes the major cause of valve heart disease in Ethiopia, it is the most encountered heart disease predisposing to IE.RHD was found to be the underlying cardiac lesion in 49% of patients seen in a cohort of children with IE, and the mortality in this cohort

was 7.3%. Congestive heart failure and systemic embolization occurred in 66% and12% respectively.

Diagnostic Clues:

Fever, hematuria, night sweating, weight loss, clubbing, changing murmur, unexplained rapid deterioration of heart failure, splenomegaly. Skin manifestations like conjunctival hemorrhage, splinter hemorrhage. Infective endocarditis is far less common in pure stenotic lesions. Though history of predisposing procedures are commonly enquired it is not commonly elicited in most of our patients.

Action When Suspecting Infective endocarditis:

All patients suspected of having or confirmed to have infective endocarditis should be referred to hospital for admission and evaluation by cardiologist or internist/pediatrician.

Modified Duke Criteria for Diagnosis of Infective Endocarditis

Major criteria:

1. Positive Echocardiogram:
   - Oscillating intracardiac mass on valve or supporting structures in the path of regurgitant jets or on implanted material in the absence of an alternative anatomic explanation.
   - Intramural abscess.
   - New partial dehiscence of a prosthetic valve.
2. Histopathological evidence of IE from excised heart valve.
3. Positive blood culture with an organism consistent with IE.
   - Typical micro-organisms in 2 separate cultures or
   - Persistently +ve blood cultures drawn 12 hours apart or
   - Single +ve blood culture of Coxiella burnetti

Minor criteria

1. Predisposing heart condition (e.g. RHD) or IV drug use.
2. Fever.
3. Vascular phenomena: major arterial emboli, septic pulmonary infarcts, mycotic aneurysm, intracranial hemorrhage, conjunctival hemorrhages and Janeway lesions.
4. Immunologic phenomena: glomerulonephritis, Osler nodes, Roth's spots and positive rheumatoid factor.
5. Microbiological evidence: positive blood culture, but does not meet a major criterion.
6. Echocardiographic abnormalities that fell short of typical lesions described above.

Decision Criteria:

Definite IE:2 Major or 3 Minor + 1 Major or 5 Minor
Possible IE: 1 Major +1 Minor, Or 3 minor
Rejected IE: firm alternative Diagnosis or response to <4 days of antibiotics.

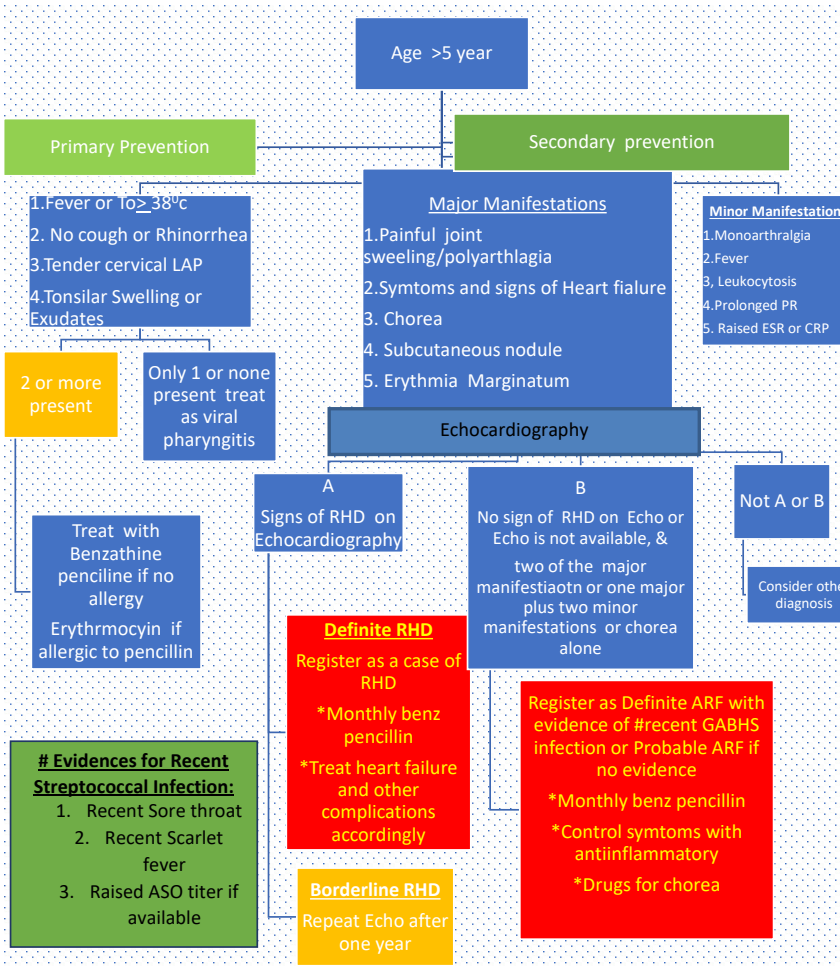
Empiric Antibiotics of Infective Endocarditis:

Choice of Antibiotics

After taking blood culture, the patient should be started on IV antibiotics:

- Crystalline penicillin 3millin Units IV 4 hourly, OR Ampicillin 2 g IV 4 hourly for 4-6 weeks. Plus
- Gentamicin 1mg/kg IV tid for 2 weeks.

Annex 1: Flow Chart for Diagnosis and treatment of bacterial pharyngitis, acute rheumatic fever, and rheumatic heart disease



REFERENCES

World Heart Federation RHD Manual 2017

SECTION 4:
NATIONAL DIABETES SCREENING, DIAGNOSIS AND MANAGEMENT PROTOCOL

1. INTRODUCTION TO DIABETES

Definition of diabetes mellitus

Diabetes mellitus is a group of metabolic disorders characterized by the presence of hyperglycemia in the absence of treatment. The heterogeneous etiopathology includes defects in insulin secretion, insulin action, or both. The long-term specific complications of diabetes include retinopathy, nephropathy, and neuropathy. People with diabetes are also at increased risk of other diseases, including cardiac, peripheral arterial and cerebrovascular disease, cataracts, erectile dysfunction, and nonalcoholic fatty liver disease. They are also at an increased risk of some infectious diseases such as tuberculosis and are likely to experience poorer outcomes.

Epidemiology and global burden of diabetes

Diabetes is found in every population in the world and in all regions, including rural parts of low- and middle-income countries. International Diabetes Federation estimates there were 463 million adults aged 20-79 with diabetes worldwide in 2019 there were an estimated 1.1 million children 0-14 years in 2019 globally.
The prevalence of diabetes in Ethiopia is estimated to be 3.2% and there are about 2 million people with diabetes in Ethiopia.

Etiopathology of diabetes

The underlying characteristic common to all forms of diabetes is the dysfunction or destruction of pancreatic beta-cells. These cells are not replaced, as the human pancreas seems incapable of renewing beta-cells after the age of 30 years. Many mechanisms can lead to a decline in function or the complete destruction of beta-cells. These mechanisms include genetic predisposition and abnormalities, epigenetic processes, insulin resistance, auto-immunity, concurrent illnesses, inflammation, and environmental factors.

Most common types of diabetes and their risk factors

The most common type of diabetes mellitus is type 2 diabetes (T2DM). T2DM accounts for between 90% and 95% of diabetes, with highest proportions in low- and middle-income countries. The majority of people with T2DM are overweight or obese, which either causes or aggravates insulin resistance. Many of those who are not obese by BMI criteria have a higher proportion of body fat distributed predominantly in the abdominal region, indicating visceral adiposity, compared to people without diabetes.

Many factors increase the risk of developing T2DM including age, overweight/obesity, physical inactivity, unhealthy lifestyles, diabetes in first degree relatives, cardiovascular diseases and its risk factors and prior gestational diabetes (GDM).

Type 1 diabetes is much less common, the risk being highest in populations of European origin. Despite T1DM occurring frequently in childhood, onset can occur in adults and 84% of people living with T1DM are adults. There are no clear risk factors for T1DM.

2. CLASSIFICATION OF DIABETES

The WHO classification of diabetes is presented in Table 1. It prioritizes clinical care and guides health professionals in choosing appropriate treatments at the time of diabetes diagnosis, providing practical guidance to clinicians in assigning a type of diabetes to individuals at the time of diagnosis

Table 1: Classification of diabetes (WHO 2019)

Type of diabetes	**Description**
Type 1 diabetes	Beta-cell destruction (mostly immune-mediated) and absolute insulin deficiency; onset most common in childhood and early adulthood.
Type 2 diabetes	Most common type, various degrees of beta-cell dysfunction and insulin resistance; commonly associated with overweight and obesity.
Hybrid forms of diabetes	
Slowly evolving, immune-mediated diabetes of adults	Similar to slowly evolving type 1 in adults but more often has features of the metabolic syndrome, a single GAD autoantibody, and retains greater beta-cell function. Used to be called latent autoimmune diabetes in adults (LADA).
Ketosis-prone type 2 diabetes	Presents with ketosis and insulin deficiency but later does not require insulin; common episodes of ketosis, not immune-mediated.
Other specific types	
Monogenic diabetes: a) Monogenic defects of beta-cell function b) Monogenic defects in insulin action	Caused by specific gene mutations. Caused by specific gene mutations. Has features of severe insulin resistance without obesity; diabetes develops when beta-cells do not compensate for insulin resistance.
Diseases of the exocrine pancreas	Various conditions that affect the pancreas can result in hyperglycemia (trauma, tumor, inflammation, etc.).
Endocrine disorders	Occurs in diseases with excess secretion of hormones that are insulin antagonists (e.g. Acromegaly, Cushing's syndrome).
Drug- or chemical-induced	Some medicines and chemicals impair insulin secretion or action, some can destroy beta-cells.
Hyperglycemia first detected during pregnancy	
Diabetes mellitus in pregnancy	Type 1 or type 2 diabetes first diagnosed during pregnancy.
Gestational diabetes mellitus	Hyperglycemia below diagnostic thresholds for diabetes in pregnancy.

3. SCREENING FOR PREDIABETES AND TYPE 2 DM

For patients with symptoms of diabetes such as polyuria (>3 litters per day or if not quantified a history of increase in urination frequency with increase in volume of urine), polydipsia, polyphagia, unexplained weight loss or fatigue, then blood tests for diabetes should be done.

For those with no symptoms, then screening should be done if they have one or more of the following indications

Indications for screening for asymptomatic individuals	Frequency of screening
All Adults Age ≥ 40 years	Every 3 years
All Adults with BMI ≥ 25 kg/m2	
Hypertension (SBP ≥ 140 or DBP ≥ 90mmHg or on treatment for hypertension)	
First degree relative with diabetes* and BMI ≥ 25 kg/m2	
History of stroke, ischemic heart disease or peripheral arterial disease	
Triglyceride >250mg/dl or HDL cholesterol<35 mg/dl (if laboratory results available)	
Women with history of gestational diabetes or history of delivering big baby > 4 kg**	
HIV	
Patients with history of prediabetes or impaired fasting blood glucose	Every year

* First degree relatives include: parents, siblings, and offspring (Children)

**In women with GDM, screen for DM 4-6 weeks after delivery with OGTT, if not possible, do FBG at 6 weeks, based on results, treat accordingly, if normal, follow every 3 years.

Common Symptoms and Signs of DM

Symptoms of diabetes
• thirst • frequent urination • blurring of vision • fatigue
Signs of diabetes
• unintentional weight loss • signs of acute metabolic deterioration (signs of severe dehydration, Kussmaul's respiration, vomit ing, altered level of consciousness) • clinical signs of chronic complications (acute coronary disease, stroke, kidney disease, vision loss, diabetic foot)

4. DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS

Test	Test Condition	Normal	Prediabetes	Diabetes*
Fasting blood sugar	At least eight hours of fasting Can drink pure water	<100 mg/dL	100-125 mg/dL	≥ 126 mg/dL
Glycated haemoglobin (HbA1C)	Does not matter when the test is taken (before or after meals)	<5.6%	5.7–6.4%	≥ 6.5%
Postprandial blood sugar (Random Plasma Glucose)	With common symptoms such as frequent urination, increased fluid intake and unexplained weight loss	-	-	≥ 200 mg/dL

Remember*:

- Diagnosis requires two abnormal test results from the same sample or in two separate samples
- Fasting values for venous and capillary plasma glucose are identical.
- FBS 101-125 mg/dl is Impaired Fasting Blood Glucose. Repeat test in 1 Year. Advise on Healthy Life-Style counselling.

Diagnostic criteria for Gestational Diabetes

Diagnose gestational diabetes when one of the following criteria is met:

- Fasting plasma glucose: 92–125mg/dl, or
- 1-hour post-load plasma glucose: ≥ 180mg/dl, or
- 2-hour post-load plasma glucose: 153-198mg/dl

Clinical Criteria for initial management of diabetes

Type 1 DM	Type 2 DM
(1) onset of disease prior to age 30 years, (2) lean body habitus, (3) requirement of insulin as the initial therapy, (4) propensity to develop ketoacidosis; and (5) An increased risk of other autoimmune disorders such as autoimmune thyroid disease, adrenal insufficiency, pernicious anaemia, celiac disease, and vitiligo.	(1) Onset of disease after the age of 30 years, (2) are usually obese (80% are obese, but elderly individuals may be lean), (3) may not require insulin therapy initially; and 4) May have associated conditions such as insulin resistance, hypertension, cardiovascular disease, dyslipidaemia, or PCOS.

5. COMPREHENSIVE MEDICAL EVALUATION OF DIABETES

A complete medical evaluation should be performed at the initial visit to:

- Confirm the diagnosis and classify diabetes.
- Evaluate for diabetes complications and potential comorbid conditions.
- Review previous treatment and risk factor control in patients with established diabetes.
- Begin patient engagement in the formulation of a care management plan.
- Develop a plan for continuing care.

A follow-up visit should include most components of the initial comprehensive medical evaluation

Ongoing management should be guided by the assessment of overall health status, diabetes complications, cardiovascular risk, hypoglycaemia risk, and shared decision-making to set therapeutic goals.

Comprehensive diabetes evaluation consists of

- Past medical and family history
- Current medical history
- Behavioral factors (diet, alcohol, tobacco, physical activity, sleep, substance use
- Medication use
- Social life assessment
- Physical Exam (V/s, Wt, Ht, BMI, fundoscopy, CVS, Thyroid, Skin, Comprehensive foot exam
- Baseline investigations.

Assessment and treatment plan

→ Setting glycemic targets
→ Lifestyle modifications
→ Monitoring and treatment of diabetes
→ Choosing drugs for diabetes management
→ Screening and treatment of complications and comorbidities
→ Indications for referral

Baseline investigations for Type 2 DM

- **Urine analysis**-If proteinuria is detected, repeat after 3 months, if still there refer to specialist or manage as per diabetic nephropathy protocol
- **Lipid profile, SGOT/SGPT /ALP** –(if available)
- **Serum Creatinine** –(if available)- If abnormal – refer to internist or nephrologist

N.B – For both Type 1 and Type 2 DM patients, check urine for ketones if blood glucose ≥250 mg/dl

Setting diabetes treatment goals

For most patients with diabetes set a target of

- FBG – 80-130mg/dl *^
- 2 hours post meal less than 180 mg/dl (secondary goal after FBG target is achieved)
- HgA1c < 7% (If available)**

*Less stringent goals may be preferred in those with short life expectancy, recurrent hypoglycemia, hypoglycemia unawareness, old age, cardiovascular diseases or advanced microvascular complications
^ 80-130mg/dl is more acceptable in those not at risk of hypoglycaemia

**HgA1c < 6.5% is an acceptable goal for those that are young, able to do self-monitoring blood glucose, normal renal function, and no other risk for hypoglycemia.

6. MANAGEMENT OF DIABETES

See the algorithm below for details.

Lifestyle modifications

- Advise on 150 minutes per week of moderate intensity exercise (e.g.-brisk walking, farming) with preferably no more than 2 days passing without exercise.
- Dietary advise:
  - Moderate consumption of complex carbohydrates (like pasta, potatoes etc.),
  - increased fiber intake,
  - A diet rich in vegetables and 1-2 servings of fruit per day.
  - use liquid oils and nuts and avocado
  - moderate consumption of meat
  - avoiding simple carbohydrates (like sugar, soft drinks, honey, cakes)
  - minimizing saturated fat intake (like butter, solid oils),
  - decrease salt consumption
  - Avoid alcohol consumption. If you drink alcohol, drink moderately-no more than one drink a day if you're a woman or two drinks a day if you're a man.
- If BMI >25 kg/m2, advise at least 5 % weight loss
- Advise on moderating salt and alcohol intake and quitting smoking

Management of Type 2 DM with Oral Agents

Initial treatment:

- Metformin does not cause weight gain or hypoglycemia and is the recommended initial treatment for people who do not achieve the desired glycemic control with diet and physical activity.
- Start 500mg PO at bedtime. Increase the dosage gradually according to the diabetes protocol.
- A second-generation sulfonylurea like glibenclamide or glimepiride can be used as initial (first-line) treatment when metformin is contraindicated or not tolerated. Sulfonylureas may cause weight gain and hypoglycemia.
- Insulin therapy can be considered when there are symptoms of diabetes or the HbA1c level is greater than 9% or FBS > 300mg/dl

Intensification of treatment when metformin alone fails to control glycaemia:

- Consider adding glibenclamide 5mg or glimepiride 2mg

Intensification of treatment when metformin and sulfonylurea fail to control glycaemia:

- Refer for insulin treatment or add human insulin to oral medications

Remember:

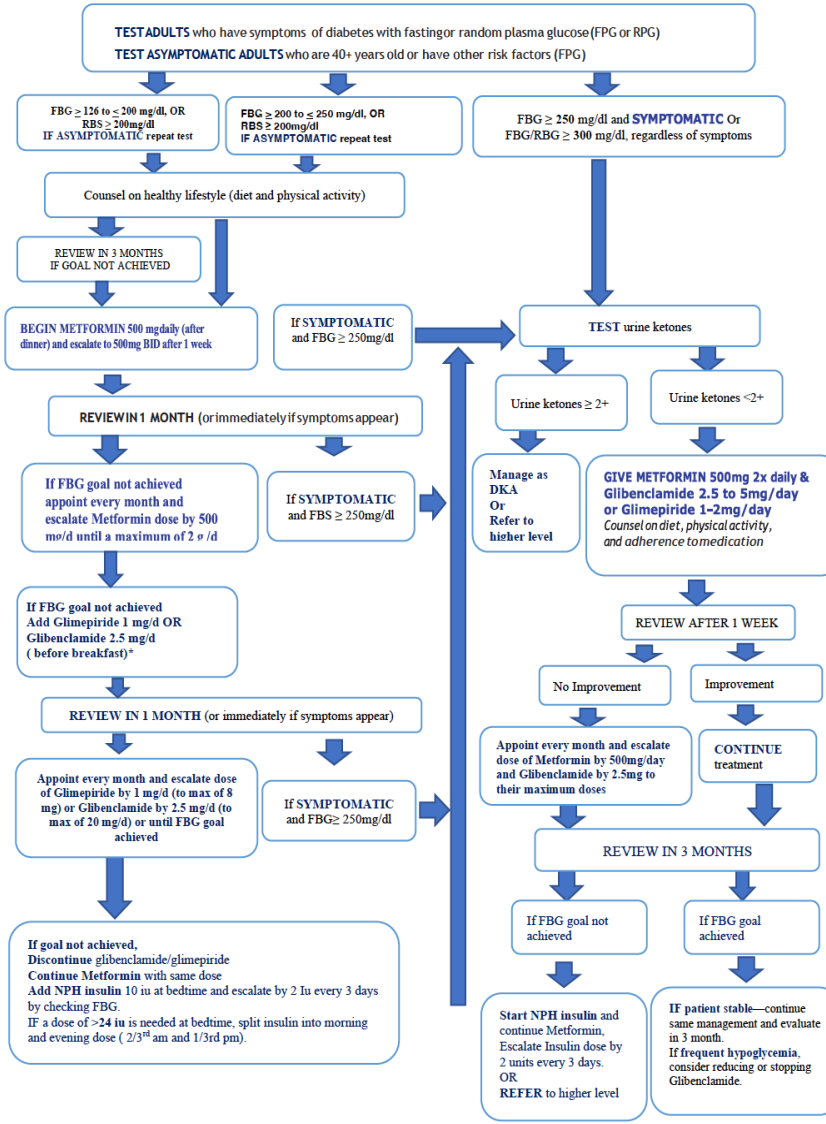
- There is a risk of hypoglycemia with sulfonylurea and insulin use if you delay your mealtime or eat less than usual, or the medicine is too much.
- Medications must be supported by healthy eating and regular physical activity. Quitting smoking and stopping harmful use of alcohol are especially important.

Management of Type 2 DM with Insulin

If goal not achieved with lifestyle changes and oral agents:

- Stop glibenclamide/glimepiride and add NPH 10 iu bedtime and escalate insulin dose by 2 iu every 3 days by checking FBG
- If a dose of >20 iu is needed at bedtime, split into morning and evening dose (2/3rd am and 1/3rd pm).
- Continue Metformin with same dose
- Monitor for hypoglycemia.

Algorithm for Control of Blood Glucose in Type 2 Diabetes*



Notes on the Type 2 DM Management flow chart:

- *Glibenclamide is mostly escalated from 5 mg /d →5 mg BID →10mg (am)/5(pm)→10 BID*
- *When initiating Glimepiride or glibenclamide or insulin advise patients on symptoms of hypoglycemia such as sweating, hunger, fatigue, tremor or altered mentation. If any of these occurs check blood glucose at the time to confirm low blood glucose or treat for hypoglycemia decrease the dose of glibenclamide or glimepiride and escalate slowly (as in 1 mg Glimepiride or 2.5 mg Glibenclamide). If on insulin, reduce dose by 4 iu and escalate by 2 IU every week.*
- *Glimepiride is preferred over glibenclamide but is more expensive.*

Type 1 DM Management Protocol

Patients with Type 1 DM need to be initiated on subcutaneous insulin injections as soon as possible. The type of insulins used should be a combination of long or intermediate acting insulin and short acting (regular) insulin. Education on diabetes, insulin, hypoglycemia and chronic complications is essential. Advise on diet and exercise is very important

INSULIN INITIATION AND DOSE ADJUSTMENT IN TYPE 1 DM

Indication	Insulin type	Starting dose	Increment	Alternative dosing
Adults T1 DM	NPH Insulin and Regular Insulin	0.4 unit/kg Sc in divided Doses as follows: 0.2 u/kg as Regular Insulin^ (1/2 AM & 1/2 PM) and 0.2 u/kg as NPH (2/3 am and 1/3 pm)	2-4 units every 3 days	Higher dose may be started in patients with severe hyperglycemia
Children	NPH Insulin and Regular Insulin	A usual starting dose of insulin is around 0.5 units per kg per day. 0.25u/kg as RI*^ (1/2 AM 0.25u/kg as RI*^ (1/2 AM AND ½ PM) and 0.25u/kg as NPH (2/3 am And 1/3 pm)	1-2 units every 3 days	In puberty, requirements may climb to 2 units per kg per day, before settling by 50% at sexual maturity.
^RI is given 30 minutes before meal				

Monitoring

- Once good glycemic control has been attained , Follow patients every 3 months*
- For those able to afford a glucometer , advise on self-monitoring of blood glucose (SMBG)
- → For Type 2 DM patients not on insulin SMBG may only be needed when changing diet, physical activity or medications and when HgA1c is abnormal despite a normal FBG if (HgA1c is available)to check for post prandial hyperglycemia
- → For patients on insulin, they should measure fasting and post prandial measurements as frequently as possible
- If HgA1C test is available, check it 2 -4 x/year

*Frequency of follow up may be more frequent if indications are there such as change in dose, hypoglycemia, recent illness or development of microvascular or macrovascular complications

7. SCREENING FOR COMORBIDITIES AND DIABETES COMPLICATIONS

Assess	When to assess	Note
Symptoms	Every visit	Frequent urination, thirst , hunger , symptoms of hypoglycemia, (Hunger, sweating , tremor, altered mentation, confusion)
Family planning	Every visit	Assess patients' conception needs. If pregnant, refer to internist or endocrinologist
CVD risk	At diagnosis and then yearly	Start moderate intensity statin if age > 40, high intensity if CVD risk > 20% or history of ASCVD
BP	Every visit	---
FBS	Every visit, preferably multiple times per month	If FBS in target, check also random blood sugar
BMI	At diagnosis and every visit	Advise > 5% weight loss if overweight or obese
Waist circumference	At diagnosis and every visit	Aim for < 80 cm in women and < 94 cm in men
Eye for retinopathy	At diagnosis if Type 2 DM and 5 yrs after diagnosis if Type 1 DM and then every 2 years	If any retinopathy detected or any visual complaints refer to ophthalmologist
Feet	Visual –every visit 60 seconds screening tool-Yearly	Visual -Ulcer, callus, erythema, deformity, in growing nail-refer to hospital
Random blood glucose	Only if symptoms of hypoglycemia or hyperglycemia	If < 70 mg/dl manage, treat as hypoglycemia If >250mg/dl, check for ketones
Urine protein	At diagnosis for Type 2 DM and starting 5 years after diagnosis for Type 1 DM , and yearly after that	If protein in urine detected, repeat after 3 months if persistent start enalapril/Lisinopril
eGFR	At diagnosis, then yearly	If eGFR< 60 ml/min/1.73m3-Refer to internist or nephrologist

Hypertension management in Diabetes

- *If BP >or equal to 140/90mmHG on multiple occasions start anti-hypertensive medications*
- *If BP>160/100 start with a combination of antihypertensive*
- *Target blood pressure is <140/90mmHG*
- *Can use hypertensive treatment regimen similar to the general population for those with no protein on their urine (Refer to national hypertensive protocol for details)*
- *If there is proteinuria preferably start/add Enalapril or Lisinopril 5 mg/day.*

Dyslipidemia management

- *Check lipid profile at diagnosis, 6 months after treatment initiation and then yearly in type 2 DM patients*
- *Start atorvastatin 40 mg /d or simvastatin 20mg/d for all diabetic patients age >40 years of age and LDL 70-190 mg/dl*
- *If ASCVD risk is >20% or LDL>190 mg/dl or there is established ASCVD start Atorvastatin 40 mg/day*

8. ACUTE COMPLICATIONS OF DIABETES

Management of Hyperglycemic Crises

(DKA and Hyperglycemic Hyperosmolar State)

Diagnosis	Evaluation and Monitoring
Suspicion based on clinical evaluation. Features vary among patients and may include polyuria, polydipsia, fruity odor, confusion, Kussmaul's breathing, confusion **Diabetic Ketoacidosis (DKA)** • Hyperglycemia: BG ≥250 mg/dL • Ketonuria >1+≥1+ • Glycosuria **Hyperosmolar Hyperglycemic State (HHS)** • Severe Hyperglycemia: BG>600 mg/dL • Change in Mental status • Moderate to severe dehydration	**Initial evaluation** Rapid and comprehensive clinical evaluation including vital signs (BP, PR, RR, T0), degree of dehydration and mental status. • Immediate: serum blood glucose and urine ketones, EKG evaluating for signs of severe hypokalemia • Additional testing: CBC, chemistry-Na+, K+, Cl, BUN, Creatinine • Evaluate for precipitating causes: urinalysis, EKG, chest x-ray, etc. **Monitoring** • Random Blood sugar q 1 hr • Urinary ketones q2 hr • Electrolytes, primarily Na+ and K+ q6hr, if possible • BUN and creatinine – daily if possible(refer if abnormality persists for 2 days) • Mental status: expect improvement with treatment if DKA or HHS are the primary cause. Consider further evaluation if not improving • Input/output, hydration status, vital signs
Initial Management of DKA	
• Start IV Fluids with 1bag NS in 1 hour • → if patient is asymptomatic and urine ketone +1, recheck urine ketone after 1 hr • → If urine ketone becomes negative escalate treatment and follow patient frequently as outpatient • If ketone >+1 or if symptomatic, give 1st dose of Regular insulin O.3 iu/kg Sc immediately along with IV fluids and refer to hospital if at health center • If at Hospital treat with the following protocol	

Fluids	Insulin	Electrolytes
• If hemodynamically unstable, giveNormal saline 1 L over 30 minutes. May repeat this until stable. ↓ • If stable, administer normal saline 1-2L over 2 hrs ↓ • Subsequent management based on vital signs, free water deficit and urine output • Replace fluid deficits gradually over 24-48 hrs(Overall 6liters for DKA and 9 liters for HHS) ↓ • Change fluids to 5%DNS or 5%DWwhen BG is <250	Initial Bolus • 0.1 u /kg IV bolus Maintenance • 0.1IU/kg/hr IV (If IV access not available and patient has no altered mentation)give 0.2 u/kg/hrsc) • If BG does not ↓by 50-70 mg/dL within 1 hr, increase rate by 50% • Continue titration as needed When BG <200mg/dL • Decrease insulin to 50% of current rate • Maintain BG 150-200 mg/dL until resolution (see criteria below).	Potassium • >5.5 mEq/L→monitor • 3.3-5.5mEq/L→2 vials KCL in every bag NS • <3.3 mEq/L→3 -4 vials KCL in every bag of fluid and recheck level. Don't give insulin until potassium > 3 .3 meq/L If lab not available: • 2 vials of KCL in every bag of fluid once urine output is adequate (>50 ml/hr)

Criteria for Resolution		Transition to long-acting insulin
DKA: • BG < 200 mg/dL • Negative urine ketones (confirm repeat in 1-2 hrs) • Patient is able to eat	HHS: • BG <200mg/dL • Improved mental status	Continue IV Insulin for 1-2 hrs after long acting insulin started • 0.4 u/kg for insulin naïve patients • Hold regular insulin if patient is not eating • May resume the usual regimen if patient was previously on insulin

Hypoglycemia management

- Hypoglycemia (abnormally low blood glucose) is a frequent iatrogenic complication in diabetic patients, occurring particularly in patients receiving sulfonylurea or insulin.
- It is most frequently defined at plasma glucose of 70 mg/dL.

Symptoms of hypoglycaemia
• headache • hunger • irritability, anxiety • paraesthesias • palpitations
Signs of hypoglycaemia
• sweating • trembling • difficulty in speaking • confusion • ataxia • stupor • pallor • seizures • coma

Signs and Symptoms of Hypoglycemia

If RBG/FBG < 70 mg/dl

- Give oral glucose 20g (4 teaspoons of sugar, 4 hard candies, or 50 ml of 40% dextrose PO)
- If unable to take orally, give instead glucose 40% 50mL IV over 2-3 minutes.
- Repeat random blood glucose after 15-20 minutes
- Repeat treatment if glucose still < 70mg/dl after 15 minutes.
- Maintain with glucose 10% solution.
    - Give the patient food as soon as she/he can eat safely.
    - Identify cause and educate about meals and doses, and reduce dose of glibenclamide/glimepiride, or insulin if the drugs are the suspected causes
    - If incomplete recovery, refer same day.
    - Discuss referral if hypoglycemia recurrent or if patient had altered mental status due to hypoglycemia
- Discuss hypoglycemia risk factors with the patient (skipping meals, physical activity more intense than usual, alcohol ingestion) and adjust medication if necessary.

9. MANAGEMENT OF CHRONIC COMPLICATIONS OF DIABETES

Diabetic nephropathy

- Check urine for protein at diagnosis for type 2 DM and starting 5 yrs after diagnosis for type 1 DM
- If no proteinuria , continue screening every year
    - If patient has proteinuria do RFT
    - If RFT abnormal , refer to specialist
    - If RFT normal repeat urine analysis after 3 months
    - If proteinuria is persistent start on Enalapril 5 mg/d
    - Appoint every month and do RFT test on every appointment
    - If creatinine has increased by more than 30% discontinue enalapril
    - If not , escalate enalapril by 5 mg each month until 20 mg /d and maintain on that dose
    - Check RFT every 6 months after that

Diabetic neuropathy

- Start screening for neuropathy using the 60 second tool mentioned below when DM is diagnosed.
    - If negative screening , then continue screening yearly
    - If abnormal, refer for management to tertiary center
- If referral not possible and patient has no urgent referral needs such as an ulcer or absent pulses or a hot swollen foot indicating Charcot's arthropathy, then advise on foot care and evaluate the foot every 3 months.
- If patient has symptoms of peripheral neuropathy such as numbness and burning sensation in the foot or hands (that aggravate mostly at night) then do Thyroid Function Test and serum vitamin B12 levels if available
- If not possible to do these tests, then start on Amitriptyline 25 mg/d at bedtime
- If it doesn't improve, refer to a tertiary center.
- Give diabetes foot care education for all patients with diabetes in groups and separately every visit to the health facility.

Table: The 60 second test

<table>
<tr><td colspan="2">Name:_____
ID:_____ Phone:_____ Facility:_____
DOB (dd/mm/ yy):_____/_____/_____
Gender: M☐ F☐ Years with diabetes:_____
Ethnicity: Black☐ Asian☐ Caucasian☐ Mixed☐ Other☐
Date of Exam (dd/mm/ yy):_____/_____/_____</td><td colspan="2">CHECK BOTH FEET
(Circle correct response)

“YES” on either foot = HIGH RISK

LEFT RIGHT</td></tr>
<tr><td rowspan="2">HISTORY</td><td>1. Previous ulcer</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>2. Previous amputation</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td rowspan="2">PHYSICAL EXAM</td><td>3. Deformity</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>4. Absent pedal pulses (Dorsalis Pedis and or Posterior Tibial)</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td rowspan="5">FOOT LESIONS
Remember to check 4th and 5,th iceb spaces/ nails for fungal infection and check for inappropriate footwear</td><td>5. Active ulcer</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>6. Ingrown toenail</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>7. Calluses (thick plantar skin)</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>8. Blisters</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>9. Fissure (linear crack)</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td rowspan="2">NEUROPATHY
MORE THAN 4/10 SITES LiCKING FEELING = “YES”</td><td rowspan="2">10. Monofilament exam (record negative reaction):
a) Right /10 negatives (≥4 negatives = Yes)
b) Left /10 negatives (≥4 negatives = Yes)</td><td>NO YES</td><td>NO YES</td></tr>
<tr><td>Total # of YES:__</td><td>Total # of YES:__</td></tr>
<tr><td colspan="4">PLAN
a) POSITIVE SCREEN- Results cvhen there are one or more “Yes” responses. Refer to a foot specialist or team for prevention, treatment and follow up. (Bony deformity, current ulcer, absent pulse are most urgent). These individuals are at increased risk of a foot ulcer and or infection. Patients should be educated on cvhat changes to observe and report, while waiting for the specialist appointment.

Referral to: _____ Appointment time:_____

b) NEGATIVE SCREEN- Results when there are all “No” responses. No referral required.
Educate patient to report any new changes to their healthcare provider and re-examine in 1 year.

One Year Date for Re-Examination (dd/mm/ yy):_____/_____/_____

Completed By:_____ Date:_____</td></tr>
<tr><td colspan="4">Additional Note:
See reverse side for recommendations from the International Diabetes Federation, & International Working Group on the Diabetic Foot.

Local referral patterns may vary depending on expertise and available resources.</td></tr>
</table>

10. DIABETES FOOT CARE GUIDELINES

Diabetes can be dangerous to your feet—even a small cut can produce serious consequences. Diabetes may cause nerve damage that takes away the feeling in your feet. Diabetes may also reduce blood flow to the feet, making it harder to heal an injury or resist infection. Because of these problems, you may not notice a foreign object in your shoe. As a result, you could develop a blister or a sore. This could lead to an infection or a non-healing wound that could put you at risk for an amputation.

To avoid serious foot problems that could result in losing a toe, foot, or leg, follow these guidelines.

Inspect your feet daily. Check for cuts, blisters, redness, swelling or nail problems. Use a magnifying hand mirror to look at the bottom of your feet. Visit your health care provider if you notice anything.

Bathe feet in lukewarm, never hot, water. Keep your feet clean by washing them daily. Use only lukewarm water—the temperature you would use on a new born baby.

Be gentle when bathing your feet. Wash them using a soft washcloth or sponge. Dry by blotting or patting and carefully dry between the toes.

Moisturize your feet but not between your toes. Use a moisturizer daily to keep dry skin from itching or cracking. But don't moisturize between the toes—that could encourage a fungal infection.

Cut nails carefully. Cut them straight across and file the edges. Don't cut nails too short, as this could lead to ingrown toenails. If you have concerns about your nails, consult your health care provider.

Never treat corns or calluses yourself. No "bathroom surgery" or medicated pads. Visit your health care provider for appropriate treatment.

Wear clean, dry socks. Change them daily.

Consider socks made specifically for patients living with diabetes. These socks have extra cushioning, do not have elastic tops, are higher than the ankle and are made from fibers that wick moisture away from the skin (cotton).

Wear socks to bed. If your feet get cold at night, wear socks. Never use a heating pad or a hot water bottle.

Shake out your shoes and feel the inside before wearing. Remember, your feet may not be able to feel a pebble or other foreign object, so always inspect your shoes before putting them on.

Keep your feet warm and dry. Don't let your feet get wet in snow or rain. Wear warm socks and shoes in cold weather.

Consider using an antiperspirant on the soles of your feet. This is helpful if you have excessive sweating of the feet.

Never walk barefoot. Not even at home! Always wear shoes or slippers. You could step on something and get a scratch or cut.

Take care of your diabetes. Keep your blood sugar levels under control.

Do not smoke. Smoking restricts blood flow in your feet.

Get periodic foot exams. Seeing your foot and ankle surgeon on a regular basis can help prevent the foot complications of diabetes.

11. REASONS FOR REFERRAL TO HIGHER LEVEL IN DIABETES

- Recurrent hypoglycemia despite dose adjustment
- Hypoglycemic unawareness
- Erectile dysfunction
- Need for insulin treatment at health center level
- Abnormal renal function test
- Abnormal retinal screening result
- Complaints of neuropathy
- Pregnancy
- Complaints of chest pain or dyspnea or abnormal cardiovascular exam
- DKA at health center level or slowly resolving DKA in primary hospitals.

REFERENCES

1- ADA Standards of Medical Care in diabetes—2021

2- WHO Classification of Diabetes 2019

3- WHO Guidelines for the prevention, management, and care of diabetes mellitus-2006

4- 2019 ESC guideline on diabetes, Pre-Diabetes and Cardiovascular Diseases

5- HEARTS Technical package for cardiovascular disease management in primary health care: evidence-based treatment protocols. Geneva: World Health Organization;2018

6- The American College of Foot and Ankle Surgeons (ACFAS). https://www.foothealthfacts.org/conditions/diabetic-foot-care-guidelines

SECTION 5:
NATIONAL PROTOCOL FOR THE DIAGNOSIS AND MANAGEMENT OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

1. CLINICAL PRESENTATION AND DIAGNOSIS OF ASTHMA

1.1 Definition

Asthma is a common chronic disorder of the airways that is complex and characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness, and an underlying chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness, and cough that vary over time and in intensity, together with variable expiratory airflow limitation. The interaction of these features of asthma determines the clinical manifestations and severity of asthma and the response to treatment.

Factors that may trigger or worsen asthma symptoms include viral infections, allergens at home or work (e.g. house dust mite, pollens, cockroach), tobacco smoke, exercise and stress. These responses are more likely when asthma is uncontrolled. Asthma can also be induced or symptoms triggered by some drugs, e.g. beta-blockers, and (in some patients), by aspirin or other NSAIDs.

Asthma flare-ups (also called exacerbations or attacks) can be fatal, even in people with apparently mild asthma. They are more common and more severe when asthma is uncontrolled, and in some high-risk patients. However, flare-ups may occur even in people taking asthma treatment, so all patients should have an asthma action plan.

Treatment with inhaled corticosteroid (ICS)-containing medications markedly reduces the frequency and severity of asthma symptoms and markedly reduces the risk of flare-ups or dying of asthma.

1.2 Diagnosis of Asthma at Health Center and Primary Hospital Level

The diagnosis of asthma at health center level is primarily clinical based on history and physical examination and treatment response as shown in the algorithm below.

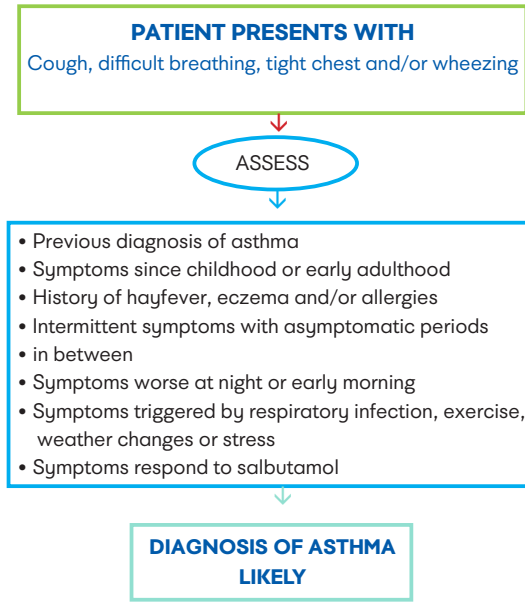


Figure: Clinical Diagnosis of Asthma

In primary hospitals if Peak Expiratory Flow Meters are available the diagnosis of asthma can be strengthened when an increase peek expiratory flow rate is demonstrated after inhalation of salbutamol as shown in the algorithm below.

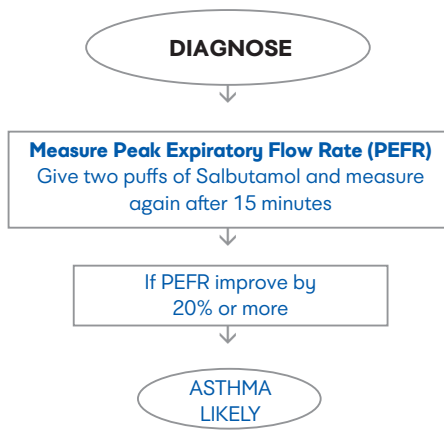


Figure: Diagnosis of Asthma Using Peak Expiratory Flow Meters.

1.3 Use of Peak Expiratory Flowmeter in Asthma Diagnosis

Peak Expiratory Flow (PEF) meters are simple handheld devices designed as personal monitoring tools in patients with asthma or COPD. A peak flow meter measures how fast air can be blown out of the lungs. It is the maximum flow rate generated during a forceful exhalation, starting from full lung inflation. Peak expiratory flow (PEF) is measured in liters per minute. Normal adult peak flow scores range between around 400 and 700 liters per minute.

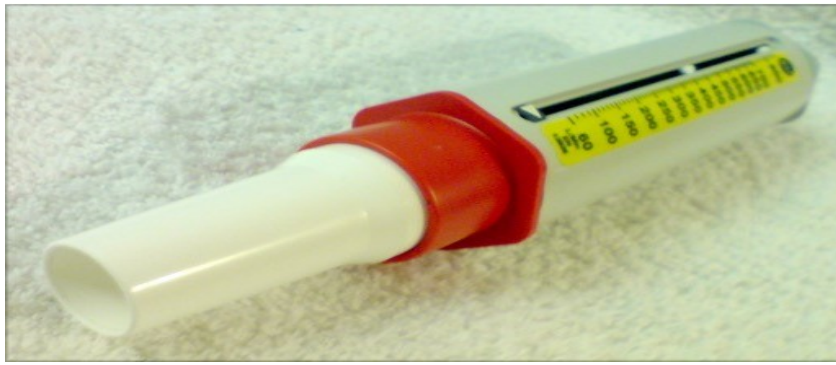


Figure 1a: Example of a handheld Peak expiratory flow meter

Figure 1b: How to Measure PEF using a peak flow meter

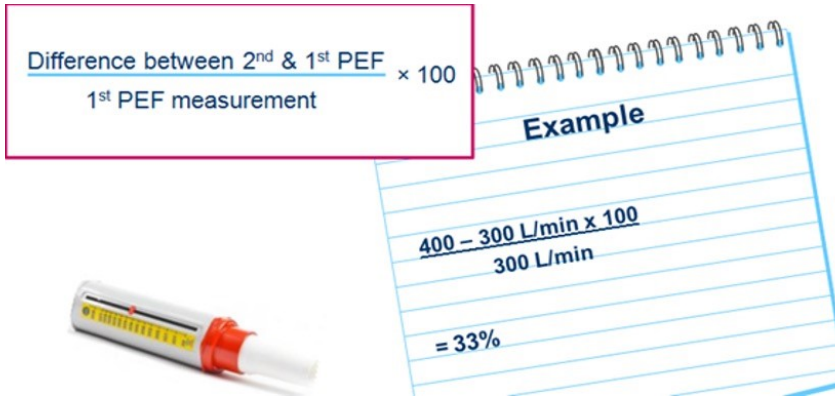


Figure 1c. Calculating percentage reversibility of PEFR

A change in PEF rate of at least 20% is accepted as being consistent with asthma. PEF rate values less than 200 L/min indicate severe airflow obstruction.

PEF rate can establish peak flow variability, quantify asthma severity, and provide both patient and clinician with objec¬tive measurements on which to base treatment decisions. It is affordable means of support in the diagnosis of asthma in the primary health care level. The standard, however, for the diagnosis of asthma is pulmonary function testing using spirometry.

1.4 Diagnosis of Asthma at General Hospital Level

In ideal situations the diagnosis of asthma should be based on clinical criteria and pulmonary function testing.

Features to make the diagnosis of Asthma

a) History of Variable Respiratory Symptoms: The "classic" signs and symptoms of asthma are intermittent dyspnea, cough, and wheezing. Refer the section Asthma diagnosis at Primary Health Care above.

b) Evidence of variable expiratory airflow limitation: Document that the variation in pulmonary function is greater than in healthy people. The ideal and most reliable test to demonstrate that variability is spirometry.

Spirometry, in which a maximal inhalation is followed by a rapid and forceful complete exhalation into a spirometer, includes measurement of forced expiratory volume in one second (FEV1) and forced vital capacity (FVC). These measurements provide information

that is essential to the diagnosis of asthma. It is recommended to be done in all patients suspected of asthma at General and Specialized Hospitals.

Figure 2: Office Spirometry Machine

After Spirometry documenting the ratio of Forced Expiratory Volume in the first second (FEV1) to Forced Vital Capacity (FVC) below 70% (below the limit of normal) is diagnostic of asthma. This demonstrates obstructive pattern of pulmonary function.

This should be followed by a bronchodilator test (salbutamol inhaler).The following criteria then establishes the diagnosis of asthma.

- An increase of FEV1 by > 200ml and > 12% from the base line value after inhaling a bronchodilator.
- FEV1 increases by more than 12% and 200ml from baseline (in children, by >12% of the predicted value) after 4 weeks of anti-inflammatory (steroid) treatment.

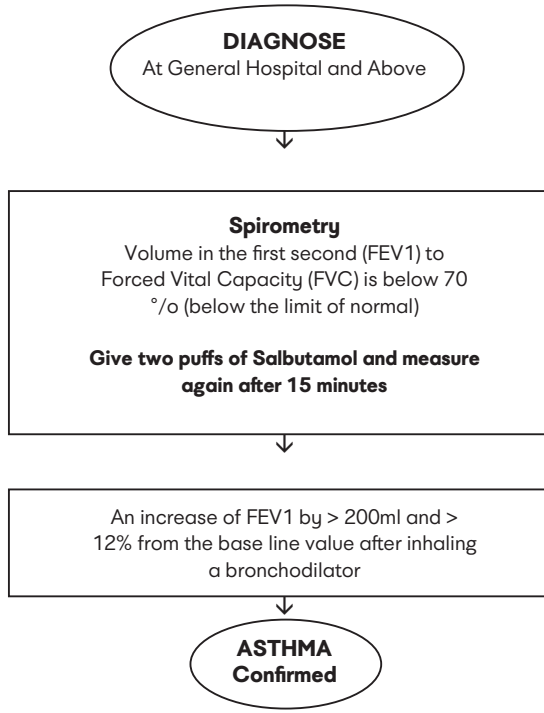


Figure: Algorithm for diagnosis of Asthma using spirometry

In the occasions where spirometry test is normal, but the patient has the typical symptoms of asthma, a bronchial challenge test can be done.

- A fall in FEV1 from baseline of ≥20% with standard doses of methacholine challenge performed in a controlled setting demonstrates variability in expiratory airflow limitation which could not be evidenced by office spirometry test.
- The other safer alternative is trial of treatment and assess the change in FEV1 post treatment. (i.e increase of FEV1 by 12% and 200 ml from baseline after 4 weeks of anti-inflammatory treatment, outside of recent respiratory illnesses, confirms significant variability).

Additional tests in Asthma Diagnosis:

Other tests can be done to rule out conditions other than asthma or identify complications or comorbidities: CBC, Gram stain, AFB stain, GeneXpert, CXR if chest infection, cardiac and other diseases suspected.

2. MANAGEMENT OF ASTHMA IN ADULTS AND CHILDREN ≥ 6 YEARS OF AGE

2.1 Assessment and management of Asthma

The main goals of asthma management are to optimize control of asthma symptoms and reduce the risk of asthma exacerbations, while minimizing medication adverse effects. Goal of asthma management:

- Avoid troublesome symptoms during the day and night
- Need little or no reliever medication
- Have productive, physically active lives
- Have normal or near-normal lung function
- Avoid serious asthma exacerbations or severe attacks

The four essential components of asthma management are patient education, control of asthma triggers, monitoring for changes in symptoms or lung function, and pharmacologic therapy.

Achieving these goals requires a partnership between patient and their health care providers. Ask the patient about their own goals regarding their asthma. Shared discussion making is associated with improved outcome.

Effective asthma management requires a preventive approach, with regularly scheduled visits during which symptoms are assessed, pulmonary function monitored, control of exposure to asthma triggers and impact of comorbid conditions reviewed, medications adjusted, and ongoing education provided.

Consider the health care system, medication availability, cultural and personal preferences, and health literacy. Take every opportunity to assess patients, particularly when they are symptomatic or after a recent exacerbation.

Components of asthma education and self-management

The important components of asthma education includes:

- What is asthma and what are its symptoms?
- What are the asthma triggers for the individual patient and how can they be mitigated?
- Which medications should be used for quick relief of asthma symptoms and which are used for asthma control?

- What is the correct technique for each inhaler that the patient uses?
- Are there barriers that prevent the patient from taking medications regularly? If so, what methods would help improve adherence?

Asthma control –Has two main domains

1. Assessment of symptom control over the last 4 weeks
2. Assessment of risk factors for poor outcomes

Table.1: Assessment of symptom control over the last 4 weeks

Symptom control assessment	Level of asthma symptom control		
In the past 4 weeks, he/she had:	Well controlled	Partly	Uncontrolled
1. Daytime asthma symptoms for more than twice/week? Yes❑ No❑	none of these	1-2 of these	3-4 of these
2. Any activity limitation due to asthma? Yes❑ No❑			
3. Reliever needed* more than once a week? Yes❑ No❑			
4. Any night waking or night coughing due to asthma? Yes❑ No❑			

Table.2: Assessment of risk factors for poor outcomes

2. Assessment of risk factors for poor outcomes
Risk factors for exacerbations
• Uncontrolled asthma symptoms
Additional risk factors, even if the patient has few symptoms
• High SABA use (≥3 canisters/year)
• Having ≥1 exacerbation in last 12 months
• Incorrect inhaler technique and/or poor adherence
• Smoking
• Obesity, chronic rhino sinusitis, pregnancy, blood eosinophilia, low socioeconomic status, depression, anxiety
Risk factors for fixed airflow limitation include
• Lack of Inhaled Corticosteroid (ICS) treatment, smoking, occupational exposure, mucus hyper secretion, preterm birth, low birth weight.
Risk factors for medication side effects include
• Frequent Oral corticosteroid (OCS) use, high dose and /or potent ICS, some drugs that decrease steroid metabolism, poor inhaler technique

2.2 Principles of Asthma Management

Two groups of patients:

1. Asthma management of patients not on treatment or for first time presenters

- For patients presenting with acute symptoms, follow the algorithm for management of asthma exacerbation
- For patients with indolent but variable symptoms once the diagnosis is confirmed, assess for any risk for poor outcome listed in table....
- Patients with any risk factor for poor outcome are eligible to start higher dose of controller therapy and based on response/control of asthma, treatment can be stepped up or down.

2. Management of asthma among patients on pharmacologic treatment

- Assess for asthma control in each visit and determine asthma severity based on the level of step needed to control the symptoms
- Reassess for risk factor for poor outcome (Table 2)

During initial presentation

Start with Step 1if:	Symptoms less than twice per month
Start with Step 2 if:	Symptoms twice a month or more, but less than daily.
Start with Step 3 if :	Symptoms most days, or waking with asthma once a week or more.
Start with step 4 if :	Symptoms most days, or waking with asthma once a week or more, and low lung function.

2.2.1 Asthma management for Adults and Adolescents 12 years and above at Health Center Level in Ethiopia

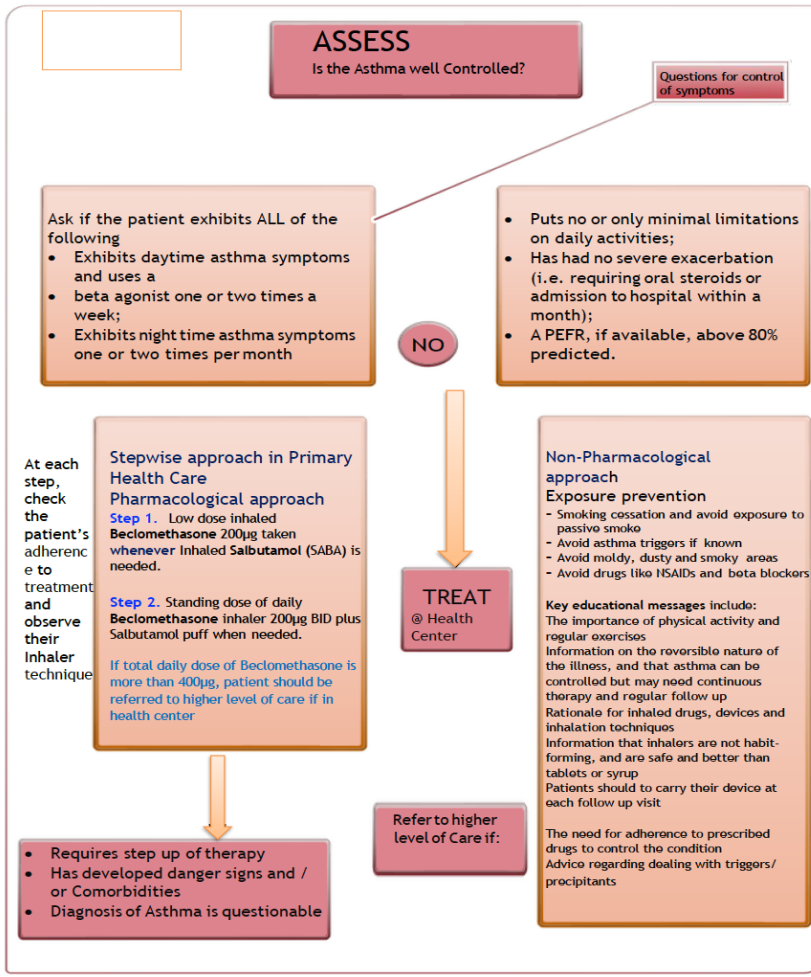
Step 1. Low dose inhaled Beclomethasone 100µg taken whenever Inhaled Salbutamol (SABA) is needed.

Step 2. Standing dose of daily Beclomethasone inhaler 200µg (1 puff) BID plus Salbutamol puff when needed.

If total daily dose of Beclomethasone is more than 400µg, patient should be referred to higher level of care

See the algorithm below.

Algorithm of Asthma Assessment and Management at Health Center Level



2.2.2 Asthma Management for Adults and Adolescents 12 years and above at Hospital Level in Ethiopia

Steps 1 and **2** – Same as in Health centers as above

Step 3 - Standing Medium dose of Beclomethasone 400µg (2Puffs of 200µg) BID alone, Or

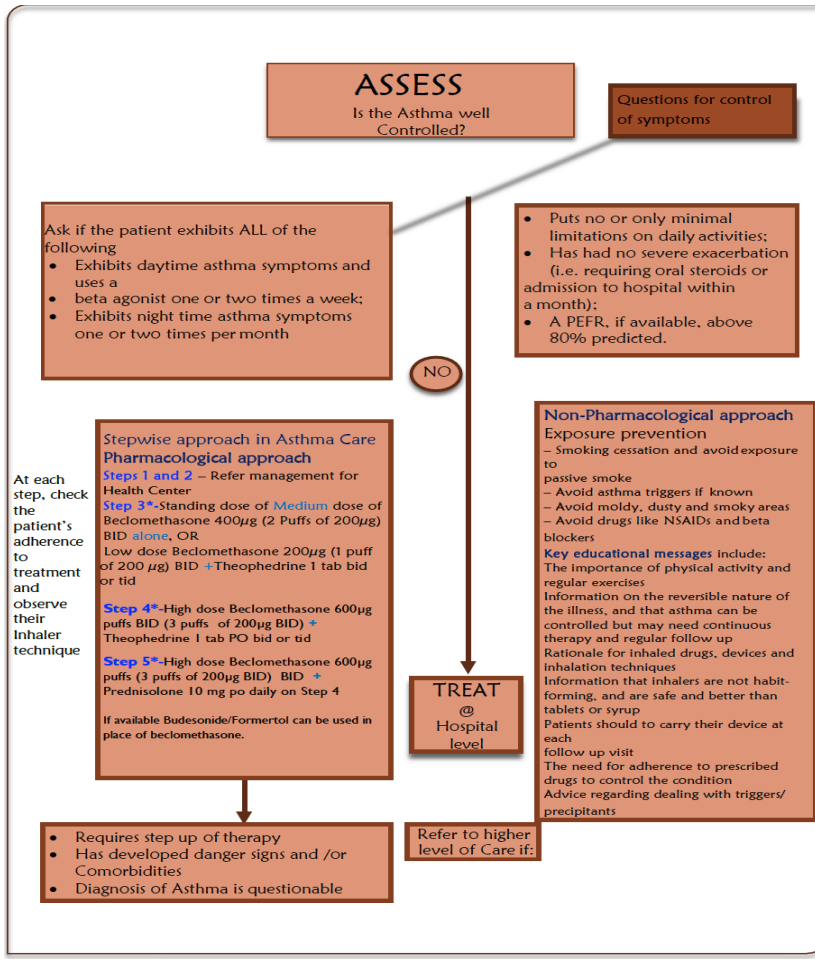
Medium dose Beclomethasone 200µg (2 puffs) BID +Theophedrine tablets PO tid

Step 4- High dose Beclomethasone 600µg puffs BID (3 puffs of 200µg BID) + Theophedrine tabs PO bid or tid

Step 5- High dose Beclomethasone 600µg puffs BID (3 puffs of 200µg BID) + Prednisolone 10 mg po daily on Step 4

See the Algorithm below.

Algorithm of Asthma assessment and management at Hospital Level



**For children 6-11 years old one puff bid.*
***Montelukast leukotriene receptor antagonist has recently shown to induce neuropsychiatric events in pediatric age groups.*
****Theophylline has reduced clearance in elderly and those with acute illness. It has a narrow therapeutic index and is not safe for those at high risk for toxicity (e.g. cardiovascular diseases, hyperthyroidism)*
§For children 6-11 years old one puff bid.

2.3 The Asthma Management Cycle to Minimize Risk and Control Symptoms

Asthma management involves a continuous cycle to assess, adjust treatment and review response.

- Assess symptom control + risk factors and comorbidities
- Adjust treatment (pharmacological and non-pharmacological)
- Review the response: symptoms, exacerbations, side effect

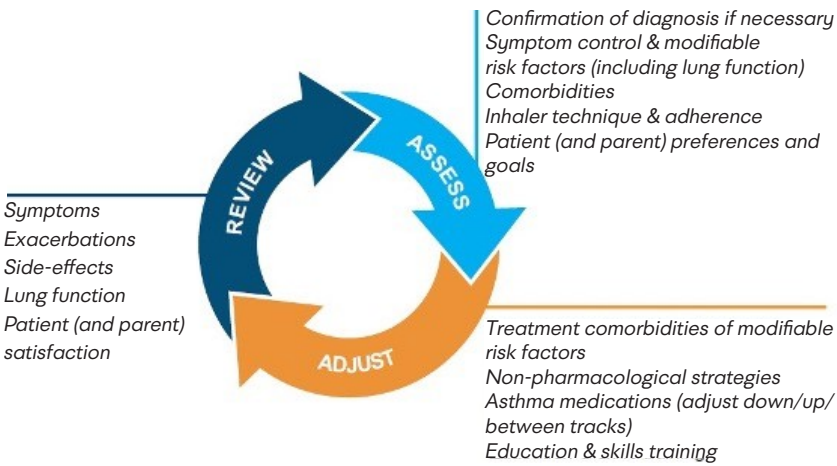


Figure: The Asthma Management Cycle

2.4 Reviewing Response and Adjusting Treatment

a) Stepping up asthma treatment.

- Sustained step-up, for at least 2-3 months if asthma poorly controlled;
  - Important: first check for common causes (symptoms not due to asthma, incorrect inhaler technique, poor adherence, persistent environmental exposures and drugs, comorbidities that may contribute to respiratory symptoms).

- Short-term step-up, for 1-2 weeks, e.g. with viral infection or allergen;
  - May be initiated by patient with written asthma action plan.
- Day-to-day adjustment;
  - For patients prescribed low-dose ICS/Formoterol maintenance and reliever regimen

b) Stepping down asthma treatment.

- Consider step-down after good control maintained for 3 months.
- Find each patient's minimum effective dose that controls both symptoms and exacerbations.

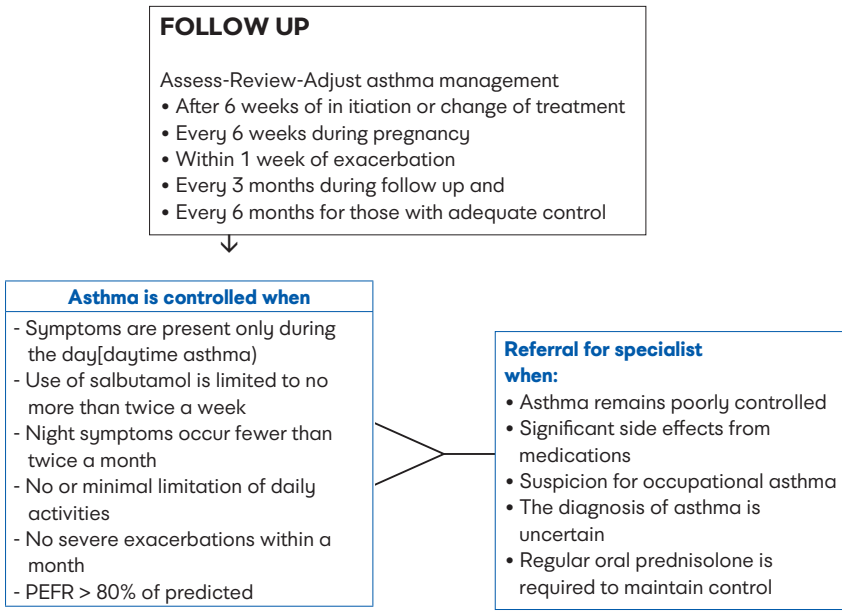
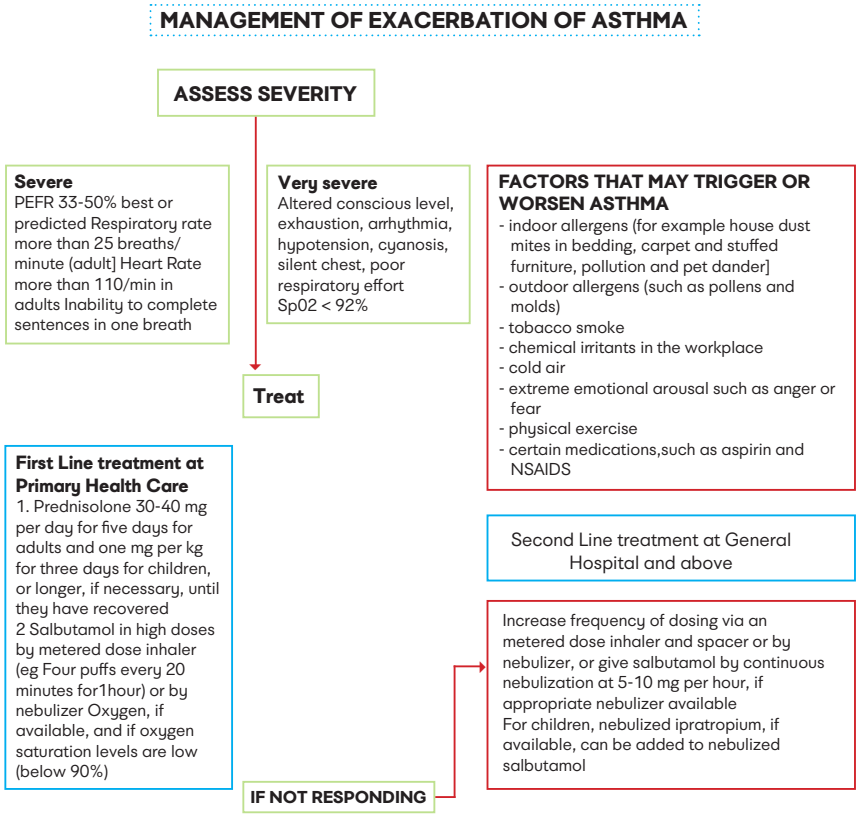


Figure: Algorithm for Asthma Follow up Management

2.5 Asthma Flare-Ups (Exacerbations)

A flare-up or exacerbation is an acute or sub-acute worsening in symptoms and lung function from the patient's usual status; occasionally it may be the initial presentation of asthma.



**Magnesium Sulfate is not recommended for those with renal insufficiency*
***Those that were taking oral theophylline maintenance therapy are not recommended to take a loading dose of IV therapy. Loading Aminophylline 5.7 mg/kg (equivalent to theophylline 4.6 mg/kg) and maintenance dose of Aminophylline 0.5 mg/kg/hour (equivalent to theophylline 0.4 mg/kg/hour).*

Follow-up after an exacerbation

- Follow up all patients regularly after an exacerbation, until symptoms and lung function return to normal
  - ✓ Patients are at increased risk during recovery from an exacerbation
- The opportunity
  - ✓ Exacerbations often represent failures in chronic asthma care, and they provide opportunities to review the patient's asthma management

- At follow-up visit(s), check:
  - ✓ The patient's understanding of the cause of the flare-up
  - ✓ Modifiable risk factors, e.g. smoking
  - ✓ Adherence with medications, and understanding of their purpose
  - ✓ Reliever should be used as-needed rather than routinely
  - ✓ Inhaler technique skills
  - ✓ Written asthma action plan

2.6 Asthma medications and common side effects

- Short Acting Beta Agonists (SABAs)- Short acting beta agonists bronchodilators should be the main therapy only during acute exacerbations but NOT recommended as a stand-alone therapy except in pediatric age group. e.g. Salbutamol inhaler
- Long Acting Beta Agonists (LABAs) provide bronchodilation for up to 12 hours after a single dose. Salmeterol and formoterol are the LABAs available for asthma. LABAs are used with inhaled corticosteroids. They should not be used for symptom relief or treatment of exacerbations.
- Corticosteroids are the most potent and consistently effective anti-inflammatory agents cur¬rently available. Inhaled corticosteroids (ICS) are the main stay of therapy for asthma. High dose ICS and long-term use of oral steroids predisposes to systemic side effects which includes adrenal suppression, osteoporosis, skin thinning, easy bruising, diabetes, hypertension, infections, glaucoma and cataracts.

Table 3: Inhaled corticosteroids (ICS) and Combinations for Adults and adolescents (≥12 years) in Ethiopia

Inhaled corticosteroid	Total daily dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (HFA)	100–200	200–400	>400
Budesonide/formoterol * (HFA-pMDI)	80/4.5	160/4.5	320/9
Fluticasone/salmeterol (DPI)	100/50	250/50	500/50

NB: DPI-Dry Powder inhaler, MDI -Metered dose inhaler HFA-Hydrofluoroalkane.

*When Budesonide/formoterol is prescribed as maintenance and reliever therapy, the maximum recommended dose of formoterol in a single day is 72 mcg.

- Theophylline: Sustained-release theophylline preparations (e.g. theophedrine 120/11mg tablets 1-4 times per day) are effective in controlling nocturnal symptoms

and as added therapy in patients with moderate or severe persistent asthma whose symptoms are inadequately controlled by inhaled corticosteroids alone.

At therapeutic doses, potential adverse effects include insomnia, aggravation of dyspepsia and gastroesophageal reflux, and urination difficulties in men with prostatic hyperplasia. Dose-related toxicities include nausea, vomiting, tachyarrhythmias, headache, seizures, hyperglycemia, and hypokalemia.

2.7 Treating Modifiable Risk Factors

Exacerbation risk can be minimized by optimizing asthma medications, and by identifying and treating modifiable risk factors.

- Guided self-management: self-monitoring of symptoms and/or PEF, a written asthma action plan, and regular medical review
- Use of a regimen that minimizes exacerbations
- Avoidance of exposure to tobacco smoke
- Confirmed food allergy: appropriate food avoidance; ensure availability of injectable epinephrine for anaphylaxis
- School-based programs that include asthma self-management skills
- Referral to a specialist center for patients with severe asthma

2.8 Non-Pharmacological Strategies and Interventions

In addition to medications, other therapies and strategies may be considered where relevant, to assist in symptom control and risk reduction.

- Smoking cessation advice: at every visit, strongly encourage smokers to quit.
- Physical activity: encourage people with asthma to engage in regular physical activity
- Investigation for occupational asthma: ask all patients with adult-onset asthma about their work history. Identify and remove occupational sensitizers as soon as possible. Refer patients for expert advice, if available.
- Identify aspirin-exacerbated respiratory disease, and before prescribing NSAIDs including aspirin, always ask about previous reactions.
- Avoid known allergens

3. DIAGNOSIS AND MANAGEMENT OF ASTHMA IN CHILDREN UNDER THE AGE OF FIVE YEARS

Diagnosis of asthma in young children with recurrent wheeze is more likely if they have:

- Wheezing or coughing that occurs with exercise, laughing or crying, and symptoms in the absence of apparent respiratory infection.
- History of other allergic disease (eczema or allergic rhinitis), allergen sensitization or asthma in first-degree relatives.
- Clinical improvement during 2–3 months of controller treatment, and worsening after cessation.

3.1 Preschool children asthma diagnosis and follow up at primary care level

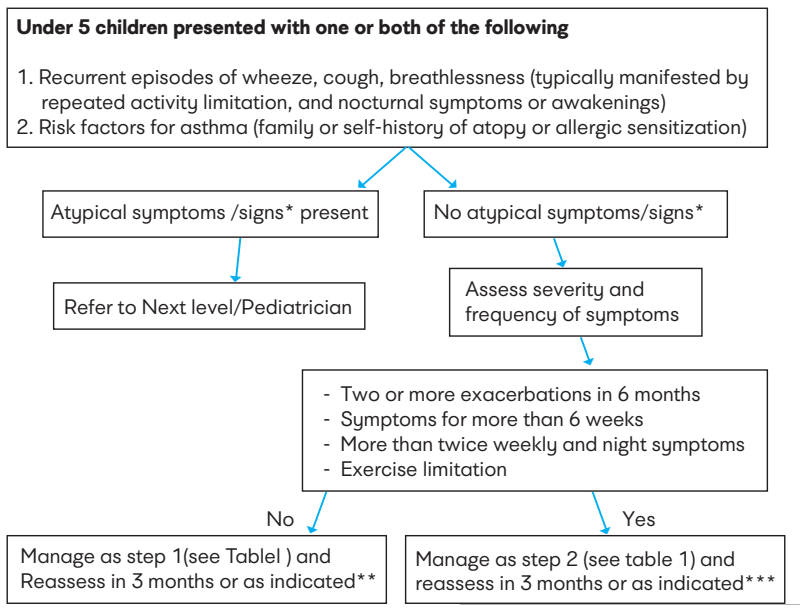


Figure 1: Approach of under 5 children with suspected asthma in primary care levels.

* Atypical symptoms and signs are: The presence of any of the following shouldn't be explained by asthma and requires referral for further evaluation: Symptom since neonatal period or age < 6 months, presence of persistent symptoms without variability, malnutrition, excessive productive/wet and persistent cough, Clubbing, desaturation apart from exacerbation and presence of other systemic symptoms.

** continue step 1 or go to step 2 based on severity and frequency of symptoms.

*** Continue same step if good symptom control for a minimum of 3 months before stepping down. Check inhalation technique regularly and refer to pediatrician if asthma not controlled on step 2 with good spacer and inhalation technique.

3.2 Preschool children Asthma diagnosis and follow up in general hospitals and beyond

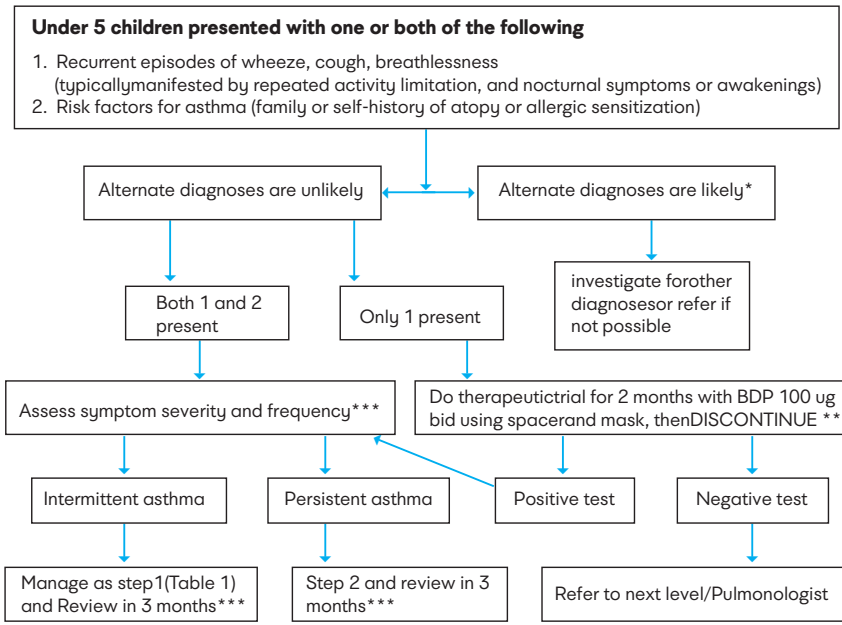


Figure 2: Approach to under 5 children with suspected asthma in general hospital and beyond levels.

* ALTERNATE diagnosis is likely if: Symptom starts early in neonatal period, persistent symptoms without variability, lack of response to appropriate SABA and controller treatment, failure to thrive, significant productive/wet persistent cough and presence of other systemic symptoms.

** Positive response is the resolution of symptoms with 2 months of daily BDP followed by symptom reappearance when discontinued.

*** See table 2 for asthma control assessment and optimize care based on control/severity and risk level. SABA- Short acting beta agonist e.g. Salbutamol puff, BDP- Beclomethasone Diproprionate.

Important notes

- Avoid use of phenotypes of wheezing for therapeutic clinical decision, use current frequency and severity of symptoms to determine the need of therapeutic intervention.
- Asthma symptoms may mimic other congenital and acquired conditions in young children and exclusion of asthma mimickers is an important task of the treating physician before commencing treatment whenever possible.
- Investigations including CXR are usually indicated to exclude suspected alternate diagnoses but not to confirm asthma.
- Referral to a specialist is warranted if the child exhibit recurrent infection, has poor response to therapy, persistent symptoms without variability, produces excessive sputum, has cyanosis, severe exacerbation of asthma, noisy breathing, dysphagia, family history of unusual respiratory diseases, symptoms occurrence in early life, and presence of failure to thrive.
- For seasonal exacerbations continue controller medications until cessation of the season and reassess 3-6 weeks after discontinuation of controller medications.

3.3 Management of asthma in Preschool children

The goals of preschool asthma management are similar to the goals in older children and adults but also targets to optimize lung growth.

3.3.1 Nonpharmacological measures

- Avoid exposure to environmental tobacco smoke
- Avoid food and drug triggers
- Avoid indoor and outdoor pollution and irritants

3.3.2. Pharmacological therapy

Steps of asthma management in under five asthma treatment: refer to table below

Table.4: Stepwise management of preschool asthma in primary (Steps 1 and 2) and general hospital and beyond (Steps 3 and 4). Avoid use of montelukast in children <12 months.

	Step 1	Step 2	Step 3	Step 4
Preferred controller	-	BDP 100 ug hid	BDP 200 ug bid	Continue step 3 controller and Refer to specialist
Other Controller option	-	Montelukast 4 mg	BDP 100 ug bid plus montelukast 4 mg daily	Asthma not controlled on double BDP dose
Reliever	**Salbutamol 4 Puffs via spacer with mask**			
Apply this step for children with:	Infrequent viral infection related wheeze with no or few interval symptoms	Therapeutic trial, frequent attack (2 or more /yr.), after any lifethreaten-ing attack	Asthma not well controlled on low dose BDP	Asthma not controlled on double BDP dose

3.2.3. Assessing asthma control in preschool children

A. Symptom control			
In the past 4 weeks, has the child had:	Well controlled	Partly controlled	Uncontrolled
I Day time asthma symptoms for more than few minutes, more than once/week? Yes ☐ No ☐	None of these	1-2 of these	3-4 of these
Any activity limitation duo to asthma? (runs/plays less than other children, tires easily during walks/playing) Yes ☐ No ☐			
Reliever needed* more than once a wook? Yes ☐ No ☐			
Any night waking or night coughing due to asthma? Yes ☐ No ☐			
B. Risk factors for poor asthma outcomes			
Assess child's risk for: • Exacerbations within the next few months* • Fixed airflow limitation** • Medication side-ettects***			

Table.5: Assessment of asthma control and risks in preschool children.

*Risk factors for exacerbations in the next few months: Uncontrolled asthma symptoms, One or more severe exacerbation in previous year, The start of the child's usual 'flare-up' season (especially if autumn/fall), Exposures: tobacco smoke; indoor or outdoor air pollution; indoor allergens (e.g. house dust mite, cockroach, pets, mold), especially in combination with viral infection, Major psychological or socio-economic problems for child or family, Poor adherence with controller medication, or incorrect inhaler technique.

** Risk factors for fixed airflow limitation: Severe asthma with several hospitalizations, History of bronchiolitis.

*** Risk factors for medication side-effects: Systemic: Frequent courses of OCS; high-dose and/or potent ICS, Local: moderate/high-dose or potent ICS; incorrect inhaler technique; failure to protect skin or eyes when using ICS by nebulizer or spacer with face mask.

3.2.4. Asthma Education in the management of under-five asthma

- PROVIDE Written action plan including for exacerbation management whenever possible (See CRDs participant manual).
- Educate proper inhalation technique and review on every visit.
- Emphasize the use of current symptoms than chance of persistence for therapeutic goal.
- Check for allergic sensitization and avoid allergens and environmental control.

4. DIAGNOSIS AND MANAGEMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

4.1 DIAGNOSIS AND INITIAL ASSESSMENT OF COPD

- The diagnosis of COPD is based on signs and symptoms and is confirmed by spirometry. However, symptoms are under recognized by patients, and COPD is under diagnosed by physicians.
- COPD should be considered in any patient over the age of 40 years who has dyspnea, chronic cough, or sputum production, and/or a history of exposure to risk factors for the disease.

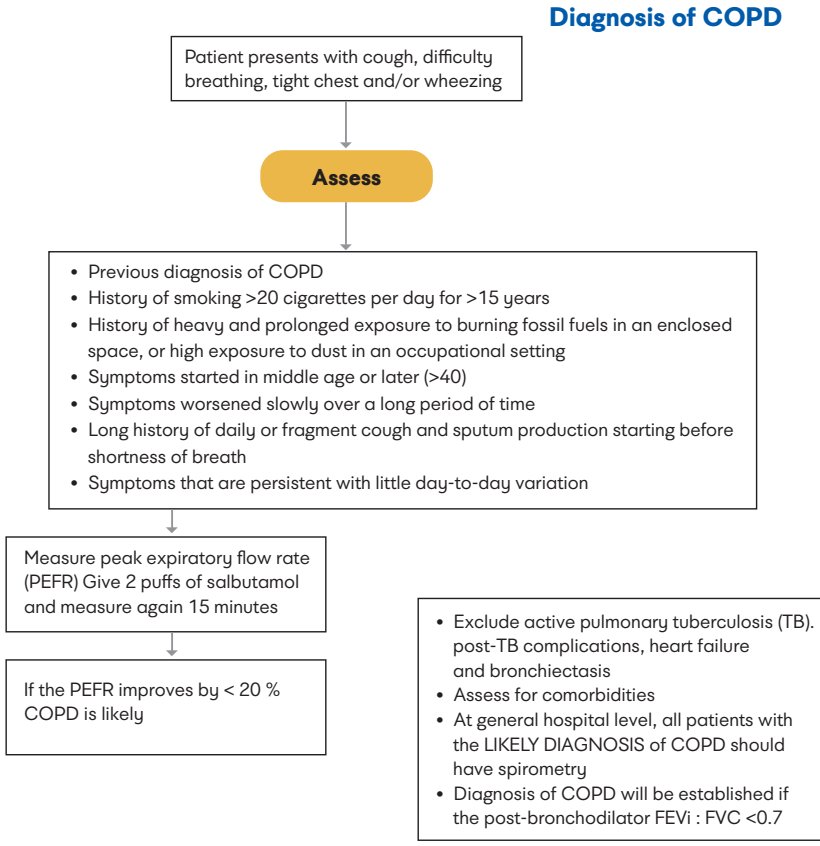


Fig.1 Diagnosis of COPD

4.1.1 Screening for COPD

- There is inadequate evidence that screening for COPD in asymptomatic persons using questionnaires or spirometry improves health outcomes.
- But screening is recommended for symptomatic patients with significant risk factors.
- The National Heart, Lung, and Blood Institute of the USA recommends spirometry for all smokers 45 years or older, particularly those who present with shortness of breath, coughing, wheezing, or persistent sputum production.

Table 9: Key indicators for considering a diagnosis of COPD

Dyspnea that is:	Progressive overtime. Characteristically worse with exercise. Persistent.
Chronic Cough:	May be intermittent and may be unproductive. Recurrent wheeze.
Chronic Sputum Production:	Any pattern of chronic sputum production may indicate COPD.
Recurrent Lower Respiratory Tract Infections	
History of Risk Factors:	Host factors (such as genetic factors, congenital/developmental abnormalities etc.). Tobacco smoke (including popular local preparations). Smoke from home cooking and heating fuels, Occupational dusts, vapors, fumes, gases and other chemicals.
Family History of COPD and/or Childhood Factors:	For example low birthweight, childhood respiratory infections etc.

(Source: GOLD 2020)

- Cough and associated sputum production are usually the first symptoms, and are often referred to as a 'smoker's cough'.
- Hemoptysis may complicate exacerbations of COPD but should not be attributed to COPD without thorough investigation.
- Breathlessness usually prompts presentation to a health professional. The level should be quantified for future reference, often by documenting what the patient can manage before stopping.
- The goals of COPD assessment are to determine the level of airflow limitation, the impact of disease on the patient's health status, and the risk of future events (such as exacerbations, hospital admissions, or death), in order to guide therapy.

- Concomitant chronic diseases occur frequently in COPD patients, including cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, anxiety, and lung cancer. These comorbidities should be actively sought and treated appropriately; when present they can influence mortality and hospitalizations independently.
- Depending on the presentation, important differential diagnoses include asthma, tuberculosis, bronchiectasis and heart failure.

TABLE 10: DIFFERENTIAL DIAGNOSIS OF COPD (Source: GOLD 2020)

DIAGNOSIS	SUGGESTIVE FEATURES
COPD	Onset in mid-life. Symptoms slowly progressive. History of tobacco smoking or exposure to other types of smoke.
Asthma	Onset early in life (often childhood). Symptoms vary widely from day to day. Symptoms worse at night/early morning . Allergy,rhinitis,and/or eczema also present. Family history of asthma. Obesity coexistence.
Congestive Heart Failure	Chest X-ray shows dilated heart,pulmonary edema. Pulmonary function tests indicate volume restriction,not airflow limitation
Bronchiectasis	Large volumes of purulent sputum. Commonly associated with bacterial infection. Chest X-ray/CT shows bronchial dilation,bronchial wall thickening.
Tuberculosis	Onset all ages. Chest X-ray shows lung infiltrate. Microbiological confirmation. High local prevalence of tuberculosis.

4.1.2 CLINICAL SCREENING OF COPD

Spirometry is required to make the diagnosis of COPD; the presence of a post-bronchodilator FEV1/FVC < 0.70 confirms the presence of persistent airflow limitation. However, spirometry is often not available and, hence, clinical criteria can be used to determine probability of COPD.

The COPD Population Screener™ (COPD-PS™) is an easy-to-use, validated tool designed to identify patients at risk for COPD (See table 11). Since spirometry is not available in

primary health care centers in Ethiopia, health professionals working in such institutions can use this tool to screen patients at risk for COPD and can make proper referral to centers with spirometry facility or manage the patients as probable COPD.

Table 11: The COPD Population Screener™ (COPD-PS™)

1. During the past 4 weeks, how much of the time did you feel short of breath?				
None of the time	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
☐ 0	☐ 0	☐ 1	☐ 2	☐ 2
2. Do you ever cough up any "stiff,"such as mucus or phlegm?				
No, never	**Only with occasional colds or chest infections**	**Yes, a few days a month**	**Yes, most days a week**	**Yes every day**
☐ 0	☐ 0	☐ 1	☐ 1	☐ 2
3. Please select the answer that best describes you in the past 12 months. I do less than I used to because of my breathing problems.				
Strongly disagree	**Disagree**	**Unsure**	**Agree**	**Strongly agree**
☐ 0	☐ 0	☐ 0	☐ 1	☐ 2
4. Have you smoked at least 100 cigarettes in your ENTIRE LIFE?				
	No	**Yes**	**Don't know**	
	☐ 0	☐ 2	☐ 0	
5. How old are you?				
	Age 35 to 49	**Age 50 to 59**	**Age 60 to 69**	**Age 70+**
	☐ 0	☐ 1	☐ 2	☐ 2

How to Score Your Screener: In the spaces below, write the number that is next to your answer for each of the questions. Add the number to get the total score.The total score can range from0 to 10.

_____ + _____ + _____ + _____ + _____ = _____

(#1) (#2) (#3) (#4) (#5) TOTAL SCORE

Notes to the Doctor/Healthcare Provider:

- Consider Biomass Fuel exposure grading at number 4 in Ethiopia

About the score:

- Score 5-10 — High risk of COPD
- Score 0-4 — Low risk of COPD

Remember that confirmation of COPD diagnosis requires spirometry.

- Other diagnostic tests can be employed to rule out concomitant disease or tailor additional treatment
    - CXR,
    - GeneXpert to rule out TB
    - CBC to exclude anemia or polycythemia
    - ECG and echocardiography in patients with signs of cor-pulmonale
- Pulse oximetry at rest, with exertion, and during sleep should be performed to evaluate for the grade of hypoxemia and the need for supplemental oxygen.

4.2 MANAGEMENT OF COPD

An effective COPD management plan includes four components:

1. Assess and monitor disease
2. Reduce risk factors
3. Manage stable COPD
4. Manage exacerbations

The goals of effective COPD management are to:

- ✓ Prevent disease progression
- ✓ Relieve symptoms
- ✓ Improve exercise tolerance
- ✓ Improve health status
- ✓ Prevent and treat complications
- ✓ Prevent and treat exacerbations
- ✓ Reduce mortality

4.2.1 Management of Stable COPD

The management of stable COPD focuses on improving breathlessness, reducing the frequency and the severity of exacerbations, and improving health status and prognosis. It includes avoidance of modifiable risk factors, provision of vaccinations, pharmacologic therapies, oxygen therapy and pulmonary rehabilitation.

Management of COPD

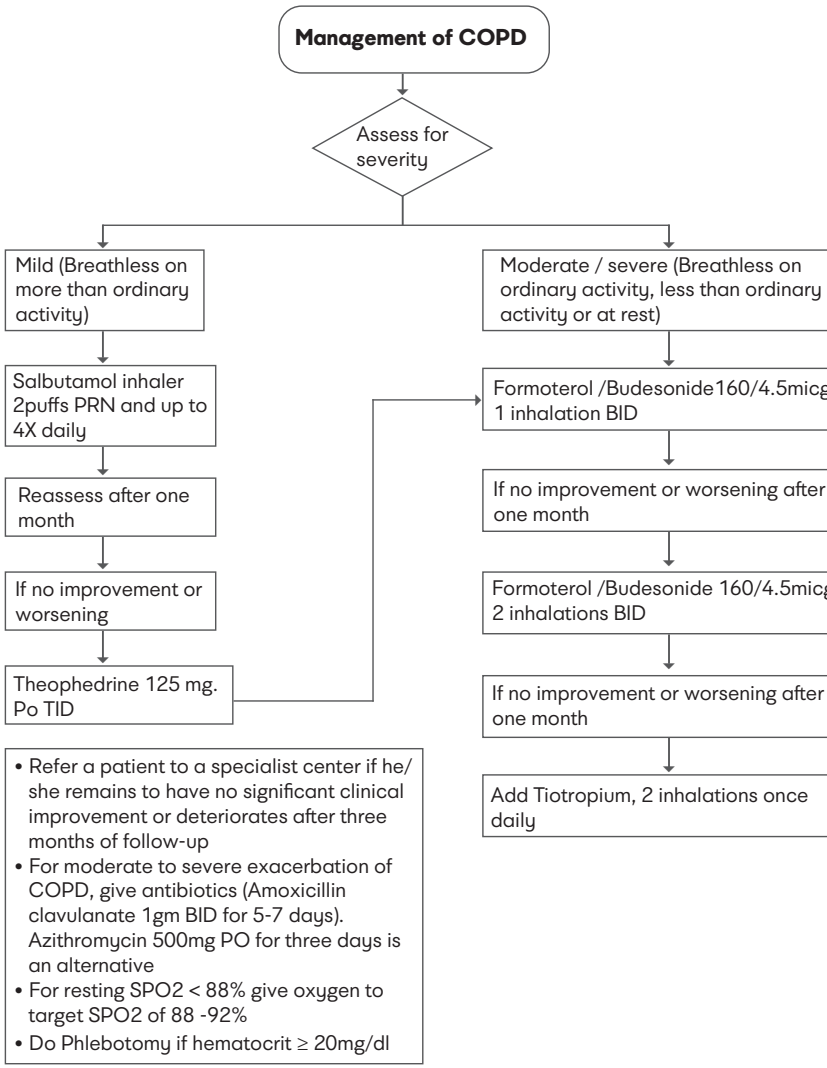


Fig.2 Management of COPD

a) Avoidance of modifiable risk factors: smoking cessation and reduction of indoor air pollution.

b) Pharmacological therapies: These are used to reduce symptoms, reduce the frequency and severity of exacerbations, and improve exercise tolerance and health status.

- Beta-2 agonists: These include SABAs and LABAs. Important side effects include tachycardia and somatic tremor.
- Oral bronchodilator therapy: Methylxanthines (theophedrine tabs) may be contemplated in patients who cannot use inhaled devices efficiently. Side effects include palpitations caused by atrial and ventricular arrhythmias, grand-mal convulsions, headaches, insomnia, nausea, and heartburn.
- Combined inhaled glucocorticoids and bronchodilators: The fixed combination of an inhaled glucocorticoid and a LABA (e.g. fluticasone with salmeterol, budesonide with formoterol) may be accompanied by an increased risk of pneumonia, particularly in the elderly.
  Use this combination especially when there is history of hospitalization for exacerbation, two or more exacerbations per year or history of (concomitant) asthma.
- Oral glucocorticoids: Oral glucocorticoids are useful during exacerbations, but maintenance therapy contributes to osteoporosis and impaired skeletal muscle function, and should be avoided.

c) Pulmonary rehabilitation: Exercise should be encouraged at all stages and patients reassured that breathlessness, while distressing, is not dangerous. Physical training, disease education and nutritional counseling reduce symptoms, improve health status and enhance confidence.

4.2.2 Management of Exacerbation of COPD

Short of accurate diagnosis in Ethiopia, COPD with acute exacerbation should be considered in every patient presenting with a recent worsening of his/her longstanding cough or dyspnea or sputum color change (purulence). Consider differential diagnosis and try to rule out pneumonia, pneumothorax, pulmonary embolism, left side heart failure, arrhythmia etc.

Measures to reduce the possibility of future exacerbations in those patients with previous history of exacerbation include smoking cessation, optimization of medication (long acting bronchodilators and ICSs) and possibly early rehabilitation.

COPD exacerbations are generally induced by viral or bacterial infections, air pollution and environmental temperature changes. Typical organisms associated with COPD exacerbations include S. Pneumoniae, H. influenzae and M. Catarrhalis.

Purulent sputum is very much suggestive of bacterial infection and those patients who have eosinophilia in the blood/airways are more likely to respond to systemic corticosteroids
Investigations: Have the following tests in all those patients at encounter. However, treatment should not be delayed until investigations are complete.

1. CBC
2. Chest x-ray
3. GeneXpert MTB/RIF
4. ECG
5. Arterial Blood Gas, if available
6. Other tests when needed to rule out other diseases
    a. CT angiography
    b. Echocardiography

Treatment of COPD Exacerbations

COPD Exacerbations are classified as:

- Mild (treated with short acting bronchodilators only, SABDs)
    - Salbutamol inhaler: 2-3 puffs every hour and then tapered to 2 puffs every 4hrs
- Moderate (treated with SABDs plus antibiotics and/or oral corticosteroids)
    - Salbutamol inhaler: 2-3 puffs every hour and then tapered to 2 puffs every 4hrs.
    - Antibiotics (increased dyspnea, increased sputum volume and presence of sputum purulence): Amoxicillin/clavulanic acid, cephalosporin's, or macrolides
    - Steroids if needed can be given orally (prednisolone 40mg) or IV (hydrocortisone or methylprednisolone). Recommended only for 5-7days.
- Severe (patient requires hospitalization or visits the emergency room). Severe exacerbations may also be associated with acute respiratory failure. Refer to Specialized Hospitals.

Supportive care for COPD Exacerbations

- DVT prophylaxis
- Proper and adequate nutrition, analgesia and hydration
- Cautious use of sedatives
- Chest physical therapy

- As needed stress ulcer prophylaxis
- Management of secondary polycythemia and cor-pulmonale Management and as needed screening for comorbidities

Smoking cessation:

- ✓ Smoking session has the greatest capacity to influence the natural history of COPD.
- ✓ A five-step program for intervention provides a helpful strategic framework. . Please refer to the 5A's brief intervention model framework in the national training manual on healthy life style counseling.

REFERENCES

1. GINA 2021
2. GOLD 2021
3. National NCD Guideline Ethiopia 2016