Republic of Kenya

MINISTRY OF HEALTH

KENYA NATIONAL CLINICAL GUIDELINES FOR THE MANAGEMENT OF DIABETES MELLITUS

SECOND EDITION 2018

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Produced by: The National Diabetes Prevention and Control Program

Division of Non-communicable Diseases
Ministry of Health, Kenya

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Enquiries regarding the Kenya National Clinical Guidelines for Management of Diabetes Mellitus should be addressed to:

National Diabetes Control Programme,
Division of Non-communicable Diseases,
Ministry of Public Health and Sanitation,
P.O. Box 30016 – 00100
Nairobi, Kenya

MINISTRY OF HEALTH
DIVISION OF NON - COMMUNICABLE DISEASES

WORLD DIABETES FOUNDATION

KENYA DIABETES MANAGEMENT AND INFORMATION CENTRE

WORLD HEALTH ORGANIZATION

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ACRONYMS

ABI	Ankle-Brachial Index
ACEI	Angiotensin Converting Enzyme Inhibitors
ADA	American Diabetes Association
AHT	Anti-Hypertensive Therapy
AKUH	Agha Khan University Hospital
ANC	Antenatal Care
ARB	Angiotensin Receptor Blockers
BMI	Basal Metabolic Rate
BGLs	Blood Glucose Levels
BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CF	Correction factor
CRP	C-reactive protein
DCC	Diabetes Comprehensive Care
DKA	Diabetes Ketoacidosis
DMI	Diabetes Management and Information Centre
DNCD	Division of Non-communicable Diseases
ECG	Electrocardiograph
FBG	Fasting Blood Glucose
FFA	Free fatty acids
GDM	Gestation Diabetes Mellitus
GFR	Glomerular Filtration Rate
HAART	Highly Active Anti-Retroviral Treatment
HIV	Human Immunodeficiency Virus
HHS	Hyperglycemic Hyperosmolar State
HDL	High Density Lipoproteins
HGT	Hourly Glucose Test
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
IHD	Ischaemic heart disease
IU	International Units
KNH	Kenyatta National Hospital
LADA	Latent Autoimmune Diabetes in Adults
MSF	Médecins Sans Frontières
LDL	Low Density Lipoproteins
MDI	Multiple Daily Injections
MTRH	Moi Teaching and Referral Hospital
MUAC	Mid Upper Arm Circumference
NIDDM	Non-Insulin-Dependent Diabetes Mellitus
NPH	Neutral-Protamine-Hagedorn
OGLA	Oral Glucose Lowering Agents
OGTT	Oral Glucose Tolerance Test
RBG	Random Blood Glucose
SMBG	Self-Monitoring of Blood Glucose
TB	Tuberculosis
TSH	Thyroid Stimulating Hormone
WC	Waist Circumference
WDF	World Diabetes Foundation
WHO	World Health Organization
WHR	Waist Hip Ratio

FOREWORD

The prevalence of chronic Non-Communicable Diseases (NCDs) such as Diabetes, Cardiovascular Diseases and Cancers has been on the rise in Kenya in the recent past. This has been occasioned by changes in the social and demographic situation in the country. The life expectancy in Kenya is improving, as the country develops rapidly. This has resulted in people living longer and at the same time adopting lifestyles that have negative impact on their health. This increase in diabetes and other NCDs has given rise to a double burden of communicable and non-communicable diseases in Kenya.

Diabetes and other NCDs are now a threat to national development as they often result in long standing illness and complications that can be very costly to treat and progressively drain the strength and resources of individuals, families and communities rendering them unproductive and poor.

In response to this crisis, the Ministry of Health prioritized prevention and management of diabetes and other NCDs in the Kenya Health Policy 2012 - 2030. Furthermore, the Ministry of Health in collaboration with Non-Governmental Organizations, Regional and International Diabetes support bodies spearheaded the development of the National Clinical Guidelines for the Management of Diabetes Mellitus to provide a standardized approach of managing Diabetes in the country.

Prevention and control of Diabetes and other NCDs is a key pillar to the attainment of Universal Health Coverage (UHC). These guidelines will standardize clinical practice that will ensure universal access to interventions addressing Diabetes and its complications. It also forms a part of the UHC delivery support documents and will contribute to the achievement of its overall aim.

The guidelines also reaffirm Kenya's commitment to the Declaration of Astana on strengthening the Primary Health Care (PHC) systems as an essential step towards achieving UHC. The guidelines are also informed by the commitments on Sustainable Development Goals (SDGs) as they intend to contribute to the general wellbeing of the individual patients, their families and communities towards productivity and shared prosperity.

The National Clinical Guidelines for the Management of Diabetes Mellitus has effectively provided for high standard of care for Diabetes with clear consideration of management interventions and technologies that are easily accessible and available for Kenyans. To this end, the guidelines align with the National drive to ensure UHC is attained.

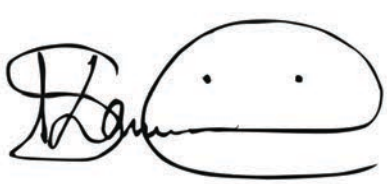
A Technical Working Group (TWG) was established under the auspices of the Division of Non-Communicable Diseases (DNCD) to develop these guidelines that are based on up to date and evidence-based management of Diabetes Mellitus. These guidelines are a synthesis of information drawn from an extensive review of local and international knowledge and experiences.

In their development, the TWG adopted a Primary Health Care (PHC) approach as this is the most effective way to sustainably integrate Diabetes and other NCDs in the care continuum. PHC enables every person, everywhere to exercise their fundamental right to health. The guidelines will ensure essential Diabetes services ranging from awareness, early diagnosis, timely referral, regularly monitoring, health and risk factor education at the community level and palliative care are accessed at every level of care.

These guidelines are suitable for use by all health workers and health institutions from both the public and private sectors in the country. They provide clear directions on what needs to be done for people living with Diabetes and provide a guide on the continuum of care required throughout the life course of the individuals living with the disease.

As a Ministry, we appreciate that the task of managing complex NCDs like Diabetes cannot be left to the Government alone. It is in this regard that we embraced a broad partnership base to tap on the know-how from the public, private, academia, pharmaceutical, patients' groups and other non-state actors in the developing of these guidelines.

I highly recommend the use of the guidelines by all health care providers across the health sector as a reference document when managing Diabetes and its related complications.



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Sicily K. Kariuki (Mrs.), EGH
Cabinet Secretary
Ministry of Health

PREFACE

Non-communicable diseases (NCDs) are the leading causes of morbidity and mortality globally causing more deaths than all other causes combined, and they strike hardest at the world's low and middle-income populations. In Kenya NCD accounts for more than 50% of total hospital admissions and over 55% of hospital deaths. It is in this regard that the Ministry of Health and partners have developed this strategic document to serve as a comprehensive guide to addressing this emerging epidemic.

As a que from the Global Action Plan on NCDs and as a follow-up to the 3 UN High level meetings on NCDs, this guidelines are meant to build the capacity of Primary Health Care workers on the prevention, diagnosis and control of diabetes across the entire continuum of care.

The hall mark of diabetes is long term complications like foot, cardiovascular, eye, nerve and renal complications that are driven by poor glycemic control. This is a grim reality considering that and among those previously diagnosed with diabetes and were currently on treatment only 7% had achieved control. This guideline will provide a standardized and harmonized road map towards improving prevention, screening, diagnosis and care of people with diabetes. It also promotes patient empowerment and recognizes the patients as a major stakeholder in diabetes care.

This guidelines are in themselves the minimum standard of care and act as a benchmark on quality and rights of access for the patients. They are however incremental in nature as the capacity of our health system varies greatly across the country and some county facilities may not have what is envisaged in this guidelines. In this regard, these guidelines should go hand in hand with capacity building and system strengthening and reform across the national and county health levels.

We are committed to ensuring that this guideline is implemented and adopted to the fullest in order to improve the lives of our population and provide the appropriate care to those living with diabetes

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Dr. Rashid Abdi Aman, BPharm., PhD
Chief Administrative Secretary
Ministry of Health

ACKNOWLEDGEMENTS

The National Clinical Guidelines for the Management of Diabetes Mellitus was prepared with the active participation of diabetes experts from the Ministry of Health, teaching institutions, Non-Governmental Organizations, private sector and teaching hospitals in Kenya. The Guidelines are based on the clinical guidelines for management of diabetes in Sub Saharan Africa developed by the International Diabetes Federation (IDF) Africa region whom we owe thanks for allowing us to use the materials.

The participation of the following individuals and organization is gratefully appreciated, Dr. Eva Njenga (diabetologist and endocrinologist), Dr. Nancy Ngugi, (diabetologist and endocrinologist, KNH), Dr. Jemima Kamano (Physician MTRH), Dr. Nancy Kunyiha (diabetologist and endocrinologist, AKUH) and Mrs. Eva Muchemi (CEO Kenya Diabetes Management and Information Centre (DMI Centre). We however acknowledge everyone who was involved in the development, review and editing this guideline, your contribution to this process will forever be indebted.

The funding for the process was provided by the World Diabetes Foundation (WDF) through the National Diabetes Comprehensive Care Project, Sanofi Aventis, Novo Nordisk and Novartis. The process received a lot of technical support from the Kenya Diabetes Management and Information Centre (DMI), Diabetes Kenya (DK), The diabetes study group, MSF Belgium, the University of Nairobi, Moi Teaching and Referral Hospital and Kenyatta National Hospital. Dr. Joyce N. Nato of the World Health Organization, Kenya Country Office provided technical advice to the drafting team.

The development of the guidelines was carried out under the auspices of the Division of Non-communicable Diseases. I would like to gratefully acknowledged the contribution and leadership of dr. Joseph Kibachio and his staff especially Mr. Zachary Ndegwa, Dr. Martin Mwangi, Dr. Loise Nyanjau, Mrs. Scholastica Mwende, Dr. Oren Ombiro and Dr. Grace Kariuki.

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Dr. Kioko Jackson K , OGW, MBS
Director of Medical Services
Ministry of Health

EXECUTIVE SUMMARY

Diabetes is an increasing problem throughout the world and is a major contributor to the growing burden of chronic disease, especially in developing countries. It is associated with significant morbidity and decreased life expectancy due to its complications, which include heart disease, stroke, amputation, blindness and kidney failure. Diabetes reduces quality of life, especially in people with complications. The complications of undetected and untreated diabetes are serious and cause great human suffering and disability, and have huge socio – economic costs resulting from premature morbidity and mortality It is also associated with increased psychosocial problems including depression and anxiety.

The key risk factors for diabetes—obesity, physical inactivity, and unhealthy diets—require interventions to change unhealthy lifestyles. These changes are most likely to occur with implementation of a coordinated range of interventions to encourage individuals to maintain a healthy weight, participate in daily physical activity, and consume a healthy diet. Diabetes education is central to implementing such changes. It is more effective when provided through multiple methods and sites, such as schools, workplaces, mass media, and health centers. Educational messages are also more effective if they are reinforced by action and behavior change techniques and approaches.

Diabetes care is a lifelong responsibility that requires people living with the disease to change many habits, such as what they eat, when they exercise and how frequently they visit a health care provider. They may need to take daily medications or insulin to keep their blood glucose levels in check. Having diabetes means that one has to adjust his lifestyle at work and at home. But these changes don't mean one won't be able to succeed at work or enjoy a healthy and fulfilling life. People living with diabetes have equal rights with those without the condition and should be protected from all forms of discrimination.

Diabetes, being a complex disorder, necessitates a systematic approach in the organization of care. In order to achieve this, there are several elements that needs to be addressed. These includes: a well-trained and dedicated personnel, management and referral protocols & algorithms, continuous supply of essential medicines and technologies, a registry of all patients in care in order to facilitate recall for non-attendance and for specific aspects of regular care and annual review charts that are useful for follow up of clinical and biochemical measurements.

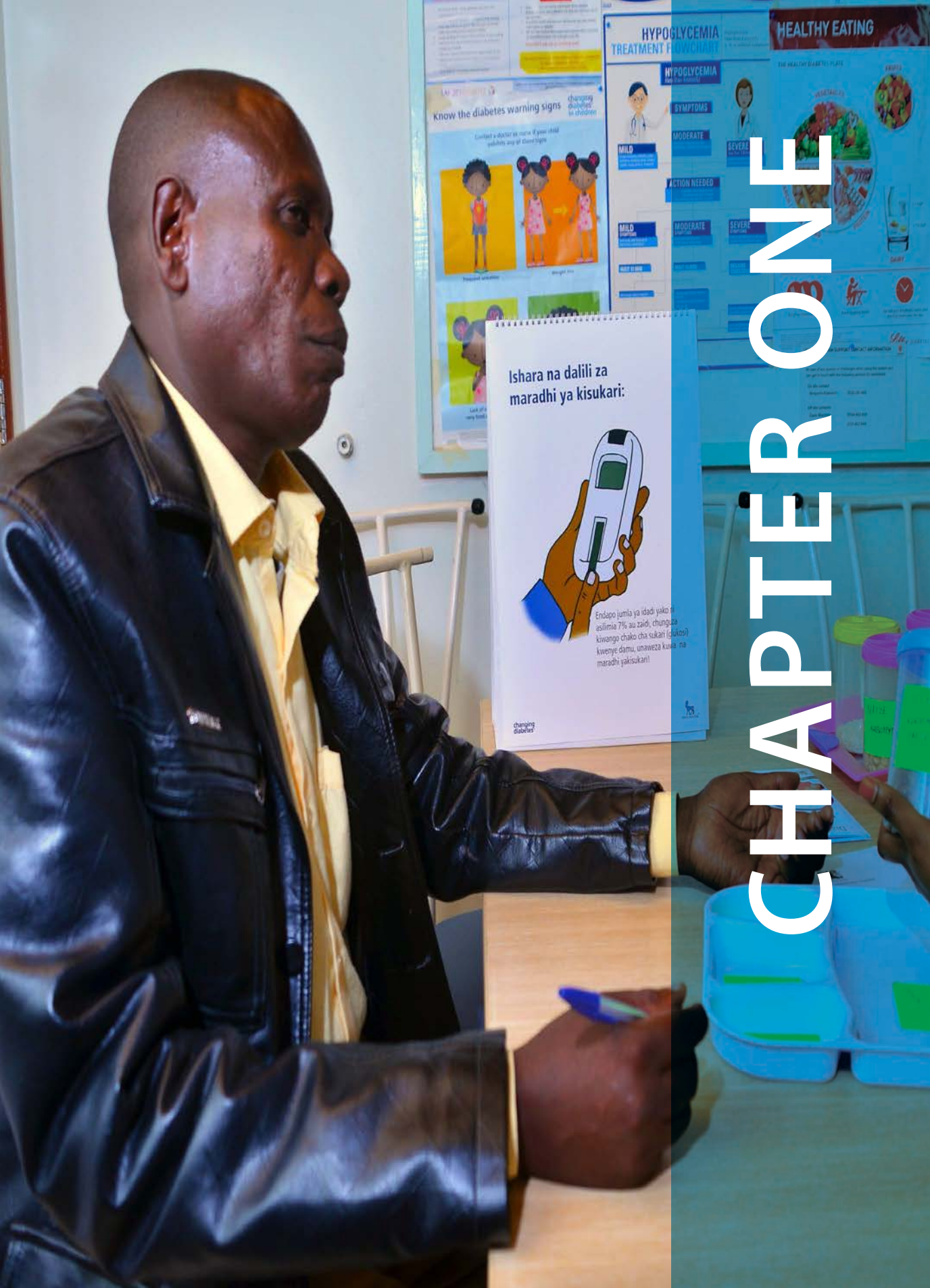
Unfortunately, the practice of diabetes care is still far from being organized and uniform across all levels. This guideline is an essential component of achieving quality diabetes care for all people with the condition. It provides recommendations of standards of care, and use evidence-based interventions to achieve those standards, in order to guide healthcare professionals, people affected by diabetes, policy-makers and administrators.

In order to improve and standardize diabetes management, the implementation of this guideline is very critical. This calls for wide dissemination of the guideline, its introduction and acceptance into all health facilities whether public, private for no-profit or private for profit. Its application will provide all the relevant information that will guide future revisions of the guidelines to suit the national needs for diabetes management.

The purpose of these Guidelines is to:

i. Provide simple and practical ways to assess persons living with diabetes and make the right diagnosis and provide the best treatment and care.
ii. Assist health care providers to identify locally appropriate and sustainable ways of improving diabetes management.
iii. Mainstream diabetes management into the health care system and strengthen self-care management.

The guideline contents is organized in 8 chapters, that comprise of: introduction to Diabetes; management of diabetes; management of complications and comorbidities; metabolic syndrome and obesity; management of diabetes in special situations; living with diabetes; prevention of diabetes and organization of diabetes care.


HYPOGLYCEMIA
TREATMENT FLOWCHART
HEALTHY EATING
Know the diabetes warning signs
changing diabetes in children
SYMPTOMS
MODERATE
ACTION NEEDED
MILD
SEVERE
Ishara na dalili za maradhi ya kisukari:
Endapo jumla ya idadi yako si asilimia 7% au zaidi, chunguza kiwango chako cha sukari (glukosi) kwenye damu, unaweza kuwa na maradhi yakisukari!
changing diabetes

CHAPTER ONE

CHAPTER ONE

INTRODUCTION TO DIABETES

1.1. Definition

Diabetes mellitus is a chronic metabolic disorder characterized by sustained elevated blood glucose (hyperglycemia) resulting from defects in insulin secretion, action or both. Diabetes, if not well controlled leads to serious complications, resulting in multiple diseases or disorders that affect multiple body organs resulting to increased morbidity and premature death.

1.2. Pathophysiology

In people that are healthy (not living with diabetes), the pancreas secretes digestive enzymes and the hormones insulin and glucagon into the bloodstream to control the amount of glucose in the body. The release of insulin into the blood lowers the level of blood glucose by allowing glucose to enter the body cells, where it is metabolized leading to normal blood glucose levels. If blood glucose levels get too low, the pancreas secretes glucagon to stimulate the release of glucose from the liver, thus raising the levels of blood glucose to normal. This process is explained in figure 1.

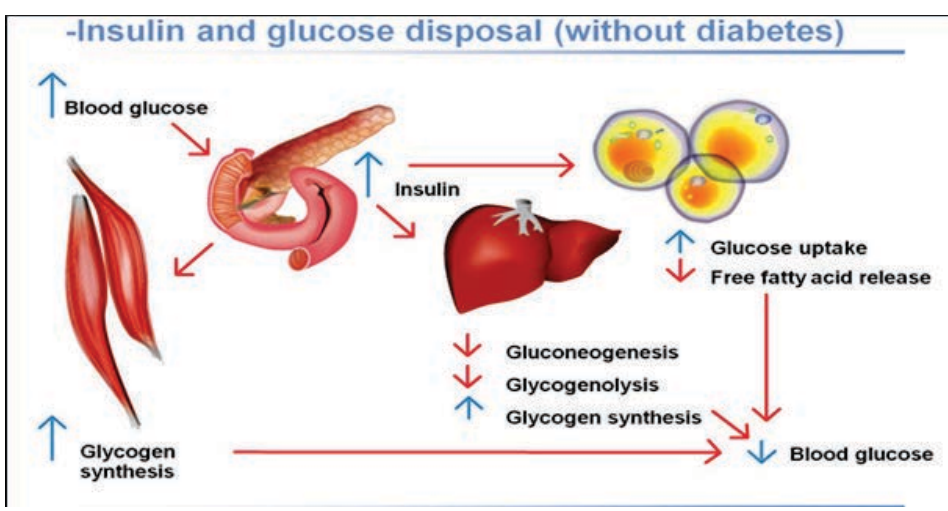


Figure 1: Glucose homeostasis in diabetes mellitus
Source: Adapted from IDF Education Modules, 2011

When this normal body process is affected, as it happens in children and young adults due to pancreatic islet B cell destruction predominantly by an autoimmune process or from insulin resistance or insufficient insulin secretion, diabetes sets in. The process of glucose homeostasis in diabetes mellitus is explained as it happens in adults or obese children and adolescents in figure 2.

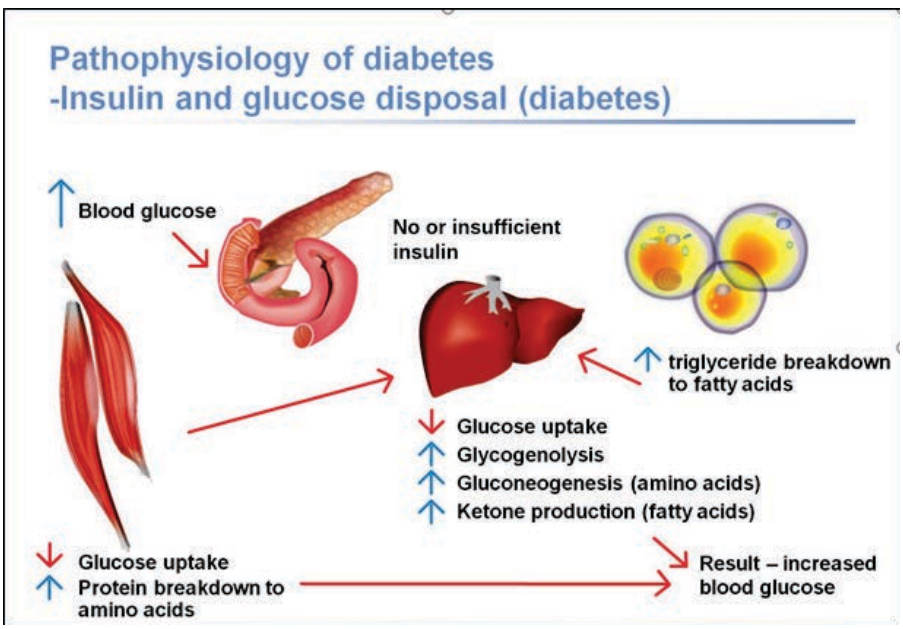


Figure 2: Glucose homeostasis in diabetes mellitus
Source: Adapted from IDF Education Modules, 2011

1.2.1. Pathogenesis and pathophysiology of type 1 diabetes

Type 1 diabetes mellitus is a chronic autoimmune disease associated with selective destruction of insulin-producing pancreatic β-cells leading to deficiency in insulin secretion. Deficiency in insulin leads to: -

i. Increased hepatic glycogenolysis and impaired non-hepatic glucose utilization (in skeletal and adipose tissue) leading to elevated plasma glucose levels
ii. When the capacity of the kidneys to reabsorb glucose is surpassed, glucosuria ensues (glucose loss via urine). Glucosuria leads to: -
    - osmotic diuresis leading to water and electrolyte loss (polyuria)
    - increased thirst (polydipsia)
    - caloric loss leading to increased appetite and food intake (polyphagia))
iii. Uncontrolled lipolysis leads to elevated levels of free fatty acids (FFA) in the plasma. Oxidation of these FFAs leads to generation of ketone bodies
iv. Increased proteolysis with weight loss

1.2.2. Pathogenesis and pathophysiology of type 2 diabetes

The pathogenesis of type 2 diabetes mellitus is characterized by:

- Impaired insulin secretion: an islet cell dysfunction in which the reciprocal relationship between the glucagon-secreting alpha cell and the insulin-secreting beta cell is lost, leading to reduced insulin production in response to increased blood glucose. However, individuals with Type 2 diabetes have detectable levels of circulating insulin, unlike patients with Type 1 diabetes.
- Peripheral insulin resistance: leads to decreased glucose transport into muscle cells, elevated hepatic glucose production, and increased breakdown of fat.

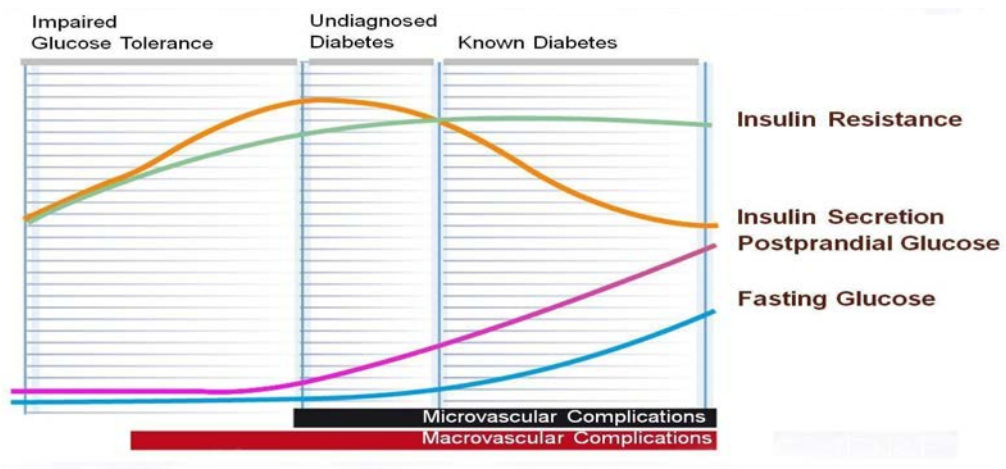


Figure 3: Natural History of type 2 diabetes
Source: IDF education modules 2011 (Adapted from Ramlo-Halsted BA, Edelman SV. Prim Care, 1999; 26:771-789

1.3. Diagnosis of diabetes

Signs and symptoms

Many of the signs and symptoms of diabetes are often missed or treated as common ailments. Patients with type 2 diabetes may present with established chronic complications of diabetes which need to be looked out for in the history and examination.

Table 1: Signs and Symptoms of Diabetes

More Common	Less Common	Severe (Diabetic ketoacidosis)
Weight loss	Excessive hunger	Frequent vomiting and acute abdominal pain
Polyuria – in younger children bedwetting is common	Blurred vision	Acetone smell on breath
Excessive thirst	Mood changes	Dehydration with continuing polyuria
Tiredness/fatigue	Skin infections	Decreased level of consciousness
	Oral or vaginal thrush	Kussmaul respiration (deep, rapid, sighing)
	Abdominal pain	Coma Shock

Source: 2012 SEMDSA Guidelines for the Management of Type 2 Diabetes

Diabetes may be diagnosed based on plasma glucose criteria, either the fasting plasma glucose (FPG) or the 2-hour plasma glucose (2-h PG) value after a 75-g oral glucose tolerance test (OGTT), glycosylated hemoglobin (HbA1c) criteria.

Table 2: Diagnostic criteria for Diabetes and pre-diabetes

Test	Intermediate hyperglycaemia	Diabetes
Fasting glucose	6.1-7.0 mmol/L (100-125 mg/dL)	≥7.0 mmol/L (126 mg/dL)
OR 2-hour glucose following ingestion of 75-g glucose load	7.8-11.0 mmol/L (140-199 mg/dL)	≥11.1 mmol/L (200 mg/dL)
OR random plasma glucose in symptomatic patient		≥11.1 mmol/L (200 mg/dL)
OR HbA1c		≥6.5% (48 mmol/mol)

Fasting is defined as no caloric intake for at least 8 hours.

The HbA1c test should be performed in a laboratory using a method that is NGSP-certified and standardized to the Diabetes Control and Complications Trial assay.

The 2-hour postprandial glucose test should be performed using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

Source: IDF Clinical practice recommendations for managing type 2 diabetes in primary care, 2017

Diagnostic cascade for Type 2 Diabetes

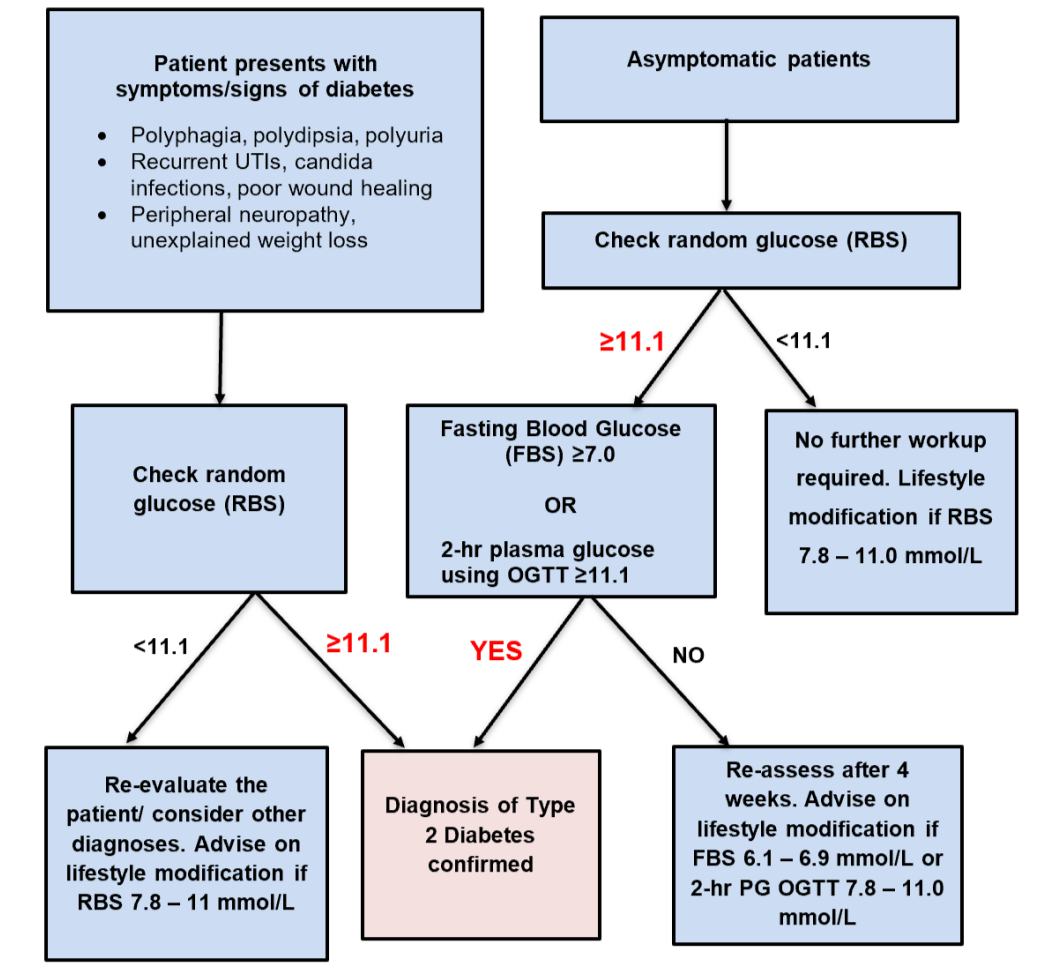


Figure 4: Diagnostic cascade for type 2 diabetes
Source: TB/DM Bidirectional screening and treatment charts, MOH, 2018

1.4. Classification of Diabetes Mellitus

The classification of diabetes has been revised by the WHO and is based on aetiology (table 4).

Table 3: The main types of Diabetes

Type	Characteristics
Type 1 diabetes	Most commonly results from autoimmune destruction of the pancreatic beta cells leading to absolute insulin deficiency. *Insulin is required for survival.* May present from 6 months of age but usually presents in childhood, adolescence and young adults. Occasionally Type 1 Diabetes may present at a later age and this is referred to as Latent Autoimmune Diabetes in Adults (LADA).
Type 2 diabetes:	Characterized by progressive loss of b-cell insulin secretion frequently on the background of insulin resistance. It is the most common type of diabetes. More common among adults but is increasingly being diagnosed in a younger population due to overweight/obesity. Many patients with Type 2 diabetes are asymptomatic.
Gestational diabetes mellitus	Diabetes diagnosed in the second or third trimester in a woman who was previously not known to have diabetes. It is often asymptomatic, and has to be screened for. Associated with poor pregnancy outcomes, especially if unrecognized and untreated. It usually resolves after delivery.
Other types of Diabetes	These are less common and include genetic disorders, infections, and diseases of the exocrine pancreas (pancreatitis, Ca pancreas), endocrinopathies (thyrotoxicosis, Cushing's syndrome, acromegaly,) o as a result of drugs (corticosteroids. anti-psychotics, HAART)

Table 4: Differences in type 1 and type 2 diabetes at diagnosis (clinical presentation, patient characteristics and pathogenesis)

Characteristic	Type 1	Type 2
Onset	Sudden, acute or sub-acute	Slow, insidious onset, progressive disease. Patient could be undiagnosed for years.
Age	Usually < 30-35 years	Older patients > 35 years*
Typical symptoms	Moderate to severe symptoms of diabetes present	Person often asymptomatic because of slow onset of the disease; asymptomatic glucosuria present
Weight	Lean, often rapid weight loss before diagnosis	Normal to overweight at diagnosis
Insulin secretion	Insulin deficient, needs insulin treatment at diagnosis	Initially inadequate insulin secretion, with progressive deficiency over time
Chronic complications at diagnosis	Not common	Common because of late diagnosis.
Insulin resistance	Absent	Present
Ketosis	Yes, often diagnosed in Ketoacidosis	Not as common as in type 1
C peptide levels	Very low or absent	Normal or reduced
Immune markers	Autoimmune disease: anti-GAD, ICA, 1A-2	Absence of auto-immune markers
Heredity	Less common	More common
Metabolic syndrome	Absent	Present; a cluster of cardiovascular disease risk factors often present, e.g. hypertension, dyslipidaemia, abdominal obesity, insulin resistance, microalbuminuria, and hypercoagulability.
Treatment	Insulin therapy	Initially: lifestyle changes +/- oral glucose lowering agents, +/- Insulin
Acute complications	DKA Hypoglycemia- associated with treatment	HHS May get DKA Hypoglycemia: Associated with treatment
Chronic complications of Diabetes	More prone to micro-vascular complications	High risk for macro-vascular diabetes: complications; also develops micro-vascular complications as disease progresses.

** Consider Type 2 DM in obese younger patients with elevated sugars that do not present like Type 1 DM*

Source: Kenya National Diabetes Educators Manual, 2010

1.5. Risk Factors

In view of the significant rise in the prevalence of diabetes in Kenya, its well-recognized morbidity, premature mortality, increasing health costs and awareness of its risk factors is an important step towards its control and prevention. The risk factors for type 2 diabetes are categorized into modifiable and non-modifiable as shown in the table 1 below. Type 2 diabetes is also found in obese children. Risk factors for type 1 Diabetes are not clearly known.

Table 5: Modifiable and Non-Modifiable Risk factors for type 2 Diabetes

Modifiable	Non-Modifiable
Overweight and Obesity	Age (>40 yrs.)
Physical inactivity	First degree relative with diabetes/genetic predisposition
Unhealthy diets- high in refined sugars, fats and low in fruits and vegetables	Polycystic Ovarian Syndrome (PCOS)
Impaired glucose tolerance /Impaired fasting glycaemia	Previous gestational diabetes or large babies (>4 kg)
Dyslipidaemia	African and Asian
Alcohol abuse and tobacco use	
Hypertension	

1.1. Screening for Diabetes Mellitus type 2

Considering the insidious nature of diabetes symptoms, misdiagnosis and the poor health seeking behaviour of the population, screening and early diagnosis are crucial to reducing morbidity and mortality related to Diabetes.

Who to screen:

Screening should be considered:

1. For all individuals with any risk factors
2. Across all populations using the relevant cut-offs

Table 6: Screening criteria for Diabetes

Sno.	Population group/Risk	Parameters
1.	Overweight or obese (adults and children)	BMI ≥**25**
2.	First-degree relative with diabetes	
3.	Women previously diagnosed with GDM or delivered a baby weighing > 4 kg	
4.	History of Cardiovascular disease	
5.	Hypertension	Blood pressure ≥140/90 mmHg or on therapy for hypertension
6.	Blood lipids ● HDL ● Triglyceride ● LDL	 <35 mg/dL (0.90 mmol/L) >250 mg/dL (>2.82 mmol/L) < 100 mg/dL (<2.59 mmol/L)
7.	Women with polycystic ovary syndrome	
8.	Physical inactivity	<150 minutes of moderate activity per week
9.	Other clinical conditions associated with insulin resistance (e.g. severe obesity, acanthosis nigricans)	
10.	Unhealthy diets	Foods low in fibre content, foods high in refined sugar, low consumption of fruits and vegetables

If screening results are normal, testing should be repeated annually, with consideration of risk status.

Source: American Diabetes Association. Classification and diagnosis of diabetes, 2017

CHAPTER TWO

CHAPTER TWO

MANAGEMENT OF DIABETES

2.0 Introduction

The overall goal of diabetes management is to improve the quality of life and productivity of people living with diabetes, control comorbidities, and prevent complications by:

- Early diagnosis
- Treatment to target
- Regular screening for complications and comorbid conditions
- Education on diabetes and complications, self-care and diet
- Community awareness on diabetes
- Establishing diabetes comprehensive centres served by a functional referral system
- Having a motivated, passionate and well-educated diabetes management team
- Provision of essential commodities and technologies

2.1. Management of Type 1 Diabetes

All children and adolescents with type 1 diabetes require insulin. Poorly controlled type 1 diabetes increases the risk of stunted growth and diabetes complications, including diabetic ketoacidosis.

Comprehensive Type 1 diabetes management includes:

a) Insulin treatment
b) Blood glucose monitoring
c) HbA1c monitoring
d) Nutritional management and physical activity
e) Diabetes education
f) Rules for sick days
g) Psychosocial support

A thorough clinical assessment of a patient with type 1 diabetes is recommended before initiating any therapy and during ongoing therapy.

Table 7: Patient assessment at initial and follow-up visits

	Initial visit	Three- to six-monthly visits	Annual visit
History			
Symptoms of hyperglycaemia, and duration of symptoms*	X	X	X
Hypoglycaemic symptoms**		X	X
Relevant family history	X		
Other risk factors (e.g. low or high birthweight)	X		
Relevant medical history			
- Co-morbid conditions (autoimmune diseases e.g. Thyroid)	X		X
- Symptoms of complications: visual, infection, foot, edema and palpitations	X	X	X
Drugs			
- Current (Side-effects and adherence)	X	X	X
- Allergies	X		X
Hypoglycaemic symptoms**	X	X	X
Vaccinations			
- KEPI (date)	X	X	X
- Influenza (date)	X		X
- Pneumococcal***	X		
Lifestyle			
- Weight /height	X		X
- Physical activity	X		X
- Eating pattern and food availability	X	X	X
- Teenagers: Alcohol and drug use, tobacco use	X	X	X
- Sexual activity	X	X	X
Psychosocial support			
- Family, school and the community support	X		X
- Depression, anxiety and other mental disorders	X	X	X
Education			
- Level of education and school performance	X	X	X
- Absenteeism per term	X	X	X
- Family and community support (Parent education level, occupation)	X		X
Home monitoring of blood glucose (glucometer and strips; chart)	X	X	X
Physical examination			
Weight	X	X	X

Height	X	X	X
Body mass index (BMI) for age and sex	X	X	X
Mid upper arm circumference (MUAC)	X	X	X
Tanner pubertal staging	X	X	X
Blood pressure (mmHg)	X	X	X
Injection sites assessment	X	X	X
Oral cavity			
- Dental caries	X		X
- Gum disease	X		X
Eyes			
- Visual acuity	X		X
- Direct fundoscopy (dilated pupils), indirect fundoscopy, or fundus photographs	X		Xa
Special investigations			
Blood tests			
- Glucose	X	X	X
- HbA1c - (Six-monthly if at target, otherwise three-monthly. Also, whenever treatment is adjusted)	X	X	X
- TSH	X		X
- Lipids: Total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides			X
- Creatinine, and calculate estimated GFR			X
- Potassium			X
- HIV	X		X
Urine			
- Glucose	X		X
- Ketones	X		X
- Protein (current g/lines albumin/creatinine ratio)			X
Other important tasks			
Education: Self-management and lifestyle adjustment, including smoking cessation	X	X	X
Setting goals	X	X	X
Family planning for teenagers and preconception counselling	X		X
Medication revision/adjustment	X	X	X

[a] *Interval for retinopathy screening can be increased to once every 2 years if the last 2 examinations were normal; more frequent examinations are required in the presence of abnormalities.*

***Symptom of hyperglycaemia include polydipsia, headaches, blurred vision, polyuria, fatigue/body malaise, weight loss*

*** Symptoms/signs of Hypoglycemia- Shakiness, nervousness or anxiety, sweating, chills and clammy extremities, irritability, confusion, including delirium, tachycardia, lightheadedness or dizziness, hunger and nausea, blurred/impaired vision, tingling or numbness in the lips or tongue, headaches, weakness or fatigue, mood changes, lack of coordination, nightmares or crying out during sleep, seizures, loss of consciousness*

****Pneumococcal vaccine should be administered once. Revaccination is recommended for individuals >64 yr. if vaccinated >5 yrs. ago, or patients with renal disease, asplenia and immunocompromised states*

2.1.1. Insulin treatment

Types of Insulin

There are two broad categories of insulin: -

1. Human Insulin- comes in three forms:
   - Short-acting (regular/soluble) insulin
   - Intermediate-acting insulin– e.g. Neutral protamine Hagedorn (NPH) insulin, Humulin N, Insulatard,
   - Pre-mix short-acting (regular) and intermediate-acting (NPH) insulins – usually in the combination 70/30 (Mixtard, Humulin), Humulin 50/50

2. Analogue insulin

   Examples are:
   - Rapid-acting - e.g. Humalog, Novo rapid, Apidra
   - Long-acting – e.g. Levemir, Lantus
   - Pre-mix – e.g. Humalog 75/25, NoVo mix 70/30

The two most common regimens used are:

i. Basal bolus regimen (the preferred option) - with short or rapid acting insulin given with main meals (usually three times per day) and intermediate-acting or long-acting insulin given once or twice daily (evening, or morning and evening).

ii. Twice-daily insulin using pre-mixed insulin or short acting and NPH

Table 8: Types of Insulin, mode of action and administration of Insulin

Insulin type	Common Brand Names	Onset of Action	Peak of action	Duration of action	When to give
Rapid acting	Insulin lispro (Humalog), Insulin glulisine (Apidra) and Insulin aspart (NoVo Rapid)	15-30 minutes	1-2 hours	3-5 hours	immediately prior to meal
Short acting (soluble)	Actrapid, Humulin R	30-60 minutes	2-4 hours	5-8 hours	30 minutes prior to meal
Intermediate acting	NPH, Humulin N, Insulatard	2-4 hours	4-10 hours	12-24 hours	30 minutes prior to meal
Long-acting	Insulin detemir (Levemir)	1-2 hours	6-12 hours	20-24 hours	once or twice daily
	Insulin glargine (Lantus)	2-4 hours	relatively peak-less	24 hours or less	once daily
Mixed	Humulin 70/30 or Mixtard 70/30 Humalog 75/25	30 minutes	4-12 hours	8-24 hours	30 minutes prior to meal

Insulin requirements

- Pre-pubertal children (outside the partial remission phase) usually require 0.5-1.0 IU/kg/day.
- During puberty, requirements may rise substantially above 1 and even up to 2 U/kg/day.
- The "correct" dose of insulin is that which achieves the best attainable glycaemic control for an individual child or adolescent, without causing obvious Hypoglycemia, and resulting in normal growth and development.

Initiating therapy in a child who is not in DKA

During insulin initiation, calculate a total daily dose of 0.5-0.75 U/kg/day. This can be given using either of the following regimens:

a. Basal bolus regimen
b. Twice-daily injections
C. Basal Bolus Regimen - also called Multiple Daily Injections (MDI). This is the preferred option.

This regimen can be given using two combinations

- Short-acting and long-acting insulin analogues
- Short-acting and intermediate-acting insulin analogues

i. Short-acting and long-acting insulin analogues
If short-acting (soluble)/rapid acting and long-acting analogue insulins are used, give:

- 60% of the total daily dose as short-acting (soluble) insulin (divided up between 3-4 pre-meal boluses)
- 40% of the total daily dose as a single evening injection of long-acting analogue insulin. (Sometimes this dose does not last for 24 hours and then can be split into two doses - morning and evening).

Example:

For a **42-kg child** who is started on **0.5 U/kg/day,** the total daily dose is **21 units.**

Table 9: Example of administration of short- and long-acting insulin as multiple daily injections

	Short-acting	Long-acting
Before breakfast	4 Units	
Before lunch	4 Units	
Before dinner	4 Units	9 Units

(rounded off to the nearest whole number).
Pre-meal doses can be adjusted depending on the size and frequency of the patient meals

ii. Short-acting and intermediate-acting insulin analogues

If short-acting (soluble) and intermediate-acting insulin is used, give:

- 70% of the total daily dose as short-acting (soluble) insulin (divided up between 3-4 pre-meal boluses)
- 30% of the total daily dose as a single evening injection of intermediate-acting insulin

Example:

For a **42-kg child** who is started on **0.5 U/kg/day**, the total daily dose is **21 Units.**

Table 10: Example of administration of Short and Intermediate-acting Insulin as multiple daily injections. as multiple daily injections.

	Short-acting (soluble insulin)	Intermediate-acting (NPH)
Before breakfast	5 Units	
Before lunch	5 Units	
Before dinner	5 Units	6 Units

(rounded off to the nearest whole number)
Pre-meal doses can be adjusted depending on the size and frequency of the patient meals

NB: In circumstances where meals are skipped or food is not available, Give the intermediate- acting insulin and skip the short acting insulin until the food is available. Do NOT completely stop insulin administration. Subsequently, doses can be adjusted daily according to blood glucose levels.

b. Twice daily injections

A starting point is to give two-thirds of the total daily insulin in the morning before breakfast and one-third before the evening meal. This may be given as pre-mixed insulin or short acting and intermediate acting insulin separately.

Example:
For a 42-kg child who is started on 0.5 U/kg/day, the total daily dose is 21 Units. Two-thirds of this dose (14 units) is given in the morning (before breakfast), and one-third of the dose (7 units) before the evening meal. At each injection, 1/3 is short acting and 2/3 is intermediate-acting.

Table 11: Example of administration of Short acting, Intermediate-acting and pre-mixed Insulin

	Short-acting	Intermediate-acting	Pre-mixed insulin
Before breakfast	5 Units	9 Units	14 Units
Before evening meal	2 Units	5 Units	7 Units

(rounded off to the nearest whole number)

It is important to note that:

i. Insulin requirements can decrease for a time during the "honeymoon period" before rising again.
ii. The total daily dose required will generally increase as the child grows, and once puberty ensues a higher dose per kg per day is often needed.

During periods of regular change in consumption of food (e.g. Ramadan) the total amount of insulin should not be reduced but redistributed according to the amount and timing of carbohydrate intake. However, if the total calorie intake is reduced during Ramadan, the daily amount of bolus insulin for meals usually needs to be reduced, for example to two-thirds or three-quarters of the usual dose.

Insulin injection techniques

Proper injection technique is vital to ensure insulin is administered in the subcutaneous tissue. It is important to avoid intramuscular insulin injections.
When starting the patient on insulin, the healthcare provider needs to ensure that the patient understands each of these essential topics

a. The Injection regimen
Once daily, twice daily or basal bolus

b. Choice of devices used
- o insulin vial and syringes or
- o pen device

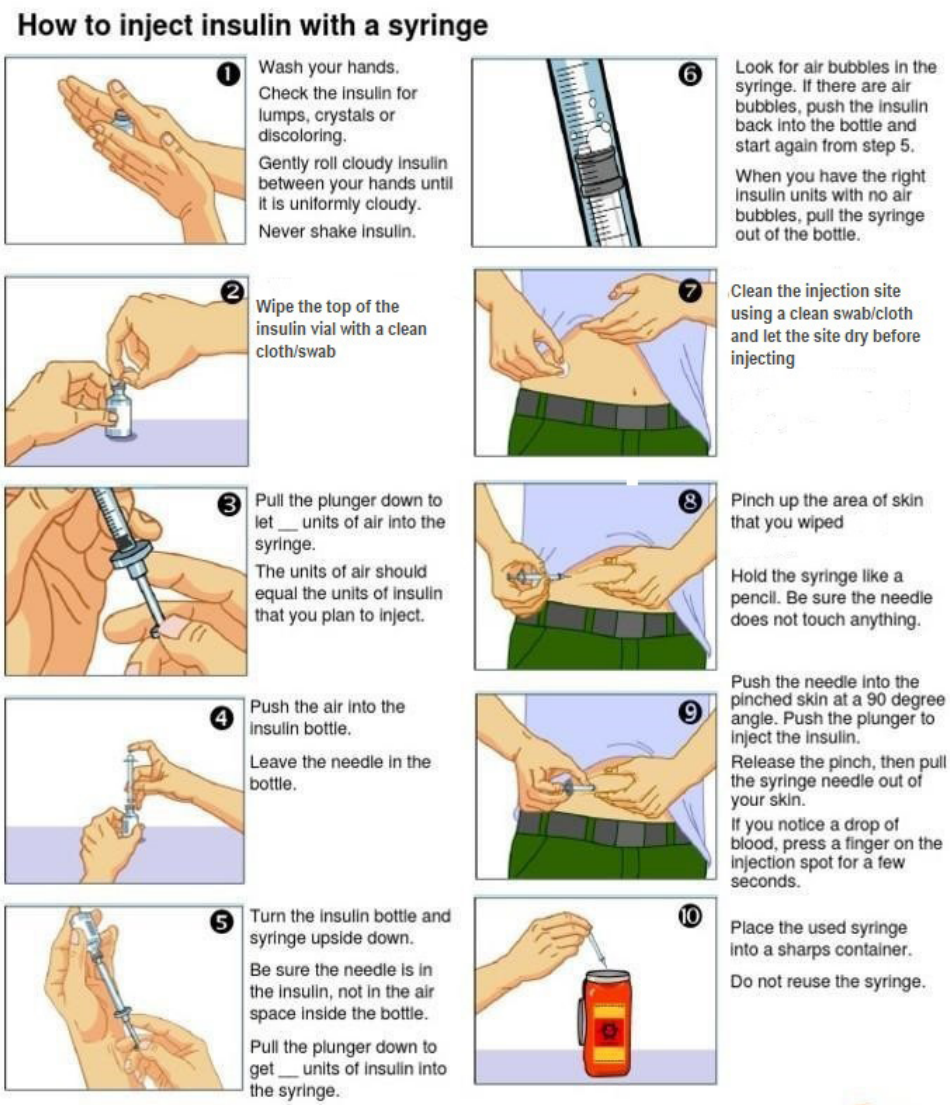
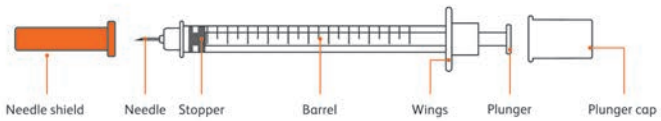


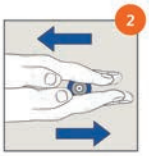
Figure 5: Injection technique using an insulin syringe *(Source: Optimizing Injection Technique in Diabetes Management Recommendations for Best Practice in Injection Technique, FIT guidelines South Africa, 1st edition)*

Parts of an insulin syringe



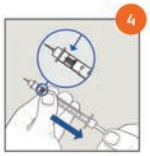
How to inject

1 Wipe the top of the insulin bottle. Arrange your supplies. Wash your hands. **To expose the plunger, twist the white plunger cap then pull it off.**



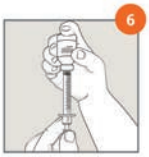
2 **If you are taking cloudy insulin, roll the bottle between your hands** until it is uniformly cloudy. To avoid the formation of air bubbles, **do not shake** the bottle of insulin.

3 To expose the needle, **twist the orange needle shield then pull it straight off,** being careful not to bend the needle or let the needle touch anything.

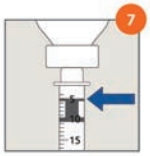


4 **Pull the insulin syringe plunger down; align the thin black line of the plunger** *(closest to the needle)* with the desired number of units on the insulin syringe. You need air in the insulin syringe equal to the amount of insulin you will take.

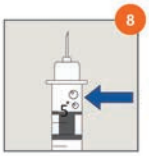
5 Hold the insulin syringe like a pencil. Push the needle straight through the center of the rubber top of the insulin bottle and **push the plunger down completely.**



6 Leave the needle in the insulin bottle. Carefully **turn the bottle and the insulin syringe upside down** so the bottle is on top.



7 Pull the plunger down slowly. Align the thin black line of the plunger *(closest to the needle)* **with the desired number of units** on the insulin syringe.



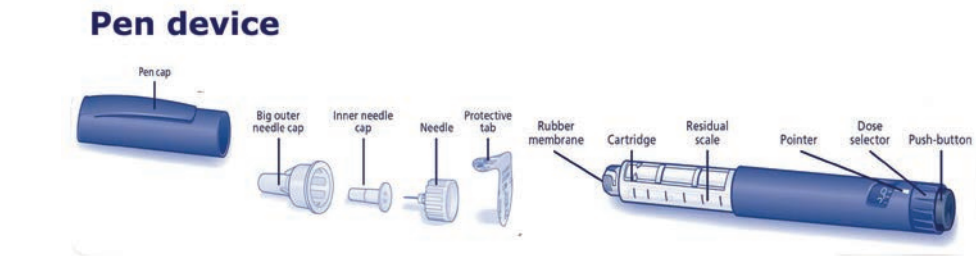
8 **If air bubbles appear in the insulin syringe, inject the insulin back into the vial.** Then redraw the insulin following steps 6 and 7.

9 Confirm the dose is correct, and then **clean a small area of skin.** Let it dry completely before injecting.

10 Hold the insulin syringe like a pencil. **Pinch up your skin** and **push the needle quickly through the skin at 90°** *(straight in)* to the skin surface. **Push the insulin in**

11 **Do not recap used needles. Use the needle once** and dispose of it properly.

Figure 6: Injection Technique using the insulin pen *(Source: Optimizing Injection Technique in Diabetes Management Recommendations for Best Practice in Injection Technique, FIT guidelines South Africa, 1st edition)*



How to use the Pen device

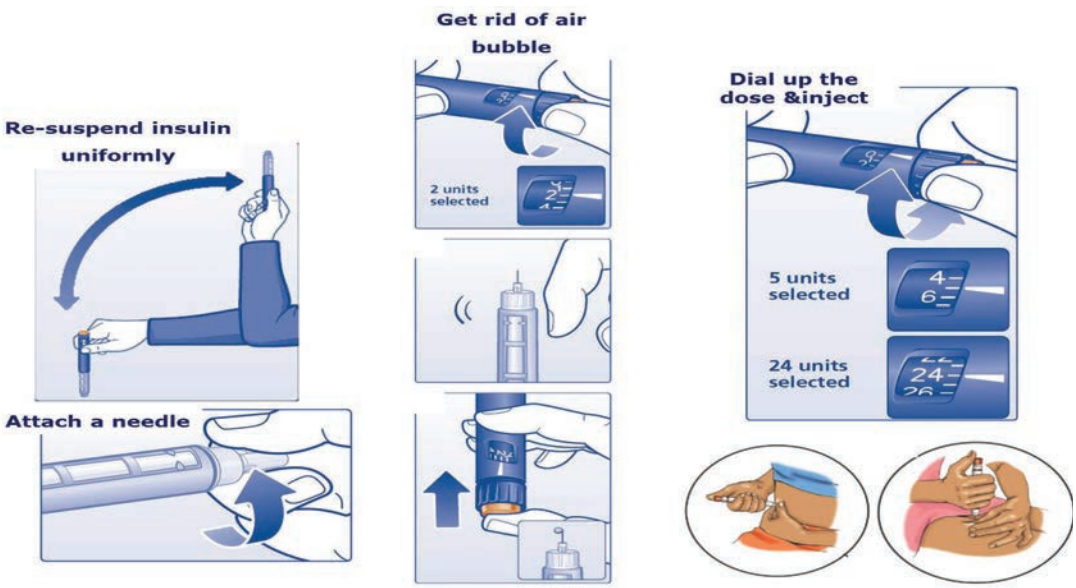


Figure7: Structure of an Insulin Pen Device and how to use it.

c. Proper injection techniques

Demonstrate the injection technique to the patient and the caregiver/family and have the patient repeat back before they leave.

- Injection sites: These are the abdomen, thighs, buttocks and upper arm. Injection sites should be clean disinfection of injection site is usually not required outside the hospital settings. Patients should never inject into sites of lipohypertrophy, inflammation or other lesions. (Refer to figure 14)
- Sites rotation is important to avoid lipohypertrophy. Patients should be given an easy to follow rotation scheme from the beginning of therapy which should be reviewed annually.
- Injection at a 90^0 angle unless the patient is very thin
- Use of lifted skin folds: A correct skin fold is made by lifting the skin with the thumb and index finger. Refer to figure 6 and 7)

Insulin injection sites for adults

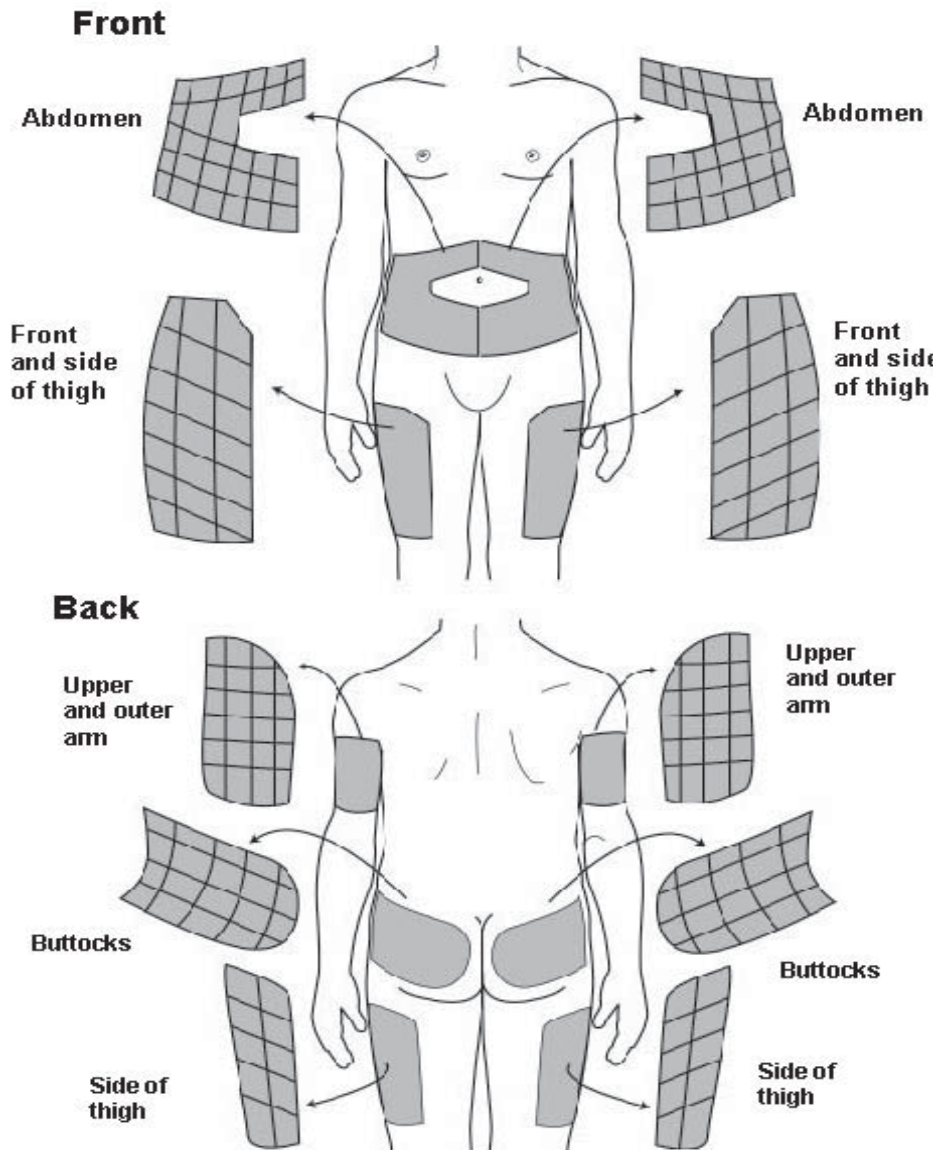


Figure 8: Adult Insulin Injection Sites

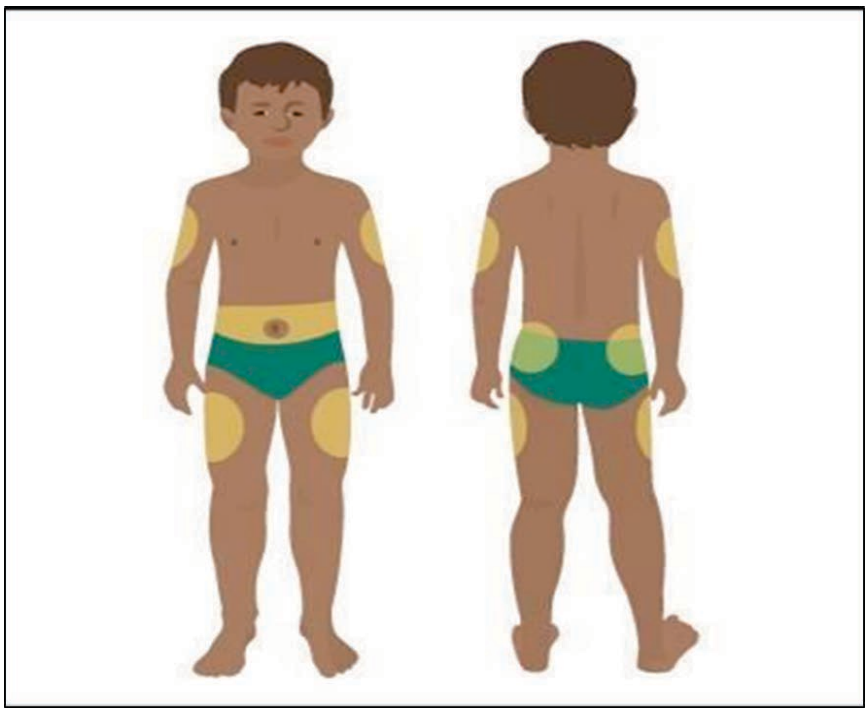


Figure9: Recommended sites for injection in children
(Source: Optimizing Injection Technique in Diabetes Management Recommendations for Best Practice in Injection Technique, FIT guidelines South Africa, 1st edition)

d. **Injection complications** and how to avoid them (lipohypertrophy)

e. **Optimal needle length - use of shorter needles which are less traumatic to the patient and help in insulin adherence.**
Shorter needles also reduce the incidence of intramuscular injections which can lead to more rapid insulin absorption and hypoglycemia
- Children: 6 mm for the insulin syringes and 4 – 6 mm in pen device
- Adults: 4 mm to 8 mm

f. **Safe disposal of used sharps**
Correct disposal procedure of used insulin syringes/needles should be taught to the patient (storing in sealed containers and brought to the hospital for proper disposal). Sharps should NEVER be placed directly in household or public trash.

Insulin storage

i. Insulin vials should be stored at 4-8 °C in a refrigerator where available or in some other method of cooler. In hot climates where refrigeration is not available, cooling jars, earthenware pot, and charcoal pot will help to preserve insulin activity.
ii. If using PEN device, insulin can be kept at room temperature for 28 days
iii. Insulin must NEVER be frozen.
iv. Direct sunlight or extreme heat (in hot climates or in a vehicle) damages insulin.
v. Patients should not use insulins that have changed in appearance (clumping, frosting, precipitation, or discolouration).
vi. Once opened, an insulin vial should be discarded after 4 weeks.

2.1.2. Blood Glucose Monitoring

Blood glucose monitoring is essential in the safe management of childhood and adolescent diabetes to help prevent acute and chronic complications, and educate and empower the child and family. Every patient must have a glucometer and blood glucose test strips

Patterns of blood glucose levels are generally more useful than single blood glucose readings. In case of scarce blood glucose testing strips, structured(point) testing for 2-3 consecutive day's pre-and post-meal will be better than staggered testing (Table 20).
If strips are readily available, a blood glucose test should regularly be done before each meal and at bedtime, prior to and following exercise.

Exercise, physical activity or play may result in low BGLs during or immediately after exercise, or a delayed hypoglycaemic effect many hours later (up to 16 hours).
All blood glucose reading should be recorded in a diary or book indicating the date and time.

Table 12: Recommended Target Blood Glucose Levels and HbA1c

Measurement	Recommended level
Pre-meal glucose	4.0 -7.0 mmol/L
Post-meal glucose	5.0 -10.0 mmol/L
Bedtime glucose	6.0 – 10.0 mmol/L
3 a.m. glucose	5.0-8.0 mmol/L
HbA1c	<7.5%

Glycaemic targets can relaxed accordingly to protect against hypoglycaemia if regular SMBG is not available

Table 13: Interpretation of Blood Glucose Level (BGL)

Blood Glucose Level (BGL)	Interpretation
Pre-meal BGL is always high	Preceding dose of intermediate or long-acting insulin is insufficient
Pre-meal BGL is always low	Previous dose of intermediate or long-acting insulin is too high
Pre-meal BGL is sometimes very high and at other times very low	Either insulin, food or exercise are not consistent and should be reviewed
BGL 2 hours after the meal is too high	The meal dose of short-acting (regular) insulin was too low
BGL 2 hours' post-meal is too low	The previous meal dose of short-acting (regular) insulin was too high

NOTE: It is important to note that the level of blood glucose can rise in the early morning (dawn phenomenon). Therefore, care should be taken if increasing the evening intermediate/long-acting dose as hypoglycemia can occur in the middle of the night and this can be dangerous.

Correction Factor: How to Lower Pre-Meal Hyperglycemia

A constant correction factor (CF) is used to calculate insulin sensitivity factor (ISF) for everyone depending on the type of insulin used.

The insulin sensitivity factor is a number that gives the level of glucose change expected per unit of insulin increase or decrease.

The CF/TDD=ISF
1 unit of insulin causes a change of glucose level equivalent to the calculated ISF.

2.1.3. Educating a child living with diabetes and his/her family

A child living with diabetes and the family should be educated on the following aspects of diabetes management:

- Insulin secretion, action, and physiology
- Insulin injections, types, absorption, action profiles, variability and adjustments
- Nutrition – food plans; qualitative and quantitative advice on intake of carbohydrate, fat, proteins, and fibre; coping with special events and eating out; growth and weight gain; 'diabetic foods'; sweeteners and drinks, prevention of disordered eating
- Monitoring (glucose, ketone), including glycated hemoglobin and agreed glucose targets
- Hypoglycemia and its prevention, recognition and management including use of glucagon
- Hyperglycemia prevention, recognition and management
- Sick day management: ketosis, and prevention of ketoacidosis
- Problem-solving and adjustments to treatment in everyday life, motivation and coping with unexpected glucose fluctuations
- Goal setting
- Micro- and macrovascular complications and their prevention, and the need for regular assessment
- Exercise, holiday planning, and travel, including educational holidays and camps
- Smoking, alcohol, and drugs
- Diabetes in schools
- Sexuality, contraception, pregnancy, and childbirth

2.1.4. Nutritional management in Children living with diabetes and his/her family

- Children living with diabetes need a healthy diet with food in amounts and proportions appropriate to the age and stage of growth (use the healthy plate model)
- Nutritional counselling should be adapted to cultural, ethnic and family traditions as well as the cognitive and psychosocial needs of the individual child
- Match the dose, type and regimen of insulin to the amount and timing of food
- Include a healthy snack between the main meals, before, during and after exercise
- Nutritional advice should address food availability/food insecurity, diet, food in take and physical activity patterns
- Excessive restriction of carbohydrate intake to lower blood glucose levels should be avoided
- Sugary soft drinks or foods with high levels of saturated fat should be avoided.
- Prevention and management of hypoglycemia, particularly before, during and after exercise should be addressed
- Education should include preventing hypoglycemia

- Ideally there should be an experienced dietitian in the diabetes team who ought to have individualized sessions with the child and the family/ caregiver
- Unexpected weight loss may be a sign of (1) illness e.g. infections, coeliac disease etc., (2) insulin omission, or (3) an eating disorder
- Growth monitoring should be done until the age of 18 years

2.2. Management of Type 2 Diabetes

The successful establishment of the diabetes health-care team and its supportive infrastructure is critical for the achievement of management goals. This includes provision of education for health-care professionals and for people living with diabetes.

A thorough clinical assessment of a patient with type 2 diabetes is recommended before initiating any therapy and during ongoing therapy.

Table 14: Clinical Assessment for initial and follow-up visits for Type 2 Diabetes

	Initial visit	Three- to six-monthly visits	Annual visit
History			
Symptoms of hyperglycaemia* and duration of symptoms	X	X	X
Hypoglycaemic** symptoms	X	X	X
Relevant family history	X		
Other risk factors (e.g. gestational diabetes, PCOS, hypertension)	X	X	X
Relevant medical history (including TB infection and exposure)			
- Co-morbid conditions	X		X
- Symptoms of complications: Cardiovascular, neurological, bladder function, sexual function (i.e. erectile dysfunction or low libido), feet, visual, infection	X	X	X
Drugs			
- Side effects		X	X
- Adherence		X	X
- Allergies	X	X	X
Vaccinations			
- Pneumococcal (date)	X		X
- Influenza (date)	X		X
Lifestyle			
- Weight	X	X	X
- Physical activity/sedentary lifestyle	X	X	X

- Eating pattern	X	X	X
- Smoking	X	X	X
- Drug abuse	X	X	X
- Alcohol	X	X	X
Psychosocial support			
- Occupation	X		X
- Family and community support (support groups)	X		X
- Depression, anxiety and other mental disorders	X	X	X
Home monitoring of blood glucose (glucometer and strips; chart)	X	X	X
Physical examination			
Weight	X	X	X
Height	X	X	X
Body mass index (BMI) (kg/m^2)	X	X	X
Waist circumference (cm)	X	X	X
Heart rate and rhythm	X	X	X
Blood pressure in mmHg (both systolic and diastolic BP)	X	X	X
Injection sites, if appropriate	X	X	X
Feet			
- Inspection: Ulcers, soft tissue, deformities, Footwear	X	X	X
- Monofilament assessment	X		X
- Vibration sense using tuning fork, or pinprick sensation	X		X
- Ankle jerk	X		X
- Foot pulses	X		X
Oral cavity			
- Dental caries	X		X
- Gum disease	X		X
Eyes			
- Visual acuity	X		X
- Direct fundoscopy (dilated pupils), indirect fundoscopy, or fundus photographs	X		X[a]
Systemic examination			
Cardiovascular system examination	X		X
Special investigations			
Blood tests			
- Glucose	X	X	X
- HbA1c (Six-monthly if at target, otherwise three- monthly. Also, whenever treatment is adjusted)	X	X	X

- Lipids: Total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides	X		X
- Creatinine, and calculate estimated GFR	X		X
- Potassium	X		X
- TSH	X		X
- HIV	X		X
Urine			
- Glucose	X		X
- Protein			
- Ketones	X		X
- Leucocytes	X		X
Urine microalbuminuria	X		X
Uric acid	X		X
Full Hemogram	X		X
Liver Function Tests (ALT, AST, ALP)	X		X
Urine microalbuminuria	X		X
Uric acid	X		X
Full Hemogram	X		X
Liver Function Tests (ALT, AST, ALP)	X		X
ECG	X		X
Cancer screening (Pap smear, breast, PSA)	X		X
Cancer screening (Pap smear, breast, PSA)	X		X
Other important tasks			
Education: Self-management and lifestyle adjustment, including tobacco cessation, alcohol cessation, Hypoglycemia avoidance and treatment, nutrition and physical activity	X	X	X
Setting goals	X	X	X
Preconception counselling and family planning		X	X
Medication revision/adjustment	X	X	X
Immunizations	X		X

[a]*Interval for retinopathy screening can be increased to once every 2 years if the last 2 examinations were normal; more frequent examinations are required in the presence of abnormalities.*

***Symptom of hyperglycaemia include polydipsia, headaches, blurred vision, polyuria, fatigue/body malaise, weight loss*

*** Symptoms/signs of Hypoglycemia- Nervousness or anxiety, sweating, chills and clammy extremities, irritability, confusion, including delirium, tachycardia, lightheadedness or dizziness, hunger and nausea, blurred/impaired vision, tingling or numbness in the lips or tongue, headaches, weakness or fatigue, mood changes, lack of coordination, nightmares or crying out during sleep, seizures, loss of consciousness.*

PCOS - polycystic ovarian syndrome

Management of Type 2 diabetes entails the following components:

i. Treatment of hyperglycemia
ii. Treatment of hypertension and dyslipidemia
iii. Prevention and treatment of micro-vascular complications
iv. Prevention and treatment of macro-vascular complications
v. Prevention and treatment of non-vascular complications

2.2.1. Treatment of hyperglycemia

Treatment of hyperglycaemia in type 2 diabetes consist of the following;

a. Non -pharmacological

i. Education
ii. Diet
iii. Physical activity
iv. Blood glucose monitoring

b. Pharmacological

i. Oral glucose lowering agents (oral hypoglycaemic agents)
ii. Insulin
iii. Combination Therapies – e.g. Oral glucose lowering agents and insulin
iv. Non-insulin injectable glucose lowering agents (GLP-1 agonists)

Non-pharmacological management

This is the cornerstone in achieving diabetes control. It includes diabetes education, medical nutrition therapy, physical activity and self-monitoring of blood glucose.

Diabetes Education

Diabetes education to the diabetic patient and the family is important in ensuring good glycemic control and prevention of diabetic complications. The diabetes education is a continuous process in the patients' follow up

Principles of diabetes education

- An evidence-based, structured education programme should be offered to all patients at the time of diagnosis, and consolidated at regular intervals thereafter. The aim is to promote patient self-management
- Diabetes education is a continuous process and different topics should be covered at separate sessions to ensure a proper understanding of the issues
- The programme should be presented by educators who have been appropriately trained
- Diabetes self-management education (DSME) should be individualized. Small-group education is the most cost-effective option but individual education sessions should also be utilized where necessary
- Educators should ensure that active learning is taking place
- Psychological and emotional assessment is needed at regular intervals
- A regular audit of the programme and its effect on outcomes is advised

Table 15: Structured diabetes education outline

Visits	Education to be conducted during the diabetes clinic visit
Visit 1	• Support system • Overview of Diabetes • Blood glucose monitoring • Nutrition • Physical Activity • Self-Glucose Monitoring
Visit 2	• Hypoglycaemia • Hyperglycaemia • Sick Days • Mindful eating • Dining Out • Physical Activity • Stress and diabetes
Visit 3	• Natural changes of diabetes • Blood pressure control • Heart health • Tobacco use • Eating for better health • Physical Activity • Diabetes and alcohol
Visit 4	• Diabetes changes over time • Problem-solving: glucose results • Complications: preventing and delaying • Foot care • Sleep habits
Visit 5	• Pregnancy: preparing, managing diabetes during pregnancy and appropriate postnatal care • Psychosocial issues, stress management and coping skills • What is the role of alternative medicine: How to make informed choices about their use of traditional and alternative medicine, potential harm and drug interactions
Educating the elderly patients:	• Assess knowledge and understanding of diabetes • Evaluate ability to learn and apply new self-care skills • Asses nutrition and physical activity • Address poly-pharmacy and co-morbidities • Assess for cognitive dysfunction, depression and physical disability

Dietary Management of Type 2 Diabetes Mellitus

Dietary modification is one of the cornerstones of diabetes management. It is based on the principle of healthy eating in the context of socio-economic, cultural and psychological influences of food choices.

Principles of dietary management of Type 2 diabetes mellitus

All members of the diabetes-care team must have knowledge about nutrition to be able to educate people living with diabetes with the support of a nutritionist. Dietary counseling is best given by a dietitian or nutritionist.

The following are principles of dietary management:

- To achieve ideal/desired weight, an appropriate diet and exercise regimen should be agreed upon between the nutritionist and the patient/care giver
- Three main meals should be eaten in a day, and binge eating should be avoided
- The diet should be individualized, based on traditional eating patterns, BMI, comorbid conditions; and should be palatable and affordable
- Animal fat, salt, diet drinks, sweeteners and foods marketed as "diabetic foods" should be avoided
- Tailoring the nutritional intervention, so that there is a careful match of both a meal-planning approach and educational materials with the patient needs, and so that there is still some allowance for flexibility
- Foods and drinks rich in refined sugars (simple sugars) should be avoided
- Eating plans should be higher in complex carbohydrates (starches) and fibre content
- Vegetables and limited numbers of fruits should be encouraged
- Food quantities should be measured in volumes using available household items, such as cups, or be countable, such as number of fruits or slices of yam or bread
- Alcohol should be avoided
- Sweeteners are not essential and should be avoided as much as possible
- Drinking of water throughout the day should be encouraged (average 8 glasses of 250 mls each)

Table 16: Dietary Recommendations in Management of Type 2 Diabetes

A. Follow a healthy, balanced eating plan

- Eat a variety of fresh fruit and vegetables every day, but avoid fruit juices
- At least half of the grain intake must be from whole grain products
- Use a variety of meat alternatives, including pulses, beans and other legumes
- Consume white meat at least twice per week
- Limit the intake of processed and fast foods
- Increase the intake of water to meet daily fluid requirements

B. Carbohydrates

- Carbohydrates should make up 45-60% of the total energy intake
- Monitoring carbohydrate intake, whether by carbohydrate counting, exchanges or experienced-based estimation, remains a key strategy in achieving optimum glycaemic control
- The use of glycaemic index and glycaemic load may provide a modest an additional benefit compared to considering only total carbohydrate content
- Limit the intake of sugar alcohols (maltitol, mannitol, sorbitol, lactitol, isomalt, xylitol) to < 10 g per day
- A sucrose intake of up to 10% of total energy intake per day is acceptable
- Limit the total fructose intake to 60 g per day
- Increase the intake of soluble and insoluble fibre to 25-50 g per day
- The use of artificial sweeteners, including acesulfame-K, aspartame, saccharine and sucralose, are safe when consumed within the daily limits established by the FDA

C. Protein

- Proteins should make up 15-20% of the total energy intake
- For individuals with type 2 diabetes with normal renal function, there is no evidence to suggest that the usual recommended protein intake should be modified
- In type 2 diabetes, ingested protein can increase the insulin response without increasing plasma glucose levels; therefore, protein should not be used in the treatment and prevention of Hypoglycemia

D. Fat

- The fat intake should be restricted to < 35% of the total energy intake
- The saturated fat (solid fats, and animal fats) intake should be restricted to < 7% of the total energy intake
- Most of the fat intake should be unsaturated fats (vegetable oils)
- Minimize the intake of trans-fats
- Two more servings of fish per week will provide the recommended omega-3 polyunsaturated fatty acids

E. Salt

- Limit all kinds of salt intake

F. Vitamins and minerals

- Mineral and vitamin supplementation may be needed in selected groups, such as the elderly, lactating and pregnant women, and vegans
- Encourage to take a variety of fruits and vegetables, fish and foods rich in vitamin D

G. Alcohol

- Adults who choose to consume alcohol should do so in moderation: one unit per day or less for women, and two units per day or less for men
- Moderate alcohol consumption, with food, does not cause acute hyperglycaemia or Hypoglycemia.
- Individuals on insulin or insulin secretagogues should be aware of the risks of delayed Hypoglycemia (for up to 24 hours after consumption); alcohol should be consumed with food to reduce the risk of Hypoglycemia

Tools used in meal planning in in diabetes nutrition therapy

There are several tools used in meal planning, however, there is no ideal meal plan that works for everyone living with diabetes. Below are some of the tools used in meal planning in diabetes care

1. Plate Model
2. Handy portion guide
3. Glycemic Index and glycemic load
4. Food groups and food servings
5. Carbohydrate counting

Plate Model

This method helps the patient to easily measure the food portions while keeping simple and practical. It divides the plate, 9 inches in diameter, into portions of vegetables, fruits, starch and proteins as indicated below

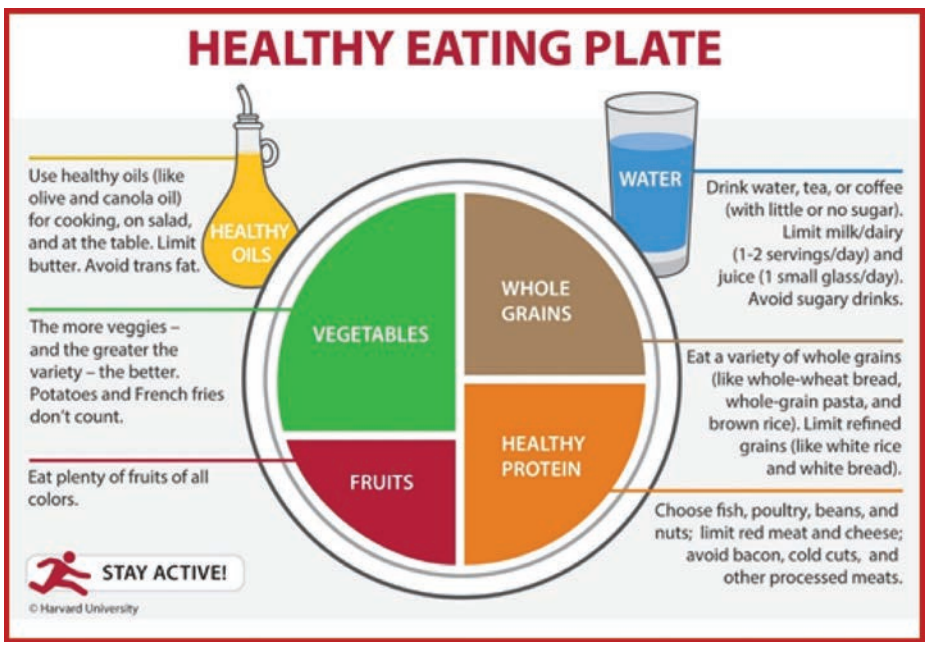


Figure 10: Plate Model

Source: Adapted from the Harvard T.H Chan school of Public Health, The Nutrition Source (www.hsph.harvard.edu/nutritionsource)

Handy portion guide

This method used patients' hands to provide quick tips for estimating portion sizes

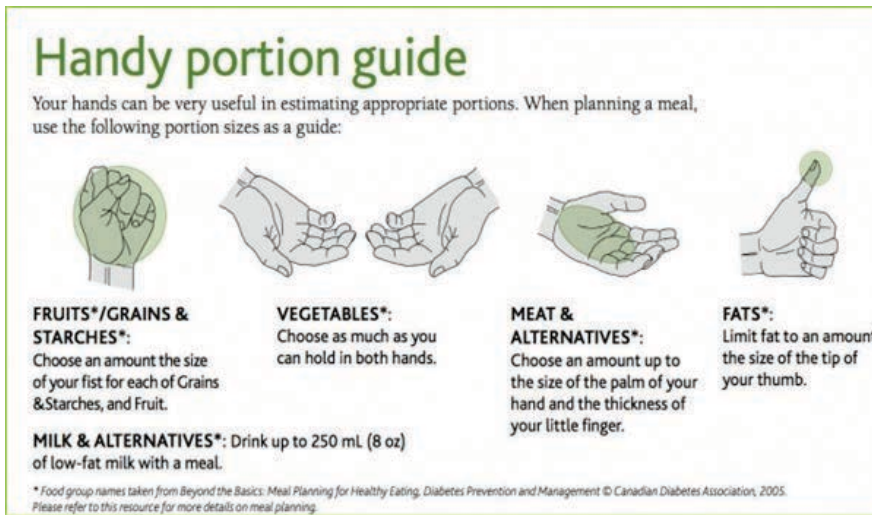


Figure 11: Handy portion guide

Glycemic Index and glycemic load

The glycemic index is a value assigned to foods based on how slowly or how quickly these foods cause increases in blood glucose levels. It ranks the carbohydrates on a scale from 0 to 100 according to the extent to which they raise blood sugar (glucose) levels after eating. Foods low in the glycemic index (GI) scale tend to release glucose slowly and steadily while foods high on the glycemic index release glucose rapidly

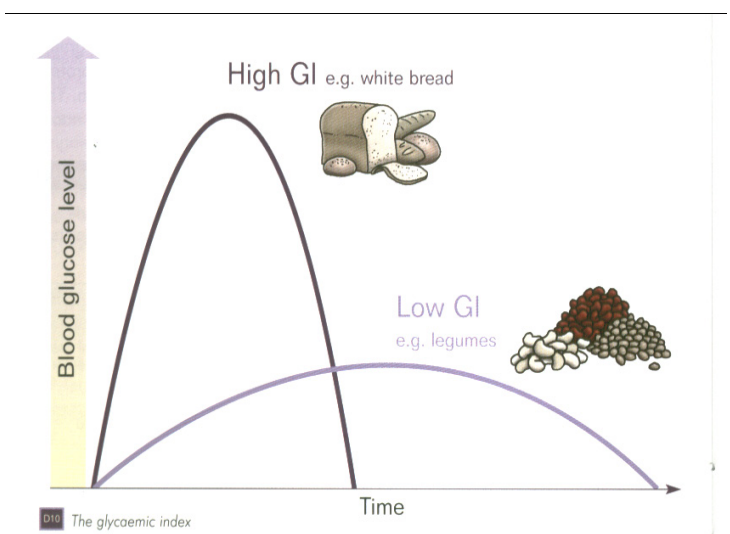


Figure 12: An illustration of low and high glycemic index food

Below is a comprehensive list of low and high glycemic foods, people living with diabetes are advised to choose more foods from the low glycemic index

Table 17: Examples of low and high glycemic index foods

High glycemic foods	Low glycemic foods
Glucose	Whole wheat or bran bread
Baked potatoes	Brown rice
French Fries	Sweet potatoes
Rice Flour	Whole wheat pasta
Mashed Potatoes	Fresh peas
Potato Chips	Whole wheat sugar free cereal
Honey	Oatmeal
Cooked Carrots	Whole grain pasta
Corn Flakes	Kidney beans
Cooked Broad beans	Fresh unsweetened fruit juice
Pumpkin	Raw carrots
Watermelon	Dairy products
Sugar (Sucrose)	Dried beans
White bread	Brown or yellow lentils
Refined sweetened cereal	Chick peas
Chocolate bars	Fresh fruit
Boiled peeled potatoes	Green vegetables, tomatoes, eggplant, zucchini, garlic, onions etc
Cola soda	Green beans
Cookies	Sugar free marmalade
Corn	Green Lentils
White rice	Split peas
Noodles	Dark Chocolate (>70% cocoa
Raisins	Fruits (Banana, Grapes, Orange,

Food groups and food servings

This method is used as a tool that is used to help the patient figure out how many servings of each food are they required to eat from every group. The key to eating well is to enjoy a variety of nutritious foods from each of the food groups.

Table 18: Food groups and recommended servings per each food group

Food group	Number of servings	What is a serving?
Starches and breads	6-11	1 Slice bread ½ cup cooked rice, cereal ¼ cup dry cereal, ½ cup pasta 3 biscuits (eat whole-grain, fortified or enriched starches, bread, and cereals)
Vegetables	3-5	½ cup vegetables cooked 1 cup vegetables raw
Fruits	2-4	1 cup fruit juice (fresh, frozen or canned without sugar) 1 medium piece fresh fruit
Milk and milk products	2-3	1 cup skim / low fat milk / ¾ cup plain or artificially sweetened yogurt
Meat and meat substitutes	2-3	57-85 g cooked lean meat fish or poultry 28.5 g meat is equivalent to: - 1 egg 28.5 g cheese ¼ cup fish (Omena, tuna, salmon or cheese
Fat	Use sparingly	1 teaspoon margarine 1 teaspoon salad dressing 1 teaspoon oil or mayonnaise 1 tablespoon peanut-butter

Carbohydrate counting

Carbohydrate counting, is a meal planning tool for people living with type 1or type 2 diabetes. It involves keeping track of the amount of carbohydrate in the foods that a person eats each day.

Carbohydrates are one of the main nutrients found in food and drinks. They include sugars, starches, and fibre. Carbohydrate counting can help one control their blood glucose levels because carbohydrates affect the blood glucose more than other nutrients.

Healthy carbohydrates, such as whole grains, fruits, and vegetables, are an important part of a healthy eating plan because they provide both energy and nutrients, such as vitamins and minerals, and fibre. Fibre helps in preventing constipation, lower cholesterol levels, and control the weight.

Unhealthy carbohydrates are often food and drinks with added sugars. Although unhealthy carbohydrates can also provide energy, they have little to no nutrients.
The amount of carbohydrate in foods is measured in grams. To count grams of carbohydrate in foods you eat, a patient will need to;

- Know which foods contain carbohydrates
- Learn to estimate the number of grams of carbohydrate in the foods
- Add up the number of grams of carbohydrate from each food to get your total for the day

Foods that contain carbohydrates include

- grains, such as bread, noodles, pasta, crackers, cereals, and rice
- fruits, such as apples, bananas, berries, mangoes, melons, and oranges
- dairy products, such as milk and yogurt
- legumes, including dried beans, lentils, and peas
- snack foods and sweets, such as cakes, cookies, candy, and other desserts
- juices, soft drinks, fruit drinks, sports drinks, and energy drinks that contain sugars
- vegetables, especially "starchy" vegetables such as potatoes, corn, and peas

Foods that do not contain carbohydrates include meat, fish, and poultry; most types of cheese; nuts; and oils and other fats.

Example of the grams of carbohydrates on needs based on an 1800 kilo calories diet per day

Carbohydrate intake for most people should be between 45 and 65 percent of total calories per day. People on low-calorie diets and people who are physically inactive may want to aim for the lower end of that range.
One gram of carbohydrate provides about 4 calories, thus divide the number of calories per day from carbohydrates by 4 to get the number of grams. For example, if a diet is based on an 1,800 total calories per day and get 45 percent of your calories from

carbohydrates, then the grams from of carbohydrates is about 200 grams of carbohydrate daily. **Calculated follows:**

- 0.45 x 1,800 calories = 810 calories
- 810 ÷ 4 = 202.5 grams of carbohydrate

Spread out the grams of carbohydrate intake throughout the day. There is a need to involve a dietitian or a nutritionist to counsel the patient on what foods to eat, how much to eat, and when to eat based on the weight, activity level, medicines, and blood glucose targets. This method also requires the patient to be motivated, read all the food labels and be willing to calculate the number of grams of carbohydrates intake per day

Physical activity and exercise

Physical activity or exercise is one of the essentials in the prevention and management of Type 2 diabetes mellitus. Regular physical activity improves metabolic control, increases insulin sensitivity, improves cardiovascular health, and helps weight loss and its maintenance, as well as giving a sense of well-being.

There are two main types of physical activity:

i. Aerobic or endurance exercise (e.g. walking or running)
ii. Anaerobic or resistance exercise (e.g. lifting weights).

Both types of activity may be prescribed to persons with Type 2 diabetes mellitus, but the aerobic form is usually preferred.

In most parts of Kenya, prescribing formal exercise in gyms or requiring special equipment is a recipe for non-adherence. Therefore, patients should be encouraged to integrate increased physical activity into their daily routine. The plan should impose minimum, if any, extra financial outlay in new equipment and materials for physical activity.

General principles and recommendations for physical activity in Type 2 diabetes mellitus

- A detailed physical evaluation of cardiovascular, renal, eye and foot status (including neurological) should be performed before starting an exercise programme.
- The presence of chronic complications may preclude certain forms of exercises.
- Prescribed physical activity programmes should be appropriate for the patient's age, socio-economic status, state of physical fitness, lifestyle, and level of glycaemic control.
- While exercise generally improves metabolic control, it can also precipitate acute complications like hypoglycemia and hyperglycaemia.
- The physical activity should be regular (3 days/week), last at least 20 - 30 minutes per session, and be of at least moderate intensity.
- Activities like walking, climbing steps (instead of taking lifts) should be encouraged.

- For sedentary persons living with diabetes, a gradual introduction using a low-intensity activity like walking is mandatory.
- Avoid strenuous exercise if ambient glycaemia is > 250 mg/dl (14 mmol/L), the patient has ketonuria or blood glucose is less than 80 mg/dl (4.5 mmol/L).
- To avoid exercise-induced hypoglycaemia, dosages of insulin secretagogues or insulin may need to be reduced and/or peri-exercise carbohydrate intake increased.
- Blood glucose should be monitored (using strips and meters) before and after planned strenuous physical activity as delayed hypoglycemia may occur.
- Proper footwear must always be worn.

Table 19: Aerobic exercise recommended for individuals with type 2 diabetes

Definition	Intensity	Frequency	Examples
Activities that consist of rhythmic, repetitive and continuous movement of the same large muscle groups for at least 10 minutes at a time	Moderate:	Minimum 150 minutes per week (30 minutes per day for 5 days)	Cycling, brisk walking, continuous swimming, dancing, water aerobics, raking leaves, shamba work, house hold chores
	Or		
	Vigorous:	Minimum 75 minutes per week (30 minutes 3 times a week)	Brisk walking up an incline, jogging, aerobics, hockey, basketball, fast swimming, fast dancing
	Or		
	Equivalent combination of moderate and vigorous aerobic exercise		

Table 20: Resistance exercise recommended for individuals with type 2 diabetes

Definition	Frequency	Examples
Activities that require muscular strength to move a weight or work against a resistance load[a]	Two to three times per week: Start with one set of 10-15 repetitions at moderate weight Progress to two sets of 10-15 repetitions Progress to three sets at heavier weights	Exercise with weight machines, free weight lifting, Resistance band (e.g. Thera-Band®) exercises

Resistance exercise should only be attempted if there are no contraindications to this kind of activity

Physical activity recommendations in Children and Adolescents

- Children and adolescents with Type 1 or Type 2 diabetes should engage in 60 minutes per day or more of moderate- or vigorous-intensity aerobic activity, as well as vigorous muscle strengthening and bone strengthening activities at least 3 days per week.
- Preparations are needed as exercise may induce hypoglycemia. Where possible, patients and families should be given tailored advice about what and how much carbohydrate to take before, during, and after exercise, as well as advice about insulin adjustment.
- Where monitoring is available, blood glucose needs to be measured before, during and after exercise.
- Approximately 1.0 – 1.5 g carbohydrate/kg body weight/hour should be consumed before and during strenuous exercise if the child is unable to monitor and reduce insulin dosage. E.g. ½ long banana/small apple, small orange.

- Hypoglycemia is more likely to occur with prolonged non-intense physical activity. It often occurs shortly after any type of exercise but is possible up to 24 hours afterwards (increased insulin sensitivity). Risk of post-exercise nocturnal hypoglycemia is high. The evening dose of intermediate- or long-acting insulin often needs to be decreased by 10-20% after exercise in the afternoon or evening, especially if not exercising on a regular basis. Special care should be taken that the bedtime blood glucose level is > 7.0 mmol/L (125 mg/dl).
- Water should be consumed to avoid dehydration.
- Where unaccustomed exercise is being taken, e.g. at a diabetes camp, reduction in total daily dose of insulin (20- 50%) is advised to avoid hypoglycemia.
- Insulin is absorbed quicker when it is injected near to muscles that are being exercised – e.g. legs in soccer. Hypoglycemia is then more likely to occur. Preferred injection site: abdomen
- If blood glucose levels are high (>14 mmol/l) with ketonuria/ketonaemia, exercise could be dangerous and should be avoided. Give approximately 0.05 U/kg, or 5% of total daily insulin dose as short-acting (soluble) iinsulin and postpone exercise until ketones have cleared. If ketones cannot be measured, a child who is feeling nauseous should not participate in exercise.
  Children and young people engaged in competitive or more intensive sport will require additional support. This should include detailed discussion about the activity and tailored advice on insulin and food adjustments.

Pharmacological Management

The goals of caring for patients with diabetes mellitus are to maintain blood glucose under control and prevent or slow down the rate of development of both acute and long-term complications. In initiating treatment for people living with type 2 diabetes the use of HbA1c test is key. The table below provides a guide for initiating therapy using the HbA1c levels.

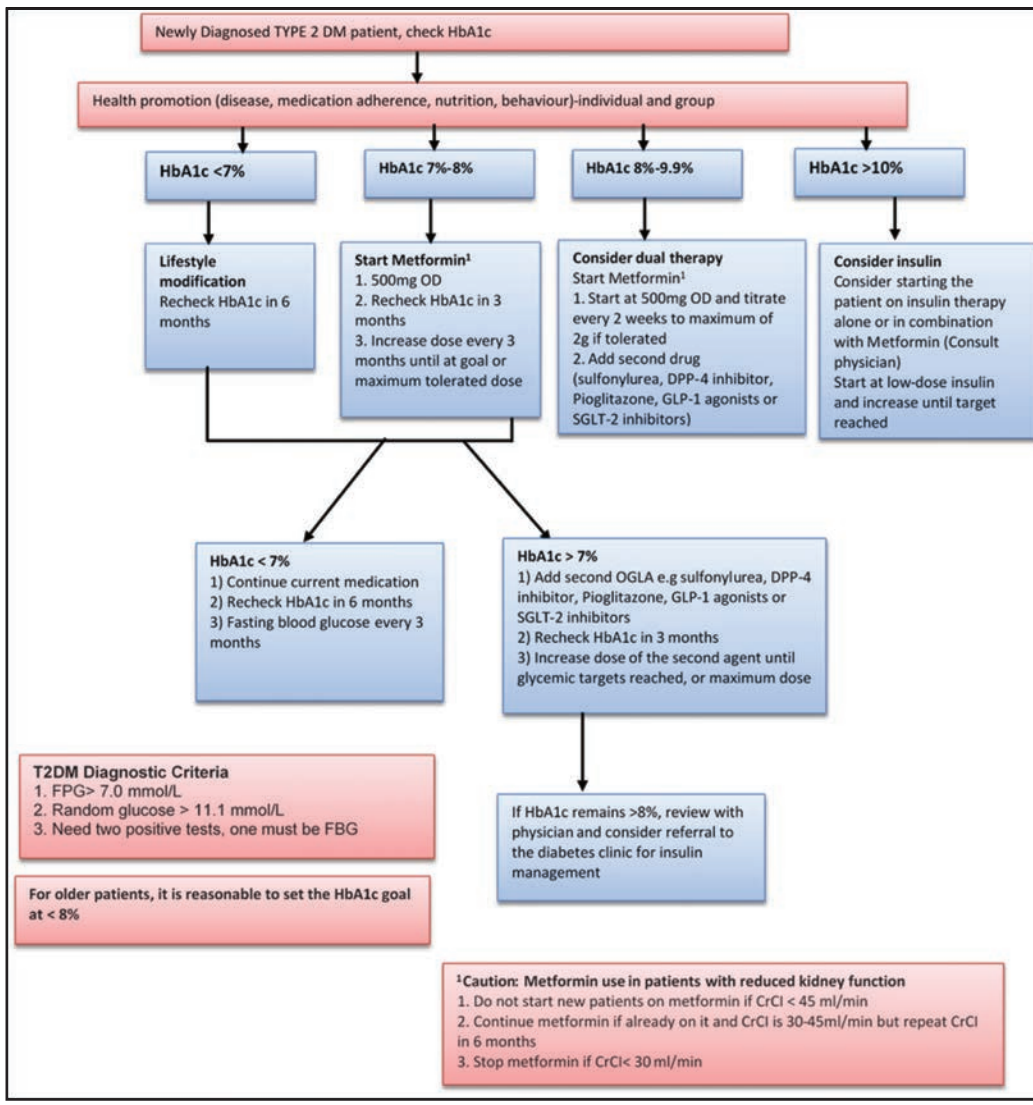


Figure 13: Medical management of Type 2 Diabetes Based on HbA1c levels
Source: Tb/DM Flowchart, MOH

Pharmacological therapy includes oral glucose lowering agents, insulin and injectable GLP-1 agonists.

i. Oral Glucose Lowering Agents (OGLAs)

These were previously referred to as oral hypoglycaemic agents

Indications:

- Oral pharmacotherapy is indicated for individual with Type 2 diabetes
- It is indicated when an individual's glycaemic targets are not met by the combination of dietary modifications and physical activity/exercise.
- In some cases, oral pharmacotherapy or insulin is indicated at the first presentation of diabetes, i.e. a fasting blood glucose level > 11 mmol/L or random blood glucose level > 15 mmol/L.

Choice of Oral Glucose Lowering Agents (OGLAs)

- The choice of OGLAs should depend on the patient's characteristics, lifestyle, degree of glycaemic control, cardiovascular and renal risks, access to drugs, economic status and agreement between the doctor and the person living with diabetes.
- The first line oral agent of choice is Metformin unless contra-indicated.
- The sulphonylureas and metformin are the agents most widely available.
- Use of the stepped-care approach is recommended, as monotherapy is seldom sufficient, because of the progressive nature of the disease (see figure 15).
- Combination therapy should be considered as initial choice if HBA1C is greater than 8 %.
- Three-drug combination therapy can be used when two-drug regimens fail to achieve target values. Such patients should be referred to a specialist. Use of combination therapy often results in an increased number of tablets to be taken and creates new adherence problems.
- Fixed combination therapies increase adherence but may inhibit flexibility in dosing prescription.

Table 21 summarizes the characteristics of the OGLAs which are frequently used in controlling glycaemia in diabetes care. The list is not exhaustive but includes agents that are most commonly used in Kenya.

Table 21: Oral glucose lowering agents, dosage, side effects and Contraindications

Name of Drug	Minimum dose	Maximal daily dose	Frequency	Major Side Effects	Contraindications/use with caution
A. Sulphonylureas ***Mechanism of action:*** Stimulate the pancreas to release insulin (regardless of time and glucose levels)					
Glibenclamide	2.5 mg	15 mg	OD or BD	Hypoglycemia, weight gain skin rashes	Caution in liver and renal disease
Gliclazide MR	30 mg	120 mg	OD	Hypoglycemia, weight gain skin rashes	Pregnancy, caution in liver disease
Glimepiride	1 mg	4 mg	OD	Hypoglycemia weight gain skin rashes	Pregnancy, caution in liver and renal disease
Glipizide	5 mg	40 mg	OD or BD	Hypoglycemia weight gain skin rashes	Pregnancy, caution in liver and renal disease
B. Biguanide ***Mechanism of action:*** (i)Reduce glucose production in liver (ii) cause (mild) reduction in peripheral insulin resistance					
Metformin	500 mg	2000 mg	OD or BD	Abdominal pain, nausea, loose bowel motions, lactic acidosis Vitamin B12 deficiency with prolonged use.	Renal failure, GFR<30 ml/min Heart failure stage 3 or 4 and liver failure
C. Thiazolidinediones ***Mechanism of action:*** (i) Improved insulin sensitivity in muscle, adipose tissue and liver (ii)Reduce glucose output from liver (iii)Change fat distribution by decreasing visceral fat and increasing peripheral fat					
Pioglitazone	15 mg	45 mg	OD	Liver impairment, fluid retention weight gain, dilutional anaemia, osteoporosis	Heart failure and liver failure; pregnancy, Bone fractures
D. Meglitinides ***Mechanism of action:*** Stimulate pancreas to release more insulin (possibly related to blood glucose level)					
Repaglinide	1.0 mg	16 mg	BD, TDS or QID (Before meals)	Liver impairment, fluid retention weight gain, dilutional anaemia	
E. Alpha glucosidase inhibitors ***Mechanism of action:*** Slow digestion of complex sugars (sucrose and starch) and therefore delays absorption, leading to slow post-meal rise in blood glucose					
Acarbose	25 mg	300 mg	TID (during meal)	Dyspepsia loose bowel motions, flatulence	None

F. DPP 4 inhibitors (Gliptins) ***Mechanism of action:*** Improve pancreatic islet glucose sensing →Increase glucose-medicated insulin secretion and suppresses glucagon secretion					
Vildagliptin	50 mg	100 mg	OD or BD	Urticaria, angioedema, and immune mediated dermatologic effects. Acute Pancreatitis, Risk of hypoglycaemia (in combination with sulfonylureas	Pancreatitis Allergy, Pregnancy, Lactation Caution with heart failure (Saxaglipting)
Sitagliptin		100 mg	OD		
Saxagliptin	5 mg	10 mg	OD		
Linagliptin	5 mg	5 mg	OD		
G. SGLT-2 inhibitors ***Mechanism of action:*** Suppress renal glucose reabsorption by blocking the sodium-glucose co-transporter 2 (SGLT-2) resulting in increased urinary glucose excretion					
Canagliflozin	100 mg	300 mg	OD	Polyurea, UTI, DKA, genital candidiasis, hypotension	Renal failure (action dependent on normal GFR) Or sensitivity to active ingredients or it's excipients
Dapagliflozin	5 mg	10 mg	OD		
Empagliflozin	10 mg	25 mg	OD		

	Metformin	Sulfonylurea	Glinides	Pioglitazone	Alpha-Glucosidase Inhibitors	DPP-4 Inhibitors	GLP-1 Agonists	SGLT-2 Inhibitors
Hypo	Neutral	Moderate/Severe	Moderate	Neutral	Neutral	Neutral	Neutral	Neutral
Weight	Slight loss	Gain	Gain	Gain	Neutral	Neutral	Loss	Loss
CKD stages 3A, 3B	Reduced dose in stage 3A Contraindicated in stage 3B	Caution higher risk hypo	Caution higher risk hypo	Neutral	Neutral	Neutral but must reduce dose except linagliptin	Caution with exenatide ER	Contraindicated in stage 3B
CKD stages 4, 5	Contraindicated	Contraindicated except glipizide and gliclazide	Contraindicated		Contraindicated	Neutral but must reduce dose except linagliptin	Contraindicated	Contraindicated
GI SE	Moderate	Neutral	Neutral	Neutral	Moderate	Neutral	Moderate	Neutral
Other SE				Edema and bone fracture		Pancreatitis Heart failure (not a class effect)		Fungal genital infections, fractures, amputations (Bone fractures and amputations may not be a class effect
Major CV events	Benefit	Neutral	Neutral	Neutral	Neutral	Neutral	Benefit (2 RCT*)	Benefit (2 RCT*)
CHF	Neutral	Neutral	Neutral	Increased risk	Neutral	Neutral	Neutral	Benefit (2 RCT**)

CKD, chronic kidney disease; CH, chronic heart failure; CV, cardiovascular; hypo, hypoglycemia; GI, gastrointestinal; SE, side effects; RCT, randomized controlled trial.
** Reduced risk in RCTs designed for non-inferiority with liraglutide, semaglutide, empagliflozin and canagliflozin*
*** Reduced risk in RCT designed for non-inferiority with empagliflozin and canagliflozin*

Figure 14: Risks and benefits of glucose-lowering agents (excluding insulin)
(Source: IDF Clinical Practice Recommendations for managing Type 2 Diabetes in Primary Care – 2017)

ii. Insulin Therapy in type 2 diabetes

Diabetes is a progressive condition, and many patients with type 2 diabetes eventually require and benefit from insulin therapy. Early patient education about expected disease progression, and avoidance of threats of future insulin therapy is important thus easing the transition to insulin therapy.

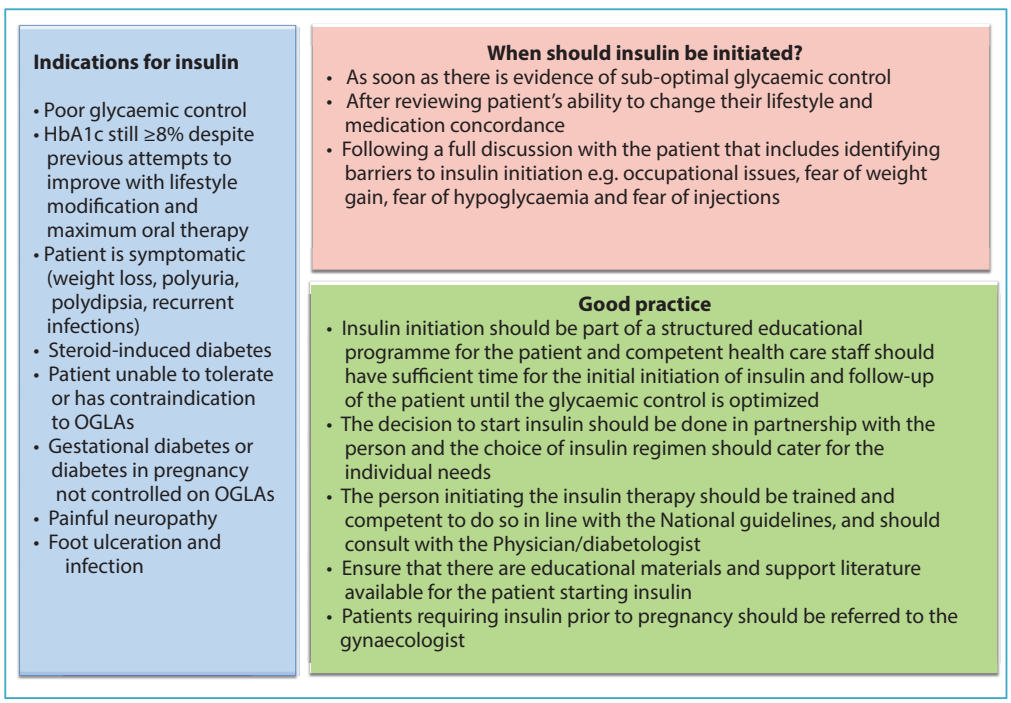


Figure 15: Initiating Insulin Therapy in Type 2 diabetes
Adapted from "Guidelines for the Management of People with Type 2 Diabetes in Shropshire, 2013"

Additional indications for use of insulin in type 2 diabetes

- Presentation in hyperglycemic emergency
- Peri-operative period especially major or emergency surgery
- Other medical conditions requiring tight glycaemic control e. g acute MI, stroke, sepsis
- Organ failure (e.g. renal, liver, heart)

NB: Latent autoimmune diabetes of adults (LADA) is a subset of Type 1 DM presenting in adulthood. All patients diagnosed with LADA should receive insulin as with all type 1 DM patients.

The regimen and dose of insulin therapy varies from patient to patient.

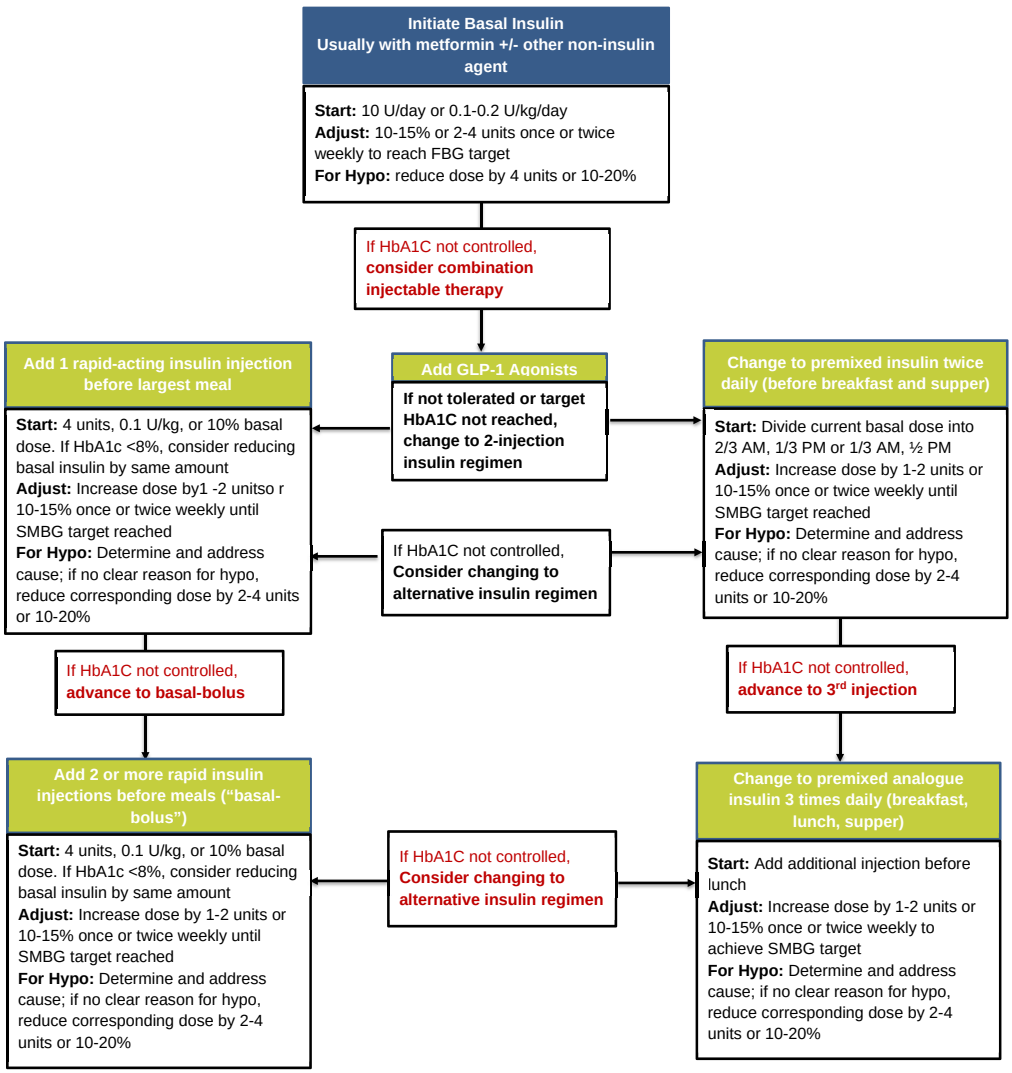


Figure 15: Initiating pharmacotherapy in type 2 diabetes
Source: Adapted from the American Diabetes Association: Diabetes Care Journals http://care.diabetesjournals.org/content/40/Supplement_1/S64)

Dose titration / adjustment requires gradual, safe and prompt titration of insulin dose according to self-blood glucose monitoring (SMBG), towards an optimal dose to ensure maximum benefit from prescribed treatment. Advancing insulin therapy for patients not achieving HbA1c goals on optimally titrated basal insulin alone often requires pre-meal insulin dosing.

Table 22: Adjusting dose of premixed insulin in adults with type 2

Fasting Glucose before Breakfast (in the absence of nocturnal hypos	**Lunch Pre Meal value**	**Evening Pre Meal value**	**Before Bed Value**
INSULIN This dose will affect pre-lunch and pre-evening meal glucose levels		**INSULIN** This dose will affect bedtime and morning fasting glucose levels	
Target 4 to 7 mmol/L	**Target 4 to 7 mmol/L**	**Target 4 to 7 mmol/L**	**Target 6 to 8 mmol/L**
Blood Glucose Monitoring out of range?	Blood Glucose Monitoring out of range?	Blood Glucose Monitoring out of range?	Blood Glucose Monitoring out of range?
High = Increase previous evening's insulin by 2 units or 10% whichever is greater	**High = Increase breakfast insulin by 2 units or 10% whichever is greater**	**High = Increase previous evening's insulin by 2 units or 10% whichever is greater**	**High = Increase evening meal insulin but not if blood tests at breakfast are 4-5 mmol/L**
Low = Decrease previous evening's insulin by 2 units or	**Low = Decrease breakfast insulin by 2**	**Low = Decrease breakfast insulin by 2**	**Low = Decrease evening meal insulin**

Source: Adapted from Guidelines for the Management of People with Type 2 Diabetes in Shropshire, 2013

Insulin is the most effective drug available to achieve glycemic targets in patients with T2DM yet there is reluctance among patients and physicians to initiate insulin. There are many barriers to insulin treatment among health care providers and patients.

Table 23: Barriers to insulin therapy

PATIENT BARRIERS	PROVIDER BARRIERS	SYSTEM BARRIERS
Psychological resistance • Myth-based fear of insulin • Fear of hypoglycaemia • Concern about weight gain • Fear of needles and pain • Self-blame • Loss of control • Social stigma Lifestyle • Time-consuming; inconvenient • Travel issues Physical/mental • Poor recall/cognitive impairment • Visual/hearing/dexterity impairment • Learning difficulties; low literacy Financial • Reimbursement issues	**Perceived patient resistance** • Patient's adherence behaviour • Belief that patient's improved status negates need to start insulin therapy • Concerns about adverse effects (hypoglycaemia; weight gain) • Provider time constraints (instruction; titration) • Lack of resources/ organizational structure to facilitate guideline adherence	**Health system barriers** • Overburdened workload among providers • Access to education • Limited training of providers in injection technique • Underutilization of resources (within clinical practices, hospitals, and community) • Reimbursement issues • Poor follow-up system • Suboptimal team collaboration; poor chronic care mode

Source: Strategies for Insulin Injection Therapy in Diabetes Self-Management, American Association of Diabetes Educators, 2011

iii. Injectable GLP-1 agonists

GLP-1 receptor agonists bind to GLP-1 receptors on existing tissues (pancreas, hypothalamus and stomach). They act to pharmacologically enhance glucose-dependent insulin release, with additional effects on reducing glucagon release, increasing satiety, and increasing gastric emptying.

GLP-1 agonists are currently only available in parenteral (subcutaneous) formulation. Two GLP-1 agonists are currently available: exenatide, which has a half-life of four hours and requires twice-daily injection, and liraglutide, which has a half-life of 11–13 hours and requires once-daily injections.

2.2.3. Blood Glucose monitoring

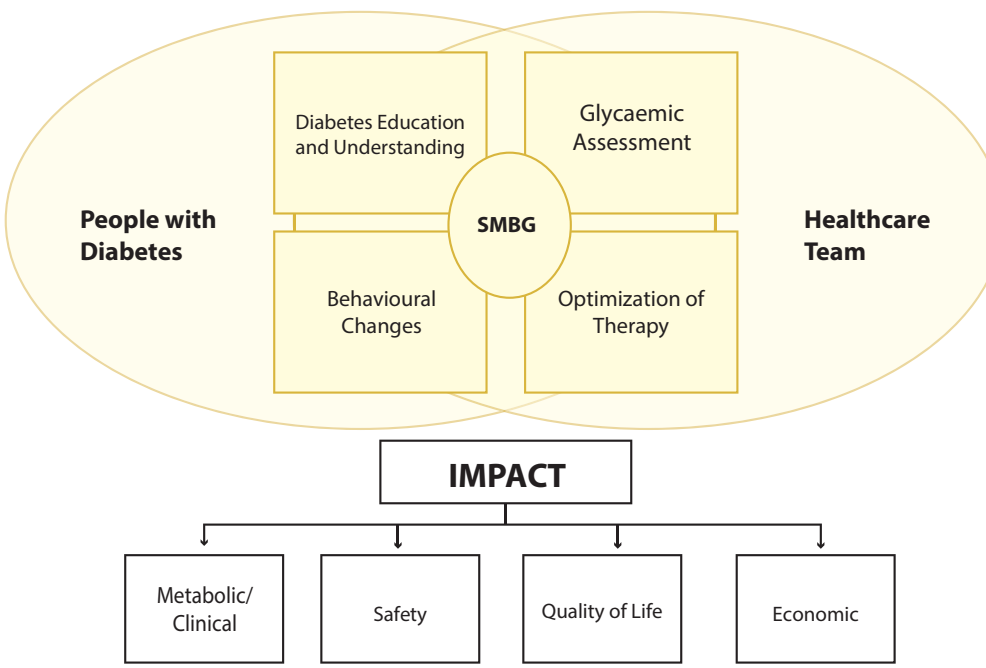


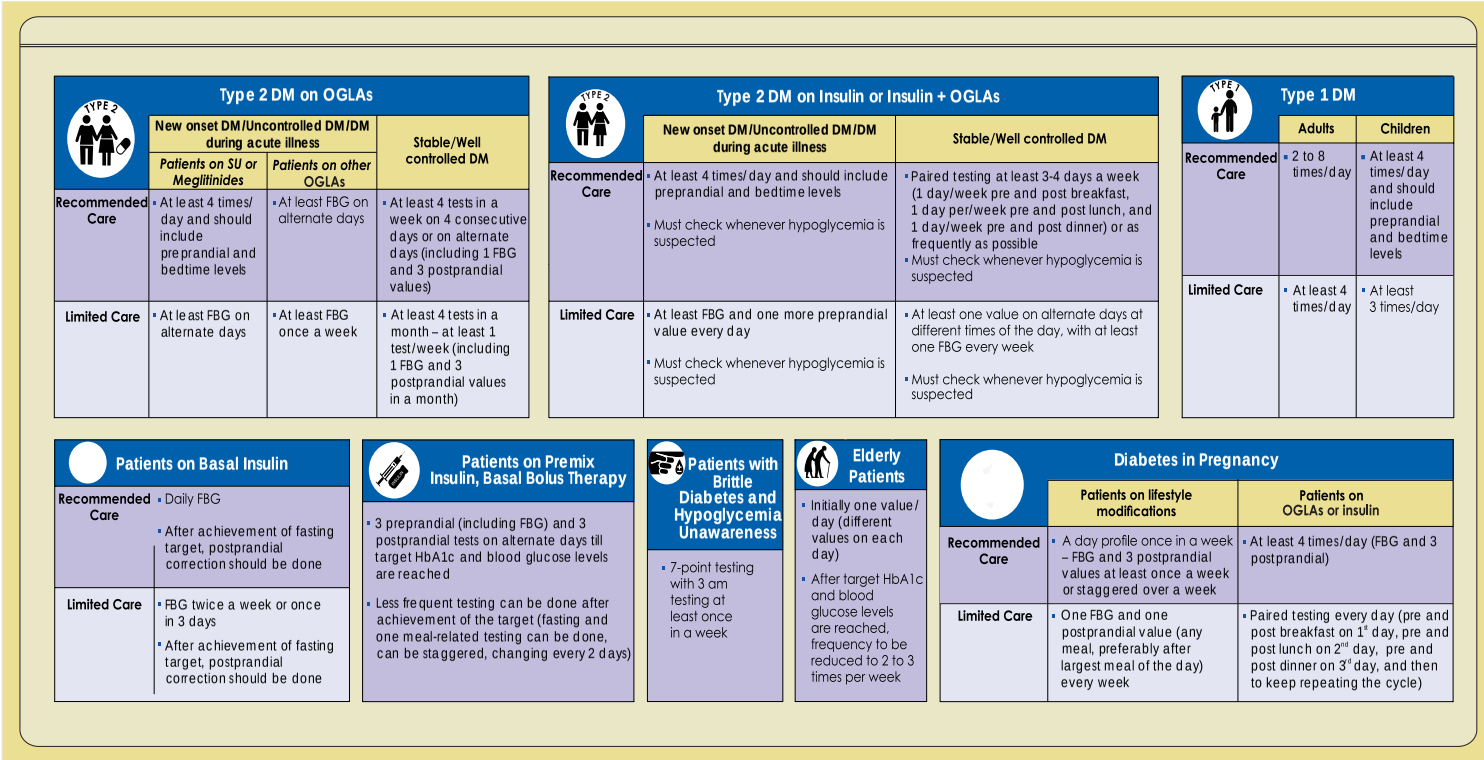
Figure 17: Self-Monitoring of Blood Glucose as a component of diabetes education

Self-Monitoring of Blood Glucose (SMBG) is an approach whereby people living with diabetes measure their blood glucose themselves using a glucose meter (glucometer). Based on the reading, they can adjust or check the effect of their treatment (diet, exercise, insulin, OGLAs, stress management etc.). Within the wider context of diabetes self-management, self-monitoring supports the maintenance of blood glucose at levels as close as possible to target values.

To fully benefit from self-monitoring, it is essential that a person living with diabetes be trained by a health care professional on the following components:

- The technical aspects of self-monitoring;
- Blood glucose targets;
- When and how often to measure blood glucose;
- What action to take based on the readings obtained;
- Re-evaluating (every 3 to 6 months) when, and how often, to self-monitor, based on your clinical condition and readings.

Without this information, self-monitoring of blood glucose will not fulfill its potential purpose, thus affecting the patient motivation and attainment of the treatment goals.



Type 2 DM on OGLAs

	New onset DM/Uncontrolled DM/DM during acute illness		Stable/Well controlled DM
	Patients on SU or Meglitinides	*Patients on other OGLAs*	
Recommended Care	▪ At least 4 times/ day and should include preprandial and bedtime levels	▪ At least FBG on alternate days	▪ At least 4 tests in a week on 4 consecutive days or on alternate days (including 1 FBG and 3 postprandial values)
Limited Care	▪ At least FBG on alternate days	▪ At least FBG once a week	▪ At least 4 tests in a month – at least 1 test/week (including 1 FBG and 3 postprandial values in a month)

Type 2 DM on Insulin or Insulin + OGLAs

	New onset DM/Uncontrolled DM/DM during acute illness	Stable/Well controlled DM
Recommended Care	▪ At least 4 times/ day and should include preprandial and bedtime levels ▪ Must check whenever hypoglycemia is suspected	▪ Paired testing at least 3-4 days a week (1 day/week pre and post breakfast, 1 day per/week pre and post lunch, and 1 day/week pre and post dinner) or as frequently as possible ▪ Must check whenever hypoglycemia is suspected
Limited Care	▪ At least FBG and one more preprandial value every day ▪ Must check whenever hypoglycemia is suspected	▪ At least one value on alternate days at different times of the day, with at least one FBG every week ▪ Must check whenever hypoglycemia is suspected

Type 1 DM

	Adults	Children
Recommended Care	▪ 2 to 8 times/day	▪ At least 4 times/ day and should include preprandial and bedtime levels
Limited Care	▪ At least 4 times/day	▪ At least 3 times/day

Patients on Basal Insulin

Recommended Care	▪ Daily FBG ▪ After achievement of fasting target, postprandial correction should be done
Limited Care	▪ FBG twice a week or once in 3 days ▪ After achievement of fasting target, postprandial correction should be done

Patients on Premix Insulin, Basal Bolus Therapy

- 3 preprandial (including FBG) and 3 postprandial tests on alternate days till target HbA1c and blood glucose levels are reached
- Less frequent testing can be done after achievement of the target (fasting and one meal-related testing can be done, can be staggered, changing every 2 days)

Patients with Brittle Diabetes and Hypoglycemia Unawareness

- 7-point testing with 3 am testing at least once in a week

Elderly Patients

- Initially one value/ day (different values on each day)
- After target HbA1c and blood glucose levels are reached, frequency to be reduced to 2 to 3 times per week

Diabetes in Pregnancy

	Patients on lifestyle modifications	Patients on OGLAs or Insulin
Recommended Care	▪ A day profile once in a week – FBG and 3 postprandial values at least once a week or staggered over a week	▪ At least 4 times/day (FBG and 3 postprandial)
Limited Care	▪ One FBG and one postprandial value (any meal, preferably after largest meal of the day) every week	▪ Paired testing every day (pre and post breakfast on 1st day, pre and post lunch on 2nd day, pre and post dinner on 3rd day, and then to keep repeating the cycle)

Figure 19: Guidance on Self-Monitoring of Blood Glucose for people living with diabetes
(Source: Research Society for the Study of Diabetes in India, RSSDI)

Methods for Monitoring Glycaemic Control

Clinical and laboratory methods are employed to monitor or assess whether the individualized glycaemic targets are being attained.

- HbA1c is the standard test for monitoring glucose control. This should be done every 3 months until patient is well controlled and subsequently every 6 months. (refer to table 18 for targets) Changes in therapy ought to be guided by glucose control as depicted by the HbA1c.
- Self-monitoring of Blood Glucose (SMBG) should be encouraged. It is the main measure used to titrate drug doses on a day to day basis
- Results of self-blood glucose tests should be recorded in a logbook or diary indicating the day and time of testing
- The clinic protocol should set out the parameters to be monitored at the initial visit, regular follow-up visits, and at the annual review (refer to table 14 for assessment and follow-up)

Examples of Self-Monitoring of Blood Glucose (SMBG) testing profiles

Intensive or 'focused' SMBG protocols use 'pattern analysis', a systematic approach to creating glucose profiles that can identify daily glycaemic patterns and then take appropriate action based upon those results. These profiles can be generated by performing 5 to 7 measurements per day over 1 to 3 days, or through 'staggered' testing, in which the individual performs pre- and postprandial testing for alternating meals over the course of a week

Meal-based SMBG (before and after selected meals) helps individuals living with diabetes understand the effects of their treatment on blood glucose concentrations and assists clinicians in identifying postprandial hyperglycaemia, guides therapeutic adjustments and provides more timely feedback regarding medication changes. The table below summarizes the SMBG testing profiles

Table 24: Examples of Self-Monitoring of Blood Glucose (SMBG) testing profiles

	Testing points						
Day	**Pre-Breakfast**	**2 hours Post-Breakfast**	**Pre-lunch**	**2-hours Post-lunch**	**Pre-supper**	**2-hours post-supper**	**Bedtime**
7-point testing profile							
Monday							
Tuesday	X	X	X	X	X	X	X
Wednesday	X	X	X	X	X	X	X
Thursday	X	X	X	X	X	X	X
Friday							
Saturday							
Sunday							
Staggered testing profile							
Monday	X	X					
Tuesday			X	X			
Wednesday					X	X	
Thursday	X	X					
Friday			X	X			
Saturday					X	X	
Sunday	X	X					
Meal-based testing profile							
Monday	X	X					
Tuesday							
Wednesday			X	X			
Thursday							
Friday							
Saturday					X	X	
Sunday							

Source: IDF Guideline on Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes

Table 25: Targets for HbA1c, fasting plasma glucose and postprandial glucose in different patient types

Patient type	Target HbA1c	Target FPG	Target PPG
Young Low risk Newly diagnosed No cardiovascular disease	< 6.5%	4.0-7.0 mmol/l	4.4-7.8 mmol/l
Majority of patients	< 7%	4.0-7.0 mmol/l	5.0 -10.0 mmol/l
Elderly High risk (high cardio-vascular risk) Hypoglycaemic unaware Poor short-term prognosis	< 8%	4.0-9.8 mmol/l	< 11.0 mmol/l
Targets for other measurement			
Weight and height		BMI of 18.5 – 24.9 kg/m2	A 10% weight loss from the current weight if obese is recommend-ed
Waist circumference		**Male**	**Female**
		<90 cm	<84 cm
Blood pressure (mmHg)		**systolic**	**diastolic**
		<140 mmHg	< 90 mmHg
If persistent, microalbuminuria / proteinuria		<125 mmHg	<75 mmHg
Lipids **(fasting)**		**Male**	**Female**
Total cholesterol		<4.8 mmol/l	<4.8 mmol/l
LDL cholesterol		<2.6 mmol/l	<2.6 mmol/l
HDL cholesterol		>1.0 mmol/l	>1.3 mmol/l
Triglycerides		<1.7 mmol/l	<1.7 mmol/l

CHAPTER THREE

CHAPTER THREE

MANAGEMENT OF COMPLICATIONS AND COMORBIDITIES IN DIABETES MELLITUS

3.1. Introduction

Diabetes may present with both acute and chronic complications, and various co-morbidities.

a. Acute complications include Diabetes Ketoacidosis, Hyperosmolar Hyper glycemic State, Hypoglycemia

b. Chronic complications may be categorized as micro and macrovascular
   - Microvascular include retinopathy, neuropathy, nephropathy, sexual dysfunction and diabetic foot
   - Macrovascular include coronary artery disease, stroke, peripheral vascular disease and diabetic foot
   - Dental disorders

c. Common comorbidities include hypertension, mental disorders and lipid disorders.

The above complications and comorbidities contribute to the high morbidity and mortality from diabetes mellitus. Most deaths resulting from diabetes are attributable to cardiovascular disease.

3.2 Acute Complications

3.2.1 Introduction

The acute metabolic emergencies of diabetes ketoacidosis, hyperosmolar hyperglycaemic state, hypoglycemia and lactic acidosis may present with coma or altered levels of consciousness in people living with diabetes. Other considerations include stroke, seizures, trauma, drug overdose, infection, and ethanol intoxication.

3.2.2 Diabetic Ketoacidosis (DKA)

DKA is one of the most serious metabolic emergencies in diabetes mellitus. It is more common in Type 1 diabetes, but may occur in patients with Type 2 diabetes (ketosis-prone type 2 diabetes).

Definition: Diabetic ketoacidosis (DKA) is an acute, major, life-threatening complication of diabetes characterized by hyperglycemia, ketoacidosis, and ketonuria.
Diabetic Ketoacidosis is characterized by:

- History of polyuria, polydipsia, abdominal pain, nausea, vomiting, missed medication, failed insulin pump for those who use it, and intercurrent illness.
- Clinical signs: dehydration, lethargy, tachypnea, deep breathing (Kussmaul breathing), acetone breath.
- Biochemical parameters:
    a. Hyperglycemia of ≥11.1 mmol/L (May rarely present with normal blood glucose)
    b. Metabolic acidosis (PH<7.3 and bicarbonate< 15 mmol/L)
    c. Ketonuria or presence of blood ketones.

Management of DKA

The main stay of management of DKA is judicious use of insulin and rehydration for both Type 1 and 2 diabetes mellitus.

Management of DKA in Type 1 Diabetes

Managing Diabetic Ketoacidosis in Type 1 Diabetes includes the following components:

1. Confirm the diagnosis

- Capillary blood glucose test > 11 mmol/L D
- Urinary or plasma ketones K
- pH < 7.3 or bicarbonate < 15 mmol/L A

2. History and Examination

- Obtain as much information about the patient's diabetes (date of diagnosis, medication, known complications etc.)
- Identify any precipitating causes (change in insulin, intercurrent infection, myocardial infarction)
- Assess the degree of dehydration (BP, capillary refill time, tissue turgor, temperature of extremities)
- Assess level of consciousness using Glasgow Coma Scale (GCS)

3. Investigations

- Blood
    - Urea/electrolytes
    - Glucose
    - Bicarbonate
    - Liver function tests
    - Full blood count
    - Arterial/ venous blood gases
    - Cardiac enzymes
    - Blood cultures

- Chest radiograph (CXR)- preferably portable
- Electrocardiogram (ECG)
- Cultures: Mid-stream urine (MSU) and other appropriate cultures e.g. cerebrospinal fluid (CSF) if meningitis suspected

4. Management (see flow chart)

- Fluids are a critical part of treating DKA. Adults with DKA generally need an average of 6 Litres for adequate rehydration. Keep a fluid balance chart ± a urinary catheter if urine output is poor. Consider central venous pressure (CVP) monitoring if fluid status is difficult to assess clinically or likely to need intensive care unit (ICU) support
- Insulin is needed to help switch from a catabolic to an anabolic state which will result in uptake of glucose into tissues and the reduction of gluconeogenesis. The end-result is to switch off the production of free fatty acids and ketones.
- Potassium replacement: Hypokalemia and hyperkalemia are potentially life-threatening conditions that can occur during the treatment of DKA. Check potassium (K+) levels after 2 hours and at 4, 8,12,16 and 24 hours or until transfer to subcutaneous insulin. Check magnesium levels at 12-24 hours.
- Oxygen: should be given and oxygen saturations monitored. Aim for oxygen saturations (SPO2) > 96%.
- Nasogastric tube: should be inserted as gastric dilation is common with potential risk of aspiration
- Conscious level: If GCS is reduced, position the patient in recovery position and consider intubation for airway protection (intubate if the patient has GCS of less than 8)
- Antibiotics if infection suspected (see antibiotic protocol)
- Heparin prophylaxis

Remember to reassess the patient frequently during the first few hours (clinical status, volume status, hourly glucose tests, potassium and sodium, blood gases) and adjust management according to any clinical changes.

5. Cerebral oedema

Cerebral oedema is a rare but often fatal complication of DKA.
It can be idiosyncratic, but its occurrence may be related to various factors including the degree of hyperglycaemia, acidosis, dehydration and electrolyte disturbance at presentation, as well as over-rapid correction of acidosis, dehydration or hyperglycaemia.
The rapidly rising intracranial pressure may present as change in neurological status (restlessness, irritability, increased drowsiness, incontinence, seizures, coma), specific neurological signs (e.g. unreactive pupils, cranial nerve palsies) or abnormal respiratory pattern, decorticate posture). The Cushing's triad (bradycardia, hypertension and wide pulse pressure) is a late presentation.

If cerebral oedema is suspected TREAT URGENTLY:

- Hypoglycemia as a cause of the change in neurological state.
- Reduce the rate of fluid administration by one-third
- Give mannitol 0.5-1 g/kg IV over 10-15 minutes, and repeat if there is no initial response in 30 minutes to 2 hours.
- Hypertonic saline (3%) 2.5-5 ml/kg over 10-15 minutes may be an alternative to mannitol, especially if there is no initial response to mannitol.
- Elevate the head of the bed.
- Intubation may be necessary for a patient with impending respiratory failure.
- After treatment has been started, if available, a cranial CT scan should be done to rule out other possible intracerebral causes of neurological deterioration, especially thrombosis or haemorrhage which may benefit from specific therapy.

Cerebral oedema is an unpredictable complication of DKA, often occurring when the general condition of the child has improved and monitoring is less strict. Survivors are often left with significant neurological deficits. Meticulous management of the DKA can decrease the risk of developing cerebral oedema. DKA should therefore be managed at the best available facility.

6. Monitoring

If biochemical parameters of DKA (pH, anion gap, urine ketones) do not improve, re-assess patient, review insulin therapy, and consider other possible causes of impaired response to insulin, e.g. infection or errors in insulin preparation. Also consider that the primary illness may be a serious infection (such as malaria) with stress hyperglycaemia rather than diabetes

- Mannitol or hypertonic saline should be available at the bedside for rapid treatment in case of cerebral oedema.
- When the child starts taking oral fluids, make sure the IV rate of fluids is decreased accordingly, not to exceed the total hourly fluid input requirements.
- This fluid restriction should be applied for 48 hrs from admission (72 hrs if there is severe hyperglycaemia at onset of treatment).
- If replacing fluid orally, ensure that the child has ORS or fruit juice once the glucose is below 15 mmol/l (270 mg/dl).

Once the urine ketones are absent, consider making the transition to subcutaneous (SC) insulin

7. Transitioning to subcutaneous insulin

Once the DKA has been adequately treated (hydration corrected, glucose controlled, ketones cleared) the patient can be transitioned to subcutaneous insulin.

The first SC dose of short-acting insulin should be given 1–2 hours before stopping the insulin infusion.

Important: It is often easier to transition to subcutaneous insulin at the next mealtime.

If the child is newly diagnosed:

- Pre-pubertal: 0.5–0.75 U/Kg/day
- Pubertal: 0.75–0.1 U/Kg/day

Otherwise determine insulin dose from consideration of the dose before admission.

Algorithim for the management of diabetic Ketoacidosis

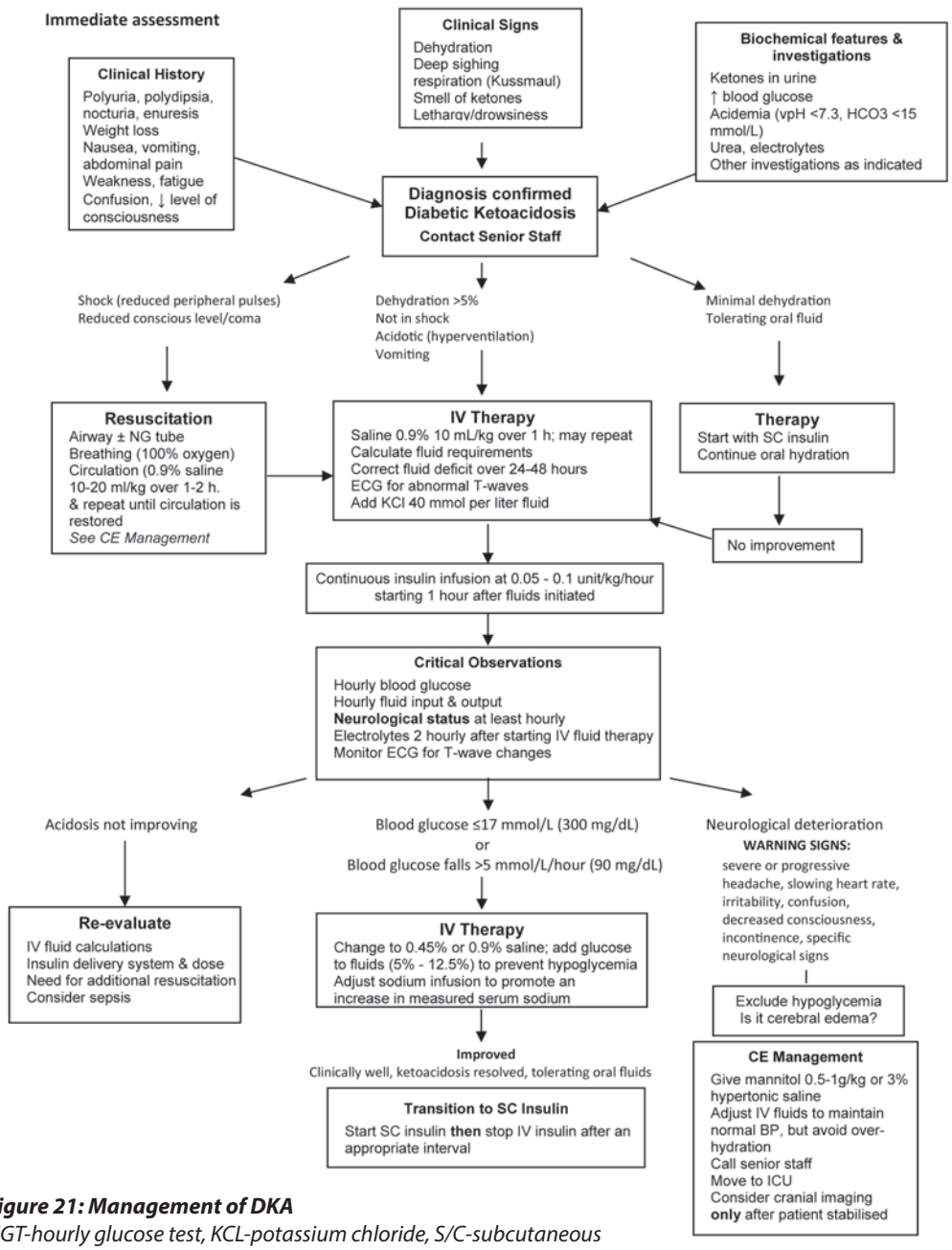


Figure 21: Management of DKA
HGT-hourly glucose test, KCL-potassium chloride, S/C-subcutaneous

Table 26: Fluid maintenance and replacement volumes based on body weight and assumption of 10% dehydration in DKA

Body weight kg	Maintenance mL/24 hr	DKA: Give maintenance + 5% of body weight/24-hr	
		mL/24 hr	mL/hr
4	325	530	22
5	405	650	27
6	485	790	33
7	570	920	38
8	640	1040	43
9	710	1160	48
10	780	1280	53
11	840	1390	58
12	890	1490	62
13	940	1590	66
14	990	1690	70
15	1030	1780	74
16	1070	1870	78
17	1120	1970	82
18	1150	2050	85
19	1190	2140	89
20	1230	2230	93
22	1300	2400	100
24	1360	2560	107
26	1430	2730	114
28	1490	2890	120
30	1560	3060	128
32	1620	3220	134
34	1680	3360	140
36	1730	3460	144
38	1790	3580	149
40	1850	3700	154
45	1980	3960	165
50	2100	4200	175
55	2210	4420	184
60	2320	4640	193
65	2410	4820	201
70	2500	5000	208
75	2590	5180	216
80	2690	5380	224

3.2.3. Diabetic Hyperosmolar Hyperglycaemic State

Hyperosmolar Hyperglycaemic State (HHS) is characterized by the slow development of marked hyperglycaemia (usually > 30 mmol/L or 540 mg/dl and usually reading 'unrecordable' on the glucometer), dehydration and pre-renal azotemia (elevated blood urea and creatinine). Ketonuria may be slight or absent. Two-thirds of cases are in previously undiagnosed cases of diabetes.

Infections, diuretic treatment, and drinking glucose-rich beverages, myocardial or cerebral ischemia may all be precipitating factors.
The condition usually affects middle- aged or elderly patients and carries a high mortality.

Treatment
Initial treatment is the same as for Diabetic Ketoacidosis; but usually insulin requirements are lower than in DKA and individuals respond well to rehydration. Owing to its high mortality, immediate referral for relevant specialist care is recommended.
ECG should be done and Heparin/anti-thrombotic agents should be given in the absence of contraindications.

3.2.4. Hypoglycemia

Hypoglycemia is a medical emergency and should be treated promptly if serious complications are to be avoided.
It is characterized by blood glucose levels < 4 mmol/L. Some patients might experience hypoglycaemic symptoms at higher blood glucose levels and clinicians should individualize care.
The commonest causes of hypoglycemia are:

- Engaging in more exercise than usual
- Delay or omission of a snack or main meal
- Poor injection technique
- Insulin overdose
- Eating insufficient carbohydrate
- Excessive use of alcohol
- Sulphonylureas overdose
- Use of long-acting oral glucose-lowering agents
- Herbal medication causing liver failure in combination with diabetes medications

Presentation

- Severe hunger
- Sudden weakness
- Cold clammy skin
- Profuse sweating
- Headache
- Palpitations
- Sudden collapse- more frequent in Type 1 DM or where there is hypoglycaemic unawareness
- Cerebral signs/ symptoms- irritability, confusion, disorientation, coma

Management

- Oral glucose /sweetened drink- without milk (Not diet drink) if patient is conscious.
- If patient is unconscious, IV 50% glucose bolus (40 - 50 ml diluted with equal volume normal saline) and followed by 10% glucose infusion if necessary. In children use 10% dextrose 2-5 ml/Kg.
- Injectable glucagon 1 mg IM if available can also be administered in unconscious patients.
- On recovery, give a long-acting carbohydrate snack.
- Prolonged IV dextrose infusion (10% for 12 - 24 h.) may be necessary if hypoglycemia is a result of long-acting sulphonylureas/ long and intermediate-acting insulin or alcohol.
- If IV access is impossible, consider nasogastric glucose
- On recovery, attempt to identify the cause of hypoglycemia and address it
- Assess the type of insulin used, injection sites (since lipohypertrophy can alter the rate of absorption) and injection techniques.
- Enquire into and address inappropriate habits of eating, exercise and alcohol consumption.
- Review of other drug therapy and renal function,
- Adjustment of the dosage of insulin or oral glucose-lowering agents if appropriate

Table 27: Management of hypoglycaemia

	Blood glucose	Description	Action
Level 1 ***Hypoglycaemia alert***	≤ 3.9 mmol/L but ≥ 3.0 mmol/L	Requires treatment with fast-acting carbohydrate Patient alert and able to eat	• **Treat with oral glucose** • Give a sugary snack and recheck blood glucose in 15 min • If blood glucose remains ≤ 3.9 mmol/L, repeat the previous step • Give a carbohydrate meal when blood glucose is ≥ 5.0 mmol/L
Level 2 ***Clinically significant hypoglycaemia***	< 3.0 mmol/L	Indicates serious, clinically significant hypoglycaemia Patient may be alert or may have reduced consciousness	• **Treat with iv glucose** • Give 10 ml 50% glucose iv and recheck blood glucose in 2 min • If blood glucose remains < 5mmol/L, repeat the previous step • Give an infusion of 10% glucose iv if more than 2 doses of iv glucose required • Give a carbohydrate meal when blood glucose is ≥ 5.0 mmol/L and the patient is alert and able to eat • Observe for 4 hrs, checking blood glucose every 1 hr
Level 3 ***Severe hypoglycaemia***	No specific value	Associated with severe cognitive impairment requiring external help for recovery Patient has reduced consciousness	• **Treat as for Level 2 hypoglycaemia** • Likely to need hospital admission

Source: Adapted from ADA Guidelines, 2018

3.2.5. Sick Day Management

Introduction

An inter-current illness can destabilize the metabolic state of a child or adult living with diabetes (especially type 1), leading to a hyperglycemic crisis, e.g. Diabetic ketoacidosis. Ailments that reduce intake significantly may also predispose to hypoglycemia. These can be prevented by certain simple steps highlighted as "Sick Day Management". The aim of the sick day management is prevention of diabetic ketoacidosis and hypoglycemia.

Metabolic Disturbance as a Result of Inter-Current Illness

The stress factors, e.g. infection, inflammatory disease, injury, surgery, and severe emotional disturbances, result in the secretion of stress or counter-regulatory hormones: glucagon, growth hormone, epinephrine, and cortisol. Acting in synergy, these hormones create a state of insulin resistance, causing increased hepatic glucose production and reduced peripheral glucose utilization. Though calorie intake is low in illness, blood glucose levels increase and ketonaemia and ketonuria may occur.

Unchecked, these metabolic disturbances may progress to full-blown diabetic ketoacidosis.

Sick day management thus serves to prevent ketoacidosis.

Principles of treatment

- Do not stop Insulin but adjust according to individualized needs.
- If supplemental insulin is required, an additional 10% - 20% of usual daily dose may be safely given with monitoring (see table 23)
- Treat underlying illness.
- Prevent dehydration.
- Monitor blood glucose and urine ketones every 4 hours.
- Watch out for symptoms that require hospital care (admission).
- If blood glucose is low, the dose of insulin should be reduced.
- Treat underlying disease: Seek medical attention sooner rather than later
- Any underlying illness should be treated on its merit e.g. for an infection give antibiotics.
- One should be advised to rest and avoid strenuous exercise/activity.
- Prevent dehydration. High fluid intake is important to prevent dehydration. Fluids chosen should contain sodium and potassium to replace loss of these electrolytes as occurs in uncontrolled Diabetes: if one is not able to follow meal plan, use fluids with sugar to provide carbohydrate. Fluids can be oral rehydration salts, broth, (meat soup), fruit juice, regular soda.

Table 28: Minimum amounts of fluid for oral rehydration

		Volume per hour	
Age in years	**Weight in kg**	**ml**	**oz.**
5	20	45 -90	1.5 - 3
10	30	75 - 120	2.5 - 4
15	55	120 - 240	4 - 8
16+	56 +	240 - 300	8 - 10

Source: Adapted from Challenges in diabetes management, Lifescan 1998.

Guidelines for regular insulin during sick days

NB: Start with the usual dose

- Two-dose treatment (NPH + rapid-acting or short-acting insulin)
- May change it to a 4–5-dose regimen, extras being the rapid/ short acting insulin at 20 – 25% TDI
- Or follow the table (Table 23)

Table 29: Guidelines for supplemental regular insulin

BG in mmol/L / **Age in years**	**15-17**	**17-20**	**>20**
0 – 6	0.5 – 1 U	1 – 2 U	2 – 3 U
7 – 11	1 – 2 U	2 – 3 U	3 – 5 U
12 – 15	2 – 3 U	3 – 4 U	4 – 8 U
> 16	3 – 4 U	4 – 6 U	6 – 12 U

Adapted from IDF, 2014

Signs and symptoms that necessitate hospital care/admission

- If the underlying condition is unclear, fever persists, or family members are un comfortable providing home care for any reason
- Weight loss continues suggesting worsening dehydration and potential circulatory compromise
- Vomiting persists beyond 2 hrs (particularly in young children)
- Caregivers/patients are unable to keep blood glucose above 3.5 mmol/L (60 mg/dL)
- Blood Glucose continues to rise despite supplemental insulin
- Fruity breath odor (acetone) persists or worsens
- Ketonuria is heavy and increasing/persistent or blood ketones are >1.0–1.5 mmol/L
- The patient is becoming exhausted, confused, hyperventilating (Kussmaul breathing) or has severe abdominal pain
- Change in neurologic status, mental confusion, loss of consciousness, seizures, progression of confusion may indicate impending or present cerebral edema; and treatment of cerebral edema is a medical emergency requiring immediate assistance with advanced medical facilities to prevent morbidity and mortality
- The child is very young (less than 2–5 years)
- Other co-morbidities e.g., epilepsy, malaria or other infections, or other diabetes related complications.
- Patients/relatives are exhausted, are not able to communicate due to language barrier or request emergency support.

Sick day management is vital in minimizing the impact of intercurrent illness. In many cases this prevents hospital admission and the accompanying costs, reducing not only the economic burden of diabetes; but also reducing the days lost because of illness. However, this is limited to those who can afford blood glucose machines and urine test strips, as well as to those patients who are highly motivated. With good education and motivation, most sick day episodes can thus be successfully managed at home or in a primary care setting.

3.3. Chronic Complications of Diabetes

3.3.1. Macrovascular Complications

The risk of CVD for people with type 2 diabetes is increased by two to three times for men and three to five times for women compared with people without diabetes. Outcomes following myocardial infarction, stroke or revascularization are also worse in people living with diabetes compared to individuals without diabetes. Atherosclerosis is often accelerated, severe and diffuse in diabetes. Chronic hyperglycaemia is an additional risk factor for atherosclerosis in patients with diabetes and adds to the well-known standard risk factor burden of race, gender, hypertension, dyslipidaemia, smoking, social deprivation and obesity. Table 24 summarizes the traditional modifiable risk factors for CVD and the recommended target values in diabetes.

Table 30: CVD risk factors and targets for type 2 diabetes

Traditional CVD risk factors	Targets
Cigarette smoking	Cessation
Dyslipidaemia	
– Total cholesterol	<4.5 mmol/L
– LDL cholesterol	<1.8 mmol/L
– HDL cholesterol	> 1.0 mmol/L (men) >1.2 mmol/L (women)
– Triglycerides	<1.7 mmol/L
Obesity	
– Waist circumference	<94 cm (men); <90 cm (men of South Asian descent) <80 cm (women)
– Body mass index	<25 kg/m2
Hypertension	
– Systolic blood pressure	<140 mmHg
– Diastolic blood pressure	<80 mmHg

Two major processes lead to cardiovascular disease:

- Atherosclerosis, and
- Hypertension

The clinical spectrum of cardiovascular disease is:

a. Coronary artery disease
b. Cerebrovascular disease
c. Peripheral vascular disease

Coronary artery disease

Coronary artery disease (CAD) is the cause of death in more than half of all diabetic patients. Patients with diabetes but without other conventional risk factors for atherosclerosis have a risk of death from CAD 2– 4 times that of age-matched controls. Those with type 2 diabetes commonly have other associated risk factors, such as hypertension or hyperlipidemia, thus further increasing their cardiovascular risk. Women living with diabetes are at increased risk, with a risk of cardiovascular death up to 7.5 times that of women without diabetes. Individuals with diabetes and CAD fare worse than do other patients with CAD. These patients present with:

- Chest pain (angina): -this can be a mild, uncomfortable feeling, similar to indigestion. However, a severe angina attack can cause a painful feeling of heaviness or tightness, usually in the centre of the chest, which may spread to the arms, neck, jaw, back or stomach. Angina is often triggered by physical activity or stressful situations.
- Lightheadedness
- Sweating
- Nausea
- Breathlessness

Those who present with a myocardial infarction (MI) are at increased risk of dying from their event or of developing heart failure. They benefit less from therapies such as thrombolysis in the setting of an acute MI. Therefore, early detection of CAD is important to ensure that medical interventions to improve outcome are instituted.

The spectrum of coronary artery disease includes: -

- Angina (which may be silent).
- Acute coronary syndrome.
- Congestive cardiac failure.
- Sudden death.

Silent ischemia

Silent ischemia is a particular concern in diabetic patients. Clinically, patients with diabetes are more likely to be without chest pain in the setting of unstable angina or MI, and thus late presentation contributes to a higher mortality in these patients. People with diabetes may also be less likely to experience exertional angina or chest pain with exercise testing, thus potentially increasing the difficulty of diagnosing significant CAD. This may further increase diabetic patients' risk in terms of late diagnosis and presentation.

Cerebrovascular disease

Cerebrovascular complications make diabetic patients 2–6 times more susceptible to a stroke event. The risk is further increased in the DM patients who also have hyperlipidemia or hypertension. The cerebrovascular risk increases by 2-3-fold in type 2 DM patients with elevated systolic blood pressure. In addition, when patients with diabetes

and hyperglycemia experience an acute ischemic stroke they are more likely to die or be severely disabled and less likely to benefit from the thrombolytic therapy.

Cerebrovascular diseases in diabetes can present either as:

i. Stroke
ii. Transient ischaemic attack
iii. Cognitive impairment/dementia

Stroke

Stroke refers to the partial or complete interruption of blood supply to the brain resulting in brain ischemia. The manifestations of stroke typically last longer than 24 hours. There are two main forms of stroke: -

a. **Ischemic stroke:** Occurs when there is occlusion (blockage) to the blood vessels supplying the brain by a thrombus or embolus. It is the more common form of stroke in diabetics.

b. **hemorrhagic stroke:** Occurs when a weakened blood vessel bursts or ruptures leading to an intracranial bleed. Common in individuals with uncontrolled hypertension.

Symptoms of stroke include:

- Sudden numbness or weakness in the face, arm, or leg, especially on one side of the body
- Sudden confusion, trouble speaking, or difficulty understanding speech
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance, or lack of coordination
- Sudden severe headache with no known cause

c. **Transient Ischaemic Attack (TIA):** Transient ischaemic attack refers to temporary obstruction of blood supply to the brain. Symptoms mimic those of stroke, but typically last less than 24 hours.

d. **Cognitive impairment:** Diabetes increases the risk of developing cognitive decline and dementia, including vascular dementia and Alzheimer's disease (AD) especially in the elderly

Evaluation for Cerebrovascular disease will include: -

- Carotid Doppler
- MRI and
- MRI angiography where indicated.

Treatment

The treatment of the cerebrovascular disease in DM patients is divided into three levels:

i. First level: to prevent the brain vessels complications by adequately controlling the blood glucose when the patients are at the stage of insulin resistance or at the early stage of diabetes; to reduce the risk factors caused by the hyperglycemia

a. Lifestyle modification-smoking cessation, diet and physical activity
b. Glycemic control: OGLAs/insulin therapy
c. Anti-platelet therapy
d. Blood pressure control
e. Treatment of dyslipidemia: statins

ii. **Second level:** to control glucose intensively after the cerebrovascular diseases occur in DM patients. The blood pressure should be reduced to the normal range to avoid the vasculopathy-induced stroke.

iii. **Tertiary prevention:** to improve the cerebral circulation after the stroke in DM patients. The patients with ischemic stroke should be treated by thrombolytic therapy in the early phase of hyper-acute cerebral infarction

Peripheral vascular disease (PVD)

PVD is a common cardiovascular complication in persons living with diabetes. In contrast to PVD in non-diabetic individuals, it is more prevalent and, because of the involvement of the distal territory of vessels and its association with peripheral neuropathy, it is more commonly asymptomatic.
Patients with PVD and diabetes thus may present later with more severe disease and have a greater risk of amputation. Moreover, the presence of PVD is a marker of excess cardiovascular risk.
It is important to diagnose PVD in patients with diabetes to elicit symptoms, prevent disability and limb loss, and identify a patient at high risk of MI, stroke, and death.

The clinical spectrum of PVD include: -

i. Intermittent claudication-defined as pain, cramping, or aching in the calves, thighs, or buttocks that appears reproducibly with walking exercise and is relieved by rest.

ii. Critical Limb Ischemia-this is a triad characterized by: -
- Rest pain
- Foot ulcers: these ischemic ulcers typically present on the lateral surface of the ankle or the distal digits
- Gangrene

Peripheral signs of peripheral vascular disease are the classic "five P's,":
- Pulselessness
- Paralysis
- Paresthesia
- Pain
- Pallor

The assessment of PVD in patients with diabetes should include a thorough medical history and physical examination to identify those patients with risk factors, symptoms and signs of PVD.

- Walking history to elicit claudication symptoms
- Foot inspection- absence of hair growth, pallor on elevation, cool and dry
  fissured skin, fissures and ulcerations in the interdigital spaces
- Palpation of peripheral pulses (femoral, popliteal and dorsalis pedis pulses)

The diagnosis is made with a determination of the ABI. It is recommended that patients with diabetes who are > 50 years of age have an ABI performed. An ABI is also useful in patients with other PVD risk factors and in those with symptoms.

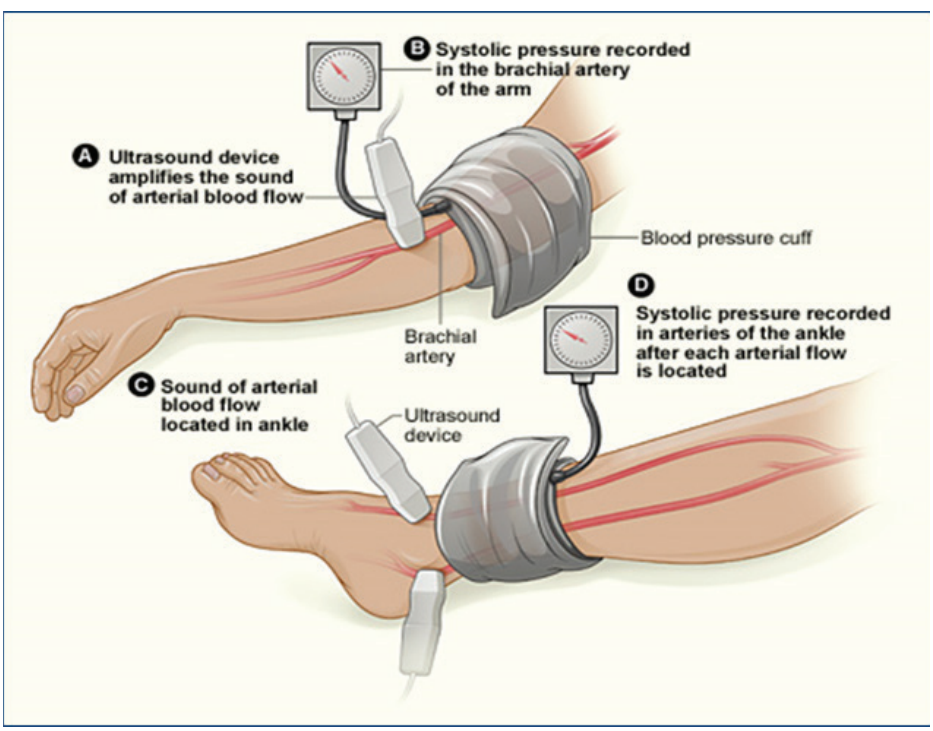


Figure 22: How to perform an ankle-branchial index
Source: National Heart Lung and Blood Institute (NIH) - National Heart Lung and Blood Institute (NIH)

The diagnostic criteria for PVD based on the ABI are interpreted as follows:

Table 31: Interpretation of ankle-brachial index (ABI) values

ABI reading	Interpretation
0.91-1.30	Normal
0.70-0.90	Mild obstruction
0.40-0.69	Moderate obstruction
< 0.40	Severe obstruction
> 1.30	Poorly compressible

An ABI value > 1.3 suggests poorly compressible arteries at the ankle level due to the presence of medial arterial calcification. This renders the diagnosis of PVD by ABI alone less reliable.
In addition to ABI, evaluation for peripheral vascular disease should also include Doppler and angiography of the lower limbs.

Treatment of the patient with diabetes and PVD should be two-fold:

i. Primary and secondary risk modification
   - Cigarette smoking cessation,
   - Glycemic control
   - Treatment of hypertension
   - Treatment of dyslipidemia
   - Anti-platelet therapy (aspirin, clopidogrel)

ii. Treatment of PVD symptoms (claudication and critical limb ischemia) and limiting progression of disease
   - Exercise rehabilitation
   - Pharmacologic therapy (e.g. Pentoxifylline, cilostazol)
   - Wound care (debridement, offloading the ulcers, appropriate dressings, treatment of infections)
   - Revascularization (for patients with debilitating claudication or CLI)

Follow-up considerations: Cardiovascular complications in DM patients

- Initial assessment for cardiovascular risk should be done in all diabetic patients, and annually thereafter.
- The assessment should be more frequent if the patient has had a cardiovascular event (Refer to ESH/ESC CVD risk stratification tool in ANNEX I).
- Referral for specialist care is required in people presenting with typical and atypical symptoms of angina, features of congestive cardiac failure, unexplained breathlessness, cardiomegaly, arrhythmias, transient ischaemic attacks or intermittent claudication of the legs.

3.3.2. Chronic Microvascular Complications

Microvascular complications involve the kidney, eyes, lower extremities. They may be present at the time of diagnosis of diabetes as the detection of the disease is frequently delayed. Most of these complications can be prevented or their progression delayed by optimal treatment of hyperglycaemia and hypertension.
Screening for the complications and prompt interventions reduce the risk of major outcomes such as blindness, nephropathy, and leg amputations.

Diabetes Nephropathy

Diabetes is one of the most common causes of chronic kidney disease. In Africa, there is a high morbidity and economic burden in patients with end-stage renal disease due to late presentation, delayed diagnosis and limited access to renal replacement therapy.

Diabetes nephropathy progresses from subclinical disease to microalbuminuria. Persistent microalbuminuria is a marker for the development of overt nephropathy in diabetes as well as being a well-established marker of increased cardiovascular risk. Patients with microalbuminuria who progress to macro-albuminuria (> 300 mg/24 h.) are likely to progress to end-stage renal disease. Intervention at the stage of microalbuminuria can retard the progression to end-stage renal disease.

Who should be screened?

- Patients with Type 1 diabetes for a duration of >5 years
- Patients with Type 2 diabetes at diagnosis

Detection and surveillance

- Check for proteinuria yearly using reagent strips.
- For patients who test positive, exclude urinary tract infections by using urine strips to check for nitrites and leucocytes or urine microscopy and culture and treat infection if present.
- During the next visit, check for presence of infection, if none test for proteinuria. If proteinuria (trace or greater) is present and there is no infection, refer for renal evaluation.
- For patients who test negative for proteinuria check for microalbuminuria annually using reagent strips or the albumin-creatinine ratio.
- If negative, repeat test annually. If positive, test sample at least one to two times within 3 to 6 months to confirm microalbuminuria. If confirmed, start ACEI or ARB treatment and optimize blood pressure control to less than 125/75 mmHg.
- Measure serum creatinine bi-annually, and if raised or rising, refer for renal evaluation.

Frequency of screening

Table 32: Frequency of screening for diabetic nephropathy based on status of kidney

Status of Kidney function	Screening Frequency
Albumin-Creatinine Ratio (ACR) – normal range and the eGFR > 60 ml/minute:	Annually
Albumin-Creatinine Ratio (ACR) - abnormal range and the eGFR < 60 ml/minute:	Serum creatinine must be repeated once three months ACR must be repeated twice within the same three months:
ACR is abnormal in two out of three tests if the eGFR < 60 ml/minute, the presence of CKD is confirmed.	The patient must be referred for further work-up to exclude non-diabetic renal disease or to confirm Chronic Kidney Disease in diabetes.

General recommendations

- Intensify management of modifiable risk factors
- Tobacco use in any form should be stopped
- Metformin should not be used once eGFR <30 ml/min/1.73 m2
- Between eGFR of between 30-45 ml/min/1.73 m2 consider the risks and benefits of metformin.
- Treat urinary infections aggressively.
- Avoid drugs toxic to the kidney e.g. Non-steroidal anti-inflammatory agents (e.g. Diclofenac), Aminoglycosides (e.g. Gentamicin)

Principles of Treatment of Nephropathy and Chronic Kidney Disease

i. Optimize glycemic control with caution in those with advanced kidney disease and those on renal replacement therapy.
ii. Treat blood pressure aggressively with a target of 125/75 mmHg.
    a. Use ACE inhibitors or ARBs as first-line drug therapy unless contraindicated. These drugs should NOT be used in pregnancy.
iii. Diet therapy and counselling
iv. Psychosocial counselling
v. Criteria for Renal Specialist referral
    a. Persistent micro-albuminuria
    b. Inability to optimize blood pressure
    c. Patients intolerant of ACE-Inhibitors/ARBs or >30% increase in creatinine levels within 3 months of initiation of these drugs

When to consider other causes of CKD in Diabetes

- Extreme proteinuria >6 g/day
- Persistent hematuria
- Rapidly falling eGFR
- Low EGFR with low or no proteinuria
- Diabetes <5 years
- Family history of non-diabetic renal disease e.g. polycystic kidney disease

Diabetes Eye Disease

Diabetes eye disease comprises both retinopathy and cataracts.

Retinopathy

Retinopathy is one of the major causes of blindness.

Risk factors for retinopathy include poor glycemic control, hypertension and pregnancy, as well as a long duration of diabetes. Diabetic retinopathy is preventable, and its progression is retarded by improved blood pressure and glycemic control. Screening for retinopathy and laser therapy can prevent blindness.

Recommendations

a. A full eye examination including visual acuity and fundoscopy (preferably after the dilatation of the pupils) should be performed at the initial contact. If no capacity for ophthalmology examination, refer as part of the initial assessment.

b. Examinations should be repeated annually or more frequently if retinopathy is progressing.

c. A comprehensive eye examination is required in women planning pregnancy, and during the first trimester. An individualized follow-up is required during pregnancy and for one year thereafter. (This does not apply to women with GDM). In women with pre-existing type 1 diabetes, fundoscopy should be performed every trimester.

d. If retinopathy is present, intensify the management of blood pressure, glycaemia, lipids and stop smoking.

e. Patients with proliferative diabetic retinopathy require guided exercises and should avoid weight-bearing exercises.

Who should be screened?

- All patients with Type 2 Diabetes Mellitus at presentation
- Patients with Type 1 Diabetes Mellitus of > 5 years duration since diagnosis (or at presentation if uncontrolled).

Urgent Referral to Ophthalmologist

- Sudden deterioration of vision
- 'Floater' sensation in the eye reported by patient
- Fundoscopy findings of dot or blot hemorrhages- 1 disc-width away from the macula.
- Cataract present,
- Proliferative or exudative retinopathy.

Diabetes Neuropathy

Neuropathies are common complications of diabetes. They significantly increase the risk of ulceration, infection and amputation, and other diabetes-related morbidities like postural hypotension, gastropathies and erectile dysfunction. Once present, it is difficult to reverse, but good glycemic control can reduce symptoms and slow progression.

There are three major categories:

- Motor neuropathy
- Sensory neuropathy
- Autonomic neuropathy

Clinical Assessment:

- Detailed history: numbness, tingling, burning sensation pain, history of trauma
- Examination of the feet: test for sensation using 10 g monofilament, 128 Hz tuning fork or cotton wool.
- Lying-and-standing blood pressure and pulse rate
- Postural/orthostatic hypotension=Drop in systolic BP > 20 mmHg or diastolic >10 mmHg with change to standing position

General measures:

- Improve glycemic control.
- Exclude or treat other contributory factors:
- Excess alcohol consumption
- Vitamin B12 deficiency
- Chronic renal failure
- Poor nutrition
- Smoking
- HIV infection

Treatment

Treatment of symptomatic peripheral neuropathy is extremely difficult, once diagnosed refer to secondary and/or tertiary center.
Treatment options for neuropathy include:

First Line:

- Tricyclic Antidepressants
- Pregabalin
- Carbamazepine
- Duloxetine
- Tapentadol

Others:

- Tramadol
- Topical capsaicin

Gastroparesis

It is a common, but often undiagnosed complication of diabetes. Treatment includes dietary modification (small frequent meals, reduce dietary fat), withdrawal/adjusting medications that may affect motility e.g. opioids and prokinetics. Treatment is challenging. Metoclopramide may be used in severe cases judiciously due to side effects.

Diabetic Foot Complications

Diabetic foot complications comprise of peripheral neuropathy (sensory neuropathy, motor and autonomic neuropathy), ischemic and structural deformities. Neuropathy contributes to 90% of the pathophysiology of diabetic foot while ischemia contributes to 10%.
Approximately 80% of amputations attributable to diabetes are potentially preventable through early detection, examination and simple interventions.

Most common predisposing factors for ulcers and amputations are:

- Peripheral neuropathy with loss of sensation
- Peripheral vascular disease
- Deformities and abnormal biomechanics
- Poor foot hygiene
- Unsuitable or no footwear
- Trauma: Perceived or non-perceived

Cornerstone of Management of Foot Problems

- Identification of the foot "at risk"
- Regular inspection and examination of the foot at risk
- Education of health workers, people living with diabetes and their families
- Appropriate footwear: The shoes and socks should also be inspected.
- Early treatment of non-ulcerative and ulcerative problems

How to reduce foot ulceration and amputations

- Optimize blood glucose, blood pressure and lipid control.
- Ensure good nutrition status to promote healing
- Encourage patient to stop tobacco smoking/use.
- Perform a detailed foot evaluation at presentation and annually.

People with demonstrated risk factors should be examined more frequently. The absence of symptoms does not mean that the feet are healthy, since the patient can have neuropathy, peripheral vascular disease or even an ulcer without any complaints.

Full examination at presentation and annually

- ASK FOR: Symptoms of neuropathy (numbness, tingling or pain) peripheral vascular disease (pain in calves on exercise and at rest)
- EXAMINE SKIN: Inspect for ulcers, callus, cracking, fragility, dryness, inter digital maceration (break down of the skin between the toes) and nail pathology
- VASCULAR: Skin color, foot and ankle pulses.
- NEUROPATHY: check protective sensation using 10 g monofilament (see figure 25)
- BONES/JOINTS: deformities, e.g. claw toes and hammer toes.
- FOOTWEAR: check for appropriate footwear and socks both inside and outside-ANNEX 3

At the examination, each person's feet must be categorized into: LOW RISK, MEDIUM RISK or HIGH RISK.
An example of an easy-to-use foot-screening assessment sheet for clinical examination is provided in ANNEX 2. It can be attached to the person's records.

FOOT CARE SCREENING FLOW CHART

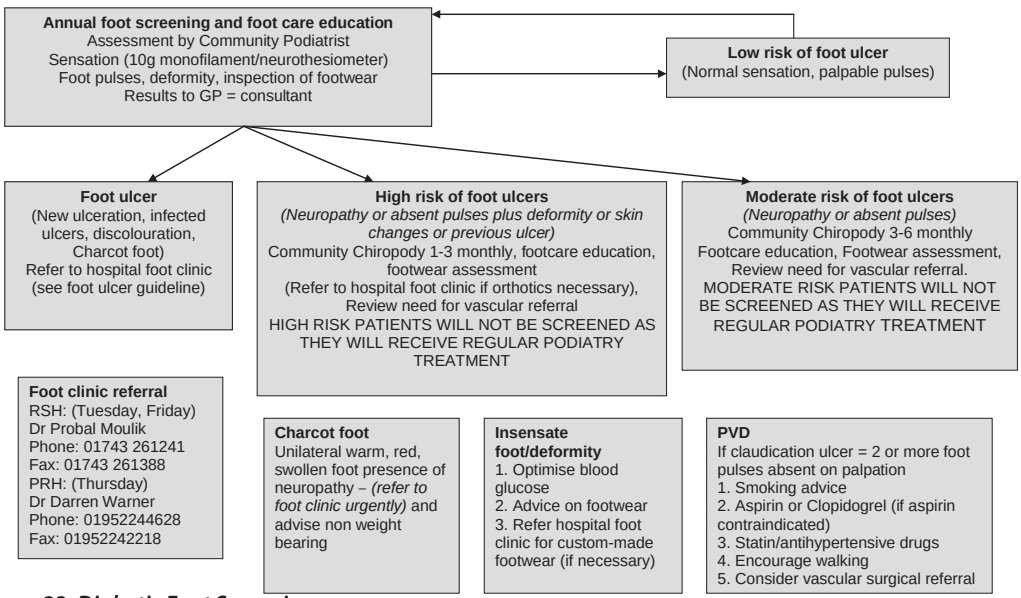


Figure 23: Diabetic Foot Screening
Source: Adapted from Guidelines for the Management of People with Type 2 Diabetes in Shropshire, 2013)

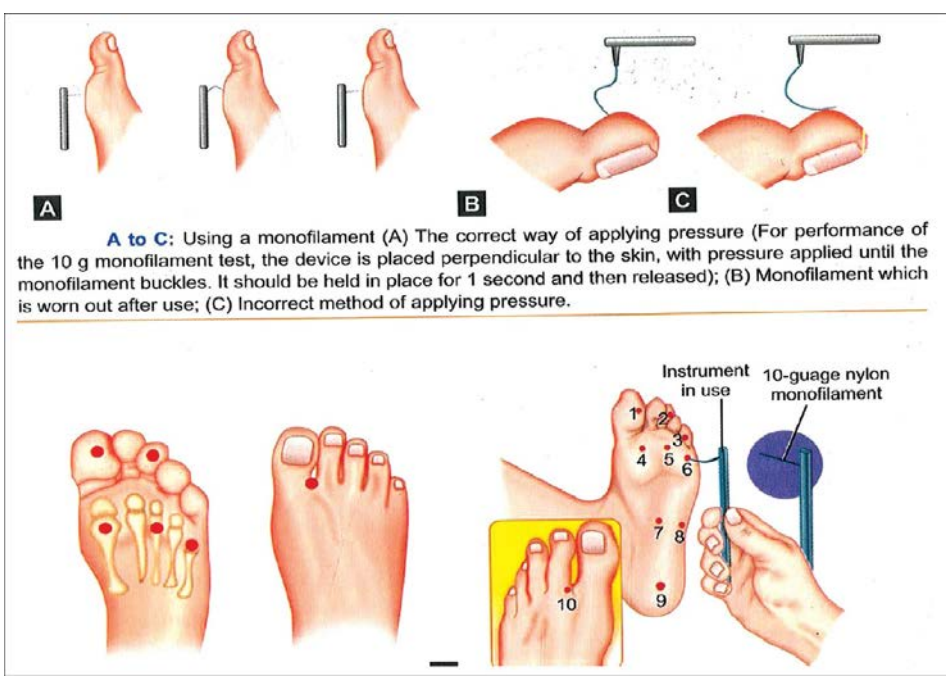


Figure 24: Performing a monofilament test for foot sensation in diabetes

FOOT ULCER MANAGEMENT FLOW CHART

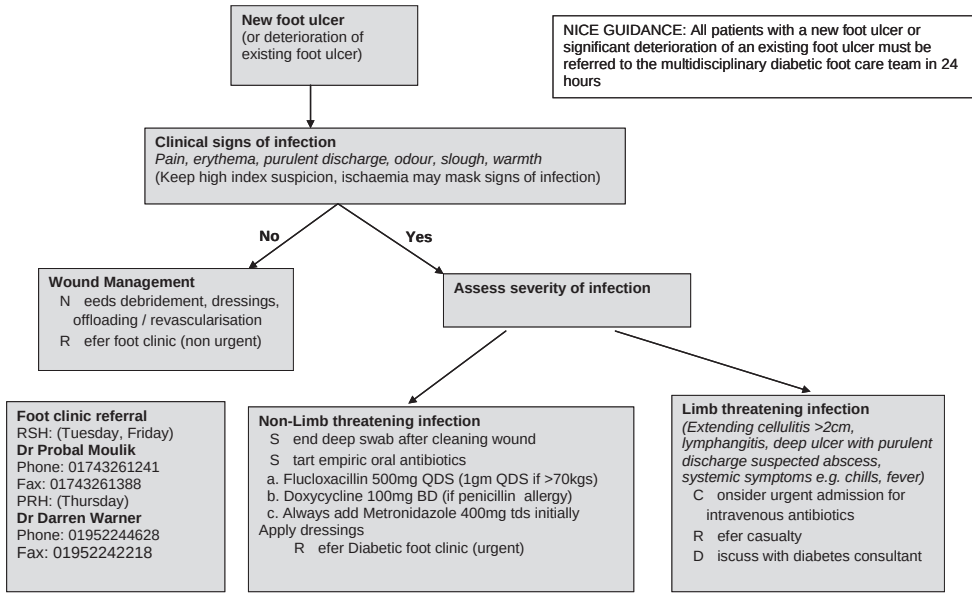


Figure 25: Performing a monofilament test for foot sensation in diabetes
Source: Adapted from Mahesh DM, Paul T, Thomas N. Peripheral neuropathy. A Practical Guide to Diabetes Mellitus. 7th ed. Jaypee; New Delhi. 2016. p. 171-189

Principle of Treatment of Diabetic Foot

This requires interdisciplinary team approach involving:

- Education
- Metabolic control
- Microbiological control
- Biomechanical control (footwear)
- Vascular strategies
- Wound care

Sexual dysfunction

Sexual dysfunction is common in diabetes in both men and women and presents with a wide spectrum of symptoms varying from problems with libido to function and has major psychosocial impact on the individual. However, data is limited on the prevalence of sexual dysfunction in women. In men, the most common presentation is erectile dysfunction which increases in prevalence with increasing age. The common causes of erectile dysfunction are psychogenic factors, medications, glycemic control, neurological and vascular dysfunction.

Assessment

- Obtain a detailed sexual history at initial assessment and during follow up.
- Refer appropriately based on history and physical examination.

Therapy

- Counsel the patient and partner
- Review medications and optimize therapy appropriately.
- Phosphodiesterase-inhibitors e.g. sildenafil and tadalafil can be used with caution in some patients with Erectile Dysfunction after cardiovascular assessment and safety is confirmed. Avoid in patients with heart failure and HIV patients on protease inhibitors.
- Urology review may be required if poor response to pharmacologic therapy.
- Assistive devices and most interventions do not change the natural history of the disease but improve the patient's quality of life.

TREATING ERECTILE DYSFUNCTION IN MEN WITH DIABETES

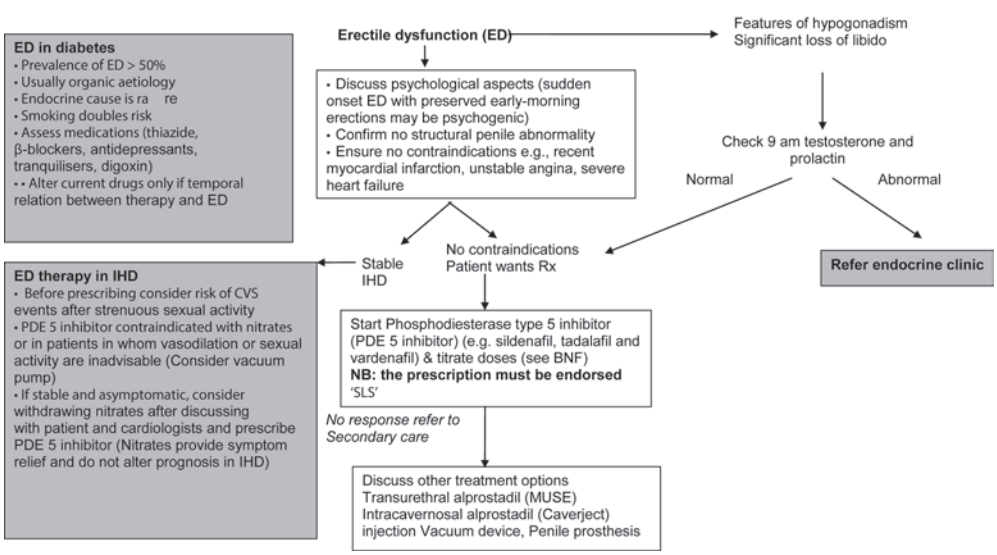


Figure 25: Management of erectile dysfunction in men living with diabetes
Source: Adapted from Guidelines for the Management of People with Type 2 Diabetes in Shropshire, 2013

Dental Disorders in Diabetes

Dental disorders are common in Diabetes. There is a high risk of plaque buildup leading to gingivitis and periodontitis. There is also a higher risk of infection following minor surgeries e.g. extraction

Recommendations

- Observe good oral hygiene practices e.g. brushing of the teeth at least twice daily and flossing.
- Biannual (6-monthly) dental reviews

3.4: Comorbidities in Diabetes Mellitus

Comorbidities are diseases or medical conditions that co-exist with the primary disease. There are various forms of co-morbidities that contribute to the morbidity and mortality associated with diabetes. They include hypertension, mental health, dyslipidemia among others.

3.4.1. Hypertension

Principles of management of hypertension in diabetes mellitus

- Determine blood pressure in people with Type 2 diabetes at every visit, using standard techniques (measure with a mercury sphygmomanometer and the right-sized cuff with the patient seated after 5 minutes).
- Classify blood pressure status using a BP of ≥140/90 mmHg as hypertensive.
- Most patients with diabetes and hypertension should be treated to a systolic blood pressure goal of 140 mmHg and a diastolic blood pressure goal of 90 mmHg.
- Lower systolic and diastolic blood pressure targets, such as 130/80 mmHg, may be appropriate for individuals at high risk of cardiovascular disease, if they can be achieved without undue treatment burden.
- In pregnant patients with diabetes and chronic hypertension, blood pressure targets of SBP 130–150 and/or DBP 80–105 mmHg are suggested in the interest of optimizing long-term maternal health and minimizing impaired fetal growth.
- If hypertensive, assessment should include a thorough history, physical examination, staging and cardiovascular risk stratification (refer to the risk stratification tool in Annex 1). Look for other components of metabolic syndrome and complications of both diabetes and hypertension.

Non-Pharmacologic Management

Integrate management of hypertension and that of diabetes, starting with:

- Diabetes Education
- Lifestyle modifications (physical exercise, diet and weight loss) and setting goals

- Diet should be low in sodium, rich in vegetables and fruits, and use of low-fat dairy products
- Reduce alcohol consumption and tobacco cessation

Pharmacologic Management

- Pharmacologic management should be considered in all patients with diabetes and a documented sustained blood Pressure of above 140/90 mmHg despite lifestyle modification
- Individualize hypertensive therapy to achieve good control.
- Multiple agents are frequently required. Fixed dose combinations should be used when Blood pressures are stable and response to individual agents is known.
- Monitor serum creatinine and potassium once a year and more frequently if there is evidence of renal impairment.
- Note the potential problems with certain anti-hypertensives:
  - Diuretics in large doses inhibit insulin release
  - Beta blockers may blunt or mask symptoms of Hypoglycemia and exacerbate peripheral vascular disease
  - Dyslipidaemia may be worsened by beta blockers and diuretics,
  - Impotence and postural hypotension may be precipitated or aggravated by alpha blockers and centrally acting agents (e.g. methyldopa).
  - Angiotensin converting enzyme (ACE) inhibitors may induce hyperkalaemia, renal failure, a persistent cough.

Table 33: Principles of management of hypertension by level of severity

Level of severity	*Management*
≥140/90	Repeat Blood pressure on different occasion and initiate lifestyle modification and pharmacologic therapy
≥160/100 mmHg	Treat with two classes of oral Anti-Hypertensive drugs
≥ 180/120 mmHg	Bring BP down to near normal below 160/100 mmHg within 48 hrs.
If patient has end organ damage	Reduce blood pressure by not more than 25% in the first 1-2 hours with an agent determined by the physician/specialist

NOTE: Avoid sublingual antihypertensive agents that have the potential to dramatically and catastrophically reduce blood pressure.

Management of Hypertension

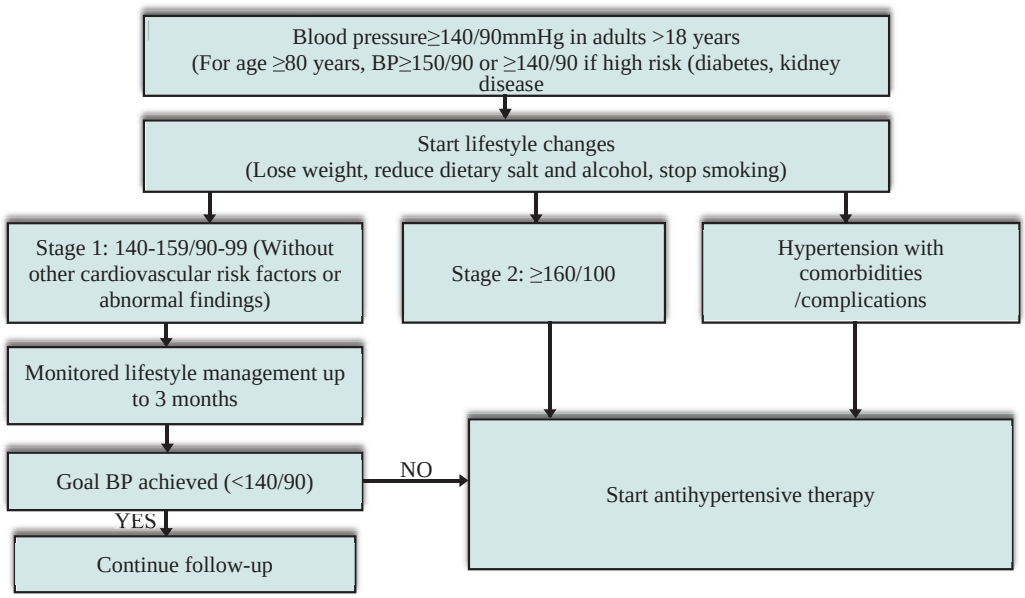


Figure 26: Algorithm for the management of hypertension in patients with diabetes mellitus

Algorithm: Management of hypertension in diabetes in Primary Care

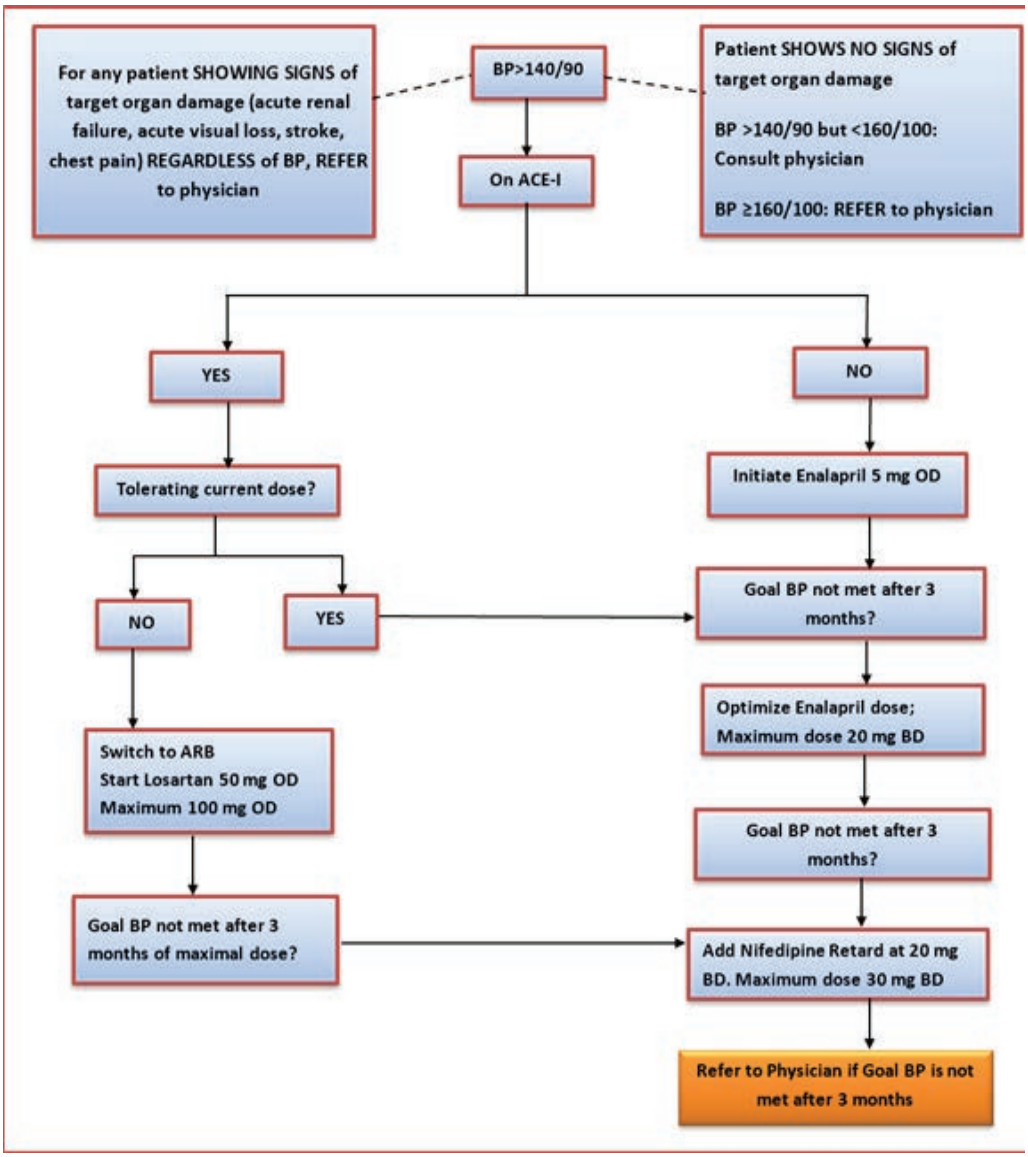


Figure 28: Management of hypertension in patients with diabetes in the Primary Care setting
Source: AMPATH

3.4.2. Mental Disorders in Diabetes

Mental health is an important aspect of Diabetes management. Adolescents living with Diabetes are a particularly vulnerable population that requires psychosocial support as an integral part of their management.
A wide spectrum of psychosocial and emotional challenges exists in people living with **Diabetes that include:**

- Depressive disorders
- Disordered eating behavior
- Anxiety disorders

Healthcare providers should be aware that psychotropic agents are known to increase the incidence of diabetes and may affect glycemic control.

Management

- All individuals should be screened at diagnosis and during follow up for any mental health issues and referred appropriately for psychotherapy.
- Counselling at diagnosis is key to acceptance, medication compliance and mitigation of mental disorders
- Consider the effects on glycemic control when patients are on psychotropics.
- Encourage peer and support group involvement as part of routine care.

3.4.3. Lipids disorders in Diabetes

The risk of coronary artery disease and other macrovascular disorders is 2 - 4 times higher in people living with diabetes than in non-diabetic subjects and increases in parallel with the degree of dyslipidaemia.

Table 34: Desired level of lipids in patients with diabetes (LDL targets in the absence of CKD and CVD, DM in patients < 40 years, duration of <10 years)

Lipids	Target(mmol/L)	Target (Mg/dl
Total cholesterol	<4.8	<93.6
LDL cholesterol	<2.6	<-46.8
HDL cholesterol	>1.2 (Female) >1.0 (Male)	>19.8
Triglycerides	<1.7	<30.6

CKD-Chronic kidney disease, CVD- Cardiovascular disease

Table 35: Lipid Targets for secondary prevention (people with history of cardiovascular event)

Lipids	Target (mmol/L)	Target (Mg/dL)
Total cholesterol	<4.8	<93.6
LDL cholesterol	<1.8	<32.4
HDL cholesterol	>1.2	>19.8
Triglycerides	<1.7	<30.6

Assessment

Measure fasting lipids including total cholesterol, triglycerides and HDL and LDL cholesterol at initial contact.

How often:

- If normal, do a risk-stratification and determine appropriate treatment.
- If abnormal or on treatment (but not on target), repeat every 3-6 months

What to do if results are abnormal:

- Use non-pharmacological interventions concurrently with statins
- Improve blood glucose control
- Reduce saturated fat intake
- Ensure regular individualized exercise
- Reduce weight if indicated
- Avoid alcohol intake if triglycerides elevated
- Referral to dietitian
- Discourage smoking

Pharmacologic Therapy

- Statin therapy is the mainstay of Pharmacologic therapy for any person with type 2 diabetes >40 years regardless of lipid level. For patients with type 1 diabetes, statin therapy should be started in individuals not responding to lifestyle modification.
- Fibrates may be used in addition for persistent hypertriglyceridemia.
- Nicotinic acid may be considered as an alternative therapy

Management

- Manage underlying associated cardiovascular risk factors.
- Life-style modification
- Initiate aspirin therapy if indicated
- Consider the use of beta-blockers, Angiotensin Converting Enzyme (ACE) inhibitors, Angiotensin Receptor Blockers (ARBs) and good glycaemic control post myocardial infarction.

Recommendation for use of Aspirin

The use of low dose aspirin (75 mg or 81 mg) in people with Type 2 diabetes reduces cardiovascular events, and is indicated in the following:

- Secondary prevention for coronary and cerebrovascular diseases
- Primary prevention for people with Type 2 diabetes over the age of 40 years, having:
    - Family history of ischaemic heart disease (IHD)
    - Cigarette smoking
    - Hypertension
    - Obesity
    - Proteinuria
    - Dyslipidaemia

However, contraindications may prevent its use, especially the presence or history of peptic ulcers, dyspepsia, heartburn or bleeding and asthma.

Aspirin should not be used in uncontrolled and malignant hypertension of more than 160/100 mmHg.

Hemorrhagic stroke must be ruled out before initiating aspirin therapy in patients with acute cerebrovascular accident. The recommended daily dose is 75 -162 mg of aspirin per day.

CHAPTER FOUR

CHAPTER FOUR

METABOLIC SYNDROME AND OBESITY

4.1. Introduction

Metabolic syndrome is a cluster of metabolic disorders. It occurs when a person has three or more of the following measurements:

- Abdominal obesity (Waist circumference of greater than 40 inches in men, and greater than 35 inches in women)
- Triglyceride level of 1.69 mmol/L (150 milligrams per deciliter of blood mg/dL) or greater
- HDL cholesterol of less than 1.03 mmol/L (40 mg/dL) in men or less than 1.29 (mmol/L) 50 mg/dL in women
- Systolic blood pressure (top number) of 130 millimeters of mercury (mm Hg) or greater, or diastolic blood pressure (bottom number) of 85 mm Hg or greater
- Fasting glucose of > 5.6 mmol/L (100 mg/dL)

Strong associations of the metabolic syndrome include:

i. Polycystic ovary disease
ii. Acanthosis nigricans
iii. Decreased fibrinolytic activity
iv. Hyperuricaemia
v. Pro-inflammatory state (elevated CRP)
vi. Microalbuminuria

4.2. Management of the metabolic syndrome

Treatment of the metabolic syndrome consists of managing the various disease components and targeting the pathophysiological derangements of the syndrome: central obesity and insulin resistance. The first line of treatment for all components is

- lifestyle change- weight loss and increased physical activity.
- Insulin sensitivity can be improved by non-pharmacological and pharmacological means.

4.3. Obesity

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. For adults, WHO defines overweight and obesity as follows:

Table 36: Definition of overweight and obesity per age category

Age category	Overweight	Obesity
Children under 5 years	Weight-for-height greater than 2 standard deviations above WHO Child Growth Standards median	Weight-for-height greater than 3 standard deviations above the WHO Child Growth Standards median
5-19 years	Overweight is BMI-for-age greater than 1 standard deviation above the WHO Growth Reference median	Greater than 2 standard deviations above the WHO Growth Reference median
≥19 years B	MI greater than or equal to 25	BMI greater than or equal to 30

Being overweight/obese significantly increases the risk of morbidity and mortality from Type 2 diabetes and its co-morbidities. Successful weight reduction has a positive impact on these outcomes. Obesity is a major component of the metabolic syndrome. In Kenya, the WHO STEPwise Survey found the prevalence of overweight and obesity at 27.9% in adults.

4.3.1. Measurements for evaluation of obesity

1. Calculation of overall obesity, the body mass index (BMI).

BMI represents overall fatness. It is derived from the patient's weight in kilograms (kg) and the height in meters (m) from the following formula:
BMI= Weight (kg)/Height (m2)

Table 37: Classification of BMI

Classification	Values (kg/m2)
Underweight <	18.5
Normal weight	18.6-24.9
Overweight 2	5-29.9
Obesity (class 1) 3	0-34.9
Obesity (class 2) 3	5-39.9
Extreme obesity (class 3) >	40

2. Determination of central fat distribution by measurement of waist circumference.

Waist circumference is an indicator of intra-abdominal fatness and is a good indicator of abdominal fat. A high waist circumference is associated with an increased risk for type 2 diabetes, high cholesterol, high blood pressure and cardiovascular disease.
Indicators of risk
Men: Waist Circumference greater than or equal to 102 cm
Women: Waist Circumference greater than or equal to 88 cm

3. Waist hip ratio

The pattern of distribution of the fat in the body (whether mostly peripherally or centrally distributed) is assessed using the waist hip ratio (WHR):
WHR = waist circumference (cm)/Hip circumference (cm)
Waist circumference (WC) should be measured midway between the lower rib margin and the iliac crest
Hip circumference is taken as the largest circumference of the hip.

Indicators of risk
Women: WHR Greater than 0.85
Men: WHR Greater than 1.0

4.3.2. General principles of the management of obesity

i. Assess dietary intake, level of physical activity, BMI, and waist circumference and advice accordingly
ii. Assess efficacy of weight loss regularly and initiate effective measures
iii. Maintain records of goals, instructions and weight progress chart

CHAPTER FIVE

CHAPTER FIVE

MANAGEMENT OF DIABETES IN SPECIAL SITUATIONS

5.1. Diabetes in Pregnancy

Hyperglycemia that is first detected during pregnancy should be classified either as Diabetes Mellitus in Pregnancy (DIP) or as Gestational Diabetes mellitus (GDM).

Diabetes in Pregnancy

- Pregnancy in a patient known to previously have Diabetes
- Hyperglycemia diagnosed for the 1st time during pregnancy, that meets the WHO criterion for DM in the non-pregnant state
- May occur at any time during the pregnancy, including the 1st trimester

Gestational Diabetes Mellitus

- Hyperglycemia diagnosed for the 1st time during pregnancy (in 2nd or 3rd trimester
- Hyperglycemia levels do not meet WHO criterion for DM
- May occur at any time during the pregnancy, but most likely after 24 weeks

The diagnostic criteria

Table 38: Diagnostic criteria for diabetes in pregnancy and gestational diabetes mellitus

	Diabetes in Pregnancy	Gestational Diabetes mellitus
Fasting Blood Glucose	≥ 7 mmol/L (126 mg/dL)	5.1-6.9 mmol/L (92-125 mg/dL)
1 hour post-prandial (after 75-g oral glucose load)	Not applicable	≥ 10 mmol/L (180 mg/dL)
2 hour post-prandial (after 75-g oral glucose load)	> 11.0 mmol/L (200 mg/dL)	8.5-11.0 mmol/L (153-199 mg/dL)
Random Blood Glucose	≥ 11.0 mmol/L (200 mg/dL) in the presence of DM symptoms	Not applicable

Source: International Federation of Gynecology and Obstetrics (FIGO) Initiative on Gestational Diabetes Mellitus 2015 (based on IADPDG 2010 and WHO 2013 recommendations)

Management of Diabetes during Pregnancy

i. Preconception planning and care

The following aspects should be discussed with women who have diabetes (and all women of reproductive age) and actioned by the attending health care provider

- Patients should be offered contraceptives to prevent unplanned pregnancy and optimize glycemic control at least 3 months before conception
- Counsel patient on the importance of good blood glucose control before pregnancy and during pregnancy to reduce the maternal, foetal and neonatal complications
- Optimize weight
- Optimize blood glucose control to targets – Patients may require insulin to optimize blood glucose control
  - HbA1c 6% - 6.5%,
  - FBS < 5.3 mmol/L,
  - One hour postprandial < 7.8 mmol/l,
  - two-hour postprandial < 6.7 mmol/l
- Should stop teratogenic medications (ACE inhibitors, ARBs, Statins) and supplements
- Adequate folate supplementation
- Stop smoking
- Good blood pressure control (<130/80 mmHg)
- Assess for nephropathy, retinopathy, thyroid dysfunction, UTI, autonomic neuropathy, cardiac dysfunction and manage/ refer accordingly
- Highlight the need for: -
  - regular visits (1st trimester: monthly visits, 2nd trimester: 2–4 weekly visits, 3rd trimester: 2-weekly visits)
  - regular home blood glucose monitoring
  - adjusting insulin doses depending on blood glucose levels
  - normal routine ANC profile and need repeat screening for complications in the 2nd and 3rd trimester (urinalysis, UECs, FBC, Ultrasound)
  - an appropriate diet
  - appropriate exercises during pregnancy

ii. Pregnancy care

- Multi-disciplinary care is important and should include the following– diabetologists/physician, obstetrician, diabetes educator, dietitian, neonatologist/pediatrician (include the process of follow up and antenatal management). Patients should be referred to facilities offering specialized care.

- Regular blood glucose monitoring to achieve the preset targets for pregnancy.
  - HbA1c 6.0% - 6.5%,
  - FBS < 5.3 mmol/L,
  - One hour postprandial < 7.8 mmol/l,
  - two-hour postprandial < 6.7 mmol/l
- Nutritional counseling should be offered during pregnancy
- Regular exercise i.e. walking at least 30 minutes per day
- Regular clinic visits
- Metformin and Glibenclamide can be used safely in pregnancy as long as sugars are controlled to target
- If sugars remain elevated, intensification of therapy must be considered, including a switch to insulin therapy
- Patients with T1DM must remain on insulin therapy titrated to target
- Due to the changes in pregnancy and increasing weight gain, most women will be better controlled on insulin management.
- Low dose aspirin (75 mg OD) should be given for pre-eclampsia prophylaxis from 12 weeks to term.
- First trimester nausea and vomiting may cause both hyper and hypoglycemia that would warrant changes in therapy and dosing.
- An ultrasound (specifically a fetal anomaly scan) should be done at 18-24 weeks to rule out congenital anomalies.
- Monthly scans should be done from 28 weeks till term to assess for fetal growth and amniotic fluid index (AFI). An AFI >25(polyhydramnios) is an indication of poor glycemic control.
- Ensure normal routine ANC profile and need repeat screening for complications in the 2nd and 3rd trimester (urinalysis, UECs, FBC, Ultrasound)
- Assess for nephropathy, retinopathy, thyroid dysfunction, UTI, autonomic neuropathy, cardiac dysfunction and manage/ refer accordingly
- Aim for delivery at 38 weeks, giving steroids to assist foetal lung maturity is beneficial
- Delivery can be spontaneous, induced, elective or emergency caesarean section
- Delivery should be in hospital

Definitive pharmacological management during pregnancy

- Insulin is the medication of choice for pregnant patients with diabetes
- Manage patients on OGLAs (Metformin and Glibenclamide) if sugars are well-controlled

iii. Management during labor or caesarean section

Glycaemic control during labour and birth is of utmost importance to avoid adverse neonatal outcomes. It is essential that blood glucose is monitored hourly during labour and birth, ensuring that it is maintained between 4-7 mmol/l. Intravenous glucose, potassium and insulin (GKI) infusions (10% dextrose 500 mls + 10 mmol of potassium chloride + Regular insulin (10-14 units) depending on blood glucose, to run 5 hourly) should be prescribed at the onset of labour. These infusions are also useful for glycaemic control during caesarian section.

Following delivery and removal of placenta insulin dose in the GKI reduces by half (GKI – 10% dextrose 500 mls + 10 mmol of potassium chloride + Regular insulin (5-7 units) to run 5 hourly) to prevent Hypoglycemia in the mother.
Once the mother is allowed to feed give the mother pre-pregnancy doses of insulin or oral hypoglycaemic.

For the neonate: -

- A blood glucose MUST be done for the neonate at birth. If baby is stable and no hypoglycemia, initiate breastfeeding.
- It's advisable to admit the neonate for 6 -24 hours in the new-born unit if hypo glycemic and symptomatic.
- Monitor blood glucose 3 hourly for 24-48 hours
- Aim at maintaining the blood glucose 4 - 7 mmol/L.
- If blood glucose is less than 2.8 mmol/L give a bolus of 10% dextrose 2 mls/kg and feed.
- Monitor for any neonatal complications.
- Encourage breastfeeding
- A neonate born to a mother who had poor control especially in the first trimester should be screened for congenital anomalies.

iv. Postpartum Care

- Ensure breastfeeding has been established
- Increase surveillance for puerperal infections especially surgical incisions and wounds.
- Patient should go back to pre-pregnancy doses of insulin or OGLAs
- Maintain blood glucose control between 5-9 mmol/L
- Encourage contraceptive use at 6 weeks. Any patient with vascular complications should avoid estrogen-containing contraceptives.

Gestational Diabetes Mellitus

GDM is asymptomatic and diagnosis must be sought after actively.

Women at high risk of GDM;

- BMI>30kg/m2
- Age > 35 years
- Previous history of GDM
- Persistent Glycosuria
- Previous large baby (> 4 kg)
- Poor obstetric history (previous miscarriages, still births, previous congenital anomalies)
- Family history of diabetes (First degree relatives)
- Pregnancy with polyhydramnios
- Polycystic ovarian syndrome
- Known IGT / IFG
- Grand multipara
- Multiple gestation

If the woman has more than one risk factor, do an RBS/FBS at first contact.
Screening

- Screening should be done at 24-28 weeks (or at first contact if patient presents late).
- Perform a 75-g OGTT - Administer 75 g of glucose orally after an 8-hr. overnight fast and do a blood glucose level after 1 hour and 2 hours (1 standard level tea spoon =5 g).
- Diagnostic criteria: Refer to table 37 above

Management

- Advise patient on healthy diet
- Monitor blood glucose regularly. Aim for: -
  - FBS < 5.0 mmol/l
  - Pre-meal < 6.0 mmol/l
  - 1 hr. post prandial < 7.8 mmol/l
  - 2 hr. post prandial < 6.7 mmol/l
- If blood glucose is not optimized within 2 weeks then put the patient on
  - OGLAs (Metformin)
  - Insulin (15 – 30% of patients will require insulin)
- Follow-up similar as for patients with diabetes in pregnancy

- Delivery at 38 weeks is advised if the sugars are well controlled. If poorly controlled consult a specialist on timing of delivery.
- Consider steroid administration for lung maturation if early delivery is indicated.
- If steroids are administered at any point in the pregnancy, anticipate difficult glycemic control and insulin therapy is advised.
- Aim target blood glucose level 4-7 mmol/L during active labor and delivery.
- Anticipate maternal and fetal/neonatal complications at delivery and plan for necessary interventions.

Postpartum Care

- After delivery
  - Stop OGLA and insulin
  - Monitor the blood glucose
  - If blood glucose goes above RBS 7.8 mmol/L or FBS 6.1 mmol/L post-delivery, manage as pre-existing diabetes
  - If blood glucoses are normal post-delivery, repeat OGTT with 75 g Glucose at 6 weeks to exclude ongoing DM. or IGT.
  - If OGTT at 6 weeks is normal encourage patients to do an annual fasting blood glucose thereafter.
  - Counsel on future risk of GDM and/or diabetes.
  - Encourage exercise, proper diet and normal BMI
  - Encourage contraceptive use at 6 weeks.

Complications of GDM and diabetes in pregnancy

Hyperglycemia in pregnancy is associated with higher incidence of both maternal and perinatal morbidity and mortality. When glycemic control is poor in the first few weeks of life as may be seen in DIP, there may be defective organogenesis in the fetus. This results in non-chromosomal congenital malformations. Other complications are tabulated in table 39 below.

Table 39: Effects of diabetes on the mother and fetus or newborn

	Maternal	Fetal/Neonatal
During Pregnancy	Miscarriages	Macrosomia > 4 kg
	Urinary tract infections	Congenital malformations
	Pre-eclampsia/Eclampsia	Sudden fetal demise
	Polyhydramnios	
	Pre-term labour	
Intra and Post-partum	Shoulder Dystocia	Musculoskeletal injuries
	Instrumental delivery	Erb's palsy (after shoulder dystocia)
	Perineal tears	Respiratory distress syndrome
	Cesarean delivery	Neonatal hypoglycemia
	Post-partum hemorrhage	Neonatal polycythemia
	Thromboembolism	Neonatal hyperbilirubinemia
	Post-partum/post-operative infection	Neonatal hypomagnesemia
		Neonatal hypocalcemia
Long term	Cardiovascular disease	Obesity
	*GDM in subsequent pregnancies	Diabetes
	*Overt DM	Metabolic Syndrome
	** Acceleration of pre-existing nephropathy and retinopathy	Hypertension

Specific to patients with GDM
****Specific to patients with DIP***

5.2 Management of diabetes during fasting

Fasting for patients with diabetes is often a personal decision. Patients who insist on fasting should be made aware of the risks involved in fasting, and it should be in done consultation with the physician.
Recommendation by physician in most cases, will be not to undertake fasting.
NB: For fasts >12 hours, please consult the health care practitioner.

The principles of Ramadan/fasting considerations are: -

- Assessment of metabolic control of the patient
- Adjustment of the diet protocol for Ramadan/ fasting
- Adjustment of the drug regimen
- Encouragement of continued appropriate physical activity
- Education on recognition of warning symptoms of dehydration, hyperglycemia and hypoglycemia

Patients may be classified as: -

- Very high risk
- High risk
- Moderate risk
- Low risk (see table 39)

Table 40: Risk categories of patients with diabetes with regards to fasting

Risk category Religious opinion	Patient characteristics	Comments
Category 1: very high risk Very high risk of hypoglycemia (poor outcome) Listen to medical advice Fasting is STRONGLY NOT advised	One or more of the following: • Severe Hypoglycemia within the three months prior to Ramadan • DKA within the three months prior to Ramadan • Hyperosmolar hyperglycaemic coma within the three months prior to Ramadan • History of recurrent Hypoglycemia • History of Hypoglycemia unawareness • Poorly controlled Type 1 DM • Acute illness • Pregnancy in pre-existing diabetes, or GDM treated with insulin or Sulphonylureas • Chronic dialysis or CKD stage 4 & 5 • Advanced macrovascular complications • Old age with ill health	If patients insist on fasting then they should: • Receive structured education • Be followed by a qualified diabetes team • Check their blood glucose regularly (SMBG) • Adjust medication dose as per recommendations • Be prepared to break the fast in case of hypo- or hyperglycaemia • Be prepared to stop the fast in case of frequent hypo- or hyperglycaemia or worsening of other related medical conditions

Category 2: high risk Listen to medical advice Fasting NOT advised	One or more of the following: • Type 2 DM with sustained poor glycaemic control* • Well-controlled Type 1 DM • Well-controlled Type 2 DM on MDI or mixed insulin • Pregnant Type 2 DM or GDM controlled by diet only or metformin • CKD stage 3 • Stable macrovascular complications • Patients with comorbid conditions that present additional factors • People with diabetes performing intense physical labour • Treatment with drugs that may affect cognitive function	If patients insist on fasting then they should: • Receive structured education • Be followed by a qualified diabetes team • Check their blood glucose regularly (SMBG) • Adjust medication dose as per recommendations • Be prepared to break the fast in case of hypo- or hyperglycaemia • Be prepared to stop the fast in case of frequent hypo- or hyperglycaemia or worsening of other related medical conditions
Category 3: moderate/ low risk Listen to medical advice	Well-controlled Type 2 DM treated with one or more of the following: • Lifestyle therapy • Metformin • Acarbose • Thiazolidinediones • Second-generation sulphonylureas • Incretin-based therapy • SGLT-2 inhibitors • Basal insulin	Patients who fast should: • Receive structured education • Check their blood glucose regularly (SMBG) • Adjust medication dose as per recommendations

**** treatment must be individualized***
**** Analogue insulins preferable***

General considerations

- Individualization of management plans
- Blood glucose monitoring- patients with type 1 diabetes and type 2 on Insulin
- Nutrition, encourage slow digesting foods including fibre containing-foods rather than refined foods.

Treatment Regimes

- Patients on insulin: Patients on twice daily insulin
- Reverse dosages and give pre-Ramadan morning dose with the evening meal and give 50-80% of pre-Ramadan evening dose with dawn meal
- Basal bolus regimes
- Decrease basal regime by 20-30%
- Increase evening bolus by 20-30% while decease morning bolus by 20-50%

Table 41: Summary of advice to Fasting patients with Type 2 diabetes

Treatment regimen	Fasting regimen	When to take OGLAs/Insulin
Diet only	Total or partial fast	Not applicable
Metformin/ Thiazo-lidinediones	Total or partial fast	With meals
Insulin secretagogues sulphonylureas	Partial fast	Before meals
Daily intermediate or long-acting insulin	Partial fast	Before first meal
Glinides	Total or partial fast	With meals
Multiple insulin doses using intermediate and short acting	Avoid fasting or pleasure fasting	Not applicable
Long-acting plus bolus fast acting insulin.	Avoid fast or partial fast	Lantus am and analogue with meals

5.3 Diabetes in the older adults

Factors that affect diabetes care in the older patient

- Impaired vision
- Impaired mobility
- Hearing impairment
- Poor nutrition
- Impaired memory/dementia
- Other illnesses such as high blood pressure, heart or renal impairment, recurrent UTI and pneumonias
- Multiple medications
- Lack of social or family support
- Depression
- Dental problems
- More prone to hypoglycemia (due to poor nutrition, renal impairment, use of long acting hypoglycemic agents)

How to cope with factors that limit diabetes care

- Hypoglycemia
  - encourage frequent small meals
  - adjust medications - if on insulin reduce insulin doses
- Use of sulfonylureas and insulin with caution due to risk of hypoglycemia, and dosage adjusted to individual patient situations.
- If on long acting OGLAs change to short acting OGLAs
  - Assess for renal impairment
  - Frequent blood glucose monitoring blood
  - Adjust blood glucose targets to appropriate for the older patients. (HbA1c 8%, blood glucose 5-10 mmol/l).
- Hearing impairment: a hearing aid, talking loudly and clearly, or using sign language
- Impaired vision: annual eye check-ups
- Impaired mobility: Assess for fall risk in all older patients. Need for regular foot screening, use appropriate footwear and supporting aids including crutches, walking frames, and artificial limbs, skin care
- Impaired memory: Additional caregiver support
- Multiple medications: educate patient and caregiver on the importance of adherence of pills, use of pill charts and pill containers. Use fixed dose combinations where possible to aid adherence.
- Dental problems: Meals need to be adapted to the person's ability to chew, dental check ups

- Lack of social and family support: Family, physical, psychosocial and emotional support is encouraged
- Vaccines: Annual flu vaccine, pneumococcal vaccine
- Need for regular clinical checkup and screening for recurrent UTI, thyroid dysfunction, liver and renal impairment, cardiac dysfunction, anemia and malignancy

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- Impaired mobility
- Hearing impairment
- Poor nutrition
- Impaired memory/dementia
- Other illnesses such as high blood pressure, heart or renal impairment, recurrent UTI and pneumonias
- Multiple medications
- Lack of social or family support
- Depression
- Dental problems
- More prone to hypoglycemia (due to poor nutrition, renal impairment, use of long acting hypoglycemic agents)

How to cope with factors that limit diabetes care

- Hypoglycemia
  - encourage frequent small meals
  - adjust medications - if on insulin reduce insulin doses
- Use of sulfonylureas and insulin with caution due to risk of hypoglycemia, and dosage adjusted to individual patient situations.
- If on long acting OGLAs change to short acting OGLAs
  - Assess for renal impairment
  - Frequent blood glucose monitoring blood
  - Adjust blood glucose targets to appropriate for the older patients. (HbA1c 8%, blood glucose 5-10 mmol/l).
- Hearing impairment: a hearing aid, talking loudly and clearly, or using sign language
- Impaired vision: annual eye check-ups
- Impaired mobility: Assess for fall risk in all older patients. Need for regular foot screening, use appropriate footwear and supporting aids including crutches, walking frames, and artificial limbs, skin care
- Impaired memory: Additional caregiver support

- Multiple medications: educate patient and caregiver on the importance of adherence of pills, use of pill charts and pill containers. Use fixed dose combinations where possible to aid adherence.
- Dental problems: Meals need to be adapted to the person's ability to chew, dental check ups
- Lack of social and family support: Family, physical, psychosocial and emotional support is encouraged
- Vaccines: Annual flu vaccine, pneumococcal vaccine
- Need for regular clinical checkup and screening for recurrent UTI, thyroid dysfunction, liver and renal impairment, cardiac dysfunction, anemia and malignancy

5.4. Management of Diabetes during Surgery

Good glycemic control has been shown to improve outcomes for patients undergoing surgery. As far as possible, patients with diabetes should be first on the theatre list.
A patient with diabetes undergoing surgery faces potential hazards in addition to the usual operative risks in a non-diabetic patient- Hyperglycaemia and ketosis
Perioperative complications - hypoglycemia, hyperglycemia and iatrogenic problems

i. Hyperglycaemia and Ketosis

- Due to the metabolic responses to stress of surgery especially in patients with insulin deficiency (type 1 and long-standing type 2 DM)
- Surgery induces a complex series of hormonal and metabolic changes
- Extensive operations cause greater metabolic disruption and insulin resistance i.e. heart surgery, laparotomies (open and laparoscopic)

ii. Perioperative complications

a. Hypoglycemia can occur in:

- Perioperative fasting
- Delayed effects of long acting insulins or OGLAs
- Major hazards' in the anaesthetized or sedated patient

b. Hyperglycaemia causes

- Wound infections due to impaired phagocyte function
- Delayed wound healing
- Myocardial infarctions
- Thromboembolic complications

c. Iatrogenic problems of diabetic control

- Hypoglycemia and hyperglycemia occur due to
  - Inadequate B/G monitoring
  - Poor management protocols

5.4.1. Pre-Operative Management

The diabetic patient requires the following tests and procedures before surgery:

- Baseline tests
  - FPG, U/E/Cs, LFT profile, Urinalysis, HbA1c, Lipid profile, Serum TSH
  - ECG
- Ensure adequate B/G/ control
  - FPG 4 - 7 mmol/l
  - Pre-meal 5 -9 mmol/l
- Patients for elective surgery not well controlled need to stabilized prior to admission for surgery. Patients with HbA1c >9% should have elective surgery postponed.
- Monitor blood pressure
  - Aim at 140/80 mmHg
  - Start anti-HT if elevated
- Prepare patient psychologically for operation
- Get written consent

5.4.2. Intraoperative management

The following are considerations for management of a patient with diabetes during surgical procedures

Table 42: Management of a patient with diabetes during surgery

Minor Surgery, OGLAs and Good glycaemic control	Major surgery or poor-glycaemic control on OGLAs	Patients on Insulin
Admit the patient day before surgery to confirm/optimize glycemic control	Admit the patient 1 – 2 days before surgery.	Admit patient 1 – 2 days before surgery.
Stop metformin/pioglitazone day before surgery.	Stop OGLAs and stabilize the blood glucose with short acting insulin.	Stabilize control if necessary, stop long acting insulin and put on short acting insulin.
Monitor blood glucose	Operate in the morning if possible.	Operate in the morning if possible.
Operate in the morning if possible.	Start GKI on morning of operation day	Start GKI on morning of operation day
Omit breakfast (and no OGLAs)	Omit breakfast and morning injection.	Omit breakfast and insulin injection.
Pre-op, intra-op and post-op avoid glucose and lactate containing fluids.	Monitor blood glucose 2 hourly. Maintain between 5-9 mmol/l	Monitor blood glucose 2 hourly Maintain between 5-9 mmol/l
Post-op – Monitor blood glucose 2 hourly and restart OGLAs with first post-op meal.	Post-op: Monitor blood glucose 2 hourly. Once allowed to feed, restart previous pre-operative s.c. insulin dose. Discontinue GKI 1 hour after eating.	Post-op: Monitor blood glucose 2-hourly. Restart previous pre-operative s.c. insulin with first post-op meal. Discontinue GKI 1 hour after eating.
	Continue with insulin regimen until restart of regular or discharge regimen.	Patients on long acting insulin can be converted back to their long acting insulin regimens.

(GKI – 10% dextrose 500 mls + 10 mmol of potassium chloride + Regular insulin (10-14 units) depending on blood glucose, to run 5- hourly
Patients with renal impairment GKI - 10% dextrose 500 mls + Regular insulin (6-8 units) to run 12-hourly

Recommendation: No minor or major operative surgery should be undertaken in a person with diabetes at a primary level health facility. Refer these patients, because specialist care is required

5.5. Diabetes and HIV

Diabetes as a HIV co-morbidity is increasing in both incidence and prevalence. HIV itself, and the treatment of the condition, both increase the risk for the development of diabetes. The increase in HIV testing and test to treat strategy has led to increased life expectancy of persons living with HIV(PLHIV). This has led to an increase in the chronic metabolic complications of both HIV and highly active anti-retroviral therapy (HAART) which amongst others include dyslipidaemia, accelerated atherosclerosis, osteoporosis, thyroid dysfunction, insulin resistance and diabetes mellitus.

5.5.1. Classification of HIV in patients with diabetes

Three subgroups of patients with HIV and diabetes can be identified:

i. Patients with pre-existing diabetes who contract HIV.
ii. Those who are diagnosed with both HIV and diabetes mellitus at the same time.
iii. Those who develop hyperglycaemia post-HAART initiation.

5.5.2. Risk factors for Diabetes in HIV patients

There are many factors that predispose HIV positive patients on HAART to developing diabetes.

i. Traditional Risk Factors for developing diabetes (similar to non-HIV patients)
ii. HIV related risk factors
    - HIV virus, viral load, CD4 count, duration of HIV infection.

HIV viral infection, through various inflammatory mediators and cytokines, can induce a state of insulin resistance. Most cases of HIV-associated diabetes are type 2 diabetes.

Auto-immune ß cell destruction has also been described.

- Rapid weight gain after the catabolic phase (return to health phenomenon). The rapid increase of body fat (visceral fat) instead of lean muscle mass that they would have lost during the catabolic phase of the disease. This can overwhelm the β cell secretory capacity leading to β cell failure, and induce insulin resistance.
- Co infection with hepatitis (Hepatitis C causes dysglycaemia)
- Dyslipidaemia with lipotoxicity
- Lipodystrophy
- Iatrogenic – Drugs (NRTIs, NNRTIs & Protease Inhibitors)

Table 43: Classification of drug classes by metabolic profile

Metabolically neutral NRTIs	Metabolically unsafe NRTIs	Protease inhibitors (PIs) with potential for adverse metabolic effects	Metabolically neutral Protease inhibitors (PIs)	Integrase Strand Transfer Inhibitors (INSTIs) (metabolically neutral)
Abacavir Tenofovir Emtricitabine Lamivudine	Stavudine* Didanosine* Zidovudine	Indinavir Ritonavir Saquinavir Lopinavir	Darunavir Atazanavir	Dolutegravir (DTG) Raltegravir

**drugs that have been phased out*

5.5.3. Screening for diabetes in HIV patients

i. All HIV positive patients should be screened for diabetes before initiating HAART or when changing ARVs.
ii. Patients with impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) should be screened every 3-6 months
iii. Patients with normal initial blood glucose levels should be screened annually.
iv. Fasting plasma glucose is preferred but standard 75 g OGTT is preferred in those with IGT or IFG with additional risk factors

5.5.4. Evaluation of a patient

Initial evaluation of a patient with both HIV and diabetes mellitus includes a detailed history which amongst others includes a detailed search for infections which are common in both conditions such as: -

- tuberculosis
- fungaemia
- sexually transmitted infections
- urinary tract infections

In addition, the evaluation should search for other chronic conditions that need to be aggressively managed and that will also influence the choice of anti-HIV drugs and diabetic drugs: -

- hypertension,
- renal impairment
- any form of dyslipidaemia
- thyroid dysfunction
- cardiac dysfunction

Initial investigations should include:

i. Full blood count
ii. Urinalysis
iii. Urea and creatinine with estimated GFR
iv. Liver function with hepatitis screen
v. CD4 count
vi. Viral load
vii. Fasting blood glucose (HbA1c may be used but the readings may be low in PLHIV)
viii. Serum lipids
ix. Thyroid function test (Serum TSH)
x. ECG
xi. Serum uric acid

5.5.5. Treatment of diabetes in HIV infected individuals

General measures

i. Appropriate treatment of opportunistic infections.
ii. Lifestyle modification, which includes physical exercise, smoking and alcohol cessation and where available, dietary advice, taking account of BMI, desired weight and comorbidities.
iii. Psychosocial support and both family and community involvement where feasible.
iv. Reinforce compliance at every visit.
v. Treatment of other cardiovascular risk factors:

•Dyslipidaemia – general measures and targets apply; the only major exception is that simvastatin is contraindicated in patients using protease Inhibitors as it competes for the same Cytochrome P450 Isoenzyme. Fluvastatin and pravastatin are safer.

•Hypertension – ACE Inhibitors and ARBs (Angiotensin Receptor Blockers) need to be used with caution: captopril has been associated with the development of Kaposi's sarcoma and enalapril may cause myalgias and diarrhoea. In addition, ARBs may compete with other drugs that are metabolized by cytochrome P450 Isoenzymes.

Use of glucose lowering agents in people living with HIV

Type 1 DM

All patients with type 1 diabetes mellitus and HIV should be managed with insulin therapy.

Type 2 DM

The following OGLAs can be used in treatment of diabetes among people living with HIV

i. Biguanides e.g. Metformin

This is the drug of choice for most patients with HIV. It should, however, be used with caution in patients with HIV associated enteropathy as the gastrointestinal side effects of metformin will be exaggerated.

It is contraindicated in patients with HIV associated nephropathy (HIVAN), liver disease, cachectic patients and tuberculosis as the risk of lactic acidosis is markedly increased. It should not be used in conjunction with thymidine-based NRTIs (Stavudine, Didanosine) as the risk of lactic acidosis is increased due to mitochondrial toxicity.

Extended release metformin is the preferred formulation of the drug.

ii. Sulfonylureas e.g. Glibenclamide, Gliclazide, Glyburide

The general principles apply as in non-HIV patients, but, caution must be exercised in patients with cachexia who might have depleted glycogen stores and who are at increased risk of Hypoglycemia.

Where possible, short acting or modified release formulations should be used.

iii. Meglitinides/Glinides

Because of their short acting profile and lower risk of Hypoglycemia, they are suitable drugs but are not commonly used locally.

iv. Insulin

Insulin remains the drug of choice for most patients with HIV and diabetes especially as both conditions are progressive. Insulin has anabolic effects, reduces inflammatory markers, has no interactions with antiretroviral drugs and can be used safely in patients with renal failure (with proper titration). It is important to note that insulin requirements might initially be high and will later fall as glucotoxicity is reversed and infections are controlled.

v. Other glucose lowering agents

There is currently no data available regarding the newer classes of drugs in HIV patients with diabetes, including DPP-4 inhibitors, SGLT-2 inhibitors and incretin receptor analogues.

Changing HAART
A patient who develops diabetes while on HAART with drugs that are potentially diabetogenic especially the protease inhibitors should be changed to anti-retroviral agents that are metabolically neutral.

5.6. Diabetes and TB

Diabetes is associated with higher risks of TB and adverse TB treatment outcomes like treatment failure and death. TB infection may progress at a faster rate in people with diabetes than in those without diabetes. In addition, TB tends to worsen glycaemic control in patients with diabetes.
A large proportion of people with diabetes as well as TB is not diagnosed, or is diagnosed very late. Early detection can help improve care and control of both illnesses

5.6.1 Effects of diabetes on TB

- Increases the risk of developing TB threefold
- Higher risk of latent TB infection
- Faster progression of TB infection to TB disease
- Altered clinical presentation of TB: More TB symptoms, poor performance status (ability to perform activities of daily living without help of others) compared to patients without diabetes
- Changes the sensitivity and specificity of conventional TB diagnostic algorithms.
- Adversely affect TB treatment outcomes by delaying the time to microbiological response/sputum culture conversion, reducing the likelihood of a favorable TB treatment outcomes, and increasing the risk of relapse or death
- Accelerate the emergence of drug-resistant TB, especially multidrug-resistant TB (defined as strains of TB resistant to both rifampicin and isoniazid)
- Interference with the activity of certain anti-TB medications

5.6.2 Effects of TB on diabetes

- TB prevalence and incidence are consistently higher in people with diabetes than in either the general population or in non-diabetic controls.
- TB may trigger the onset of diabetes, and worsen glycaemic control in existing diabetes
- TB medications may interfere with the treatment of diabetes through drug interactions

5.6.3 TB screening among diabetes patients

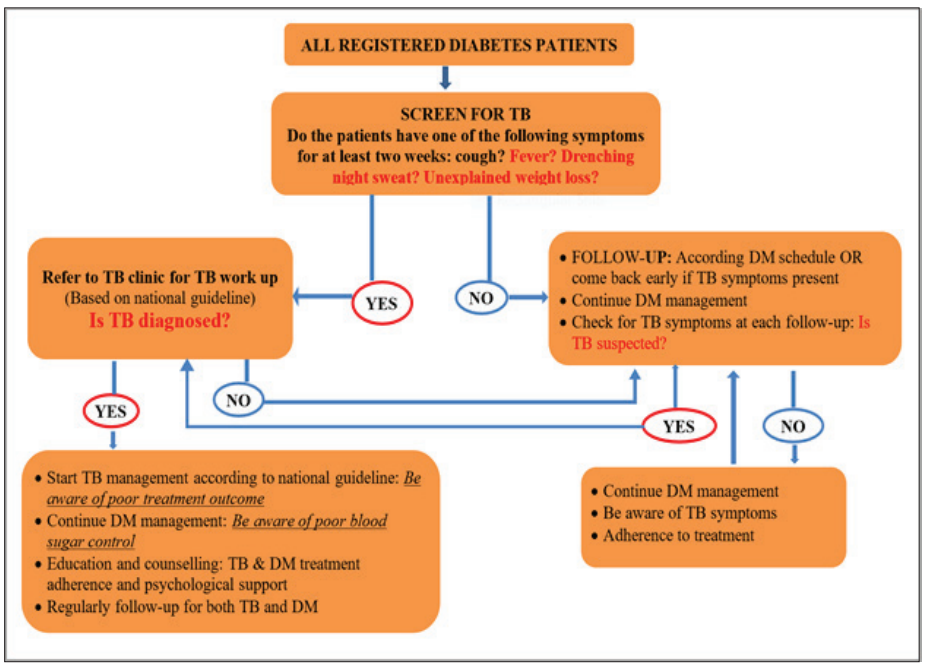


Figure 29: Algorithm for screening people living with diabetes for TB

Table 44: First line anti - TB regimen

	Intensive phase	Continuation phase
Adult and Pediatric TB except TB meningitis and osteo-articular TB	2RHZE	4RH
TB meningitis and osteo-articular TB	2RHZE	10RH

R-Rifampicin, H-Isoniazid, Z-Pyrazinamide, Ethambutol

- All TB/DM patients should receive pyridoxine for the duration of TB treatment to prevent neuropathy from anti TB drugs.
- Rifampicin may cause new-onset dysglycaemia or worsen glycemic control in existing diabetes.
- Rifampicin decreases concentrations of rosiglitazone by 54–65% and of the related drug pioglitazone by 54%
- Insulin requirements might increase when on rifampicin
- If the patient is on DR TB treatment with aminoglycosides, there should be close monitoring of the renal functions and liver function tests.
  In renal impairment, the dose of anti-TBs should be adjusted downwards according to the creatinine clearance.
- Do a renal function test monthly for DR TB/ Diabetes patients.
- Glycaemic control needs to be closely monitored in underweight co-morbid patients who would need an increased caloric intake and dose of Oral Glucose Lowering Agents (OGLAs)/insulin adjusted accordingly.
- OGLAs are contraindicated in severe TB disease but may be used with caution once the disease has settled.
- Insulin is the recommended treatment for patients with severe TB, renal and liver impairment.

Recommendation
Need for integrated chronic care model clinic.

CHAPTER SIX

CHAPTER SIX

LIVING WITH DIABETES

6.1. Introduction

Diabetes mellitus is a lifelong condition, but if well controlled one can live a long healthy productive life. People living with diabetes require lifestyle adjustments in their diet, exercise and frequency of review by their medical providers. They may need to take daily medications or insulin to keep their blood glucose levels in check. Having diabetes means adjusting at work and at home. But these changes don't mean one won't be able to succeed at work or enjoy a healthy and fulfilling life. People with diabetes have equal rights with those without the condition and should be protected from all forms of discrimination.

6.2. Employment

A person with diabetes, particularly if treated with insulin, requires certain adjustments in ordinary daily life. Health-care providers require the knowledge, skills and attitudes to provide appropriate advice.

The commonest problem is prejudice in the workplace. Such prejudice is usually because of ignorance and misperceptions that all people with diabetes will have work performance issues.

This prejudice causes some people with diabetes to try and conceal their condition from their employers and workmates. This must be discouraged as concealment may result in poor adherence, lack of appropriate social support, anxiety and consequently poor performance.

Persons living with diabetes should be encouraged to disclose their condition to the employer as they have a right to support in the workplace. Disclosure will improve capacity to perform and live positively.

Individuals in shift work need special attention to tailor the work conditions to support optimal performance with their conditions and prevent possible acute events during working hours.

Patients should be encouraged to disclose to at least two colleagues and to health personnel where there are staff clinics to allow persons who can provide first aid in case of an acute diabetes emergency.

A person living with diabetes should be eligible for any form of employment and career.

6.3. Driving, Flying and Operating Machines

The healthcare provider should establish the profession of their patients. Individuals in the above professions should receive detailed and individually-tailored management plans to prevent catastrophic events related to diabetes emergencies.

All drivers, pilots and machine operators must act responsibly and schedule their medications and eating pattern to avoid Hypoglycemia. Individuals who are newly diagnosed and whose sugars are not stable should avoid driving and operating machinery.
In addition, it is their responsibility to disclose severe hypoglycemia, and other diabetes related complications (e.g. visual impairment from retinopathy) that may lead to adverse outcomes, and ensure appropriate measures are in place to avoid these events, even if it means changing the nature of work duties.

Individuals on insulin and insulin secretagogues should be advised to inform their employers and the licensing authorities.
Pilots should refer to the Kenyan Aviation Guidelines for further guidance.

Basic Advice:
- Inform your Insurance Company of your condition
- Always keep glucose or sweet eatables accessible at all times
- Never drink alcohol and drive, fly or operate machinery
- Never miss a meal if you intend to drive, fly or operate machinery.

6.4. Insurance

Most people with diabetes are asked to pay additional premiums for life assurance and sickness insurance. Some are denied insurance outright.
There should be unbiased access to insurance policies (life or sickness) at a reasonable cost.

Individuals should be encouraged to enroll with the National Hospital Insurance Fund (NHIF).

Insurance providers and employers should be encouraged to invest more in screening, prevention and quality care outpatient programs to minimize overall costs incurred by managing the complications of diabetes.

6.5. Sports, recreational and occupational exercise

Regular exercise is an integral part of management of diabetes. It has many benefits including glycemic and blood pressure control as well as improvement of general well-being.

Treatment with insulin and oral glucose lowering agents (OGLAs) do not preclude vigorous sports and exercise, unless underlying ischemic heart disease or significant microvascular complications, e.g. advanced retinopathy, are present.
There is a possibility of Hypoglycemia as a result of exercise or vigorous sports. Hypoglycemia may occur some hours after exercise, because the liver and muscles are still replenishing glycogen stores. Exercise with poor glycemic control may predispose to DKA.
Exercise or sports may need to be accompanied by extra food or adjustment in OGLA or insulin dosage.
If vigorous sporting activity is being considered, the person should consult with their healthcare provider, and should have good metabolic control to reduce the risk of Hypoglycemia and DKA.

Principles of Exercise in the setting of Diabetes

1. **Level of glycaemia.** Test for blood glucose before and after exercise and if any symptoms of hypoglycemia
   Avoid moderate to vigorous exercise if:
   - FBS>13.8 or RBS>16 mmol/L
   - Presence of ketones
   - Poor glycemic trend in the preceding days.
2. **Timing of exercise should be in relation to injection.** The dose of rapid acting
   Insulin should be reduced before the period of exercise.
3. **Exercise in relation to meals:** Take a glucose rich snack before exercise e.g. a banana, fruit juice, a slice or two of bread. One can sip juice during exercise.
4. **Presence of complications:** If individual with chronic complications (Neuropathy, retinopathy, cardiovascular complications) should involve a healthcare provider in prescription of exercise.

Table 45: Insulin adjustment before exercise

	Duration of exercise and the recommended percent reduction in bolus insulin at the meal before planned exercise	
Intensity of aerobic exercise	**30 minutes**	**60 minutes**
Mild	25%	50%
Moderate	50%	75%
Heavy	75% -	

Source: Kelly D, Hamilton JK and Riddell M.C. Blood glucose levels and performance in a sports camp for adolescents with a basal-bolus insulin regimen (ultra-Lente-lispro) in children with type 1 diabetes mellitus: a field study. Diabetes care 2001: 24: 4: 625-630

6.6. Diabetes and School

It is normal for parents to feel anxious about having a child with diabetes in school. With good planning and appropriate education, children can have a normal school experience and engage safely in all school activities

- Parents should inform the school of their child's condition, requirements for care and provide contacts of child's healthcare provider.
- It is important that the needs of each student with diabetes are recognized and accommodated according to the student's individual care plan.
- It is essential that school personnel have accurate and current information about diabetes and how it is managed to reduce stigma and other problems that may put the student's health and safety at risk.

The school environment should provide the following: -

- Right for admission to school and right to appropriate care
- Right to integrate into school environment and engage in all activities
- Right to attain development goals, peer acceptance and development of self-esteem.
- Facilitate timely access to diabetes management supplies (insulin) and equipment e.g. glucometers, strips and sharps containers.
- Unrestricted access to healthy snacks, water and bathroom breaks.
- Classroom glucose monitoring
- Access to identified and trained personnel within the school (school nurse, teacher or other staff)

6.7. Caregiver and Family Support

Caregivers and family are an integral part of diabetes care. Caregivers should be trained on the basics of diabetes management including response to acute emergencies.

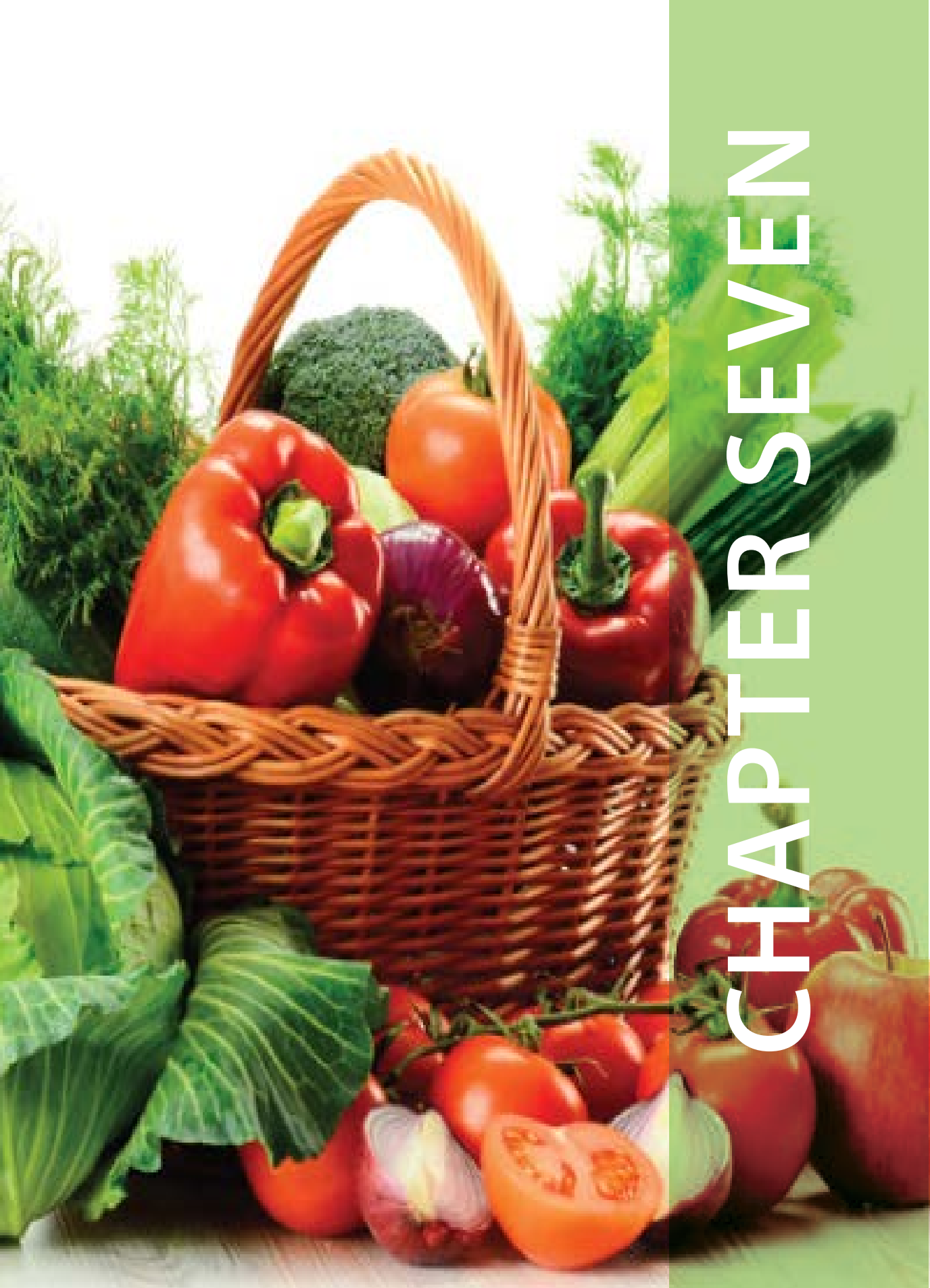
The key areas of support include:

- Adherence with medication, follow up and diabetes self-management
- Adherence to healthy lifestyle
- Psychosocial support
- They may form the link between the client and the healthcare worker.

The role of the caregiver comes with the potential for burn-out and stress due to the chronic nature of the condition.

Tips for caregiver:

- Continue to take care of your own health and walk the talk.
- Find someone to talk to when caregiving becomes overwhelming and/or seek peer/group support.
- Avoid taking on too much and learn to say no and prioritize.
- Ask for and accept help. Involve family, friends and the health care provider



CHAPTER SEVEN

CHAPTER SEVEN

PREVENTION OF DIABETES

7.1. Introduction

Prevention refers to actions aimed at eradicating, eliminating or minimizing the impact of diabetes and disability. (Last, 2008)
Diabetes prevention can be categorized into groups:

- Primordial Prevention
- Primary prevention
- Secondary prevention
- Tertiary prevention

7.2. Primordial Prevention

Primordial prevention refers to prevention of adoption of risk factors which can predispose to type 2 diabetes.
Social and environmental conditions contribute to the emergence of risk factors for diabetes. These include eating patterns, levels of physical activity, habits such as tobacco use and alcohol consumption.

The main intervention in primordial prevention is through individual and mass health education. These include school and community-based programs that promote physical activity, improve nutrition, limit alcohol consumption and prevent smoking and other tobacco use. Advocate for comprehensive Worksite Wellness Programs.

7.3. Primary Prevention

Primary prevention can be defined as an action taken prior to the onset of diabetes, which reduces the possibility that diabetes will occur. It therefore has an impact by reducing both the need for diabetes care and the need to treat diabetes-related complications.

Primary prevention can be achieved by health promotion which include health education, environmental modification, nutritional intervention, lifestyle and behavioral changes. This can be achieved through population (mass) strategy and high-risk individual strategy.

While there is yet no conclusive evidence to suggest that type 1 diabetes can be prevented, primary prevention of type 2 diabetes is potentially possible. The components of lifestyle modification and their aims should include, but not be limited to, the following list:

- Obese/ Overweight patients - Weight loss of 5-10% with an aim to achieving ideal sustained body weight
- Modify dietary patterns focusing on
  - Reduction in fat intake
  - Increase in fibre, vegetables and fruits intake
- Increase in physical activity levels. e.g. brisk walking 30 minutes, five times a week. Exercise should be tailored to the individual
- Alcohol intake should be limited to less than one drink per day of any type (1 standard alcoholic drink per day (7 units per week) for women, 2 standard alcoholic drinks (14 units per week) for men.
- Screening of people at high risk of developing diabetes
- Cessation of tobacco use.

7.4. Secondary prevention

This involves action that halts the progress of diabetes at its early stage and prevent complications. Secondary prevention attempts to arrest the diabetes progression, restore health by seeking out unrecognized disease and treating it before irreversible pathological changes take place.
There are several landmark studies that have shown that good glycemic with HbA1c < 7%, blood pressure <140/80 mmHg and lipid control prevent progression of complications of diabetes.

7.5. Tertiary Prevention

Actions taken when diabetes has progressed beyond its early stages. It is defined as all the measures available to reduce or limit impairments and disabilities, and to promote the patients' adjustment to irreversible conditions. This involves strict metabolic control, diabetes education, effective treatment, screening and monitoring of complications. Examples - regular assessment for foot, eye, kidney, skin and heart disease. The blood glucose, blood pressure and lipid control are important in tertiary prevention.

CHAPTER EIGHT

CHAPTER EIGHT

ORGANIZATION OF DIABETES CARE

8.1. Introduction

Diabetes is a complex disorder, a systematic approach to the organization of care is essential. There are several elements to this approach. These include:

- well trained and dedicated personnel,
- calibrated and functioning equipment,
- management and referral protocols,
- continuous supply of medication,
- a register of all patients to facilitate recall for non-attendance and for specific aspects of regular care,
- legible patient records
- Diabetes care management flow charts and algorithms
- Annual review charts are useful for follow up of clinical and biochemical measurements.
- A history, clinical examination and appropriate biochemical evaluation.

A process of regular audit with the implementation of interventions to improve care needs to be instituted. The clinic should be a one stop care center that is multi-disciplinary and patient centered clinic.

8.2. Leadership and governance

Diabetes screening, treatment and care is complex and requires clear leadership at all levels of care. The division of Non-Communicable Diseases at the Ministry of Health provides national leadership on implementation of Diabetes prevention, care and treatment. To achieve the desired outcomes of the National NCD Strategy, the National Diabetes Program will provide technical leadership in planning for diagnosis, treatment, resource mobilization, palliation, research and data management for Diabetes.

At the county level, county NCD coordinators and county health management team will be responsible for the coordination of diabetes related activities. The counties will coordinate the establishment of diabetes care committees at facility level.

Roles and Responsibilities for each Level

National level:

- Assess the Diabetes epidemiological and health delivery patterns in the country.
- Develop national level policies, strategic plans and planning guides for lower levels.
- Support resource mobilization.
- Coordinate stakeholders and partners on Diabetes management in the health sector.
- Consolidate, analyze and disseminate Diabetes data.
- Support human resource development and deployment for Diabetes management.
- Support infrastructure and equipment procurement for Diabetes management

NCD County coordinators:

- Coordinate Diabetes management at county level.
- Advocate for resource allocation for county health care needs.
- Consolidate data from the county facilities.
- Monitor service delivery and ensure quality and responsiveness of Diabetes management.
- Support supervision and training coordination.
- Plan for management and utilization of available resources for service delivery.
- Manage inputs including staff, equipment and pharmaceuticals.
- Organize service coverage, collection of data and appropriate referral management.

Community unit linked to health institutions:

- Assist in establishment of Patient Support Group
- Patient referral and follow-up.
- Advocacy for prevention and control of Diabetes.
- Provision of palliative care for people with chronic complications
- Integration of Diabetes issues into other community-based programs e.g. Microfinance

Table 46: Personnel and services offered per health-care tier

Health Care Tier	Personnel	Services offered
Community Services	– Community Health Worker – Community Health Extension Worker – Trained health personnel – Nutritionists	– Distribution of IEC materials – Health promotion and behaviour change communication (BCC) – Community mobilization – Screening and outreach – Home based and palliative care; home blood glucose monitoring – Community Health Information Systems – Contact tracing and defaulter tracing – Support groups establishment – Referral and linkages
Dispensary and Health Centre (Primary Care Service)	– Nurse – Clinical Officer – Public Health Officer/ Public Health Technician – Medical Officer – Nutrition	– Distribution of IEC materials – Health promotion and behaviour change communication (BCC) – Screening for diabetes, hypertension and TB – Centre for in- and outreach screening services – Diagnosis and management of uncomplicated diabetes and hypertension – Initiation of 1st line diabetes medication for uncomplicated DM – Nutritional assessment and counselling – Referral for diabetes related complication – Follow-up care – Palliative care – Diabetes data collection and reporting – Diabetes Foot Screening

County Referral Service (Primary Referral Services)	– Specialists – Public Health Officer – Diabetes educators – CHEW – Nurse – Clinicians – Nutritionist – Medical Officer – Pharmacist	– Distribution of IEC materials – Health promotion and behaviour change communication (BCC) – Screening for diabetes and TB – Diagnosis of diabetes and hypertension – Initiation of diabetes and hypertension treatment and follow-up, including second-line therapy, insulin and comorbidity management – Inpatient care – Nutritional assessment and counselling – Diabetic foot assessment and management – Referral for special conditions e.g. cardiac complications – Palliative care – Coordination/M&E – Research – Diabetes data collection and reporting
National Referral Services (Tertiary Referral Services)	– Nurse – Pharmacist – Clinicians/specialists – Nutritionist – Counsellors/diabetes educators	– Same as County Referral Services plus – Management of severe complications

IEC-Information,e ducation and communication; BCC-b hav iour chng communica

8.3. Requirements for a Diabetic Clinic

- **Well trained, dedicated and motivated staff**

- **Adequate space:**
  - For individual consultation
  - For group education

- **Protocols covering:**
  - Screening and diagnosis
  - Regular care, including referrals

- **Equipment:**
  - Tape measure (waist circumference)
  - Weighing Scale
  - Height measure
  - Functional and calibrated BP machines, with pediatric, normal and large cuff sizes
  - Monofilament and 128 Hz tuning fork
  - Glucometers in good working order
  - HbA1c testing equipment, to enable testing on site
  - Appropriate educational material

- **Diabetes Care Package** - All new diagnosed patients should be provided with a minimum care package that should contain (a glucose testing meter, one-month supply of testing strips, medicines supply and if on insulin, provided with syringes to last for one month and educational materials

- **Regular supply of medication**
  - Supplies shall be dispensed to cover for at least 30 days. For instance, patients on insulin should be provided with a pack ('Diabetes Care Package') containing a 30-day supply of insulin, 30 insulin syringes with the smallest available needle gauge and educational material (injection technique and rotation chart)

- **Register with recall system for non-attenders**

- **Annual audits of:**
  - Numbers of patients receiving designated processes of care
  - Numbers of patients reaching targets for glycaemia, blood pressure (BP) and lipids as per National Guidelines
- A checklist of minimum expected history, clinical examination, investigations, treatment and the intervals for review that is initial, 3-6 months or annually. The care at each visit will depend on whether it is an initial consultation, follow-up consultation or an annual review. (Refer to Table 6 and 12)

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APPENDICES

ANNEX 1: CARDIOVASCULAR RISK STRATIFICATION TOOL

Other risk factors, asymptomatic organ damage or disease	Blood pressure (mmHg)			
	Pre-HTN SBP 130–139 or DBP 85–89	Stage 1 HTN SBP 140–159 or DBP 90–99	Stage 2 HTN SBP 160–179 or DBP 100–109	Stage 3 HTN SBP ≥180 or DBP ≥110
No other RF		Low risk	Moderate risk	High risk
1–2 RF	Low risk	Moderate risk	Moderate to high risk	High risk
≥3 RF	Low to moderate risk	Moderate to high risk	High risk	High risk
OD, CKD stage 3 or diabetes	Moderate to high risk	High risk	High risk	High to very high risk
Symptomatic CVD, CKD stage ≥ 4 or diabetes with OD/RFs	Very high risk	Very high risk	Very high risk	Very high risk

BP = blood pressure; CKD = chronic kidney disease; CV = cardiovascular; CVD = cardiovascular disease; DBP = diastolic blood pressure; HT = hypertension; OD = organ damage; RF = risk factor; SBP = systolic blood pressure.

Risk factors(RF) include: smoking, age (men >55 yrs, women <65 years), dyslipidaemia, male sex, obesity, central adiposity, family history of premature CVD(men <55 years, women <65 years) and impaired glucose tolerance)

Figure 30: Stratification of total CV risk based on SBP and DBP and prevalence of Risk factors, asymptomatic OD, diabetes, CKD stage or symptomatic CVD

Adapted from the ESH/ESC Guidelines for the management of arterial hypertension, 2013

ANNEX2: APPROPRIATE FOOT WARE FOR PEOPLE LIVING WITH DIABETES

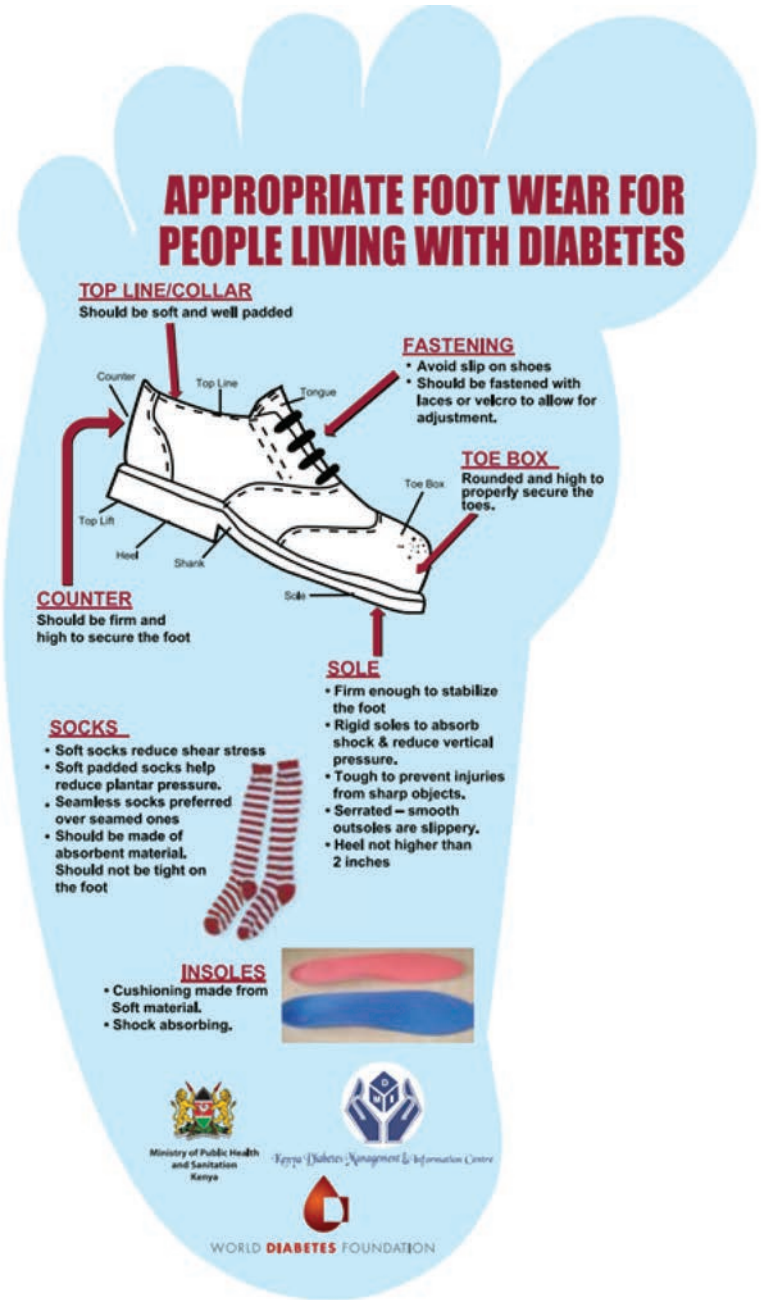

Figure 31: Appropriate Footwear for persons living with diabetes

ANNEX 3: EXAMPLE OF 7 POINT TESTING PROFILE CHARTERED FOR 3 DAYS

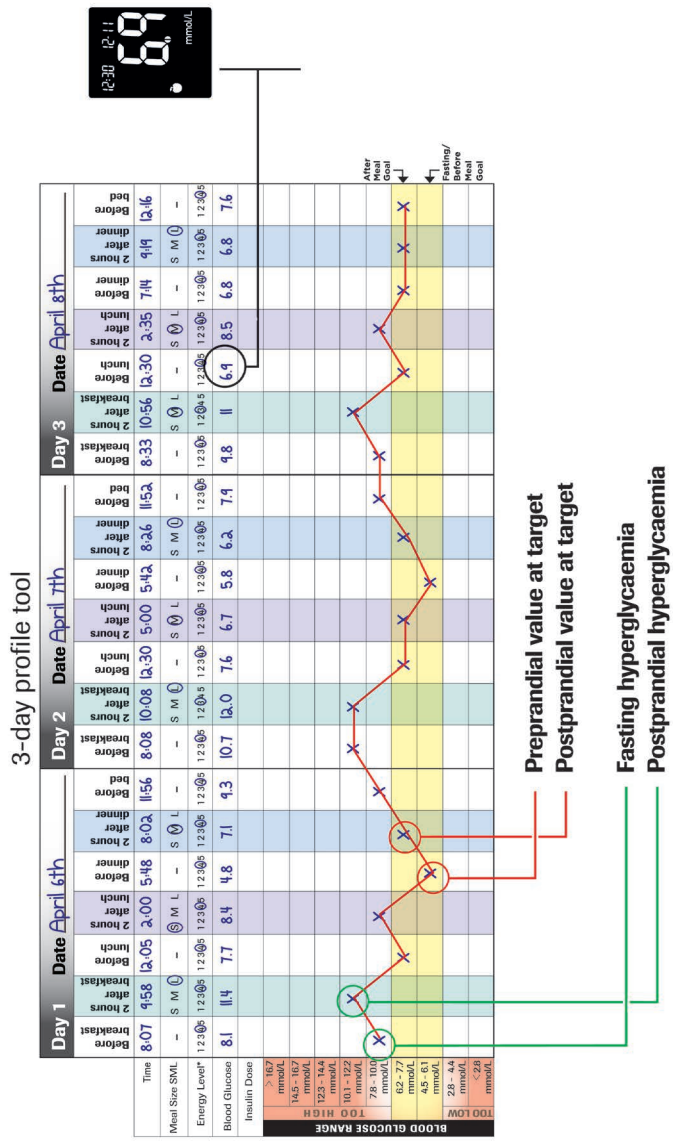

Figure 32: Example of a charted for 3 days 7-point testing profile
Source: Roche Accu-Chek®

Table 47: List of Technical Working Group Members – Clinical Guidelines

Name	Organization
Dr. Joseph Kibachio	MOH-DNCD
Zachary Ndegwa	MOH-DNCD
Dr. Gladwell Gathecha	MOH - DNCD
Scholastica Owondo	MOH-DNCD
Dr. Martin Mwangi	MOH-DNCD/ FELTP
Samuel Kiogora	MOH-CHS
Peris Mbugua	MOH-DNCD
Dr. Loise Nyanjau	MOH DNCD
Dr. Ephantus Maree	MOH-DNCD
Dr. Grace Kariuki	MOH-DNCD/FELTP
Dr. Oren Ombiro	MOH-DNCD/FELTP
Eva Muchemi	DMI Centre
Eric Omondi	DMI Centre
Dr. Catherine Karekezi	DMI centre
Anne Gathura	Nairobi County
Dr. Claris Ambale	Machakos County
Dr. Bernadine Lusweti	Thika level 5
Dr. Eva Njenga	Diabetologist
James Katama	CHAK HQ
Dr. Nancy Kunyiha	Diabetologist/AKUH
Dr. Nancy Ngugi	Diabetologist/KNH
Isaac Miruka	KNH
Irene Kamau	KNH
Dr. Paul Laigong	KNH
Dr. Jemimah Kamano	MTRH/AMPATH
Dr. Nicholas Kirui	MTRH/AMPATH
Jackline Kerubo	MTRH
James Nduati	Public Health Specialist
Dr. Joyce Mbogo	Pediatrician
Beatrice Gachambi	MSF
Dr. Yvonne Nzomukunda	MSF
Lili-Marie Wangari	MSF
Dr. Evelyn Mwania	Novartis
Dr. Ningala Kinyua	BD
Lilly Kamande	Roche
Karim Mounir	Boehringer Ingelheim


Canon

Ministry of Health

Division Non-Communicable Diseases

Division of Non-communicable Diseases
Afya House, Cathedral Road
P.O. Box 30016 – 00100
Nairobi, Kenya.

Telephone: +254 202 71 7 071

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