GUIDELINE FOR MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN PRIMARY CARE SETTINGS AND OUTPATIENT CLINICS IN THE KINGDOM OF BAHRAIN

TYPE 2 DIABETES MELLITUS
DEC 2014
There is now extensive evidence on the optimal management of diabetes, offering the opportunity of improving the immediate and long-term quality of life of those with diabetes. Unfortunately such optimal management is not reaching many, perhaps the majority, of the people who could benefit. Reasons include the size and complexity of the evidence-base, and the complexity of diabetes care itself. One result is a lack of proven cost-effective resources for diabetes care. Another result is diversity of standards of clinical practice. Guidelines are one part of a process which seeks to address those problems. The IDF Global Guideline for type 2 diabetes were developed to concise the size and complexity of the evidence-base available, as well as simplify the complexity of diabetes care itself in the context of cost-effectiveness.
As the IDF president, I am pleased to have the IDF Global Guidelines adopted locally in the Kingdom of Bahrain, to help increase awareness on diabetes care and management.
Acknowledgment

This guideline is Adapted from the 2012 International Diabetes Federation (IDF) Global Guideline.

The approach adopted has been to advice on the IDF recommended care:

*Recommended care* is evidence-based care which is cost-effective in most nations with a well-developed service base, and with health-care funding systems consuming a significant part of national wealth. *Recommended care* should be available to all people with diabetes and the aim of any health-care system should be to achieve this level of care.
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# National Guideline for Type 2 Diabetes

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1- Screening and diagnosis:

- Detection programs are usually based on a two-step approach:
  
  **Step 1:**
  - Identify high-risk individuals: age, waist circumference (Male 94 cm or more, Female 80 cm or more), family history, cardiovascular history, gestational history and drug history.
  - Other risk factors are shown in the table:

<table>
<thead>
<tr>
<th>Other Diabetes Risk Factors</th>
<th></th>
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<tbody>
<tr>
<td>Raised triglycerides</td>
<td>raised TG levels ≥ 1.7 mmol/l (150 mg/dl), or specific treatment for this lipid abnormality.</td>
</tr>
<tr>
<td>Reduced HDL-cholesterol</td>
<td>&lt; 1.03 mmol/l (40 mg/dl) in males &lt; 1.29 mmol/l (50 mg/dl) in females or specific treatment for this lipid abnormality.</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Raised blood pressure is defined as systolic pressure ≥ 130 mmHg and/or ≥ 85 mmHg. Or treatment of previously diagnosed hypertension.</td>
</tr>
<tr>
<td>Family history of diabetes</td>
<td>First degree relative with diabetes.</td>
</tr>
<tr>
<td>Pre-existing cardiovascular disease</td>
<td>Ischaemic heart disease, cerebrovascular disease, peripheral arterial disease.</td>
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</tbody>
</table>

- In the absence of the above criteria, testing for diabetes should begin at age ≥45 years.

**Step 2 - Glycemic measure in high-risk individuals:**
Diabetes can be diagnosed on any of the following World Health Organization (WHO) criteria:
- Fasting plasma glucose (FPG) ≥7.0 mmol/l (126 mg/dl) or,
- 75 g oral glucose tolerance test (OGTT) with FPG ≥7.0 mmol/l (126 mg/dl) and/or 2 hour plasma glucose ≥11.1 mmol/l (200 mg/dl) or,
- Glycated haemoglobin (HbA1c) ≥6.5% /48 mmol/mol, or
- Random plasma glucose ≥11.1 mmol/l (200 mg/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 elevated.

- Where a random plasma glucose level ≥5.6 mmol/l (≥100 mg/dl) and <11.1 mmol/l (<200 mg/dl) is detected, a FPG should be measured, or an OGTT performed, or an HbA1c measured.

- People with screen-detected diabetes should be offered treatment and care.

**This guideline does not deal with lesser degrees of hyperglycaemia detected on screening.**
2- Diabetic Patient’s Education:
Make patient-centered, structured self-management education an integral part of the care of all people with type 2 diabetes:
- From around the time of diagnosis. An ongoing basis, based on routine assessment of need, on request.
- Use an appropriately trained multidisciplinary team (Include health-care professional with specialist training in diabetes, nurse, care-giver, health promoter, social worker, dietician, pharmacist, dentist,…..) to provide education to groups of people with diabetes or their care-givers.
- Ensure that education is accessible to all diabetic patients and/or their care-givers, either referred from the general physician, high risks detection clinic, NCD clinic or self-referral.
- Personal data and BMI will be taken. Determine which type of diabetes, presence of family history and type of unhealthy lifestyles.

Advices in general:

- **Lifestyles:**
  * Practicing physical activity
  * Applying healthy dietary habits
  * Quit smoking
  * Avoiding alcohol abuse
  * Taking enough sleep

- **Self-care:**
  * Taking medications
  * Taking injection by him/her self
  * Foot care
  * Monitor sugar status

- **Follow-up:**
  * Regular blood, eyes, renal and foot testing
  * Taking appointment for follow-up

- **Others:**
  * Diabetic complications
  * Awareness sessions about diabetic patients and different seasons such as Ramadan, Hajj, summer, winter, ashore, etc….
  * Awareness about potential risk of alternative medicine.
  * Use techniques of active learning (engagement in the process of learning and with content related to personal experience), adapted to personal choices and learning styles.
  * Use modern communications technologies to advance the methods of delivery of diabetes education such as the trusted social media; Ministry of Health, etc…

- **Provide ongoing self-management support:**
  * Rising the awareness:
  * Symptoms of the disease
  * Self-care
  * Complications
  * Sources of assistance when needed

- **Providing the necessary skills:**
  * The ability to take right decision.
  * The ability to manage time.
  * The correct way to choose and cook healthy.
*The correct way to exercise.
*Sending the patients to the physician or the nurse to teach them self-injection.

- **Promoting positive attitudes and believes:**
  *Religious motivation for coexistence with the disease.
  *Individual responsibility.
  *Create social norms to renounce smoking, drugs and alcohol.
  *Accept the disease and live with it from the patient him/her-self and others.
  *Promote a culture of healthy food and practicing physical activity in the community.

- **Providing a supportive environment:**
  *Provide curative and rehabilitative services for patients
  *Providing healthy food at home and workplace
  *Places to practice the sport
  *Policies and laws supportive of health.

- **Checklist for diabetic patient’s education by specific person in the multi-disciplinary team:**
  *Responsibility of the multi-disciplinary team
  *Each patient should have one
  *Should be filled by all team members on different intervals not specifically on the same date
  *To be done regularly and kept in patient’s file
  *To count number of visits for each member in the multi-disciplinary team and this will be one of the indicators to be measured by the end of the year

**Checklist for diabetic patient’s education by specific person in the multi-disciplinary team:**

<table>
<thead>
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<td>Health Center</td>
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<th>Nurse</th>
<th>Health promoter</th>
<th>Social worker</th>
<th>Dentist</th>
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<th>Dietician</th>
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3- Psychological care:

- In communicating with a person with diabetes, adopt whole-person approach and respect that person's central role in their care.

- Explore the social situation, attitudes, beliefs and worries related to diabetes and self-care issues. Assess well-being (including mood and diabetes distress), periodically, by questioning or validated measures (e.g. WHO-5). Discuss the outcomes and clinical implications with the person with diabetes, and communicate findings to other team members where appropriate.

- Counsel the person with diabetes in the context of ongoing diabetes education and care.

- Refer to a mental health-care professional with acknowledge of diabetes when indicated. Indications may include: severe coping problems, signs of major depression, anxiety disorder, personality disorder, addiction and cognitive decline.

4- Lifestyle management:

- Offer lifestyle advice to all people with type 2 diabetes around the time of diagnosis.
- Review and reinforce lifestyle modification yearly and at the time of any treatment change or more frequently as indicated.
- Review and provide ongoing counseling and assessment yearly as a routine, or more often as required or requested, and when changes in medication are made.
- Advise people with type 2 diabetes that lifestyle modification, by changing patterns of eating and physical activity, can be effective in controlling many of the adverse risk factors found in the condition.
- Provide access to a dietitian (nutritionist) or other health-care professional trained in the principles of nutrition, at or around the time of diagnosis, offering an initial consultation with follow-up sessions as required, individually or in groups.
- Individualize advice on food/meals to match needs, preferences, and culture.
- Advise on reducing energy intake and control of foods with high amounts of added sugars, fats or alcohol.
- Match the timing of medication (including insulin) and meals.
- Provide advice on the use of foods in the prevention and management of hypoglycaemia where appropriate.
- Introduce physical activity gradually, based on the individual's willingness and ability, and setting individualised and specific goals. Encourage increased duration and frequency of physical activity (where needed), up to 30-45 minutes on 3-5 days per week, or an accumulation of 150 minutes per week of moderate-intensity aerobic activity (50-70% of maximum heart rate).
- In the absence of contraindications, encourage resistance training three times per week.
- Provide guidance for adjusting medications (insulin) and/or adding carbohydrate for physical activity.
5- **Glucose control levels:**

- Advise people with diabetes that maintaining an HbA1c below 7.0% / 53 mmol/mol minimizes the risk of developing complications.

- A lower HbA1c target may be considered if it is easily and safely achieved.

- A higher HbA1c target may be considered for people with co-morbidities or when previous attempts to optimise control have been associated with unacceptable hypoglycemia.

- An individual’s HbA1c target should be regularly reviewed taking into account benefits, safety and tolerability.

- Treatment should be reviewed and modified if 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.

- Equivalent values for HbA1c and capillary plasma glucose are as follows:

<table>
<thead>
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<th>Normal</th>
<th>Target</th>
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<tbody>
<tr>
<td>HbA1c</td>
<td>&lt; 6.0% / 42 mmol/mol</td>
<td>&lt; 7.0% / 53 mmol/mol</td>
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<tr>
<td>Fasting/pre-meal capillary plasma glucose</td>
<td>5.5 mmol/l (100 mg/dl)</td>
<td>6.5 mmol/l (115 mg/dl)</td>
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<tr>
<td>Post meal capillary plasma glucose</td>
<td>7.8 mmol/l (140 mg/dl)</td>
<td>9.0 mmol/l (160 mg/dl)</td>
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6- **Clinical monitoring:**

- Monitor blood glucose control by measuring HbA1c using high-precision methods standardized to criteria aligned to the international reference values and subject to stringent quality assurance testing when no conditions are present in a patient that would preclude its accurate measurement.

- Measure HbA1c every 2 to 6 months depending on level, stability of blood glucose control and changes in therapy.

- Provide HbA1c result, measured either at site-of-career in the laboratory, before the clinical consultation.

- Abnormal hemoglobin's may affect the values obtained for HbA1c in some assays. To determine whether abnormal hemoglobin's are present, use high-performance liquid chromatography (HPLC) or mass spectrometry.

- If HbA1c is invalid, measure blood glucose or fructosamine to monitor diabetes control. HbA1c can be falsely low or high in certain patients if its affected by abnormal haemoglobin turnover, the presence of variant hemoglobin's, co-existing illnesses such as hematological disorders, renal or liver disease, or the effect of some drugs.

- Fructosamine should not be used as a routine substitute for HbA1c measurement. It should not be used if a patient has proteinuria.
7- Self-monitoring:

- Self-monitoring of blood glucose (SMBG) should only be made available to people with diabetes when they have the knowledge, skills and willingness to use the information obtained through testing to actively adjust treatment, enhance understanding of diabetes and assess the effectiveness of the management plan on glycemic control.
- The purpose(s) of performing SMBG and using SMBG data should be agreed between the person with diabetes and the health-care provider.
- SMBG on an ongoing basis should be available to those people with diabetes using insulin.
- SMBG should be considered for people using oral glucose lowering medications as an optional component of self-management, and in association with HbA1c testing:
  - To provide information on, and help avoid, hypoglycemia.
  - To assess changes in blood glucose control due to medications and lifestyle changes.
  - To monitor the effects of foods on postprandial glycaemia.
  - To monitor changes in blood glucose levels during undercurrent illness.
- Regular use of SMBG should not be considered patrol routine care where diabetes is well controlled by nutrition therapy or oral medications alone.
- SMBG protocols (intensity and frequency) should be individualised to address each individual’s specific educational/behavioral/clinical requirements, and provider requirements for data on glycemic patterns to monitor therapeutic decision making.
- Structured assessment of self-monitoring skills, the quality and use made of the results obtained, and of the equipment used, should be made annually.

8- Glucose control therapy:

- Begin oral glucose lowering medications with lifestyle interventions to maintain blood glucose control at target levels. Maintain support for lifestyle measures throughout the use of these medications. Consider each initiation or dose increase of an oral glucose lowering medications as a trial, monitoring the response in 3 months. Consider discontinuing ineffective therapies.

- **First-line therapy**
  - Begin with metformin unless there is evidence of renal impairment or other contraindication.
  - Titrate the dose over early weeks to minimize discontinuation due to gastrointestinal intolerance.
  - Monitor renal function and use metformin with caution if estimated glomerular filtration rate (eGFR)<45 ml/minutes/1.73 m2 (0.75 ml/second/1.73 m2).
  - Discontinue the metformin if the serum creatinine exceeds 150 micromol/liter and / or the eGFR below 30 ml/minute/1.73 m2 (<0.5 ml/second/1.73 m2).
  - Other options include a sulfonylurea (or glinide) for rapid response where glucose levels are high, oral-glucosidase inhibitors in some populations; these agents can also be used initially where metformin cannot.
  - In some circumstances dual therapy may be indicated initially if it is considered unlikely that single agent therapy will achieve glucose targets.

- **Second-line therapy**
  - When glucose control targets are not being achieved, add a sulfonylurea.
  - Other options include adding metformin if not used first-line, α-glucosidase inhibitor, a dipeptidylpeptidase 4 (DPP-4) inhibitor or a thiazolidinedione.
  - A rapid-acting insulin secretagogue is an alternative option to sulfonylureas.

- **Third-line therapy**
  - When glucose control targets are no longer being achieved, start insulin or add a third oral agent.
- If starting insulin, add basal insulin or use premix insulin (see below).
- If adding a third oral agent options include an α-glucosidase inhibitor, a DPP-4 inhibitor or a thiazolidinedione.
- Another option is to add a glucagon-like peptide-1 receptor agonist (GLP-1 RA).

**Fourth-line therapy**
- Begin insulin therapy when optimised oral blood glucose lowering medications (and/or GLP-1 RA) and lifestyle interventions are unable to maintain target glucose control.
- Intensify insulin therapy if already using insulin.

**Insulin therapy**
- Do not unduly delay the commencement of insulin.
- Maintain lifestyle measures, support for work and activities of daily living and after introduction of Insulin.
- Consider every initiation or dose increase of insulin as a trial, monitoring the response. Explain to the person with diabetes from the time of diagnosis that insulin is one of the options available to manage their diabetes and that it may turn out to be the best, and eventually necessary, way of maintaining glucose control, especially in the longer term.
- Provide education (see Chapter 2: Education) and appropriate self-monitoring (see Chapter 7: Self-monitoring).
- Explain that starting doses of insulin are low (.2 u/kg/day), for safety reasons, but that eventual dose requirement is expected to be 30-100 units/day.
- Continue metformin, other oral agents may also be continued.

**Begin with:**
- A basal insulin once daily such as neutral Protamine Hagedorn (NPH) insulin, insulin glargine or insulin detemir;
- Once or twice daily premix insulin (biphasic Insulin).
- Initiate insulin using a self-titration regimen (Dose increases of two units every 3 days) or with biweekly or more frequent contact with a health-care professional.
- Aim for pre-meal glucose levels of <6.5 mmol/l (<115 mg/dl).
- Monitor glucose control for deterioration and increase dose to maintain target levels or consider transfer to a basal plus mealtime insulin regimen.
Blood pressure control:
Recommendations

- Measure blood pressure at least annually, and at every routine clinic visit in people with known CVD, if found to be above target blood pressure levels at previous visits (see below), or if on blood pressure lowering treatment.

- Measure blood pressure with a validated meter in Good working order and an appropriately sized cuff (Large or normal depending on arm size). Measure blood pressure after sitting for at least 5 Minutes, with arm at heart level, using first and fifth Phases of Korotkoff sounds. Use 24 hour ambulatory blood pressure monitoring (ABPM) if ‘white coat’ or masked hypertension suspected, but Adjust targets down by 10/5 mmHg. Home blood pressure is recommended, but not to be considered an alternative to (ABPM) but rather complimentary and synergetic . The latter can give more readings over prolonged periods.

- Consider secondary causes of raised blood pressure if there is evidence of renal disease, electrolyte Disturbance or other specific features.

- Consider blood pressure lowering treatment if blood Pressure is consistently above 140/85 mmHg.

- All people with known CVD should receive blood Pressure lowering therapy unless contraindicated or Not tolerated.

- Aim to maintain blood pressure ≤140/85 mmHg, if Therapy is well tolerated. Revise individual targets Upwards if there is significant risk of postural Hypotension and falls. Higher targets should be used In the elderly (see Chapter17: Older People).
- Initiate a trial of lifestyle modification with Appropriate education (see Chapter 4: Lifestyle Management), aiming to reduce energy intake, salt intake, alcohol intake and inactivity.

- In diabetes not complicated by raised albumin excretion rate any agent can be used as first line Therapy except for a-adrenergic blockers, with Consideration of costs, and actively titrating dose According to response.

  1. Angiotensin converting enzyme-inhibitors (ACE-inhibitors) and angiotensin-II receptor Blockers (ARBs) may offer some advantages Over other agents in some situations, But do not use the two together (see Chapter 10: Cardiovascular risk protection and Chapter 12: Kidney damage). They are less effective in people of African Extraction.

  2. Calcium channel blockers (CCBs) should be Avoided in congestive heart failure with low ejection fraction.

  3. Use β-adrenergic blockers in people with Angina; β-adrenergic blockers and ACE inhibitors In people with coronary artery Disease; ACE-inhibitors or diuretics in those With heart failure; ACE-inhibitor plus low Dose thiazide or thiazide-like diuretic (indapamide or chlorthalidone), or ACE-inhibitor plus CCB in people with cerebrovascular disease. Care should be taken with combined thiazide and β-adrenergic blockers because of risk of deterioration in metabolic control.

BP9 Add further medications from a different class if Targets are not reached on maximal doses of current Medications, reviewing for adverse effects and likely Adherence problems as tablet numbers increase. The Preferred combinations are:

  4. ACE-inhibitor plus CCB.

  5. ACE-inhibitor plus low dose thiazide or thiazide like Diuretic (indapamide or chlorthalidone). Accept that blood pressure target may not be achievable with three or more anti-hypertensive Medications in some people.

10- Cardiovascular risk protections:

Cardiovascular risk protection through blood glucose control, blood pressure control, and lifestyle interventions is dealt with elsewhere in this section deals with cardiovascular risk assessment, lipid modifying therapy and anti-platelet therapy.

1-Assess cardiovascular risk factors at diagnosis and at least annually thereafter including:

- Current or previous CVD.
- Age and BMI (abdominal adiposity).
- Conventional CVD risk factors including smoking, blood pressure, serum lipids and family history of premature CVD.
- Renal damage (particularly albuminuria).
- Atrial fibrillation (for stroke).

2- Assessment of absolute CVD risk is an option for stratifying risk.

3- People with a previous CVD event should be treated with lifestyle modification, low-dose aspirin (or clopidigrel), high dose statins and blood pressure lowering medications, unless contraindicated or considered clinically inappropriate.
4- High risk individuals should be actively treated to reduce CVD risk with lifestyle modification and pharmacotherapy. Anti-platelet therapy is recommended in high risk individuals who have not had a CVD event as primary prevention in the following:

- Men aged ≥ 50 years or women aged ≥ 60 years who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).

**Aspirin is not given for patients whom they are intolerant or allergic to aspirin**

5- Ensure optimal management through lifestyle measures, and measures directed at good blood glucose and blood pressure control.

6- Arrange smoking cessation advice in smoker's contemplative of reducing or stopping tobacco consumption.

7- Treat high risk individuals with statins unless contraindicated or considered clinically inappropriate.

8- Consider the addition of fenofibrate where serum triglycerides are >2.3 mmol/l (>200 mg/dl) and high density lipoprotein (HDL) cholesterol is low, especially when retinopathy is present. Combination of gemfibrozil with a statin is not recommended.

9- Consider other medications for dyslipidemia (bile acid binding resins, ezetimibe, sustained release nicotinic acid, concentrated omega-3 fatty acids) in those failing to reach lipid lowering targets or intolerant of conventional medications.

10- Lipid targets are as follows:

- LDL cholesterol <2.0 mmol/l (<80 mg/dl)
- Triglyceride <2.3 mmol/l (<200 mg/dl)
- HDL cholesterol >1.0 mmol/l (>39 mg/dl)
- Non-HDL cholesterol <2.5 mmol/l (<97 mg/dl)

LDL cholesterol should be <1.8 mmol/l (<70 mg/dl) in established CVD. If drug treated patients don't reach the above targets on maximum tolerated statin therapy, a reduction in LDL cholesterol of ~ 30-40%from baseline is an alternative therapeutic goal.

11- Refer early for further investigation and consideration of revascularization those with problematic or symptomatic peripheral arterial disease, those with problems from coronary artery disease, and those with evidence of carotid disease.
11- Eye screening:

1- Ensure that examination of the eyes of people with type 2 diabetes is performed around the time of diagnosis and then routinely yearly as part of a formal recall process:

   • Measure and document visual acuity, corrected with glasses or pinhole.
   • Assess retinopathy:
     ** Using retinal photography through dilated pupils, performed by an appropriately trained health-care professional, or
     ** By examination by an ophthalmic specialist.

2- Discuss the reasons for eye examination with the person with diabetes.

3- Use tropicamide to dilate pupils, unless contraindicated, after discussing the implications and obtaining agreement of the person with diabetes.

4- Classify the findings of eye examination as requiring routine review, earlier review or referral to an ophthalmologist (if not making the examination). The following frequency of screening is suggested:

   • Yearly if no retinopathy.
   • 6-8 months if minimal unchanged retinopathy.
   • 3 to 6 months if worsening since last examination.
   • More often during pregnancy.

5- The following situations require specialist referral:
   • The same day:
     ◆ Sudden loss or decrease of vision/Evidence of pre-retinal and/or vitreous hemorrhage, new vessel formation or ruberosis iridis.
     ◆ Visual field defect/Evidence of retinal detachment.
     ◆ Severe pain
   • Within 1-2 months (as advised by an ophthalmologist) if no clinical significance indicates otherwise:
     ◆ Advanced retinal lesions (4:2:1 rule).
     ◆ Micro aneurysms or retinal hemorrhages in 4 quadrants.
     ◆ Venous beading in 2 quadrants.
     ◆ IRMAs in 1 quadrant.
     ◆ Unexplained deterioration of visual acuity.
     ◆ Macular edema.
     ◆ Unexplained retinal findings.
     ◆ Cataract.
     ◆ Inability to visualize fundus.

6- Advise that good control of blood glucose, blood pressure and blood lipids can help to reduce the risk of eye damage developing or worsening.

7- Advise that diabetic retinopathy is not a contraindication for use of aspirin if this is indicated for prevention of CVD.

8- Advise that tests of intra-ocular pressure should be made periodically.
Procedure of Referral to the ophthalmologist:
1. All type 2 diabetic patients should be referred for regional retina screening as per the above guidelines.
2. The requesting forms should be filled by the requesting physician in the general clinics and by the NCD nurse in the NCD and/or Central diabetes clinics.
3. Appointment to the regional retina screening should be taken by the patient in his/her health center.
4. After examination in the regional retina screen clinic, the results are categorized by diagnosis as outlined previously.
5. The results-filled forms are sent to the concerned health center by the ophthalmology technician and addressed to the diabetes nurse.
6. The diabetes nurse sends the results to the medical record section to be kept in the patient’s files.
7. The patient may be scheduled earlier appointments based on the result and according to the guidelines.
8. The examining ophthalmologist should send a feedback to the concerned health center.

12- Kidney damage:

Recommendations

These guidelines are concerned with preventative diabetes Care. No advice is given on further investigation of kidney Disease by a renal specialist, or subsequent tertiary care.

Recommended care

KD1 Kidney function should be assessed at diagnosis and Annually by:
• Urine test for albuminuria.
• Measurement of serum creatinine and calculation of eGFR.

KD2 Urinary albumin: creatinine ratio (ACR) measurement in an early morning first void spot specimen is the preferred method for assessment of albuminuria / 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.

KD3 If ACR is raised (microalbuminuria ACR >2.5 mg/mmol in men, >3.5 mg/mmol in women), repeat ACR twice over the following 4 months.

Micro albuminuria 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 >30 mg/mmol indicates macro albuminuria.

KD4 Chronic kidney disease is diagnosed on the basis of a raised urine albumin/protein or a reduced eGFR (<60 ml/min/1.73 m2) calculated from the MDRD formula and using a standardized creatinine assay.

KD5 Individuals with chronic kidney disease should be managed as follows:
• Use ACE-inhibitors or ARBs in individuals with Micro- or macro albuminuria, titrated to maximum tolerated dose.
• Intensify management of blood pressure (Target ≤130/80 mmHg) using blood pressure lowering medications and dietary modification (Low salt intake) (See Chapter 9: Blood Pressure control).

• Intensify management of blood glucose (see chapter 6: Glucose control levels and Chapter 9: Glucose control therapy).

• Monitor ACR, eGFR and serum potassium.

• Advise limiting protein intake to 1 g/kg daily if protein uric.

• Intensify other renal and cardiovascular protection measures (see Chapter 12: Kidney damage and Chapter 10: Cardiovascular risk protection).

KD6 Agree 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.

Limited care
KD1 Check annually for proteinuria in an early morning urine sample (or a random sample) using a dipstick.
If test is positive exclude urinary tract infection by microscopy (and culture if possible).
Measure serum creatinine and calculate eGFR Annually.

KD2 Manage those with proteinuria as follows:
• If available consider use of ACE-inhibitors or ARBs taking into account cost.
• Aim for blood pressure >130/80 mmHg using any blood pressure lowering medication and control of salt intake.
• Aim to achieve targets for blood glucose control.
• Aim to improve lipid profile using available medications.
• Check protein uric status annually.
• Measure serum creatinine and calculate eGFR annually.

Comprehensive care:
KDC1 the principles as for Recommended care, but assessment of albuminuria would always be by a laboratory quantitative method (ACR).

KDC2 Investigations to exclude other possible causes of renal disease for all with raised ACR or Protein: creatinine ratio might include autoantibodies, ultrasound, biopsy.

Rationale
Diabetes is now the leading cause of CKD in many developed countries. The prevalence of CKD in people with type 2 diabetes varies between 25 and 50% and it is associated with increased risk of morbidity and premature mortality. With increasing numbers of people with type 2 diabetes, younger age of onset, and better cardiovascular protection measures, the health impact of CKD in individuals with diabetes are growing. While the major effort of management must go to primary prevention (good blood glucose and blood pressure control from early diagnosis), the success of interventions at a later stage suggests that detection of developing kidney damage is useful.
Evidence-base
CKD is defined as a glomerular filtration rate (GFR) <60 ml/min/1.73 m² or evidence of kidney damage with or without a decreased GFR as evidenced by microalbuminuria; macroalbuminuria/proteinuria; glomerular hematuria; Pathological abnormalities; anatomical abnormalities [1]. The two main manifestations of CKD in people with type 2 diabetes are a reduction in eGFR or the presence of albuminuria/proteinuria. A number of evidence-based Guidelines specifically address CKD in people with type 2 diabetes [2-6]. There is a strong evidence base that treatment in the early stages of CKD reduces progression of kidney damage. Therefore there is general agreement that people with type 2 diabetes should be screened regularly (at diagnosis and then annually) to detect early indications of kidney damage and receive treatment.

The ACR is the preferred method of detecting albuminuria but cut-off values differ somewhat between guidelines with microalbuminuria being defined as 2.0-20.0 mg/mmol (men) and 2.8-28.0 (women) in Canada [6], 2.5-30.0 mg/mmol (men) and 3.5-30.0 mg/mmol (women) in Europe [3,5], and 2.5-25.0 mg/mmol (men) and 3.5-35.0 (women) in Australia [4] and macroalbuminuria as >20/28 mg/mmol, >30 mg/mmol and >25/35 mg/mmol respectively. Issues surrounding screening tests are reviewed in detail in the NICE and Australian type 2 guidelines [4,5], with attention drawn to the day-to-day variation in albumin excretion which underlines the need for confirmatory testing.

Monitoring of changes in GFR is emphasized in all guidelines, which recommend serum creatinine measurement and calculation of estimated GFR [2-6]. Assessment of both ACR and eGFR are necessary in order to stage CKD.

The UKPDS provided clear evidence for the benefits of blood glucose control and blood pressure control in delaying the development of kidney disease [7,8].

More recent studies have also demonstrated renal benefits of intensive blood glucose control [9, 10]. Other evidence for the importance of blood pressure control in prevention comes from trials of various blood pressure lowering medications [2-6]. Choice of agent stems from evidence on the additional benefits of agents which target the renin-angiotensin system in offering renal and cardiovascular (see Chapter 11: Cardiovascular risk protection) protection. Over and above the blood pressure-lowering effect. Both ACE-inhibitors and ARBs delay progression from micro- to macro-albuminuria in people with type 2 diabetes and hypertension. ARBs have been shown to delay progression of nephropathy in those who have macroalbuminuria and renal insufficiency (serum creatinine >1.5 mg/dl [>130 μmol/l]).

Advice to treat to tighter targets those with albuminuria is now a minority view, with general advice converging towards a target of 130/80 mmHg [2-6].

Cardiovascular risk is increased in people with microalbuminuria, and further increased in those with proteinuria and/or reduced GFR. The issue of cardiovascular risk is addressed elsewhere in this guideline (see Chapter 11: Cardiovascular risk protection).

Consideration
Although it is possible to treat kidney failure by dialysis or transplantation, availability of these very expensive treatments is severely limited in a global context. This makes efforts at prevention all the more important. It has been estimated that once a dipstick test is positive, time to kidney failure is about 9 years, but that this time-interval can be doubled through appropriate treatment of blood pressure. The issue of targets can be a particular problem in people with type 2 diabetes who are often elderly, and in whom attainment of 140/80 mmHg or less is challenging even with multiple medications and reasonable lifestyle intervention.
Implementation
Management of blood pressure overlaps with the advice given in Chapter 10: Blood pressure control. Repeat blood pressure measurement and dose titration of medications requires good access to health services for people with evidence of renal damage. Management of CKD requires access to laboratory for ACR and creatinine estimations, and availability of multiple blood-pressure-lowering medications in particular renin-angiotensin system blockers.

Evaluation
The percentage of people with appropriate urine albumin and serum creatinine measurements should be ascertained. Where abnormalities are detected, evidence of action to ensure tight blood pressure control is required, together with achieved blood pressure. Level of eGFR at which referral to nephrologists occurred may also be determined.

Potential indicators
Indicator Denominator Calculation of indicator Data to be collected for calculation of indicator
- Percentage of people with type 2 diabetes, having at least one measurement for micro albuminuria in the past year.
  - Number of people with type 2 diabetes seen in the past year.
  - Number of people with type 2 diabetes having at least one measurement for micro albuminuria in the past year as a percentage of the number of people with type 2 diabetes seen in the past year.
  - Documentation and date of the micro albuminuria measurement.
- Percentage of people with type 2 diabetes having at least one creatinine measurement (and eGFR calculated) in the past year.
  - Number of people with type 2 diabetes seen in the past year.
  - Number of people with type 2 diabetes having at least one creatinine measurement (and eGFR calculated) in the past year as a percentage of the number of people with type 2 diabetes seen in the past year.
  - Documentation and date of the creatinine measurement (and calculated eGFR).

Global Guideline for Type 2 Diabetes

References


13- Foot care Recommendations:

1. Assess feet of people with diabetes as part of an annual review for lesions which require active treatment and for risk factors for ulcer and amputation:
   - History of previous foot ulceration or amputation, symptoms of peripheral arterial disease, 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; footwear.
   - Detection of neuropathy by 10 g monofilament (or 128 Hz tuning fork); a biothesiometer is an option for quantitative assessment (cut-off point for ulcer risk >25 volts); non-traumatic pinprick.
   - Palpation of foot pulses (dorsally Pedi's and posterior tibial). Doppler ankle: brachial pressure ratio (<0.9 for occlusive vascular disease) may be used where pulses are diminished to quantify the abnormality.

2. Discuss the reasons for foot review with each person with diabetes as part of the foot-care educational process.

3. Agree 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 need and risks of ulcer and amputation.

4. Classify risk of ulcer or amputation according to findings of the foot assessment:
   - No added risk: no risk factors and no previous history of foot ulcer or amputation.
   - At risk: one risk factor and no previous history of foot ulcer or amputation.
5. Manage according to risk classification level:

- **High risk:**
  - Two or more risk factors.
  - Previous ulcer or amputation (very high risk).

6. People with foot ulceration or infection require the following management:

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; generic penicillin's, macrolides, clindamycin and/or metronidazole as indicated as first-line medications, with ciprofloxacin or coamoxicillin as examples of second-line medications.

- Probing to bone, radiology and scans, and magnetic resonance imaging where indicated for suspected osteomyelitis.

- Reduce weight bearing, relief of pressure (custom made off-loading shoes or casting, rest) and optimal pressure distribution (casting if indicated and not contraindicated).

- Investigation and treatment (referral) for vascular insufficiency.

- Specialist footwear and orthotic care (e.g. insoles), and individualized discussion of prevention of recurrence, when ulcer has healed.

- Optimal blood glucose control.
7. Amputation should not be considered unless:

1. A detailed vascular evaluation has been performed by the vascular staff.

2. Ischemic rest pain cannot be managed by analgesia or revascularization.

3. A life-threatening foot infection cannot be treated by other measures.

4. A non-healing ulcer is accompanied by a higher burden of disease than would result from amputation.

A specialist foot-care team will include doctors with a special interest in diabetes foot care, people with educational skills, and people with formal training in foot care (usually podiatrists or trained nurses).
14- Nerve Damage:

**Guidelines for investigating patients with Distal Symmetrical Polyneuropathy (DSP)**

1. Screening laboratory tests should be considered for all patients with distal symmetrical polyneuropathy.
2. Routine screening should include routine biochemistry, blood glucose, serum B12, TSH and serum protein immunofixation electrophoresis.

**Treatment of patients with Distal Symmetrical Polyneuropathy (DSP)**

1. Establish the diagnosis of peripheral neuropathy by history and examination (monofilament with or without temperature, non-traumatic pin-prick, vibration, ankle reflexes), and/ or simple quantitative testing (e.g. biothesiometer vibration perception)
2. Neuropathy disability score (NDS) is a simple and quick tool to diagnose and monitor patients (Figure 1). An NDS of 6 or higher was equated with increased risk of insensate foot ulceration in clinical trials.
3. Establish realist goals for treatment with the patient. Remember that you might not be able to control moderate to severe neuropathic pain completely. Patients should understand even 20 to 30% reductions in their pain control is an achievement.
4. Optimize glycemic control, lipid levels and blood pressure
5. Identify relevant co-morbidities (e.g cardiac, renal, or hepatic disease, depression, or gait instability that might be relieved or exacerbated by neuropathic pain treatment or that might require dose adjustment or additional monitoring of therapy.
6. There are several neuropathic pain treatments available with class A and B evidence as shown in Table 1.
7. Have an adequate trial for each drug used to treat neuropathic pain before you switch to alternative drug (as shown in table 2)
**Neuropathy Disability Score (NDS)**

<table>
<thead>
<tr>
<th>Vibration Perception Threshold</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>128-Hz tuning fork; apex of big toe: normal = can distinguish vibrating/not vibrating</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Temperature Perception on Dorsum of the Foot</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use tuning fork with beaker of ice/warm water</td>
<td>Normal = 0</td>
<td>Abnormal = 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pin-Prick</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apply pin proximal to big toe nail just enough to deform the skin; trial pair = sharp, blunt; normal = can distinguish sharp/not sharp</td>
<td>Present = 0</td>
<td>Present with reinforcement = 1</td>
</tr>
<tr>
<td>Achilles Reflex</td>
<td>Absent = 2</td>
<td>NDS Total out of 10</td>
</tr>
</tbody>
</table>

---

**Figure 1. The Modified Neuropathy Disability Score**

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**Table 1**

<table>
<thead>
<tr>
<th>Recommended Drug and Dose</th>
<th>Not Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level A</strong></td>
<td></td>
</tr>
<tr>
<td>Pregabalin, 300–600 mg/day</td>
<td></td>
</tr>
<tr>
<td><strong>Level B</strong></td>
<td></td>
</tr>
<tr>
<td>Gabapentin, 900–3600 mg/day</td>
<td>Oxcarbazepine</td>
</tr>
<tr>
<td>Sodium valproate, 500–1200 mg/day</td>
<td>Lamotrigine</td>
</tr>
<tr>
<td>Venlafaxine, 75–225 mg/day</td>
<td>Lacosamide</td>
</tr>
<tr>
<td>Duloxetine, 60–120 mg/day</td>
<td>Clonidine</td>
</tr>
<tr>
<td>Amitriptyline, 25–100 mg/day</td>
<td>Pentoxifylline</td>
</tr>
<tr>
<td>Dextromethorphan, 400 mg/day</td>
<td>Mexiletine</td>
</tr>
<tr>
<td>Morphine sulphate, titrated to 120 mg/day</td>
<td>Magnetic field treatment</td>
</tr>
<tr>
<td>Tramadol, 210 mg/day</td>
<td>Low-intensity laser therapy</td>
</tr>
<tr>
<td>Oxycodone, mean 37 mg/day, max 120 mg/day</td>
<td>Reiki therapy</td>
</tr>
<tr>
<td>Capsaicin, 0.075% qid</td>
<td></td>
</tr>
<tr>
<td>Isosorbide dinitrate spray</td>
<td></td>
</tr>
<tr>
<td>Electrical stimulation, percutaneous nerve stimulation x 3–4 weeks</td>
<td></td>
</tr>
<tr>
<td>Medication class</td>
<td>Starting dosage</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Secondary-amine TCAs</td>
<td>25 mg at bedtime</td>
</tr>
<tr>
<td>SSNRI</td>
<td></td>
</tr>
<tr>
<td>Duloxetine</td>
<td>30 mg once daily</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>37.5 mg once or twice daily</td>
</tr>
<tr>
<td>Calcium channel α2-δ ligands</td>
<td></td>
</tr>
<tr>
<td>Gabapentin</td>
<td>100-300 mg at bedtime</td>
</tr>
<tr>
<td></td>
<td>or 100-300 mg 3 times daily</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>50 mg 3 times daily or</td>
</tr>
<tr>
<td></td>
<td>or 75 mg twice daily as tolerated</td>
</tr>
<tr>
<td>Topical lidocaine</td>
<td>Maximum of 3 patches daily for a maximum of 12 h</td>
</tr>
<tr>
<td></td>
<td>5% lidocaine patch</td>
</tr>
<tr>
<td>Opioid agonists</td>
<td></td>
</tr>
<tr>
<td>Morphine, oxycodone, methadone, and levorphanol</td>
<td>10-15 mg morphine every 4 h or as needed (equianalgesic dosages should be used for other opioid analgesics)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>50 mg once or twice daily</td>
</tr>
</tbody>
</table>

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* SSNRI = selective serotonin norepinephrine reuptake inhibitor; TCA = tricyclic antidepressant.

- Consider lower starting dosages and slower titration in geriatric patients.
- First-line only in certain circumstances (see text).

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15- Diabetes and Sexual Dysfunctions:

Introduction:
Diabetes has been associated with sexual dysfunction both in men and in women. Hyperglycemia, which is a main determinant of vascular diabetic complications, may participate in the pathogenetic mechanisms of sexual dysfunction in diabetes. On the other hand, diabetic people may present with several clinical conditions, including hypertension, overweight and obesity, metabolic syndrome, cigarette smoking, or atherogenic dyslipidemia, which are themselves risk factors for sexual dysfunction in both sexes [1-2].

Definitions:
The definitions of sexual dysfunctions according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (APA,2013), which contains a chapter on sexual dysfunctions, was published in 2013 [3]. The DSM V has specifies specific duration and severity (frequency) criteria for most of the disorders. Most sexual dysfunction diagnoses require that the problems have persisted for at least six months and to occur on approximately 75% of sexual occasions to be diagnosed as sexual dysfunctions. Eight specific diagnoses are specified: delayed ejaculation, erectile disorder, female orgasmic disorder, female sexual interest/arousal disorder( SIAD), genito-pelvic pain/penetration disorder( GPPD),male hypoactive sexual desire disorder, premature (early) ejaculation, and substance/medication induced disorder. There are also two non-specific codes: other specified sexual dysfunction and unspecified sexual dysfunction. The DSM 5 also asks the clinician to specify subtypes as lifelong or acquired and generalized or situational as well as to specify severity as mild, moderate or severe.

DSM-5 Definitions and Criteria for Sexual Dysfunctions:

Erectile disorder:
A. At least one of the following symptoms must be experienced on almost or all (approximately 75%-100%) occasions of sexual activity (in identified situational contexts or, if generalized, in all contexts): 1) Marked difficulty in obtaining an erection during sexual activity 2) Marked difficulty in maintaining an erection until completion of sexual activity 3) Marked decrease in erectile rigidity.
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.

Delayed Ejaculation:
A. Either of the following symptoms must be experienced on almost all or all occasions (approximately 75%-100%) of partnered sexual activity (in identified situational contexts or, if generalized, in all contexts) and without the individual desiring delay: 1) Marked delay in ejaculation 2) Marked infrequency or absence of ejaculation.
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.
Female Orgasmic Disorder:
A. Presence of either of the following symptoms and experiences on almost all or all (approximately 75%-100%) occasions of sexual activity (in identified situational contexts or, if generalized) in all contexts: 1) Marked delay in, marked infrequency of, or absence of orgasm 2) Markedly reduced intensity of orgasmic sensations.
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress (e.g. partner violence) or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.

Female Sexual Interest/Arousal Disorder:
A. Lack of, or significantly reduced, sexual interest/arousal as manifested by at least three of the following: 1) Absent/reduced interest in sexual activity 2) Absent/reduced sexual/erotic thoughts or fantasies 3) No/reduced initiation of sexual activity, and typically unreceptive to a partner’s attempts to initiate 4) Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (approximately 75%-100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts) 5) Absent/reduced sexual interest/arousal in response to any internal or external sexual/erotic cues (e.g. written, verbal, visual) 6) Absent/reduced genital or nongenital sensations during sexual activity in almost all or all (approximately 75%-100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts).
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress (e.g. partner violence) or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.

Genital-Pelvic Pain/Penetration Disorder:
A. Persistent or recurrent difficulties with one (or more) of the following: 1. Vaginal penetration during intercourse 2) Marked vulvovaginal or pelvic pain during vaginal intercourse or penetration attempts 3) Marked fear or anxiety about vulvovaginal or pelvic pain in anticipation of, during, or as a result of vaginal penetration 4) Marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration.
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress (e.g partner violence) or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.

Male Hypoactive Sexual Desire Disorder
A. Persistently or recurrently deficient (or absent) sexual/erotic thoughts or fantasies and desire for sexual activity. The judgment of deficiency is made by the clinician, taking into account factors that affect sexual functioning, such as age and general and sociocultural contexts of the individual’s life.
B. The symptoms in Criteria A have persisted for a minimum duration of approximately 6 months.
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.
Premature (Early) Ejaculation:
A. A persistent or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately 1 minute following vaginal penetration and before the individual wishes it. NOTE: Although the diagnosis of premature (early) ejaculation may be applied to individuals engaged in nonvaginal sexual activities, specific duration criteria have not been established for these activities.
B. The symptom in Criteria A must have been present for at least 6 months and must be experienced on almost all or all (approximately 75%-100%) occasions of sexual activity (in identified situational contexts or if generalized, in all contexts).
C. The symptoms in Criteria A cause clinically significant distress in the individual.
D. The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition.

Substance/Medication-Induced Sexual Dysfunction:
A. A clinically significant disturbance in sexual function is predominant in the clinical picture.
B. There is evidence from the history, physical examination, or laboratory findings of both 1 and 2. 1). The symptoms in Criteria A developed during or soon after substance intoxication or withdrawal of exposure to a medication 2) The involved substance/medication is capable of producing the symptoms in Criteria A.
C. The disturbance is not better explained by a sexual dysfunction that is not substance/medication-induced. Such evidence of an independent sexual dysfunction could include the following. The symptoms precede the onset of the substance/medication use: the symptoms persist for a substantial period of time (e.g. about 1 month) after the cessation of acute withdrawal or severe intoxication; or there is other evidence suggesting the existence of an independent non-substance/medication-induced sexual dysfunction (e.g. a history of recurrent non-substance/medication-induced episodes).
D. The disturbance does not occur exclusively during the course of a delirium.
E. The disturbance causes clinically significant distress in the individual.

Other specified sexual dysfunction:
This category applies to presentations in which symptoms characteristic of a sexual dysfunction that cause clinically significant distress in the individual predominate but do not meet the full criteria for any of the disorders in the sexual dysfunctions diagnostic class. The other specified sexual dysfunction is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for any specific dysfunction. This is done by recording “other specified sexual dysfunction “ followed by the specific reason (e.g. “sexual aversion”).

Unspecified sexual dysfunction:
This category applies to presentations in which symptoms characteristic of a sexual dysfunction that cause clinically significant distress in the individual predominate but do not meet the full criteria for any of the disorders in the sexual dysfunctions diagnostic class. The unspecified sexual dysfunction category is used in situations in which the clinician chooses not to specify that the criteria were not met for a specific sexual dysfunction, and includes presentations for which there is insufficient information to make a more specific diagnosis.

Diabetes as a Risk Factor for Men Sexual Dysfunction:
Diabetes is a very common condition affecting men of all ages. The sequelae of diabetes are well documented and include vascular and neurological damage, both of which are major causes of ED, as they result in vascular insufficiency and diabetic neuropathy, respectively.
Erectile dysfunction has been reported to occur in at least 35-90% of men with diabetes mellitus with the onset of ED occurring in an earlier age (10 to 15 years before) than those without diabetes mellitus [4-6]. In the MMAS study, the age-adjusted probability of complete ED was three times higher in men who reported having treated diabetes mellitus than those without diabetes [7]. Weinhardt and Carey [8] in 1996 published a comprehensive review of empirical literature, regarding the prevalence of ED among men with diabetes mellitus, they reviewed a large amount of the associations between ED and diabetes mellitus in their literature review of 1990 [8]. Some of their observations are reported in Table 1.

Table 1. Associations of Diabetes Mellitus (DM) with Erectile Dysfunction:
- Erectile Dysfunction is usually present within 10 years of diagnosis of DM.
- Usually occurs at a younger age group in insulin dependent DM.
- ED may be first sign of DM in as high as 12% of cases in males.
- Poorly controlled DM may produce a reversible temporary ED once controlled.
- ED in almost all patients with DM related neuropathy.
- DM macrovascular complications related to age of patient.
- DM microvascular complications related to duration of DM and glycemic control.


Diabetes mellitus has also been associated with retrograde and anejaculation. [9]

4. Diabetes as a Risk Factor for Women Sexual Dysfunction:
Kadri et al [10] in their descriptive epidemiological study of Moroccan women reported significant associations for diabetes with orgasmic dysfunction, dyspareunia and sexual aversion. Also Danish women with diabetes have been found to have low sexual desire significantly more often than non-diabetic women [11]. Moreover, women with “more” diabetic complications reported significantly more sexual dysfunctions. In one large study that evaluated 613 Jordanian diabetic women and 524 controls, it was found that the longer duration of diabetes, older age, higher BMI, the presence of CVD, and the presence of diabetic complications was significantly associated with worse sexual function [12].

5. Epidemiology of Sexual Dysfunctions in Primary Care:
A major rationale for the inquiry process is how common the detected phenomena are in general. The extent of sexual problems found in medical practices has been studied on several occasions. Several studies specific to the prevalence of sexual dysfunctions among diabetics were mentioned in the previous section. We have more evidence concerning the prevalence of sexual problems in men than women although the data base in both groups is rapidly growing. Correlates of erectile dysfunction in men include diabetes, vascular disease, age, dyslipidemia and cigarette smoking.

Screening Criteria:
Given the immense numbers of patients with sexual problems, the need becomes obvious for a triage system whereby the nature of a problem and its impact can be evaluated and proper action taken: (1) further assessment and treatment or (2) referral. The beginning of this process requires a reasonable, respectful, and regular practice by which the presence of sexual problems can be identified with just a few questions. To accomplish this goal, some sort of sex screening question must be included in an assessment. There is no universally applicable sex-screening formula. Several
approaches can be used, depending, for example, on such factors as the comfort and skill of the interviewer or the age of the patient. Screening questions asked of adolescents might well differ from questions asked of elders. When judging the usefulness of the proposed sex-screening process, one should consider the four following criteria, that is, questions should:

- Cover a wide spectrum of common problems.
- Be few in number.
- Justify the severity criterion.
- Be concerned with problems that have effective treatments.

The definition and the screening mechanism must be broad enough to encompass problems with sexual function and sexual practices. Problems with sexual function are reported by patients rather than observed by health professionals. In contrast, some sexual practices may be seen only as problematic by health professionals. In both instances, the onus remains on the health professional to elicit the information.

**Screening Tools for Sexual Dysfunction:**

Sexual problem identification should be regarded as a routine and necessary aspect of medical care for both men and women. This principle is applied to all new patient visits, especially for individuals at risk, such as men or women above the age of 50, patients with chronic illnesses or medical conditions, following major surgery or hospitalization, during major life changes (e.g., divorce, child birth), as well as during return or follow up visits for these patients. The depth and extent of sexual inquiry should be individualized, based on the clinical setting, patient characteristics, and type of visit.

Screening checklists can provide a valuable resource in identifying and assessing sexual problems in men and women. These simple tools have the obvious benefits of providing validated and cost efficient identification of the problem, as well as preliminary assessment of current and past sexual functioning. To facilitate initial identification of a sexual problem, two brief screening checklists have been developed by the ICSM committee [13] It should be emphasized that, although valuable in recognizing and identifying sexual dysfunction, screening tools should not be substituted for a thorough sexual, medical, and psychosocial history. Moreover, further evaluation of these symptoms is always recommended prior to initiating sexual medicine therapy.

**THE BRIEF SEXUAL SYMPTOM CHECKLIST FOR MEN (BSSC-M) AND WOMEN (BSSC-W) [13]:**

This brief checklist consists of 4 simple questions and it is suitable for use in primary care settings, as well as for screening and addresses the patient’s level of satisfaction with sexual function (the major outcome measure in sexual health) [13]. Additionally, it assesses duration, the type/s of sexual problems experienced, as well as the willingness of the person to discuss the problem with a health care provider. Three of the four questions are common for men and women, while the fourth question (type of problem) is specific for gender.
Table 2. THE BRIEF SEXUAL SYMPTOM CHECKLIST FOR MEN (BSSC-M)

Please answer the following questions about your overall sexual function

1. Are you satisfied with your sexual function?
   □ Yes □ No

   If No, please continue.

2. How long have you been dissatisfied with your sexual function?
   ......................................................................................................................

(a. The problems with your sexual function is: (mark one or more)
Problems with little or no interest in sex  □
Problems with erection  □
Problems ejaculating too early during sexual activity  □
Problems taking too long, or not being able to ejaculate or have orgasm □
Problems with pain during sex □
Problems with penile curvature during erection □
.......................................................................................................................... : Other □
..........................................................................................................................

(b. Which problem is most bothersome (circle)  □ □ □ □ □

3. Would you like to talk about it with your doctor?
   □ Yes □ No □

Table 3. THE BRIEF SEXUAL SYMPTOM CHECKLIST FOR WOMEN (BSSC-W)

Please answer the following questions about your overall sexual function

1. Are you satisfied with your sexual function?
   □ Yes □ No

2. How long have you been dissatisfied with your sexual function?
   ......................................................................................................................

(a. The problems with your sexual function is: (mark one or more)
Problems with little or no interest in sex  □
Problems with decreased genital sensation (feeling) □
Problems with decreased vaginal lubrication (dryness) □
Problems reaching orgasm □
Problems with pain during sex □
.......................................................................................................................... : Other □
..........................................................................................................................

(b. Which problem is most bothersome (circle)  □ □ □ □ □

4. Would you like to talk about it with your doctor?
   □ Yes □ No □

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**Diagnostic and Treatment Algorithm:**

The first step includes the basic evaluation; medical, sexual and psychosocial history are mandatory for every patient, while focused physical exam and laboratory tests are highly recommended. Recommended laboratory tests for men and women with sexual problems typically include fasting glucose, cholesterol, lipids and hormonal profile (sex hormones, gonadotropins, TSH). As with the physical examination, these tests are performed primarily to identify or confirm specific etiologies (e.g. hypogonadism), or to assess the role of potential medical comorbidities or concomitant illnesses (e.g. diabetes, hyperlipidemia). Additional laboratory tests (e.g., thyroid function) may be performed at the discretion of the physician, based on the medical history and clinician’s judgment. Step 2 includes the interpretation of the findings and identification of needs for specialized tests. In the majority of the patients optional tests are not necessary. However, physicians may make the final decision either to proceed with specialized tests/referral or to treatment [14]. Step 3 includes patient/partner education, which is of major significance and a necessary prelude for shared decision making. Step 4 includes the development of a mutually agreed upon treatment plan, equally considering the available treatment options for a certain diagnosis, as well as patients’ needs and preferences. Finally, step 5 refers to the important phase of follow-up, emphasizing that the overall goal of treatment is improvement of patient’s subjective sexual well being and not merely relief of symptoms and/or restoration of sexual function[13].

Figure 1. The 5 step-wise diagnostic and treatment algorithm for Sexual Dysfunctions in men and women[13].

**Glycemic Control and Lifestyle Modifications:**

As a consequence of its multifactorial etiology, the treatment of sexual dysfunctions in diabetic men requires a global approach. The first step is to correct the modifiable risk factors and to promote lifestyle changes. Tight glycemic control, so as to maintain an HbA1c concentration less than 7%, is recommended for all nonpregnant adults with diabetes to minimize the risk of long-term microvascular complications. Although several studies demonstrate an association between poor glycemic control and the risk of ED, it is still not clear whether intensive glycemic control may have beneficial effects on erectile function. Many cross-sectional studies have shown that better glycemic control is associated with improved erectile function [15-16].

In an ancillary study of the Epidemiology of Diabetes Intervention and Complication Study (EDIC) [17], a period of intensive therapy significantly reduced the prevalence of ED among men suffering from diabetes for 10 years or more and microvascular complications, compared with those with a 1- to 5-year history of disease, but without complications. In type 2 diabetic men, limited data have been reported on risk reduction interventions for ED, and these have had conflicting results. Further studies, including adequate sample size and validated ED measurements, are needed to clarify whether intensive glycemic control may produce benefits for erectile function in men with poor glycemic control. Lifestyle changes, such as increased physical activity, a Mediterranean diet, and reduced caloric intake, have been associated with the amelioration of erectile function in the general male population. Esposito et al [18] used their database of subjects participating in randomized controlled trials to evaluate whether improvements in erectile function were related to success in achieving lifestyle changes. After ranking men according to their success in achieving the goals of intervention (weight loss, low intake of saturated fat, high consumption of monounsaturated fat and fiber, and moderate physical activity), a strong correlation was observed between the success score and the restoration of erectile function. Moreover, at the 2-year examination point, the number of men without ED was significantly higher in the group randomized to intensive lifestyle changes compared with that of men in the control group. Wing et al [19] evaluated 1-year changes in erectile function in 306 overweight men with type 2 diabetes mellitus participating in the Look AHEAD (Action for Health in Diabetes) trial; from baseline to 1 year, 8% of men assigned to the intensive
lifestyle intervention reported a worsening of erectile function compared to 22% of the control participants. Moreover, the overall IIEF score improved from 17.3 to 18.6 (P < 0.04 and P < 0.06, after adjusting for baseline differences) in the intervention group. The suggested mechanisms by which weight loss, healthy diet, and physical exercise can improve erectile function include the amelioration of endothelial dysfunction, insulin-resistance, and low-grade inflammatory state associated with diabetes and metabolic diseases – all of which are risk factors for ED [20]. In this vein, the resulting improved inflammatory status may help contribute to reduce the burden of sexual dysfunction in diabetic men.

**Referral to the Specialized Sexual Health Care Clinic:**
In Bahrain, primary care physicians are the point of first contact with the healthcare system for many people, and physician provides continuous and comprehensive care for patients using a patient-centered approach. Moreover, the high prevalence of systemic illnesses and their treatment impose a significant And identified risk of sexual dysfunction. They significantly increase the likelihood of erectile dysfunction, giving the primary care physicians an opportunity to intervene. For this reason, a specialized sexual health clinic in the primary care setting is of utmost importance. Recognition of the high prevalence of sexual dysfunction in the general population has led to the conclusion that management of sexual disturbances constitutes a primary care practice specialty and addressing patients’ sexual histories should be part of routine care in primary care settings. Currently, a specialized sexual health care clinic is operational since May 2010. The clinic falls under the services provided by the Ministry of Health at the Kingdom of Bahrain. The clinic is managed by a consultant family physician and clinical sexologist. Highest degree of confidentiality is maintained and assured throughout the referral and consultation process.

**Table 4. Indications for referral to the specialized sexual health care clinic:**

<table>
<thead>
<tr>
<th>Some common Indications for referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Males or females with sexual dysfunction or sexual concerns</td>
</tr>
<tr>
<td>2. Primary / lifelong sexual dysfunction</td>
</tr>
<tr>
<td>3. Reluctance of the primary care physician to deal with sexual dysfunction</td>
</tr>
<tr>
<td>4. Patient request</td>
</tr>
<tr>
<td>5. Gender Dysphoria</td>
</tr>
<tr>
<td>6. Treatment failure or failure to respond to oral PDE inhibitors</td>
</tr>
<tr>
<td>7. Relationship problems</td>
</tr>
<tr>
<td>8. Complex medical problems (codmorbidities)</td>
</tr>
<tr>
<td>9. Medicolegal cases</td>
</tr>
</tbody>
</table>

**11. Conclusion:**
Sexuality is a complex interaction of biology, culture, developmental, and current intra and interpersonal psychology. A bio-psychosocial model of sexual dysfunction provides a compelling argument for combined therapy integrating sex therapy and sexual pharmaceuticals. Restoration of lasting and satisfying sexual function requires a multidimensional understanding of all of the forces that created the problem, whether a solo physician or multidisciplinary team approach is used. Each clinician needs to carefully evaluate their own competence and interests when considering the treatment of a person’s sexual dysfunction, so that regardless of the modality used, the patient receives optimized care. Combining sexual pharmaceuticals and sex therapy is the “oral therapy” of choice to optimize treatment for all sexual dysfunctions. This is true for men with erectile dysfunction, premature ejaculation, or retarded ejaculation and will also be true for female sexual
dysfunction. Less medication is required when you modify immediate causes while appreciating other psychological obstacles.

References


16- Detection & Management of Diabetes in pregnancy:

Diabetes in pregnancy is associated with risks to the mother and to the developing fetus. Miscarriage, pre-eclampsia and preterm labour are more common in women with pre-existing diabetes. In addition, diabetic retinopathy can worsen rapidly during pregnancy. Stillbirth, congenital malformations, macrosomia, birth injury, perinatal mortality and postnatal adaptation problems (such as hypoglycaemia) are more common in babies born to women with pre-existing diabetes. Therefore, these guidelines have been developed with the aim of standardising the care of expectant diabetic mothers, improves their care based on recent evidence based recommendations.

I. Gestational Diabetes:

Gestational diabetes is defined as any degree of glucose intolerance with onset or first recognition during pregnancy, whether or not the condition persisted after pregnancy, and not excluding the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy.

A. Detection of Gestational Diabetes:

1. Screen for undiagnosed type 2 diabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria.

As the incidence of obesity and diabetes is increasing in women of childbearing age and the number of pregnant women with undiagnosed type 2 diabetes have increased. It is reasonable to screen women with risk factors for type 2 diabetes (Table 1) at their initial prenatal visit, using standard diagnostic criteria (Table 2).
Table 1—Criteria for testing for diabetes in asymptomatic adult individuals
Testing should be considered in all adults who are overweight (BMI ≥ 25 kg/m²) and have additional risk factors:
- Physical inactivity
- First-degree relative with diabetes
- Women who delivered a baby weighing > 9 lb (4.5Kg) or more
- Previous gestational diabetes
- Hypertension (≥ 140/90 mmHg or on therapy for hypertension)
- HDL cholesterol level < 35 mg/dL (0.90 mmol/L) and/or a triglyceride level > 250 mg/dL (2.82 mmol/L)
- Women with polycystic ovarian syndrome
- HbA1C ≥ 5.7%, IGT, or IFG on previous testing
- Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
- History of CVD.

Table 2—Criteria for the diagnosis of diabetes in non pregnant patients
- HbA1C ≥ 6.5%.
OR
- FPG ≥ 126 mg/dL (7.0mmol/L).
  Fasting is defined as no caloric intake for at least 8 h.*
OR
- Two-hour PG ≥ 200 mg/dL (11.1mmol/L) during an OGTT.
  The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200mg/dL (11.1mmol/L).

*In the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.

2. Women with diabetes in the first trimester should receive a diagnosis of overt, not gestational diabetes.

3. Women who have had gestational diabetes in a previous pregnancy should be offered early OGTT at 1st prenatal visit and a further OGTT at 28 weeks if the results are normal (Table 3)
**Table 3—Screening for and diagnosis of GDM**

- **“One-step” (IADPSG consensus)”**
  - Perform a 75-g OGTT, with plasma glucose measurement fasting, 1 h and 2 h, at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes.
  - The OGTT should be performed in the morning after an overnight fast of at least 8 h. The diagnosis of GDM is made when any of the following plasma glucose values are exceeded:
    - Fasting: ≥ 92 mg/dL (5.1 mmol/L)
    - 1 h: ≥ 180 mg/dL (10.0 mmol/L)
    - 2 h: ≥ 153 mg/dL (8.5 mmol/L)

- **“Two-step”**
  - Perform a 50-g GLT (no fasting), with plasma glucose measurement at 1h (Step 1), at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes.
  - If the plasma glucose level measured 1 h after the load is ≥ 140 mg/dL* (7.8 mmol/L), proceed to 75g OGTT (Step 2). The 75g OGTT should be performed when the patient is fasting.
  - The diagnosis of GDM is made when at least two of the following four plasma glucose levels (measured fasting, 1 h, 2 h, 3 h after the OGTT) are met or exceeded:
    - Fasting 95 mg/dL (5.3 mmol/L)
    - 1 h 180 mg/dL (10.0 mmol/L)
    - 2 h 155 mg/dL (8.6 mmol/L)
    - 3 h 140 mg/dL (7.8 mmol/L)

*IADPSG: International Association of Diabetes and Pregnancy Study Groups

** We have agreed in our meeting that will continue our current practice of screening for GDM which is similar to “Two Step” protocol.

4. Screen for GDM at 24–28 weeks of gestation in pregnant women not previously known to have diabetes or other risk factors (Table 3).

**B. Management of Gestational Diabetes:**

1. Women with gestational diabetes should be informed that good glycaemic control throughout pregnancy will reduce the risk of fetal macrosomia, trauma during labour, induction of labour or caesarean section, neonatal hypoglycaemia and perinatal death.

2. Women with gestational diabetes whose pre-pregnancy body mass index was above 27 kg/m2 should be advised to restrict calorie intake (to 25 kcal/kg/day or less) and to take moderate exercise (of at least 30 minutes daily).
3. If diet and exercise fail to maintain blood glucose targets during a period of 1–2 weeks, hypoglycaemic therapy should be considered.

4. The following targets for maternal capillary glucose concentrations are recommended:
   - Preprandial: ≤ 95 mg/dL (5.3 mmol/L), and either:
   - 1-h postmeal: ≤ 140 mg/dL (7.8 mmol/L) or
   - 2-h postmeal: ≤ 120 mg/dL (6.7 mmol/L)

5. Screen women with GDM for persistent diabetes at 6–12 weeks postpartum, using the OGTT and non pregnancy diagnostic criteria.

6. HbA1C for diagnosis of persistent diabetes at the postpartum visit is not recommended.

7. As women with a history of GDM have a greatly increased subsequent diabetes risk, they should be followed up with subsequent screening for the development of diabetes or prediabetes at least every 3 years.

8. Lifestyle interventions or metformin should be offered to women with a history of GDM who develop prediabetes.

II. Management of Pregnant patients with Preexisting Diabetic:

I. Preconception care:

1. Women contemplating pregnancy need to be seen by a multidisciplinary team experienced in diabetes management both before and during pregnancy.

2. Starting at puberty, preconception counselling should be incorporated in the routine diabetes clinic visit for all women of childbearing potential.

3. They should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.

4. Advised to take folic acid (5 mg/day) until 12 weeks of gestation to reduce the risk of having a baby with a neural tube defect.

5. Aim to maintain their HbA1c close to normal as possible (below 7%) to reduce the risk of congenital malformations. There is no threshold for HbA1C values below which risk disappears entirely. However, malformation rates above the 1–2% background rate of non-diabetic pregnancies appear to be limited to pregnancies in which first-trimester HbA1C concentrations are 1% above the normal range for non-diabetic patients.

6. Women with diabetes whose HbA1c is above 10% should be strongly advised to avoid pregnancy.

7. Given advice and have access to effective contraception until stable and acceptable glycemia is achieved.
8. Be evaluated and if indicated is treated for diabetic retinopathy, nephropathy, neuropathy, and CVD.

9. Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including Statins (category X: contraindicated for use in pregnancy), Angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II receptor antagonists ARBs. These are category C (risk cannot be ruled out) in the first trimester but category D (positive evidence of risk) in later pregnancy and should generally be discontinued before pregnancy or as soon as pregnancy is confirmed. Alternative antihypertensive agents suitable for use during pregnancy should be substituted.

10. Antidiabetic agents need to be evaluated prior to conception and either discontinued before conception or as soon as pregnancy is confirmed. Metformin and acarbose are classified as category B (no evidence of risk in humans), but other antidiabetic agents are category C (data are insufficient to establish the safety of these agents in pregnancy).

II. Antenatal care for women with diabetes:

- Women with diabetes who are pregnant should be offered immediate contact with a joint diabetes and antenatal clinic.
- Women with diabetes should have contact with the diabetes care team for assessment of glycaemic control every 1–2 weeks throughout pregnancy.
- Antenatal appointments for women with diabetes should provide care specifically for women with diabetes, in addition to the care provided routinely for healthy pregnant women.
- At each appointment women should be offered ongoing opportunities for information and education. (Table 4)
(Table 4) - Specific antenatal care for women with diabetes:

<table>
<thead>
<tr>
<th>Appointment</th>
<th>Care for women with diabetes during pregnancy</th>
</tr>
</thead>
</table>
| **1st appointment (joint diabetes & antenatal clinic)** | • Offer information, advice and support in relation to optimising glycaemic control.  
• Take a clinical history to establish the extent of diabetes-related complications.  
• Review medications for diabetes and its complications.  
• Offer retinal and/or renal assessment if these have not been undertaken in the previous 12 months. |
| **7–9 weeks** | • Confirm viability of pregnancy & gestational age |
| **Booking appointment (ideally by 10 weeks)** | • Discuss information, education and advice about how diabetes will affect the pregnancy, birth and early parenting (such as breastfeeding and initial care of the baby) |
| **16 weeks (Secondary care)** | • Offer retinal assessment at 16–20 weeks to women with pre-existing diabetes who showed signs of diabetic retinopathy at the first antenatal appointment |
| **20 weeks (Secondary care)** | • Offer anomaly scan  
• four chamber view of the fetal heart and outflow tracts |
| **28 weeks** | • Offer ultrasound monitoring of fetal growth and amniotic fluid volume  
• Offer retinal assessment to women with pre-existing diabetes who showed no diabetic retinopathy at their first antenatal clinic visit |
| **36 weeks** | • Offer ultrasound monitoring of fetal growth and amniotic fluid volume  
• Offer information and advice about:  
  • timing, mode & management of birth  
  • changes to hypoglycaemic therapy during & after birth  
  • management of the baby after birth  
  • initiation of breastfeeding & the effect of breastfeeding on glycaemic control  
• contraception and follow-up |
| **38 weeks** | • Offer induction of labour, or caesarean section if indicated |
III. Target ranges for blood glucose during pregnancy:

1. Individualised targets for self-monitoring of blood glucose should be agreed with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia.

2. For women with preexisting type 1 or type 2 diabetes who become pregnant, the following are recommended as optimal glycemic goals, if they can be achieved without excessive hypoglycemia:
   - Premeal, bedtime, and overnight glucose 60–99 mg/dL (3.3–5.4 mmol/L)
   - Peak postprandial glucose 100–129 mg/dL (5.4–7.1 mmol/L)
   - HbA1C <6.0%

3. HbA1c should not be used routinely for assessing glycaemic control in the second and third trimesters of pregnancy.

4. Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketonuria or ketonaemia if they become hyperglycaemic or unwell.

5. Healthcare professionals should be aware that the rapid-acting insulin analogues (aspart and lispro) have advantages over soluble human insulin during pregnancy and should consider their use.

6. Women with insulin-treated diabetes should be advised of the risks of hypoglycaemia and hypoglycaemia unawareness in pregnancy, particularly in the first trimester.

7. During pregnancy, women with insulin-treated diabetes should be provided with a concentrated glucose solution and women with type 1 diabetes should also be given glucagon, women and their partners or other family members should be instructed in their use.

8. During pregnancy, women who are suspected of having diabetic ketoacidosis should be admitted immediately for level 2 critical care, where they can receive both medical and obstetric care.

IV. Retinal assessment during pregnancy:

- Pregnant women with pre-existing diabetes should be offered retinal assessment following their first antenatal clinic appointment and at again at 28 weeks if the first assessment is normal.
If any diabetic retinopathy is present, an additional retinal assessment should be performed at 16–20 weeks.

If retinal assessment has not been performed in the preceding 12 months, it should be offered as soon as possible after the first contact in pregnancy in women with pre-existing diabetes.

Diabetic retinopathy should not be considered a contraindication to rapid optimisation of glycaemic control in women who present with a high HbA1c in early pregnancy.

Women who have preproliferative diabetic retinopathy diagnosed during pregnancy should have ophthalmological follow-up for at least 6 months following the birth of the baby.

Diabetic retinopathy should not be considered a contraindication to vaginal birth.

V. Renal assessment during pregnancy:

- If renal assessment has not been undertaken in the preceding 12 months in women with pre-existing diabetes, it should be arranged at the first contact in pregnancy.
- If serum creatinine is abnormal (120 micromol/litre or more) or if total protein excretion exceeds 2 g/day, referral to a nephrologist should be considered (eGFR should not be used during pregnancy).
- Thromboprophylaxis should be considered for women with proteinuria above 5 g/day (macroalbuminuria).

VI. Diabetic mother and Antihypertensive:

- In a pregnancy complicated by diabetes and chronic hypertension, target blood pressure goals of SBP 110–129 mmHg and DBP 65–79 mmHg are reasonable, as they contribute to improved long term maternal health.
- Lower blood pressure levels may be associated with impaired fetal growth.
- During pregnancy, treatment with ACE inhibitors and ARBs is contraindicated, since they may cause fetal damage.
- Antihypertensive drugs known to be effective and safe in pregnancy include methyldopa, labetalol, diltiazem, clonidine, and prazosin.
- Chronic diuretic use during pregnancy has been associated with restricted maternal plasma volume, which may reduce uteroplacental perfusion.
VII. Screening for congenital malformations:
- Women with diabetes should be offered antenatal anomalies scan at 20-22 weeks.
- Women with diabetes should be offered antenatal examination of the four chamber view of the fetal heart and outflow tracts at 18-20 weeks.

VIII. Monitoring fetal growth and wellbeing:
- Pregnant women with diabetes should be offered ultrasound monitoring of fetal growth and amniotic fluid volume every 4 weeks from 28 to 36 weeks.
- Routine monitoring of fetal wellbeing before 38 weeks is not recommended in pregnant women with diabetes, unless there is a risk of intrauterine growth restriction.

IX. Preterm labour in women with diabetes:
- Diabetes should not be considered a contraindication to antenatal steroids for fetal lung maturation or tocolysis.
- Women with insulin-treated diabetes who are receiving steroids for fetal lung maturation should be closely monitored.
- Betamimetic drugs should not be used for tocolysis in women with diabetes.

X. Intrapartum care:
- Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labour, or by elective caesarean section if indicated, after 38 completed weeks.
- Diabetes should not in itself be considered a contraindication to attempting vaginal birth after a previous caesarean section.
- Pregnant women with diabetes who have an ultrasound-diagnosed macrosomic fetus should be informed of the risks and benefits of vaginal birth, induction of labour and caesarean section.
- During labour and birth, capillary blood glucose should be monitored on an hourly basis in women with diabetes and maintained at between 4 and 7 mmol/litre.
- Women with type 1 diabetes should be considered for intravenous dextrose and insulin infusion from the onset of established labour.
• Intravenous dextrose and insulin infusion is recommended during labour and birth for women with diabetes whose blood glucose is not maintained at between 4 and 7 mmol/litre.

XI. Neonatal care:
• Women with diabetes should be advised to give birth in hospitals where advanced neonatal resuscitation skills are available 24 hours a day.
• Babies of women with diabetes should be kept with their mothers unless there is a clinical complication or there are abnormal clinical signs that warrant admission for intensive or special care.
• Blood glucose testing should be carried out routinely in babies of women with diabetes at 2–4 hours after birth.
• Blood tests for polycythaemia, hyperbilirubinaemia, hypocalcaemia and hypomagnesaemia should be carried out for babies with clinical signs.
• Babies of women with diabetes should have an echocardiogram performed if they show clinical signs associated with congenital heart disease or cardiomyopathy, including heart murmur.

XII. Postnatal care:
• Women with insulin-treated pre-existing diabetes should reduce their insulin immediately after birth and monitor their blood glucose levels carefully to establish the appropriate dose.
• Women with insulin-treated pre-existing diabetes should be informed that they are at increased risk of hypoglycaemia in the postnatal period, especially when breastfeeding, and they should be advised to have a meal or snack available before or during feeds.
• Women with pre-existing type 2 diabetes who are breastfeeding can resume or continue to take metformin and glibenclamide immediately following birth but other oral hypoglycaemic agents should be avoided while breastfeeding.
• Women with diabetes who are breastfeeding should continue to avoid any drugs for the treatment of diabetes complications that were discontinued for safety reasons in the preconception period.
XIII. follow-up after birth:

- Women with pre-existing diabetes should be referred back to their routine diabetes care arrangements.
- Women with diabetes should be reminded of the importance of contraception and the need for preconception care when planning future pregnancies.

References

1. ADA. Standards of Medical Care in Diabetes. American Diabetes Association, Volume 37, Supplement 1, January 2014


4. SOGC. Screening for Gestational Diabetes Mellitus. The Society of Obstetricians and Gynaecologists of Canada No. 121, November 2002

17- Older people Recommendations:

Diagnosis of diabetes in older people should be in accordance with WHO criteria which apply to all age groups (see Chapter 1: Screening and diagnosis). Asymptomatic older people should be screened for undiagnosed diabetes as outlined in Chapter 1: Screening and diagnosis.

Clinicians should be alert to isolated post-challenge hyperglycaemia which is common in older people.

An agreement should be negotiated between the clinician and the patient or principal carer on treatment aims and goals of care designed to optimise patient empowerment.

Glucose-lowering interventions should aim to achieve an HbA1c of 7.0-7.5% / 53-59 mmol/mol. A higher target may be appropriate in the presence of modifying factors such as vulnerability to hypoglycaemia, presence of co-morbidities, cognitive and mood status, and limited life expectancy.

Care should be taken in commencing blood glucose lowering medications unless FPG is consistently 6 mmol/l or higher.

As a precaution to reduce the risk of hypoglycaemia, particular care should be taken to avoid FPG <6.0 mmol/l on treatment.

At initial assessment, all older people with diabetes should have a:
- Basic assessment of walking and activities of daily living abilities including the use of walking aids and special footwear, and a history taken enquiring about falls.
- History taken of any recent memory problems.
- Nutritional evaluation using a recognized assessment tool (e.g. the Malnutrition Universal screening Tool [1]).
- Cardiovascular risk assessment and review/discussion of modifiable risk factors including smoking cessation.

Structured patient educational should be accessible to all older people and take into account culture, language, nutritional preferences, ethnicity, level of disability, geographical factors and needs of carers.

**Provide continuing care and support including:**

- Promoting self-management including SMBG if indicated (see Chapter 8: Self-monitoring) within the context of the family and clinical setting.
- Annual Review including weight and height, MI, blood pressure, falls risk assessment, assessment for foot (see Chapter 14: Foot care) and eye problems (see Chapter 12: Eye screening), eGFR and urine albumin and lipid profile.

Regularly review those on oral agents taking into consideration the often increased risk of hypoglycaemia, renal dysfunction, polypharmacy and difficulties in adherence to treatment. Metformin can be considered as first-line glucose lowering therapy, and as an adjunct to insulin therapy in those requiring insulin.

Sulfonylurea is suitable as second-line therapy but is best avoided in those at higher risk of hypoglycaemia (the frail, housebound, or resident of a care home).

Where risk of hypoglycaemia is moderate and an insulin secretagogue is being considered, an agent with a lower hypoglycaemic potential should be used.

A DPP-4 inhibitor may be considered as second-line therapy. A GLP-1 RA may be considered in obese non-frail older subjects as third-line therapy with metformin and a sulfonylurea.

Insulin treatment should not be delayed but offered as an option when clinical features are appropriate.

A basal insulin regimen may be safer in terms of hypoglycaemia risk than a pre-mixed insulin regimen.

Blood pressure lowering treatment should be commenced when blood pressure is consistently 140/90 mmHg or higher in people aged 70 to 80 years and if consistently 150/90 or higher in people aged over 80 years.

Aim for a target clinic blood pressure below 140/90 mmHg in people aged 70 to 80 years. Aim for a target clinic blood pressure below 150/90 mmHg in people aged over 80 years.

Caution should be exercised in implementing aggressive blood pressure lowering therapy in older people.
18- In-patient care:

Recommendations

Recommended care:
In-patient care organization HO1 All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team.

HO2 Designate a diabetes-trained health-care Professional to:
- Manage and co-ordinate systems of care related to diabetes management of in-patients.
- Co-ordinate training of hospital staff in awareness of the needs of people with diabetes.
- Implement strategies to prevent disempowerment of those who could self-manage their diabetes.
- Plan for discharge and follow-up.

HO3 Provide access for people with diabetes and hospital:
Staff to a multidisciplinary diabetes team.

HO4 Ensure laboratory/service support for:
- Assays including plasma glucose, HbA1c, basic hematology and biochemistry, and lipid profile.
- Microbiological investigation.
- Radiology and other imaging.

HO5 Patients with hyperglycaemia in the hospital who do not have a prior diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge.

General ward care

HO6 Encourage self-management of diabetes (food choice, self-monitoring, insulin dose adjustment where appropriate) integrated into usual ward care.

Management during in-patient procedures

HO7 Evaluate blood glucose control and metabolic and vascular complications (in particular renal and cardiac status) prior to planned procedures; Provide advice on the management of diabetes on the day or days prior to the procedure.

HO8 Ensure the provision and use of an agreed protocol for in-patient procedures and surgical operations.

HO9 Aim to maintain pre meal blood glucose targets <8.0 mmol/l (140mg/dl) and random blood glucose <10 mmol/l (180 mg/dl), provided these targets can be safely achieved.

HO10 IV insulin delivery where needed, would generally be given as a glucose/insulin/potassium infusion.

HO11 Ensure awareness of special risks to people with diabetes during hospital procedures, including risks from:
• Neuropathy (heel ulceration, cardiac arrest).
• Intra-ocular bleeding from new vessels (Vascular and other surgery requiring anticoagulation).
• Medication (risks of acute renal failure causing lactic acidosis in people on metformin, for Example with radiological contrast media).

Critical care situations

HO12 Provide access to intensive care units (ICU) for life-threatening illness, including blood glucose control usually with IV insulin therapy.

HO13 Provide protocol-driven care to ensure detection and immediate control of hyperglycaemia for anyone with a presumed acute coronary event or stroke, normally using IV insulin therapy with transfer to subcutaneous insulin therapy once stable and eating.

HO13 Once insulin therapy is started, a glucose range of 8.0-10 mmol/l (140-180 mg/dl) is recommended for the majority of critically ill patients while avoiding Hypoglycemia.

HO15 Emergency rooms must have clearly visible standing orders stating all critically ill patients must have their blood glucose checked.

Limited care:

HOL1 The principles are as for Recommended care, but hospitals should designate an individual in charge of matters relating to in-patient diabetes, to co-ordinate training in awareness of the needs and provision of in-patient care for people with diabetes, and the provision and use of guidelines and protocols.

HOL2 Laboratory assays should include plasma glucose and basic biochemistry; basic radiology should be available.

HOL3 Management of plasma glucose levels during in-patient procedures will generally be as for Recommended care. Where this is not possible or carries special risk, frequent subcutaneous short acting insulin with frequent monitoring may be used in emergency situations, or longer acting insulin (e.g. NPH insulin) for minor procedures or more stable health states.

Global Guideline for Type 2 Diabetes

Comprehensive care:

HOC1 The principles are as for Recommended care, but would include repeated review by a diabetes specialist where general health state is changing or glucose control is problematic.

HOC2 Maintain staff trained in aspects of diabetes management on any ward or procedure area with a significant throughput of people with diabetes.

HOC3 Use telematics review of blood glucose control to a specialist’s office for people in critical situations.
**Rationale:**

Hyperglycaemia is found, and requires management, in hospital settings not only in people with known diabetes but also in people with previously unrecognised diabetes and in people with hospital-related hyperglycaemia which reverts to normal after discharge. Prevalence of diabetes in hospitalized adult patients is of the order of 10-20%. Hospital care for people with diabetes may be required for metabolic emergencies, in-patient stabilisation of diabetes, diabetes-related complications, intercurrent illnesses, surgical procedures, and labour and delivery.

**Evidence-base:**

Some guidelines and recent publications have addressed in-patient management of hyperglycaemia [1-4]. There are three situations in which hyperglycaemia can occur in hospital – people with known diabetes, previously undiagnosed diabetes, or transient hospital-related hyperglycaemia.

There is an established association between hyperglycaemia in hospitalised patients and poor outcomes. In general evidence supports targeted glucose control in the hospital setting to improve clinical outcomes. However there is some uncertainty as to how low the glucose targets should be since recent studies in critically ill patients have not shown a significant improvement in mortality with intensive glycemic control and some have reported increased mortality [5] and increased risk of severe hypoglycaemia. The NICE-SUGAR RCT compared intensive glycaemic control (target 4.5-6.0 mmol/l [81-108mg/dl]) with standard glycaemic control (target 8.0-10.0 mmol/l [144-180 mg/dl]) in 6,104 critically ill participants, most of whom required mechanical ventilation [5].

Mortality was significantly higher in the intensive versus the conventional group in both surgical and medical patients and severe hypoglycaemia was more common in the intensively treated group. This suggests that it may not be necessary to target blood glucose values <7.8 mmol/l (140mg/dl), and that a highly stringent target of 6.1 mmol/l (110mg/dl) may actually be dangerous.

In a recent meta-analysis of 26 trials, pooled relative risk of death with intensive insulin therapy was 0.93 compared with conventional therapy (95% CI: 0.83-1.04) [6]. The pooled relative risk of hypoglycaemia with intensive therapy was 6.0 (95% CI: 4.5-8.0). The overall conclusion was that intensive insulin therapy increased the risk of hypoglycaemia but provided no overall benefit on mortality in the critically ill, but there was a possible mortality benefit for patients admitted to the surgical ICU.

The ADA [1] recommends that critically ill patients in ICU would normally be treated with an insulin infusion aiming to maintain glucose level between 7.8 and 10 mmol/l (140-180 mg/dl). Glucose targets <6.1 mmol/l (110 mg/dl) are not recommended. Insulin infusion should also be considered during other illness requiring prompt glycaemic control, or prolonged fasting. There is a lack of studies on non-critically ill patients but the general glucose target range is also 7.8 to 10 mmol/l (140-180 mg/dl), as long as these can be achieved safely.

Insulin is the preferred therapy in the hospital setting in the majority of clinical situations. This would usually comprise scheduled subcutaneous basal insulin with supplemental short acting insulin if required. Prolonged therapy with sliding scale insulin is not routinely recommended. Continuation of oral agents may be appropriate in selected stable patients who are expected to consume meals at regular intervals. Specific caution is required with metformin due to the possibility that a contraindication may develop during the hospitalisation, such as renal insufficiency, unstable haemodynamic status, or need for an imaging study that requires a radio-contrast dye.
Self-management in the hospital may be appropriate for competent adult patients who are medically stable and successfully self-managing their diabetes at home. The patient and physician, in consultation with nursing staff, must agree that patient self management is appropriate under the conditions of hospitalisation.

**Consideration:**
It is important that hospitals designate a ‘diabetes lead’ individual who would be in charge of matters relating to diabetes, and could co-ordinate training of staff in awareness of the needs of those with diabetes, and develop strategies to prevent disempowerment of those who could self-manage their diabetes.

Major considerations include that diabetes should not complicate the management of whatever condition resulted in admission to hospital, and that a person’s diabetes should not emerge from hospital worse than when they were admitted. While the evidence over use of protocol-driven IV insulin regimens is not conclusive, the widespread and general adoption of these regimens globally appears telling.

**Implementation:**
Systems of care and protocols need to be put in place and staff trained to ensure their effectiveness. Standardised protocols, developed by multidisciplinary teams, should specify insulin dose, include guidelines for identifying patients at risk for hypoglycaemia, and actions to be taken to prevent and treat hypoglycaemia. Bedside glucose monitoring requires defined administrative responsibility, a procedure manual, training, policies regarding frequency and procedures for alert values, quality control and regular maintenance of equipment.

**Evaluation:**
Evaluation should consider evidence of the availability of trained staff (and training courses) and of protocols as above. Audits can be made of ward blood glucose control, and blood glucose control during surgery, after MI and in intensive care. Admissions to coronary care can be reviewed to ensure measurement of blood glucose is occurring, and appropriate actions are then taken while in the unit and during follow-up.

Global Guideline for Type 2 Diabetes
Potential Indicator:

Indicator Denominator Calculation of indicators
Data to be collected for calculation of indicators

- Percentage of people with type 2 diabetes admitted to hospital with a care plan for the hospitalisation.
- Number of people with type 2 admitted to hospital over a given period of time.
- Number of people with type 2 diabetes admitted to hospital with a care plan for the hospitalisation as a percentage of the number of people with type 2 admitted to hospital over a given period of time.
- Documentation of presence of diabetes and of a care plan.

References:


### Acronyms and abbreviations:

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<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tr>
<td>ABPM</td>
<td>Ambulatory blood pressure monitoring</td>
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<tr>
<td>ACCOMPLISH</td>
<td>Avoiding Cardiovascular events in Combination therapy in Patients Living with Systolic Hypertension</td>
</tr>
<tr>
<td>ACCORD</td>
<td>Action to Control Cardiovascular Risk in Diabetes</td>
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<td>ACE-inhibitor</td>
<td>angiotensin converting enzyme-inhibitor</td>
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<td>ACR</td>
<td>Aalbumin:creatinine ratio</td>
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<td>ADA</td>
<td>American Diabetes Association</td>
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<td>ADDITION</td>
<td>Anglo-Danish-Dutch study of Intensive treatment in people with screen detected diabetes in primary care</td>
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<td>ADVANCE</td>
<td>Action in Diabetes and Vascular disease; preterax and diamicron-MR Controlled Evaluation</td>
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<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<td>ALLHAT</td>
<td>Antihypertensive and Lipid-Lowering treatment to prevent heart Attack Trial</td>
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<tr>
<td>ARB</td>
<td>Angiotensin-II receptor blocker</td>
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<td>ASCEND</td>
<td>Acute Study of Clinical Effectiveness of Nesiritide in Decompensated heart failure</td>
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<tr>
<td>ASCOT-BPLA</td>
<td>Anglo-Scandinavian Cardiac Outcomes Trial – Blood Pressure Lowering Arm</td>
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<td>BMI</td>
<td>Body mass index</td>
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<td>BP</td>
<td>Blood pressure</td>
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<tr>
<td>bpm</td>
<td>Beats per minute</td>
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<tr>
<td>CCB</td>
<td>Calcium channel blocker</td>
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<td>CCT</td>
<td>Controlled clinical trial</td>
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<td>CHARISMA</td>
<td>Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance</td>
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<td>CKD</td>
<td>Chronic kidney disease</td>
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<td>CVD</td>
<td>Cardiovascular disease</td>
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<td>DBP</td>
<td>Diastolic blood pressure</td>
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<td>Abbreviation</td>
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<tr>
<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
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<td>DDG</td>
<td>German Diabetes Association</td>
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<tr>
<td>DPP-4</td>
<td>Dipeptidyl peptidase 4</td>
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<tr>
<td>DRS</td>
<td>Diabetic Retinopathy Study</td>
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<tr>
<td>DSME</td>
<td>Diabetes self-management education</td>
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<tr>
<td>eAG</td>
<td>Estimated average glucose</td>
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<tr>
<td>eGFR</td>
<td>Estimated glomerular filtration rate</td>
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<td>ETDRS</td>
<td>Early Treatment Diabetic Retinopathy Study</td>
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<td>FIELD</td>
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<td>FPG</td>
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<td>GFR</td>
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<td>GLP-1 RA</td>
<td>Glucagon-like peptide-1 receptor antagonist</td>
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<tr>
<td>HbA1c</td>
<td>Glycated haemoglobin</td>
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<td>HDL</td>
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<td>HIV</td>
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<td>HPLC</td>
<td>High-performance liquid chromatography</td>
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<tr>
<td>ICU</td>
<td>Intensive care unit</td>
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<td>IDF</td>
<td>International Diabetes Federation</td>
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<td>IFCC</td>
<td>International Federation of Clinical Chemistry and Laboratory Medicine</td>
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<td>IRMA</td>
<td>Intra retinal microvascular abnormalities</td>
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<td>IV</td>
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<td>LDL</td>
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<td>Look AHEAD</td>
<td>Action for Health in Diabetes</td>
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<td>Global Guideline for Type 2 Diabetes</td>
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<td>MDRD</td>
<td>Modification of diet in renal disease formula</td>
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<td>MI</td>
<td>Myocardial infarction</td>
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<td>MNT</td>
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<td>NICE</td>
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<td>NICE-SUGAR</td>
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<td>NPH insulin</td>
<td>Neutral protamine Hagedorn insulin</td>
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<td>OGTT</td>
<td>Oral glucose tolerance test</td>
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<td>ONTARGET</td>
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<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>Self-management support</td>
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<td>Systolic blood pressure</td>
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