Clinical Practice Recommendations for the Management of Type 2 Diabetes Mellitus 2020

Executive Summary
Diagnosis of diabetes

Recommendations

Recommended care

Prediabetes can be diagnosed with any of the following criteria:

- Impaired fasting glucose (IFG): FPG 100 mg/dL to 125 mg/dL or
- Impaired glucose tolerance (IGT): 2-h PG during 75-g OGTT 140 mg/dL to 199 mg/dL or
- HbA1c ≥ 5.7–6.4%

Diabetes can be diagnosed with any of the following criteria:

- FPG ≥ 126 mg/dL*
- FPG ≥ 126 mg/dl and/or two hour plasma glucose ≥ 200 mg/dL using 75 g OGTT
- HbA1c ≥ 6.5% **
- Random plasma glucose ≥200mg/dL in the presence of classical diabetes symptoms

Asymptomatic individuals with a single abnormal test should have the test repeated to confirm the diagnosis unless the result is unequivocally abnormal.

Limited care

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NOTE

- Point of care device for estimation of HbA1c is not recommended for diagnosis
- Capillary glucose estimation methods are not recommended for diagnosis
- Venous plasma is used for estimation of blood glucose
- Plasma must be separated soon after collection because the blood glucose levels drop by 5–8% hourly if whole blood is stored at room temperature.


*FPG is defined as glucose estimated after no caloric intake for at least 8–12 hours.

** Using a method that is National Glycohaemoglobin Standardization Program (NGSP) certified. For more on HbA1c & NGSP, please visit [http://www.ngsp.org/index.asp](http://www.ngsp.org/index.asp)
Prevention

Recommendations

Recommended Care

• Each health service provider should have a program to detect people with undiagnosed diabetes.
  o This decision should be based on the prevalence of undiagnosed diabetes and available support from health care system/service capable of effectively treating newly detected cases of diabetes.
  o Opportunistic screening for undiagnosed diabetes and prediabetes is recommended. It should include:
    ▪ Individuals presenting to health care settings for unrelated illness
    ▪ Family members of diabetes patients
    ▪ Antenatal care
    ▪ Dental care
    ▪ People aged ≥30 years should be encouraged for voluntary diabetes testing
    ▪ overweight children and adolescents at onset of puberty in high risk patients
  o Wherever feasible, community screening may be done
• Detection programs should be usually based on a two-step approach:
  o Step 1: Identify high-risk individuals using a risk assessment questionnaire
  o Step 2: Glycaemic measure in high-risk individuals
• Where a random non-FPG level ≥100 to <200 mg/dL is detected, OGTT should be performed.
• Use of HbA1c as a sole diagnostic test for screening of diabetes/prediabetes is not recommended.
• Early diagnosis could provide the opportunity to prevent or delay diabetes, CVD and their complications.
• Universal Screening and Diagnosis of Gestational Diabetes Mellitus must be done to identify women at very high risk of future diabetes and CVD.
• Diagnosis of Gestational Diabetes Mellitus may help identify offspring’s at high risk of T2DM and help offer early preventive care.

• People with high blood glucose during screening need further diagnostic testing to confirm diabetes while those with screen-negative to diabetes should be retested as advised by the physicians.
• Paramedical personnel such as nurses or other trained workers should be included in any basic diabetes care team.

Prediabetes

• People with screen-positive for prediabetes (FPG = 100-125 mg/dL or 2-h plasma glucose in the 75-g OGTT = 140-199 mg/dL or HbA1c = 5.7-6.4%) should be monitored for development of diabetes annually.
• Simultaneously screened and treated for modifiable risk factors for CVD such as hypertension, dyslipidaemia, smoking, and alcohol consumption.
• Screening strategies should be linked to health care system with capacity to provide advice
on lifestyle modifications:
- Aligned with ongoing support national programs available at community health centres
- Patients with IGT, IFG should be referred to these support programs.
- People with prediabetes should modify their lifestyle including:
  - Attempts to lose 5-10% of body weight if overweight or obese
  - Participate in moderate physical activity (e.g., walking) for at least 150 mins/week, spread uniformly throughout the week
  - 6–8 h of sleep daily
- Healthy lifestyle measures including diet and physical activity are equally important for non-obese patients with prediabetes.
- People with prediabetes failing to achieve any benefit on lifestyle modifications after 6 months may be initiated on oral antidiabetic agents (OADs):
  - Metformin: In younger individuals with one or more additional risk factors for diabetes regardless of BMI, if overweight/obese and having IFG+IGT or IFG+HbA1c >5.7%, addition of metformin (500 mg, twice daily) after 4 months of follow-up is recommended.
  - Alternatively, alpha-glucosidase inhibitors (AGIs) such as acarbose or voglibose may be initiated if metformin is not tolerated.
- Other pharmacological interventions with pioglitazones, orlistat, vitamin D, or bariatric surgery are not recommended.
- People with prediabetes should be educated on:
  - Weight management
  - Physical activity
  - Alcohol and tobacco consumption

Limited Care
- Detection programs should be opportunistic and limited to high-risk individuals in very limited settings.
- The principles for screening are as for recommended care.
- Diagnosis should be based on FPG or capillary plasma glucose if only point-of-care testing is available.
- Using FPG alone for diagnosis has limitations as it is less sensitive than 2h OGTT in Indians.

Prediabetes
- The principles of detection and management of prediabetes are same as for recommended care.
- Linkages to healthcare system with capacity to provide advice on lifestyle modifications and alignment with on-going support national programs available at community health centres where patients detected with prediabetes can be referred are critical.
### Medical nutrition therapy (MNT) and lifestyle modifications

#### Recommendations

<table>
<thead>
<tr>
<th>Recommended care</th>
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<tbody>
<tr>
<td><strong>MNT</strong></td>
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<tr>
<td>- The nutrition chart and support should be made in conjunction with a trained nutritionist along with physician/diabetologist.</td>
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<tr>
<td>- <strong>Carbohydrates</strong></td>
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<td>- Carbohydrate content should be limited to 50–60% of total calorie intake.</td>
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<td>- Complex carbohydrates should be preferred over refined products.</td>
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<td>- Low glycaemic index (GI) and low glycaemic load (GL) foods should be preferred.</td>
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<td>- Quantity of rice should be limited as it has high GI (GI: 73). Parboiled or brown rice (GI: 68) should be preferred over white rice.</td>
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<td>- Fibre intake: 25-40 gm per day.</td>
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<td>- <strong>Proteins</strong></td>
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<td>- Protein intake should be maintained at about 15% of total calorie intake.</td>
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<td>- Quantity of protein intake depends on age, sarcopenia and renal dysfunction.</td>
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<td>- Non-vegetarian foods are sources of high quality protein, however intake of red meat should be avoided.</td>
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<tr>
<td>- <strong>Fats</strong></td>
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<tr>
<td>- Fat intake should be limited (&lt;30% of total calorie intake).</td>
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<td>- Oils with high monounsaturated fatty acid (MUFA) and polyunsaturated fatty acid (PUFA) should be used.</td>
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<td>- Use of 2 or more vegetable oils is recommended in rotation.</td>
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<tr>
<td>- For non-vegetarians, consumption of 100–200 g of fish/week is advised as good source of PUFA and for vegetarians, vegetable oils (soybean/ safflower/ sunflower), walnuts and flaxseeds are recommended.</td>
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<tr>
<td>- Avoid consumption of foods high in saturated fat (butter, coconut oil, margarine, ghee).</td>
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<td>- Saturated fatty acids (SFAs) intake should be less than 10% of total calories/day (&lt;7% for individuals having high triglycerides).</td>
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<td>- Use of partially hydrogenated vegetable oils (Vanaspati) as the cooking medium should be avoided.</td>
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<td>- Reheating and refrying of cooking oils should be avoided.</td>
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<td>- <strong>Food groups and patterns</strong></td>
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<td>- Diet rich in fruits, leafy vegetates, nuts, fibre, whole grains and unsaturated fat is preferred.</td>
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<td>- Food plate should include pulses, legumes, unprocessed vegetables and low fat dairy.</td>
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<td>- Extreme diets including low-carbohydrate ketogenic, gluten free must be planned and executed following consultation with physician and nutritionist, and for a short period.</td>
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<td>- Overall salt consumption should be &lt;5 g/day (with sodium consumption &lt;2300 mg/day).</td>
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<tr>
<td>- Avoid or decrease alcohol intake.</td>
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• Smoking should be avoided. Smoking cessation therapies may be provided under observation for patients who wish to quit in a stepwise manner.
• Intake of artificial sweeteners in moderate amounts (not more than 2-3 g/day [1/2 teaspoon]) is advised.
• Meal plans with strategic meal replacements (partial or full meal replacements) may be an option under supervision when feasible.

Lifestyle modifications
• Recommended care could be imparted by physician and diabetes educator.
• Careful instructions should be given for initiating exercise programme. Help of a physical instructor can be taken.
• Lifestyle advice should be given to all people with T2DM at diagnosis. It should be an effective option for control of diabetes and increasing CV fitness at all ages and stages of diabetes.
• Lifestyle intervention is a cost-effective approach in prevention of T2DM.
• Lifestyle interventions should be reviewed yearly or at the time of any treatment or at every visit.
• Advice people with T2DM that lifestyle modification, by changing patterns of eating and physical activity, can be effective in managing several adverse risk factors related to T2DM.
• Physical activity should be introduced gradually, based on the patient’s willingness and ability and the intensity of the activity should be individualized to the specific goals.
• A total of 60 min of physical activity is recommended every day for healthy Indians in view of the high predisposition to develop T2DM and CAD
  • ≥30 min of moderate-intensity aerobic activity each day
  • 15 min of work-related activity
  • 15 min of muscle-strengthening exercises (at least 3 times/week)
• In the absence of contraindications, encourage resistance training 2-3 times/week.
• Physical activity with or without yoga should be done for 30 min every day or 45-60 min in individuals not practicing any other form of physical activity.
• While effect of yogic practices is encouraging, it should not replace aerobic exercise.
• Use of monitoring tools like accelerometers, GPS units, pedometers, mobile based apps or devices to measure the intensity and duration of physical activity may be encouraged.

Behavioural lifestyle intervention (BLI)
• BLI involves patient counselling for strategies such as tailoring goals, self-monitoring and stimulus control.
• BLI approaches have shown to improve adherence to lifestyle changes and achieve more sustained effects.
• Diabetes self-management support is important and could be done with physician or educator with small groups or face-to-face discussions in chat rooms.

Limited care
• Nutritional counseling may be provided by health care providers (HCPs) trained in nutrition therapy, not necessarily by an accredited dietician nutritionist.
• Overall, low simple carbohydrates, sugar and fried foods along with high protein intake are recommended.
- Salt intake should be restricted.
- Encourage increased duration and frequency of physical activity (where needed), up to 30–45 min on all days of the week or an accumulation of at least 150 min per week of moderate-intensity aerobic activity (50–70% of maximum heart rate).
- Mass awareness campaign for healthy diet and lifestyle should be conducted.
### Oral Antidiabetic Agents

#### Recommendations

**Recommended care**

- Begin OADs when lifestyle interventions alone are unable to maintain blood glucose control at target levels. (*Consider use of drugs at time of diagnosis*)
  - Maintain support for lifestyle measures throughout
    - Consider each initiation or dose increase of OADs as a trial, monitoring the response through glucose monitoring (FPG, PPG, self-monitoring of blood glucose [SMBG] or HbA1c) every 2–3 months.
  - Consider CV/ heart failure risk, renal/hepatic (NASH) risk while deciding therapy
  - Patient-centric approach: consider cost and benefit risk ratio when choosing OADs
  - Individualise therapy based on target HbA1c for each patient based on: age, duration of diabetes, comorbidities, cost of therapy, hypoglycaemia, weight gain, durability
  - Consider initiating combination therapy if the HbA1c > 1.5 above the target
- **First-line therapy**
  - Metformin (unless renal impairment or other contraindication like< BMI 19)
  - If eGFR<is between 45- 30: reduce dose of metformin by 50%; stop metformin if eGFR<30. Closely monitor renal function every 3 months
  - Other options: sulfonylurea (or glinides) for rapid response where glucose levels are high or dipeptidyl peptidase-4 (DPP-4) inhibitors or AGI- these agents can be used initially for cases where metformin is contraindicated or not tolerated
  - In some cases, dual therapy may be indicated initially if it is considered unlikely that single agent therapy will achieve glucose targets. (*Indication for dual therapy*)
- **Second-line therapy** add on therapy: Patient-centric approach
  - If glucose control targets are not achieved: Add sulfonylurea or thiazolidinediones (TZDs) or sodium-glucose cotransporter 2 inhibitors (SGLT2) inhibitor, or DPP-4 inhibitor, or AGI
  - Individualise patient care based on comorbidities
- **Third-line therapy**
  - If glucose targets are not achieved with two agents: start third oral agent- AGI, DPP-4 inhibitor, SGLT2 inhibitor, or TZDs (depending on second-line agent used) or start insulin or glucagon-like peptide 1(GLP-1) agonists
- **Fourth-line or fifth therapy**: occasionally 4/5 OADs considered
  - Consider GLP-1 agonists or insulin if glucose targets are not achieved with OADs
  - Begin insulin therapy when optimized OADs and lifestyle interventions are unable to maintain target glucose control.
  - Intensify insulin therapy if insulin is being used already. (*see section on insulin*)
- In the presence of IR, addition of TZDs must be considered
- For patients with established atherosclerotic cardiovascular disease (ASCVD), heart failure diabetic kidney disease (DKD) or in need of weight reduction consider using SGLT2 inhibitors
- If postprandial hypoglycaemia is the issue AGI or glinides may be considered
- In elderly patients with increased risk of hypoglycaemia, use a DPP-4 inhibitor as an alternative to sulfonylurea
**Limited care**

- The principles as for recommended care along with considerations for cost and availability of generic therapies. In low cost situations, sulfonylurea or metformin or TZDs may be used.
- Newer sulfonylureas have benefit of low cost and reduced hypoglycaemia (than older OADs); comparable CV safety with DPP4i and may be considered. TZDs have established CV safety and may be considered as add on to metformin
## Injectables

### Recommendations

#### Recommended care

- **Insulin Therapy:** a three step protocol involving initiation, titration, and intensification is recommended for all patients requiring insulin.
- **Initiation**
  - “Providers should avoid using insulin as a threat or describing it as a sign of personal failure or punishment.” [233]
  - With newer effective OADs available, insulin should considered only if patient fails to achieve or maintain HbA1c levels following administration of three OADs of which one should be a newer agent or if patient is intolerant to any individual agent or combination of agents.
  - Therapeutic choice of regimen, preparation, and delivery device, should be made through a process of shared, informed decision making
  - Initiate with once-daily basal insulin, once-daily premixed/co-formulation insulin, or twice-daily premixed insulin, either alone or in combination with GLP-1 analogues (either alone or in combination with basal insulin, in same pen device) or other OADs, based upon patient’s age, clinical features, glucose profile, risk of hypoglycaemia, and patient preference.
  - Basal bolus insulin regimens may be needed in severe hyperglycaemia, and in life threatening or organ/limb threatening clinical situations.
  - Analogue insulins may be used in preference to human insulins with possible lower risk of nocturnal and symptomatic hypoglycaemia; however, economic considerations must be taken into account.
    - Match timing of insulin and meals.
    - Counselling/education about SMBG and hypoglycaemia prevention, recognition and treatment are recommended to all patients initiating with insulin.
    - Provide guidance for adjusting insulin dose adjustments, administration, storage and other practical aspects.
- **Titration**
  - Initiate insulin as defined in the algorithm, using a self-titration regimen. (dose increases of 2–4 unit (U) units every three days or biweekly) or with more frequent contact with a healthcare professional
  - Aim for pre-meal glucose levels of < 115 mg/dl, and PPG levels of 140–180 mg/dl. These targets can be individualized, based upon the risk of hypoglycaemia and the urgency for glycaemic control
  - Titration should be done at regular and short intervals, to attain glycaemic goals without causing hypoglycaemia and as guided by the physician orHCPs
  - Titration should be done to control FBG first, followed by prandial control of meal with highest glycaemic excursion in sequential order.
- **Intensification**
  - Intensification of insulin therapy is recommended when patients fail to achieve glycaemic goals even after optimal dose titration.
  - Several options can be considered during intensification:
    - Switch to premix insulin twice-daily or thrice-daily(rarely)
- Use high mix insulins, or adopt a heteromix insulin regimen
- Switch to insulin co-formulation based regimen
- Add prandial insulin (basal plus or basal bolus) with largest meal of the day
- Add GLP-1 analogues

- The choice of intensification strategy should be based upon dietary pattern, lifestyle, gluco-phenotype, risk of hypoglycaemia and weight gain, affordability, as well as patient preference.
- Basal plus regimen can be used as a stepwise approach to insulin intensification, leading to basal-bolus prescription. It is associated with lesser risk of hypoglycaemia and weight gain than basal bolus regimen.
- Both premix insulin therapy and co-formulation insulins are acceptable methods of intensification. Co-formulation insulin offers the advantage of lower risk of hypoglycaemia and nocturnal hypoglycaemia.
- Follow insulin intensification as recommended in the algorithm.

**GLP-1 analogues**

- OADs with proven CV benefit should be considered to reduce the risk.
- Viable second-line or third-line options for the management of patients with uncontrolled hyperglycaemia.
- Can be considered in overweight/obese patients as second line therapy in patients with metformin inadequacy and as as first line therapy in patients with metformin intolerance.
- To be added to insulin therapy preferably basal insulin only if glycaemia goals are not achieved with reasonably high doses of insulin, or if unacceptable weight gain or hypoglycaemia occurs. Dose reduction of insulin may be needed in such cases. Transient gastrointestinal side effects may occur.

**Limited care**

- All conventional insulins have similar glycaemic lowering efficacy as analogs but with slight increased risk of hypoglycaemia and lack of flexibility of administration.
- Insulin supplies should be assured and be of consistent quality and type.
Note: Although hydroxychloroquinone has recently been approved by DCGI for the treatment of T2DM as third line therapy, the data is still lacking with regards to head-head trials versus metformin, SUs, DPP-4 inhibitors and GLP-1 RA
# Postprandial hyperglycaemia

## Recommendations

### Recommended care

- Postprandial hyperglycaemia is defined as 2-hour plasma glucose level of >200 mg/dl during an OGTT with 75 g anhydrous glucose for which treatment strategies to lower PPG should be implemented.
- PPG should be measured 1–2 hours after a meal.
- Target PPG: 160 mg/dL as long as hypoglycaemia is avoided.
- Both non-pharmacologic and pharmacologic therapies should be considered
  - MNT: diet with low glycaemic load is recommended
  - Pharmacological agents:
    - AGIs (acarbose or voglibose), DPP4 inhibitors, or GLP-1 analogues (preferably short acting) as first line therapy
    - Glinides and short acting sulfonylureas as second line agents
    - Rapid acting insulin analogues should be preferred over the regular insulin when postprandial hyperglycaemia is a concern
    - Combination therapy of AGI with other agents may be considered for better control of postprandial hyperglycaemia
- SMBG should be considered as it is the most practical method for monitoring postprandial glycaemia.
- Efficacy of treatment regimens should be monitored frequently to guide therapy towards achieving PPG targets.
Acute Metabolic Complications

Recommendations

Recommended Care

- Treatment individualization based on careful clinical and laboratory assessment is needed.
- Management goals should include:
  - Restoration of circulatory volume and tissue perfusion
  - Resolution of hyperglycaemia
  - Correction of electrolyte imbalance and reversal of ketosis
  - Identification and prompt treatment of precipitating events
  - Avoiding complications of therapy, particularly cerebral oedema
  - Prevention of recurrent episodes
- Meticulous monitoring of clinical and biochemical response using a flow chart is essential to document hour-by-hour clinical observations, intravenous and oral medications, fluids, and laboratory results.
- Admission to intensive care unit or comparable setting with adequately trained nursing and medical staff and 24-h laboratory services for frequent monitoring is warranted for children <2 years of age and in case of compromised circulation, coma, and risk of cerebral oedema.
- Emergency assessment should follow the general guidelines of advanced life support, with particular attention to airway and breathing patterns, severity of dehydration, mental status, source of infection, level of consciousness (Glasgow coma scale), frequent monitoring of clinical and laboratory parameters.
- If laboratory measurement of serum potassium is delayed, perform an electrocardiogram for baseline evaluation of potassium status. A cardiac monitor should be used for continuous electrocardiographic monitoring to assess T waves for evidence of hyper- or hypo-kalaemia and monitor for arrhythmias.
- In the unconscious or severely obtund patient, secure the airway and empty the stomach by continuous nasogastric suction to prevent pulmonary aspiration.
- A peripheral intravenous catheter should be inserted for convenient and painless repetitive blood sampling.
- Fluid replacement should begin before starting insulin therapy to restore peripheral circulation.
- Adequate oxygenation should be maintained using supplemental oxygen to patients with severe circulatory impairment or shock.
- Give antibiotics to febrile patients after obtaining appropriate cultures of body fluids.
- The rate of fluid administration should not exceed 1.5–2 times the usual daily maintenance requirements.
- Insulin administration should begin at a dose of 0.05–0.1 U/kg/h, 1–2 h after starting fluid
replacement therapy.
- In critically ill and mentally obtund patients, continuous intravenous insulin is the standard-of-care.
- Bicarbonate administration is not recommended except for treatment of life-threatening hyperkalaemia.
- In patients with multiple risk factors for cerebral oedema, have mannitol or hypertonic saline at the bedside and the dose to be given calculated beforehand. If neurologic status deteriorates acutely, hyperosmolar therapy should be given immediately.
## Hypoglycaemia

### Recommendations

#### Recommended care

- Risk of hypoglycaemia should be assessed in every visit in patients with T2DM by using questionnaires (Appendix XX).
- Patient should be well educated and informed regarding:
  - The symptoms, causes, and risks associated with hypoglycaemia
  - Usage of SMBG tools with frequent monitoring especially patients taking insulin
  - Insulin dose adjustment considering blood glucose values
- A strict monitoring of hypoglycaemic episodes is recommended for patients taking insulin, sulfonylureas or meglitinides alone or in combination.
- Modern insulins or modern sulfonylureas should be used instead of respective traditional drugs in patients with high risk of hypoglycaemia.
- Oral glucose (15–20 g) is preferred in conscious hypoglycaemic patients (glucose alert value of <70 mg/dL). Repeat the treatment, if SMBG shows continued hypoglycaemia after 15 min. Patient should consume a meal or snack once SMBG returns to normal, to prevent recurrence of hypoglycaemia
- Intramuscular glucagon or intravenous glucose is preferred for unconscious patients or patients with clinically significant hypoglycaemia (glucose alert value of <54 mg/dL). Repeat intramuscular or subcutaneous glucagon dose of 0.5 mg if there is no symptomatic improvement.
- Glucagon to be avoided in patients with sulfonylurea induced hypoglycaemia.
- Treatment should be modified in the event of hypoglycaemia occurring repeatedly at a particular time of the day or in the event of hypoglycaemia unawareness.

#### Limited care

- All patients with risk of hypoglycaemia should be enquired about symptomatic and asymptomatic hypoglycaemia at each visit.
- Patients along with their family members should be well educated about identification and management of hypoglycaemia, especially night-time hypoglycaemia.
- Hypoglycaemia should be strictly managed and monitored in special situations such as elderly, pregnancy, fasting, and metabolic disorders.
Chronic complications: Retinopathy

Recommendations

Recommended Care

- Documentation of formal history of vision and visual acuity either by recording it on sheet or electronic medical record (EMR) should be made mandatory first at the time of diagnosis and then periodically.
- Ensure that examination of the eyes of people with T2DM is performed around the time of diagnosis and then routinely every 1–2 years as part of a formal recall process:
  - Measure and document visual acuity, corrected with glasses or pinhole
  - Record ocular pressure and assess the condition of the iris and lens
  - Assess retinopathy:
    - Using retinal photography through dilated pupils, performed by an appropriately trained healthcare professional, or
    - Through examination by an ophthalmologist
- Discuss the reasons for eye examination with the person with diabetes.
- Counseling must include components on smoking, diet, alternative medicines, exercise, and appropriate choice of drugs for BP and lipids.
- Counsel women who are planning pregnancy on the risk of progression of retinopathy during pregnancy, especially if there is pre-existing retinopathy. Ensure regular follow-up throughout pregnancy and up to 1 year post-partum.
- Use tropicamide to dilate pupils, unless contraindicated (rule out history of glaucoma), after discussing the implications and obtaining agreement of the person with diabetes.
- Classify the findings of eye examination as required: routine review, earlier review or referral to an ophthalmologist (if not making the examination).
- The following frequency of screening is suggested:
  - 1–2 years, if no retinopathy, depending on clinical situation
  - 12 months, if minimal unchanged retinopathy
  - 2–4 months, after any active ophthalmic intervention
  - 3–6 months, if worsening since last examination
  - More often during pregnancy
- The following situations require specialist referral:
  - The same day:
    - Sudden loss of vision
    - Evidence of retinal detachment
  - Within one week:
    - Evidence of pre-retinal and/or vitreous haemorrhage
    - New vessel formation or rubeosisiridis
    - Inability to see or assess disc or fovea
    - Raised ocular pressure
Within 1–2 months:
  - Advanced retinal lesions (4:2:1 rule)
    - Microaneurysms or retinal haemorrhages in 4 quadrants
    - Venous beading in two quadrants
    - IRMAs in one quadrant
  - Unexplained deterioration of visual acuity
  - Macular edema
  - Unexplained retinal findings
  - Cataract
  - Inability to visualize fundus

- Stepped approach should be adapted to manage hyperglycemia, as intensive glycemic control can cause transient (early) worsening of symptoms and even lead to cotton wool spots.
- GLP-1 agonists may initially worsen diabetic retinopathy, and hence must be used with caution.
- Advise that good control of blood glucose, BP and blood lipids, and cessation of smoking can help to reduce the risk of development or worsening of eye complications.
- Advise that DR is not a contraindication for use of aspirin, if this is indicated for prevention of CVD.
- Advise that tests of intra-ocular pressure should be made periodically.
- Explain guarded prognosis about regaining vision after intra-ocular lens (IOL) surgery in mature/hypermature cataract because of poor assessment of retina in the presence of mature cataract.
- Discourage use of alternative medicines as they can cause further complications.

**Limited care**

- Use direct fundoscopy through dilated pupils, performed by a member of the health-care team who is properly trained and has appropriate experience to assess retinopathy.
- Check visual acuity.
- Repeat review, referral and preventative therapy are as for recommended care.
- Less-frequent examinations (every two years) may be considered following one or more normal eye examinations.
- Discourage use of alternative medicines as they can cause further complications.
Chronic complications: Neuropathy

Recommendations

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<tr>
<td>All patients with T2DM should be assessed for diabetic neuropathy at the time of initial diagnosis and annually.</td>
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<tr>
<td>Diagnose sensorimotor nerve damage by history and examination (10 g monofilament with or without temperature, non-traumatic pin-prick, vibration [128 Hz tuning fork], ankle reflexes), and/or simple quantitative testing (e.g. biothesiometer vibration perception). Use serum B12, thyroid function tests, creatinine/urea, and alcohol abuse and medication history to exclude other causes.</td>
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<tr>
<td>Diabetic Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS) in T2DM population has been found to be a useful resource in evaluating diabetic sensorimotor polyneuropathy as an important bedside tool.</td>
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<tr>
<td>Diagnose symptomatic (painful) diabetic neuropathy by excluding other possible causes of the symptoms. Manage by stabilizing blood glucose control, and treatment with tricyclic antidepressants, if simple analgesia is not successful. If a one month trial of tricyclic therapy is not successful, further treatment options include pregabalin/gabapentin and duloxetine, then tramadol and oxycodone.</td>
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<td>Weight gain and lifestyle measures need a reinforcement with the use of antidepressants and gabapentin and pregabalin.</td>
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<tr>
<td>Further management normally requires referral to a pain control team. Be aware of the psychological impact of continuing symptoms, particularly if sleep is disturbed. In patients with diabetic neuropathy and co-morbid depression, anxiety and sleep loss, duloxetine should be preferred.</td>
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<tr>
<td>A visual record of simple graphic tool to measure response to therapy must be mandated, which will save patients from over/unnecessary treatment.</td>
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<td>Tools e.g. pain scale should be encouraged in clinical practice.</td>
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<tr>
<td>Diagnose erectile dysfunction by history (including medication history), exclusion of endocrine conditions (measure prolactin and testosterone), and a trial of a phosphodiesterase type-5 (PDE5) inhibitor (where not contraindicated by nitrate therapy). Consider other approaches such as intra-urethral or intracavernosal drugs and sexual and relationship counselling, where PDE5 inhibitors fail or cannot be used.</td>
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<tr>
<td>Discourage use of alternative medicines as they can cause further complications.</td>
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<tr>
<td>Diagnose gastroparesis by history, trial of a prokinetic drug (metoclopramide, domperidone) and if troublesome, by gastric emptying studies.</td>
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<td>Diagnose CV autonomic neuropathy by resting heart rate and heart rate response to provocation tests (lying-standing, Valsalva, deep breathing), and by lying and standing BP. Inform anesthetists when relevant, where this is present.</td>
</tr>
<tr>
<td>Every patient must undergo a simple assessment e.g. questionnaire-based assessment for depression.</td>
</tr>
</tbody>
</table>
Limited Care

- Screen and diagnose sensorimotor nerve damage by history of symptoms, and sensory assessment by 10g monofilament or tuning fork with/without non-traumatic disposable pin-prick.
- NSS and NDS in T2DM population has been found to be a useful resource in evaluating diabetic sensorimotor polyneuropathy as an important bedside tool.
- Manage symptomatic (painful) diabetic neuropathy by excluding other causes, stabilizing glycaemic control, and treatment with tricyclic antidepressants if simple analgesia is not successful. Opiate analgesia may be necessary as locally available.
- Assess erectile dysfunction by history and examination and consider possible contributions of other medication or disease.
Chronic complications: Diabetic kidney disease

Recommendations

**Recommended Care**

- Kidney function should be assessed at diagnosis and annually by:
  - Urine test for albuminuria
  - Measurement of serum creatinine and calculation of eGFR
- Urinary albumin to creatinine ratio (ACR) measurement in an early morning first void (mid-stream) spot specimen is the preferred method for assessment of microalbuminuria/proteinuria. Where a first void specimen is not possible or practical, a random spot urine specimen is acceptable. ACR can be measured in the laboratory or at site-of-care.
- Control hyperglycaemia, exclude urinary or systemic infections, or pyrexia and avoid strenuous exercise before testing for albuminuria.
  - If ACR is raised (microalbuminuria) i.e. ACR >25 mg/g in men, >35 mg/g in women, repeat ACR twice over the following four months:
    - Microalbuminuria is confirmed if ACR is elevated in two out of three tests, in the absence of infection or overt proteinuria
    - If both repeat tests are not raised, check again annually
    - An ACR >300 mg/g indicates macroalbuminuria
- DKD is diagnosed on the basis of a raised urine albumin/protein or a reduced eGFR (<60 mL/min/1.73 m²) calculated from the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. CKD-EPI is the preferred formula.
- The Modification of Diet in Renal Disease (MDRD) formula for calculation of eGFR is not validated above 70 years age.
- For patients <18 years of age (including infants, toddlers, children, and teens), the Bedside Schwartz equation should be used.
- Individuals with DKD should be managed as follows:
  - Identified high-risk individuals (hypertensives, duration of diabetes >3-5 years, family history of nephropathy/HF/ASCVD) must get preference for SGLT2 inhibitors for glycemic management if feasible and accepted by patients (eGFR >30 mL/min/1.73 m²)
  - Use angiotensin converting enzyme (ACE)-inhibitors or angiotensin receptor blockers (ARBs) and/or SGLT2 inhibitors in individuals with micro- or macro-albuminuria, titrated to maximum tolerated dose
  - Intensify management of BP (target ≤130/80 mm Hg) using BP lowering medications and dietary modification (low salt intake)
  - Intensify management of blood glucose
  - Monitor ACR, eGFR and serum potassium
  - Advise limiting protein intake to 1 g/kg of high biological value protein daily. In those with advancing CKD, restrict to 0.8 g/kg daily with advice for caution in patients consuming non-vegetarian diet
  - Intensify other renal and CV protection measures
  - Assessment and management of anemia and bone disease and appropriate vaccination
Smoking leads to the progression of end-stage renal disease (ESRD) in diabetes so patients must be counselled for quitting smoking.

Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease, difficult management issues (stress, obesity, high uric acid, UTIs, anemia with timely use of Erythropoietin analogues, BP to targets, Nocturnal BP control stressed).

- Agree to a referral criteria for specialist renal care between local diabetes specialists and nephrologists. Referral criteria might include eGFR <30 mL/min/1.73 m², progressive deterioration of kidney function, persistent proteinuria, biochemical or fluid retention problems or difficult diagnosis (to rule out non diabetic renal disease where fundus is normal and no proteinuria).
- Rule out non-diabetic kidney disease in patients with early onset of nephropathy (<5 years), absence of retinopathy, heavy proteinuria, presence of active urinary sediments or unexplained rapid decline in eGFR.

### Limited Care

- Check annually for proteinuria in an early morning urine sample (or a random sample) using a dipstick. If test is positive exclude UTIs by microscopy (and culture if possible).
- Measure serum creatinine and calculate eGFR annually.
- A simple inexpensive screening procedure for urinary protein excretion which can be used as a diagnostic test in outpatient has been reported in Indian population. Estimated proteinuria is useful in serial evaluation of kidney function.
- Manage those with proteinuria as follows:
  - Consider use of ACE inhibitors or ARBs and SGLT2 inhibitors unless contraindicated or issues with tolerability
  - Aim for BP ≤130/80 mm Hg using any BP lowering medication and control of salt intake
  - Aim to achieve targets for blood glucose control
  - Aim to improve lipid profile using available medications
  - Check proteinuria status annually
  - Measure serum creatinine and calculate eGFR annually
Chronic complications: Diabetic Foot and Peripheral Arterial Disease

Recommendations for Foot care

- Assess feet of patients with diabetes at every visit for lesions requiring active treatment and for risk factors for ulcer and amputation:
  - History of previous foot ulceration or amputation, symptoms of peripheral arterial disease (PAD), physical or visual difficulty in self-foot-care
  - Foot deformity (hammer or clawed toes, bone prominences), visual evidence of neuropathy (dry skin, dilated veins) or incipient ischemia, callus, nail deformity or damage. Patient footwear should also be assessed
  - Detection of neuropathy by 10 g Semmes Weinstein monofilament (or 128 Hz tuning fork); a biothesiometer (to assess vibration perception threshold) is an option for quantitative assessment (cut-off point for ulcer risk >25 volts) and non-traumatic pin-prick.
  - Palpation of foot pulses (dorsalis pedis and posterior tibial). Doppler ultrasound examination or ankle:brachial pressure (ABI) ratio (<0.9 for occlusive vascular disease) may be used where pulses are diminished to quantify the abnormality.
- Discuss the reasons for foot review with each patient with diabetes, as part of the foot-care educational process.
- Must emphasize to completely refrain from walking bare foot, including at visits to religious places.
- Timely screening and early detection of diabetic neuropathy may help in prevention of the progression to diabetic foot.
- Agree upon a foot-care plan based on the findings of annual foot review with each person with diabetes. Assess and provide necessary foot-care education according to individual needs and risks of ulcer and amputation.
- Classify and manage according to risk classification level based on findings of foot assessment:

<table>
<thead>
<tr>
<th>Risk classification level</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>No added risk; No risk factors; no previous history of foot ulcer or amputation</td>
<td>o Provide structured foot-care education</td>
</tr>
<tr>
<td><strong>At risk:</strong></td>
<td><strong>High risk:</strong></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>One risk factor; no previous history of foot ulcer or amputation</td>
<td>≥2 risk factors; previous ulcer or amputation (very high risk)</td>
</tr>
</tbody>
</table>

- Foot-care team to regularly review every 6 months.
- At each review:
  - Inspect both feet – ensure provision of local management as indicated
  - Educate patient to wash feet daily (with careful drying, particularly between the toes), use emollients to lubricate dry skin, cut toe nails straight across, and avoid using chemical agents or plasters or any other technique to remove callus or corns
  - Evaluate footwear – provide appropriate advice
  - Enhance foot-care education

- Foot-care team to frequently review every 3–6 months.
- Educate patient to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation to prevent a first or recurrent plantar foot ulcer.
- At each review:
  - Inspect both feet – ensure provision of local management as indicated
  - Evaluate footwear – provide advice and specialist insoles and shoes if indicated
  - Consider need for vascular assessment or referral, if indicated
  - Evaluate and ensure appropriate provision of intensified foot-care education

- People with foot ulceration or infection require the following management:
  - Pressure off loading
  - Refer to multidisciplinary foot-care team within 24 hours for:
    - Appropriate wound management, dressings and debridement as indicated
    - Infections should be classified as mild (superficial with minimal cellulitis), moderate (deeper than skin or more extensive cellulitis), or severe (accompanied by systemic signs of sepsis). Consideration of systemic antibiotic therapy (often longer term) for extensive cellulitis or bone infection as indicated.
      - First-line medications: generic penicillin, cephalosporins, macrolides, clindamycin and/or metronidazole, as indicated
      - Second-line medications: amino-quinolones co-amoxicillin, ipipenem
    - Probing to bone, radiology and scans, magnetic resonance imaging and biopsy where indicated for suspected osteomyelitis
    - Reduce weight bearing, relief of pressure (walking with crutches, rest) off loading and optimal pressure distribution (casting, if indicated)
    - Investigation and treatment (referral) for vascular insufficiency
    - Specialist therapeutic footwear and orthotic care (e.g. insoles) and individualized discussion of prevention of recurrence, when ulcer has healed
    - Optimal blood glucose control
  - Amputation should not be considered unless:
    - A detailed vascular evaluation has been performed by the vascular team
    - Ischemic rest pain cannot be managed by analgesia or revascularization
    - A life-threatening foot infection cannot be treated by other measures
A non-healing ulcer is accompanied by a higher burden of disease that would result in amputation

**Limited care**

- Risk assessment and classification: Similar to ‘recommended care’ but with sensory assessment by 10 g monofilament or tuning fork, with or without non-traumatic disposable pin-prick only and peripheral circulation assessment by palpation of pedal pulses.
- NSS and NDS in T2DM population have been found to be a useful resource and an important bed-side tool in evaluating diabetic sensorimotor polyneuropathy.
- Classification of infection: Similar to ‘recommended care’ but antibiotic therapy would be with generic penicillin, quinolones, macrolides and/or metronidazole, given intravenously for deep tissue infections and adjusted by response or culture results.
- Vascular referral would be according to findings and local revascularization facilities.
Fat and Type 2 Diabetes Mellitus

Recommendations

Recommended Care

- The cut-off points for overweight and obesity in Indian T2DM patients are as follows:
  - BMI 18–22.9 kg/m²: normal
  - BMI 23–24.9 kg/m²: overweight
  - BMI ≥25 kg/m²: generalized obesity
  - Waist circumference (WC) ≥90 cm for men and ≥80 cm for women: abdominal obesity

- Criteria for metabolic syndrome is as follows:
  - Abdominal or central obesity (WC ≥90 cm for men and ≥80 cm for women) plus
  - Any 2 of the following four factors:
    - Increased triglycerides (≥150 mg/dL or specific treatment)
    - Reduced HDL cholesterol (men:<40 mg/dL; Women:<50 mg/dL or specific treatment)
    - Increased blood pressure (systolic BP ≥130 or diastolic BP ≥85 mm Hg or treatment of previously diagnosed hypertension)
    - Increased fasting plasma glucose (FPG ≥100 mg/dL or previously diagnosed T2DM)

- Maintaining healthy lifestyle is recommended for management of metabolic syndrome. This includes:
  - Moderate calorie restriction (to achieve a 5–10% loss in body weight)
  - Increase in physical activity; up to 150 min/week of moderate to vigorous intensity physical activity
  - Change in dietary composition (low-calorie diet)
  - Combination of aerobic and resistance training exercise
  - Change in behavioural pattern

- Overweight and obese people with T2DM should be initiated on exercise therapy, prescribing a combination of aerobic and muscle strengthening activities (200-300 min/week).

- Pharmacotherapy for obese patients with T2DM should be considered in addition to lifestyle changes in those with BMI > 27 kg/m² without co-morbidity, or a BMI >25 kg/m² with co-morbidity
  - Metformin should be first line drug for all T2DM patients
  - GLP-1 analogues, DPP-4 inhibitors and SGLT2 inhibitors may be preferred as add-ons to metformin in obese T2DM patients
  - Lipase inhibitors (orlistat) and/or Lorcaserin may be used for inducing weight loss in addition to OADs in patients who have BMI1>

- Surgical treatment (bariatric surgery) is indicated in patients with BMI >32.5 kg/m² with co-morbidity, and BMI >37.5 kg/m² without co-morbidity

- Surgical options for weight loss surgery include
  - Restrictive procedures: Laparoscopic adjustable gastric banding (LAGB) and sleeve gastrectomy
  - Malabsorptive procedures: Bilio-pancreatic diversions (BPD)
  - Combined procedures: Roux-en-Y gastric bypass (RYGB)
- Experimental procedures: Illeal interposition and duodeno-jejunal bypass, various implantable pulse generator
- Comprehensive lifestyle changes including dietary modification, exercise, behavioral management, pharmacotherapy and bariatric surgery are the most effective interventions for weight management in T2DM patients
Infections and Vaccinations

Recommendations

Recommended care

- All adult diabetes subjects should be educated about administering pneumococcal and influenza vaccine and those age of > 60 years should be advised to be vaccinated.
- For individuals with diabetes, a single dose of pneumococcal conjugate vaccine (PCV13) to start and a second dose (in immunocompromised or > 65 years old) after one year and a booster dose after five years with pneumococcal polysaccharide vaccine (PPSV23) is recommended.
- World Health Organization recommends vaccination against the H1N1 virus.
- Irrespective of age, immunization is recommended in all patients with:
  - renal failure
  - diabetes and immune-compromised state due to concomitant conditions
  - diabetes and chronic lung diseases like chronic obstructive pulmonary disease (COPD), bronchial asthma
  - diabetes patients who smoke
  - poor hygienic conditions (especially slum dwellers) and those who frequently travel to high risk areas
- Vaccination is contraindicated/postponed in patients with:
  - hypersensitivity to the active substances or to any of the excipients of the vaccine
  - history of chicken egg allergy particularly when considering flu shot
  - recent history of Guillain-Barre syndrome within six weeks of a previous influenza vaccination in the case of flu shot
  - postponed in patients with febrile illness or any acute infection
- In patients with chicken egg allergy, chemoprophylaxis with amantadine/rimantadine or immunization using a protocol as reported by Murphy and Strunk may be considered

Limited care

The principles for infections and vaccinations during diabetes are as for recommended care subject to availability and affordability of pneumococcal and influenza vaccines.
Clinical monitoring

Recommendations

Recommended Care

- Monitor blood glucose control by measuring HbA1c using high-precision methods standardized and aligned to the international reference values.
- Advise individuals with diabetes that maintaining an HbA1c <7.0% minimizes the risk of developing complications.
- A lower HbA1c target may be considered:
  - If it is easily and safely achieved.
  - A higher HbA1c may be considered:
    - For individuals with previous attempts to optimize control have been associated with unacceptable hypoglycaemia.
- Treatment should be reviewed and modified if a HbA1c level is above the agreed target on two consecutive occasions.
- Advice those in whom target HbA1c levels cannot be reached that any improvement is beneficial.
- SMBG enables patients to detect and prevent asymptomatic hypoglycaemia and glucose variability and to make appropriate adjustments in treatment medications and nutrition therapy to achieve HbA1c targets.
- In patients on insulin a combination of HbA1c and SMBG is useful in achieving glycaemic control.
- Measure HbA1c every two to six months depending on level, stability of blood glucose control and changes in therapy and report HbA1c results in percentages.
- Anaemia must be considered before a proper diagnosis based on HbA1c values is made. Anaemia and abnormal haemoglobin may affect the values obtained for HbA1c in some assays. To determine whether abnormal haemoglobin is present, use high-performance liquid chromatography or mass spectrometry.
- Measure blood glucose when patients are hospitalized, either at site-of-care or in the laboratory. Site-of-care capillary blood glucose meters should be monitored by certified quality assurance schemes. Ascertain whether meters are calibrated against plasma or blood.
- When prescribing CGM, robust diabetes education, training, and support are required for optimal continuous glucose monitor implementation and ongoing use.
- Sensor-augmented pump therapy may be considered for children, adolescents, and adults to improve glycaemic control without an increase in hypoglycaemia or severe hypoglycaemia. Benefits correlate with adherence to ongoing use of the device.

Limited Care

- If HbA1c measurement is not available, blood glucose measured either at site-of-care or in the laboratory could be used for clinical monitoring.
- Site-of-care capillary blood glucose meters should be quality controlled by certified quality assurance schemes or by reference to laboratory methods.
- In very limited settings, diabetes control may need to be based on measurement of plasma glucose levels alone.
# Self-monitoring of Blood Glucose

## Recommendations

### Recommended care

- The purpose(s) of performing SMBG and using the data should be explained.
- Recommended target levels should be adequately explained to patient/provider and mutually agreed.
- Patients should be informed that PPG levels should be checked after 1/2 h from the start of the meal and not the end of the meal.
- SMBG technique should be properly explained to the patient and should be evaluated regularly with appropriate feedback given.
- Single use of lancet/pricking needles (disposable injection needles are commonly used in India in place of lancets) is recommended.
- SMBG device should comply with the ISO 15197:2013 requirements.
- SMBG accuracy is instrument and user dependent, so it is important to evaluate each patient’s self-monitoring skills including monitoring technique, interpretation of blood glucose results, impact on patient’s quality of life, and continued benefit to the patient, both initially and at regular intervals thereafter (a questionnaire will be developed for annual evaluation of the patients).
- The need for and frequency of SMBG should be re-evaluated at each routine visit.
- Structured assessment of self-monitoring skills, the quality and utilization of outputs and of the equipment, should be done annually.
- SMBG on an ongoing basis should be available to all the patients with diabetes using insulin.
- Patients may be allowed to make minor adjustments to insulin dosage and changes in diet and exercise based on the SMBG readings.
- SMBG protocols (intensity and frequency) should be individualized to address each individual’s specific educational/behavioural/clinical requirements (to identify, prevent or manage acute hyper- and hypoglycaemia) and provider requirements for data on glycaemic patterns and to monitor impact of therapeutic decision-making.
- SMBG plays an important role when a patient suspects low blood glucose or after treating for low blood glucose until they are normo-glycaemic, and prior to critical tasks such as driving. For many patients, this will require testing 6–10 (or more) times daily, although individual needs may vary.
- SMBG should be considered as an optional component of self-management for people using OADs, and in association with HbA1c testing:
  - To provide information on, and help avoid, hypoglycaemia
  - To assess changes in blood glucose control due to medications and lifestyle changes
  - To monitor the effects of food on post-prandial glycaemia
  - To monitor changes in blood glucose levels during recurrent illness
- SMBG may be useful in T2DM
  - during periods of acute illness; using sulphonylureas or glinides as combination or monotherapy
  - To identify hypoglycaemia especially in the first three months of starting
sulphonylureas

- In patients who experience episodes of hypoglycaemia and those who have reduced awareness of hypoglycaemia
- For drivers, individuals who fast and women under preconception care.

- Intensive or regular SMBG may be recommended if a person with diabetes is on multiple daily insulin injections, pre-gestational diabetes on insulin, history of hypoglycaemia unawareness, have brittle diabetes or with poor metabolic control on multiple OADs and/or basal insulin.

- All patients on multiple-dose insulin therapy should perform SMBG at least two times/day (ideally before any insulin injection). More frequent testing may be required in:
  - Patients with frequent hypoglycaemia or hypoglycaemic symptoms
  - Patients not at HbA1c target levels

- For patients on intensive insulin regimens who are on multiple doses of insulin or on insulin pumps should be tested three or more times daily (at fasting, all pre-meals, post-meals, at bedtime, prior to exercise and periodically at 3 am).

- For patients with brittle diabetes or hypoglycaemia unawareness, 7-point testing is recommended with a 3 am testing at least once a week. Whenever hypoglycaemia is suspected or during intercurrent acute illness, SMBG may not be ideal in this case and CGM may be required.

- In patients on basal insulin, daily fasting levels are recommended. Post-prandial correction should be done after correcting fasting blood glucose.

- Patients on premix insulin or basal bolus therapy should be advised to perform three pre-prandial (including fasting) and three post-prandial tests on alternate days till target A1C and blood glucose levels are reached. After achievement of the target, less frequent testing can be done; fasting and one meal-related testing can be done, can be staggered (changing every 2 days).

- In patients with hemodynamically unstable conditions or end stage organ disease, the frequency or timing of SMBG should be customized based on the individual case. More frequent monitoring may be required based on the clinical situation.

- In accordance with the sick day rule, the frequency of SMBG should be increased in special situations like fever, vomiting and persistent polyuria with uncontrolled blood glucose, especially if abdominal pain or rapid breathing is present. Ketone test should be performed as and when needed.

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**Limited care**

- SMBG using meters with strips, should be considered for people with diabetes using insulin or drugs like sulphonylurea and glinides.

- If a patient chooses to reuse the lancet or pricking device, proper antiseptic precautions should be taken. The lancet/pricking device should be discarded when the tip goes blunt or the prick becomes painful or if it comes in contact with another individual’s blood.

- If a patient decides to reuse pricking needle, proper care must be taken as mentioned below:
  - Cover should be placed back on the needle immediately.
  - Needle should not touch any surface apart from the inside of the needle cover.
Recommended Care

**Glucose meters and SMBG**
- Glucose meters meeting the accuracy standards of the International Organization for Standardization (ISO 15197:2013) should be preferred.
- Lancet/pricking needles should preferably be used only once and in the case of resource-limited settings, the patient may choose to reuse them provided, proper antiseptic precautions are taken.
- Whether to prescribe SMBG or not shall be decided on the basis of the type of therapy, level of glycaemic control, the risk of hypoglycaemia, and need for short-term adjustment of treatment.
- Structured testing regimens should be defined for patients on SMBG and it is more likely to be recommended in individuals with uncontrolled diabetes HbA1C ≥8.0%.
- Training on how to interpret and respond to their glucose data should be provided to all patients.
- SMBG protocols (intensity and frequency) should be individualized based on: patient’s specific educational/ behavioural/clinical requirements, and provider requirements for data on glycaemic patterns to monitor therapeutic decision making.
- In general, once-daily testing should include readings from different times of the day: pre-lunch and pre-dinner readings is the best overall twice-daily testing strategy.
- SMBG should be available on an ongoing basis to insulin-requiring patients.
- Individuals on intensive insulin regimens should perform SMBG prior to meals and snacks, at bedtime, occasionally post prandial, prior to exercise, when they suspect hypoglycaemia, after treating hypoglycaemia until they are normoglycaemic, and prior to critical tasks such as driving.
- SMBG should be considered for people on OHAs as an optional component of self-management, and in association with HbA1C testing.
- Pregnant patients with insulin-treated diabetes should preferably perform SMBG on a daily basis, failing which, at least weekly monitoring may be recommended.
- In older patients, less frequent monitoring may be recommended, and the target should be relaxed to ward off hypoglycaemia.
- Regular SMBG is not necessary where diabetes is well controlled by nutrition therapy or oral medications alone.

**Continuous glucose monitoring (CGM)**
- CGM should be considered in conjunction with HbA1C for glycaemic status assessment in those T2DM individuals treated with intensive insulin therapy who are not achieving glucose targets
- CGM may be considered in women with GDM or pregnant women with T2DM and as a supplemental tool to SMBG in individuals with hypoglycaemia unawareness and/or frequent hypoglycaemic episodes.
- CGMs should be used as close to daily as possible to gain maximal benefit.
- CGMs can be a helpful tool in diabetes education by facilitating effective communication between clinicians and patients. All users should get trained on how to interpret and respond to their glucose data.
• Only CGM systems with an acceptable level of sensor accuracy should be used and when assessing hypoglycaemia the accuracy of the CGM data in the lower glycaemic range should be considered.

Continuous subcutaneous insulin infusion (CSII) or insulin pump therapy
• CSII or insulin pump therapy may be considered in paediatric patients or in adults on ≥4 insulin injections per day (intensively managed insulin-dependent T2DM).
  Common indications being:
  - High HbA1C levels on injection therapy
  - Recurrent episodes of hypoglycaemia or hypoglycaemia unawareness
  - Patients on high doses of insulin or poor glycaemic control despite intensive therapy
  - Presence of or a future risk of diabetes-related complications, or recurrent DKA/recurrent hospitalizations
  - Dawn phenomenon
  - Glycaemic variability causing challenges in diabetes management
  - Unpredictable food or meal intake patterns
  - Patients seeking improved quality of life

• Insulin pump therapy seems to be safe and effective for maintaining glycaemic control and for better outcomes in pregnancies complicated by GDM / T2DM and requiring large insulin doses. However, it is not recommended as a part of routine practice.
• During hospital admissions, CSII is not recommended in critically ill patients if the hospital/ICU staff is not familiar with the device
• In non-critically ill patients, continued use of CSII is recommended if the patient can manage the use of the device himself or has trained assistance for the same.
• CSII should be prescribed to only those eligible patients who are willing and motivated to monitor glucose levels at least four times a day, quantify food intake, and comply with follow-up. Patients must be psychologically stable and in the case of young candidates, they should have adequate support from motivated caregivers who can learn and can commit to the different aspects of diabetes management.
• CSII should only be initiated at a well-equipped centre that has trained resources to initiate and follow-up the patients on CSII.
• Continuous training and retraining would be required to learn the techniques and excel in CSII management.

Clinical decision support tools and diabetes management platforms
• Technologies that aid patients and/or healthcare providers in the diagnosis and management of diabetes, can improve both the short-term and long-term disease outcomes.
• Adequate training need to be provided to the healthcare professionals in using the clinical decision support tools and diabetes management platforms.
• From among the various diabetes self-management tools and platforms available, patients must be encouraged to adopt the most appropriate tool that would best suit their disease needs and lifestyle.
• Patients must be encouraged to seek timely guidance and frequent reassessment from a trained healthcare team and must be made aware that the adoption of various diabetes self-management tools does not diminish the importance of the former.
# Recommendations on the technologies suggested for recommended care and limited care

<table>
<thead>
<tr>
<th>Technology</th>
<th><strong>Recommended Care</strong></th>
<th><strong>Limited Care</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glucometer</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Diabetes Apps</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Insulin pump</strong></td>
<td>Yes; indications should be discussed and apart from usual indications, CSII as an option to improve quality of life of the individual should be discussed.</td>
<td>Can be discussed when there is a compelling indication</td>
</tr>
<tr>
<td><strong>CGM</strong></td>
<td>Yes; indications should be discussed</td>
<td>Can be discussed when there is a compelling indication</td>
</tr>
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</table>
### Fasting and Diabetes

#### Recommendations

##### Recommended care

- **Fasting to be avoided in individuals with T2DM especially if they also have:**
  - Uncontrolled or unstable glycaemia; recurrent diabetic ketoacidosis (DKA), significant macrovascular/ microvascular complications or hypoglycaemic unawareness
- **Individuals with T2DM should abstain from fasting if they are:**
  - On intensive insulin therapy or experience frequent hypoglycaemic episodes
  - Non-adherent to advice on diet, drug regimens, and daily activities
  - Antenatal or nursing or elderly or children
- **Diabetic individuals who wish to fast must**
  - Consult a physician prior to fasting
  - Should be encouraged to participate in pre fast counselling/assessment to optimize monitoring/therapeutic strategies for optimal glycaemic control
- **During fasting, patients with diabetes should always:**
  - Carry some sweets/ glucose source in case of hypoglycaemia
  - Carry identification card displaying diabetic status and current medication
  - Test blood glucose levels regularly (especially, if unwell during fasting)
  - Treat promptly if glucose levels are deranged
  - In case of dehydrated or hypoglycaemic episode- end the fasting immediately
  - Discuss with the physician regarding change in dose, and timing of insulin injections
- **Hypoglycaemia may be prevented in four levels including primordial, primary, secondary and tertiary, using ASAP (Anticipate, Suspect, Act to treat, Prevent) strategy**
- **Metformin, incretin based therapies (sitagliptin, vildagliptin and liraglutide) and pioglitazone, newer sulfonylureas like gliclazide MR and glimepiride are the preferable agents to be used during fasting that is spread over a number of days or weeks.**
- **To minimize T2DM- related AEs during fasting, patient centred diabetes education, fasting nutrition plan with regular glucose monitoring and adjustment of treatment regimens is recommended**

##### Limited care

- **SMBG using meters with strips, should be considered for people with diabetes using insulin or drugs like sulphonylurea and glinides.**
- **If a patient chooses to reuse the lancet or pricking device, proper antiseptic precautions should be taken.** The lancet/pricking device should be discarded when the tip goes blunt or the prick becomes painful or if it comes in contact with another individual’s blood.
- **If a patient decides to reuse pricking needle, proper care must be taken as mentioned below:**
  - Cover should be placed back on the needle immediately.
  - Needle should not touch any surface apart from the inside of the needle cover.
  - Cleaning the needle with alcohol should be avoided as it can make the point blunt.
Special situations

Type 2 Diabetes Mellitus and Surgery

Recommendations

**Recommended care**

- Conduct preoperative assessments: baseline HbA1c, blood glucose level, serum electrolytes and creatinine level, physical examination, history of diabetes and current treatment regimen, symptoms of microvascular and macrovascular complications.
- Maintain post prandial glucose of 140-180 mg/dL in-hospital ICU and 100–180 mg/dl as a guideline for general care medical and surgical wards.
- OADs or noninsulin injectable like sulfonylureas, meglitinides, TZDs, SGLT-2 inhibitors, GLP-1 agonists must be discontinued on the day of surgery and metformin should be discontinued a night before surgery.
- In patients subjected to surgery, insulin basal-bolus regimen should be followed.
- For longer and complex surgeries IV insulin infusion is recommended.
- Monitor blood glucose more frequently ranging from 0.5-2 hours.
- On the day of surgery, avoid alterations in long acting basal insulin until there is a tendency of hypoglycaemia and if patient is on diet restriction preoperatively. 75-100% of long acting insulin daily dose may be used on the day of surgery.
- Patient should be provided with clear instructions about the return to their preoperative OADs and management of hypoglycaemia.
- Resume the regular OAD medications only after the patient is medically stable and retaining oral meals regularly. Do not resume metformin in patient with renal dysfunction.
- Non-emergency procedures should be cancelled if patients have metabolic abnormalities (DKA, HHS, etc.) or glucose level >400-500 mg/dL.
- Multidisciplinary care team within an institution should formulate appropriate protocol to be followed during the hospital/surgical course for hyperglycaemia screening, monitoring, and treatment to reduce errors and improve postoperative outcomes.

**Limited care**

- Delay surgery until fluid volume status (BUN, creatinine and urine output) are stable and metabolic (pH, plasma glucose, creatinine, BUN, electrolytes) control is achieved.
- Tailor the post prandial insulin requirements according to the nutritional mode of patient.
- Avoid respective doses of subcutaneous insulin to prevent “stacking” of insulin.
Type 2 Diabetes Mellitus and Pregnancy

Recommendations

**Recommended care**

- Preconception care should be introduced in the routine diabetes care and maternal complications should be addressed
- All diabetic women and girls of child bearing potential should be educated about the risk of unplanned pregnancy and its outcomes, use of contraceptives and financial planning
- Need for strict glycaemic control, use of insulin, maintenance of safe level of HbA1c, i.e. 6.5%-7.0% to minimize risk of neonatal complications must be explained
- Insulin is the first line therapy to treat T2DM in pregnant women with pre-existing diabetes. Replace all the other anti-glycaemic medication with insulin treatment
  - If adequate blood glucose levels not achieved during pregnancy with multiple daily insulin infusions, insulin pump therapy for safe treatment must be introduced
  - Educate about teratogenic effects of ACEi, ARBs, atenolol and statins
- Prevention of dyslipidaemia:
  - Carry out lipid assessment until glycaemic target is achieved, maintain LDL cholesterol <130 mg/dL
  - Initiate treatment with fibrate to achieve triglyceride level <400 mg/mL (fasting) to minimize the occurrence of pancreatitis.
- A dose of 400 µg/day of folic acid should be recommended to avoid neural tube defects
- Antepartum care
  - During first 10 weeks of pregnancy offer retinal and renal assessment if not assessed
  - Offer ultrasound monitoring during week 16-32 to detect foetal growth and to detect structural abnormalities, if any
- Intrapartum care
  - Capillary blood glucose level should be within the optimum level of 70-110 mg/dL (3.9-6.1 mmol/L) during labour
  - Use of fixed dose of insulin analogue with dextrose infusion must be preferred to achieve target glycaemic levels during labour
- Postpartum care:
  - Monitor blood glucose level, consider insulin dose reduction to avoid hypoglycaemia
  - Reminder about importance of contraceptives in women with pre-existing diabetes and pre-conception care and planning for pregnancies in future

**Limited care**
- Multi-disciplinary clinic constituting perinatologist, dietician, endocrinologist, obstetrician, diabetes counsellor should be developed for ideal management of diabetes
- Monthly assessments of HbA1c level should be carried out. SMBG level at fasting, pre and post-prandial intervals to attain optimum glycaemic control
Type 2 Diabetes Mellitus and Critical Illness

Recommendations

<table>
<thead>
<tr>
<th>Recommended care</th>
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<tbody>
<tr>
<td>• Maintain glycaemic target of 140–180 mg/dL in medically morbid patients and a target of 110-140 mg/dL in surgically morbid patients</td>
</tr>
<tr>
<td>• Intensive Insulin therapy should be initiated when the blood glucose level is more than 180 mg/dL</td>
</tr>
<tr>
<td>• Patients on continuous IV insulin infusion should be monitored frequently to avoid the risk of hypoglycaemia</td>
</tr>
<tr>
<td>• Monitor blood glucose on hourly basis and then every 2 hours once blood glucose level is stable or 3 consecutive readings fall near the target glycaemic range</td>
</tr>
<tr>
<td>• Insulin in the form of continuous IV infusion is the only recommended route of administration in the critical care setting.</td>
</tr>
<tr>
<td>• Use of SSI, long or intermediate acting insulin regimens and premixed insulin, subcutaneously are not recommended</td>
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<tr>
<td>• On admission in the hospital, there should be mandatory testing of blood glucose, in 24 hours at least two readings should be obtained</td>
</tr>
<tr>
<td>• Include postprandial blood glucose testing in patients on oral feed</td>
</tr>
<tr>
<td>• Capillary method should be followed for the point-of-care monitoring of blood glucose</td>
</tr>
<tr>
<td>• CGMS should be preferred for glucose monitoring in critically ill patients</td>
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<tr>
<th>Limited care</th>
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<tbody>
<tr>
<td>• Use validated written or computerized protocols for predefined insulin dosage based on glycemic fluctuations</td>
</tr>
<tr>
<td>• Hospitals should have a record of hypoglycaemic episodes and should be evaluated for root cause</td>
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Type 2 Diabetes Mellitus in Young and Adolescents

Recommendations

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>• Risk-based screening for prediabetes and/or T2DM should be considered in asymptomatic children and adolescents, performed after the onset of puberty or after 10 years of age, whichever occurs earlier.</td>
</tr>
<tr>
<td>▪ If tests are normal, repeat testing at a minimum of 3-year intervals, or more frequently if BMI is increasing.</td>
</tr>
<tr>
<td>• Fasting plasma glucose, 2-h plasma glucose during a 75-g oral glucose tolerance test, and A1C can be used to test for prediabetes or diabetes in children and adolescents.</td>
</tr>
<tr>
<td>▪ Panel of pancreatic autoantibodies tested to exclude the possibility of autoimmune T1DM.</td>
</tr>
<tr>
<td>• Treatment of youth-onset T2DM should include lifestyle management (long-term weight management, vigorous physical activity, healthy eating patterns), diabetes self-management education (self-monitoring of blood glucose), and pharmacologic treatment.</td>
</tr>
<tr>
<td>• A family-centred approach to nutrition and lifestyle modification is essential and nutrition recommendations should be culturally appropriate and sensitive to family resources.</td>
</tr>
<tr>
<td>• Bariatric surgery may be considered in adolescents with marked obesity (BMI &gt;35 kg/m2) and uncontrolled glycaemia and/or serious comorbidities despite lifestyle and pharmacologic intervention.</td>
</tr>
<tr>
<td>• Blood pressure should be measured and optimized to reduce risk and/or slow the progression of diabetic kidney disease.</td>
</tr>
<tr>
<td>• Youth with T2DM should be screened for the symptoms of other comorbidities including laboratory studies when indicated for neuropathy, retinopathy, non-alcoholic fatty liver disease, obstructive sleep apnoea, polycystic ovary syndrome (in female adolescents), cardiovascular disease, and dyslipidaemia.</td>
</tr>
<tr>
<td>• Starting at puberty, preconception counselling should be incorporated into routine diabetes clinic visits for all females of childbearing potential.</td>
</tr>
<tr>
<td>• Patients should be screened for smoking and alcohol use at diagnosis and regularly thereafter.</td>
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</tbody>
</table>
Sexual Dysfunction

Recommendations

Recommended care

- A detailed history and examination should be conducted in an unintimidating private setting with structured interviews by encouraging discussion regarding sexual concerns in both men and women with diabetes.
- Appropriate language considering the patient’s age and culture should be used to make the patient comfortable.
- Psychological and social disturbances if any, should be discussed in an empathetic manner.
- Promotion of lifestyle changes to reduce the associated risk factors should be encouraged in patients with diabetes of both sexes.

Men

- Adult men with diabetes should be screened with a detailed sexual function history for ED as early as when they are diagnosed with diabetes.
- Detection of ED and evaluation of the response to treatment should be performed by validated questionnaires such as IIEF or Sexual Health Inventory for Men.
- PDE-5 inhibitors may be offered as a first-line therapy for the treatment of ED in men with diabetes as they improve the quality of life of the patients and are associated with low side-effects.
- Symptoms of hypogonadism including lack of interest in sex and ED should be investigated further with a screening for serum testosterone concentration in the morning. Testosterone replacement may be beneficial in men with diabetes with symptomatic hypogonadism.

Women

- To identify whether a diabetic woman has sexual dysfunction, eliciting a detailed history in a compassionate manner and examination is the first step.
- Several self-reported validated questionnaires such as Female Sexual Function Index, the Female Sexual Distress Scale, the Brief Index of Sexual Functioning for Women, and the Derogatis Interview for Sexual Function have been developed to assess FSD.
- Currently, the therapeutic recommendations for FSD includes maintaining a healthy lifestyle, achieving an optimal glycemic control, genitourinary infection control, resolving psychosocial issues.
- Treatment with water-based vaginal lubricants, hormone replacement therapy, clitoral therapy device, genital infection control therapy are recommended.
- Treatment strategies with dehydroepiandrosterone supplementation, estrogen or
androgen replacement, flibanserin (serotonin 1A receptor agonist and a serotonin 2A receptor antagonist) and PDE-5 inhibitors are investigated, however, currently there is limited evidence for their use.

**Limited care**

- Adult men with diabetes should be screened with a detailed sexual function history for ED, as early as when they are diagnosed with diabetes.
- Symptoms of hypogonadism including lack of interest in sex and ED should be investigated further with a screening for serum testosterone concentration in the morning.
- Promotion of lifestyle changes to reduce the associated risk factors should be encouraged in men with diabetes and SD
- To identify whether a woman with diabetes has sexual dysfunction, a detailed history and examination is the first step.
- Currently, the therapeutic recommendations for FSD include maintaining a healthy lifestyle, achieving an optimal glycemic control, genitourinary infection control, resolving psychosocial issues
Complementary and Alternate Therapy

Recommendations

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<tbody>
<tr>
<td>• Physicians, diabetologists and registered dieticians who are trained to practice modern system of medicine are advised not to prescribe complementary and alternative medicine to treat T2DM.</td>
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<tr>
<td>• Complementary and alternative medicine therapies should not replace conventional modalities of T2DM management</td>
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