Case study:

*Individual diagnosed with gestational diabetes*

Authored by Margaret McGill and Anne-Marie Felton on behalf of the *Global Partnership for Effective Diabetes Management*.

The *Global Partnership for Effective Diabetes Management* is supported by an unrestricted educational grant from Bristol-Myers Squibb, AstraZeneca LP.
This case study outlines the treatment of a woman who develops gestational diabetes.

The case reflects a full range of treatment and management tools available in the European/US context.*

*The management of patients is subject to social, economic, gender, age, co-morbidity and ethnic variables, and is dependent on the range of treatment options available in specific regions or countries.
Individual diagnosed with gestational diabetes

- Julia, 39 years old, married, 26 weeks pregnant with her second child
- First child weighed 3.8 kg (8.4 lbs) at birth
- No GDM during first pregnancy
  - She struggled to lose the weight following birth
- She has gained 8 kg so far during the course of her pregnancy
- Family history of type 2 diabetes
  - Mother and aunt
- Julia works long hours and snacks on food intermittently during the day
- She is moderately active although exercise levels have decreased during the pregnancy

Current status
- 39 years old
- 26 weeks pregnant
- Weight: 69 kg (152.1 lbs)
- Height: 156 cm (5 ft 1 in)
- *BMI: 28.4 kg/m²

*Pre-pregnancy BMI (weight gain is measured during pregnancy). BMI, body mass index; GDM, gestational diabetes.
Laboratory measures/physical examination

- As part of her routine obstetric care Julia has regular check-ups
- Recently she has been feeling sick in the afternoon and struggles to keep food down
- She is concerned about the amount of weight she is gaining

<table>
<thead>
<tr>
<th>Clinical chemistry</th>
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<tbody>
<tr>
<td>FPG: 5.8 mmol/l</td>
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<tr>
<td>HbA\textsubscript{1c}: 5.8%</td>
<td></td>
</tr>
<tr>
<td>Ketone body: Negative</td>
<td></td>
</tr>
<tr>
<td>Anti-GAD antibody: Negative</td>
<td></td>
</tr>
<tr>
<td>LDL cholesterol: 2.07 mmol/l</td>
<td></td>
</tr>
<tr>
<td>HDL cholesterol: 2.04 mmol/l</td>
<td></td>
</tr>
<tr>
<td>Triglycerides: 1.49 mmol/l</td>
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<tr>
<td>Heavy first baby, high maternal weight gain</td>
<td></td>
</tr>
<tr>
<td>Not currently on any medication</td>
<td></td>
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<td>Her mother died following an MI at the age of 76</td>
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FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA\textsubscript{1c}, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MI, myocardial infarction.


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Medical history

- Heavy first baby, high maternal weight gain
- Not currently on any medication
- History of diabetes in her immediate family
- Her mother died following an MI at the age of 76

FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA\(_{1c}\), glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MI, myocardial infarction.
Laboratory measures/physical examination

- As part of her routine obstetric care Julia has regular check-ups
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**Clinical chemistry**
- FPG: 104.4 mg/dl
- HbA\textsubscript{1c}: 40 mmol/mol
- Ketone body: Negative
- Anti-GAD antibody: Negative
- LDL cholesterol: 80 mg/dl
- HDL cholesterol: 79 mg/dl
- Triglycerides: 58 mg/dl
- Total cholesterol: 128 mg/dl

**Blood pressure**
- Systolic/diastolic: 118/70 mmHg

**Medical history**
- Heavy first baby, high maternal weight gain
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FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA\textsubscript{1c}, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MI, myocardial infarction.
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<tr>
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</tr>
<tr>
<td>Triglycerides:</td>
<td>&lt;150 mg/dl</td>
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<td>Total cholesterol:</td>
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FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA₁c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MI, myocardial infarction.
Are elevated blood glucose levels a normal part of pregnancy?

• Metabolic changes during pregnancy lower glucose tolerance, which increases BG levels and raises insulin production\(^1\)
• As pregnancy develops, demand for insulin increases – a normal physiological process in the majority of pregnancies
  – However, some women (approx. 2–6%) will develop GDM during pregnancy\(^1,2\)
• Diagnosis of GDM is usually confirmed using an OGTT:\(^1,3\)
  – Women fast overnight (≥8 hours) before attending hospital the following day
  – A blood sample is taken on arrival and a sugary drink (usually containing 75 g glucose [100 g in the USA is more usual]) consumed before a second blood sample 2 hours later

**Question**
Which of the following 2-hour BG levels following a 75 g OGTT represents a cut-off value for GDM?

- ≤7.2 mmol/l (130 mg/dl)
- 7.3–7.7 mmol/l (132–139 mg/dl)
- ≥7.8 mmol/l (141 mg/dl)


BG, blood glucose; GDM, gestational diabetes; OGTT, oral glucose tolerance test.
Defining gestational diabetes

- GDM has been defined as a 2-hour BG level $>7.8 \text{ mmol/l (141 mg/dl)}$ following a 75 g OGTT\(^1\)
- In the USA the values for a diagnosis of GDM following a 75 g OGTT are:\(^2\)
  - Fasting $\geq 92 \text{ mg/dl (5.1 mmol/l)}$
  - 1 hour $\geq 180 \text{ mg/dl (10.0 mmol/l)}$
  - 2 hour $\geq 153 \text{ mg/dl (8.5 mmol/l)}$
- Screening for GDM in all pregnant women remains controversial\(^1\)
  - However, recent ADA guidelines suggest all pregnant women should be screened between Weeks 24 and 28 of pregnancy\(^2\)

ADA, American Diabetes Association; BG, blood glucose; GDM, gestational diabetes; OGTT, oral glucose tolerance test.

Risk factors for gestational diabetes development

• GDM is glucose intolerance that begins, or is first recognized, during pregnancy\(^1\)
• Prevalence of 2–6% (10–20% in high-risk populations)\(^1\)
• Risk factors include:\(^1\)
  – Ethnicity
  – Increased maternal age
  – Previous GDM
  – Family history of diabetes
  – Maternal obesity
  – High weight gain in pregnancy
  – Previous large baby
  – Polycystic ovary syndrome
  – Medications, e.g. corticosteroids, antipsychotics
• Of the above, previous GDM, advanced maternal age and obesity have the highest impact on GDM risk\(^1\)

GDM, gestational diabetes.

Glycaemia and pregnancy outcomes

- Risk of adverse maternal, fetal and neonatal outcomes continuously increases as a function of maternal glycaemia – even within ranges previously considered normal for pregnancy\(^1\)

\(^a\)Incidence of birth weight >90th percentile was ~5 times higher in women with FPG >5.6 mmol/l (26.3%) compared with those whose FPG was <4.2 mmol/l (5.3%)

\(^a\)Incidence of primary caesarean section was more than doubled in women with 1-hour BG >11.8 mmol/l (32%) compared with those whose 1-hour BG was <5.8 mmol/l (12%)

-- See slide 27 in deck for copyright acknowledgement.

BG, blood glucose; FPG, fasting plasma glucose.

Glycaemia and pregnancy outcomes

- Risk of adverse maternal, fetal and neonatal outcomes continuously increases as a function of maternal glycaemia – even within ranges previously considered normal for pregnancy\(^1\)

\(^{a}\)Incidence of birth weight >90th percentile was ~5 times higher in women with FPG >101 mg/dl (26.3%) compared with those whose FPG was <76 mg/dl (5.3%)

\(^{a}\)Incidence of primary caesarean section was more than doubled in women with 1-hour BG >213 mg/dl (32%) compared with those whose 1-hour BG was <105 mg/dl (12%)

BG, blood glucose; FPG, fasting plasma glucose.

See slide 27 in deck for copyright acknowledgement.

Blood glucose levels and next steps

- An FPG of 5.8 mmol/l (104.4 mg/dl) (2-hour OGTT was 8.6 mmol/l; 155 mg/dl) and HbA$_{1c}$ of 5.8% (40 mmol/mol) are reflective of elevated glucose levels
  - Her doctor is concerned Julia has developed GDM
- GDM is associated with an increased long-term risk of type 2 diabetes and CVD in both mother and infant,\(^1\) and additional adverse maternal, fetal and neonatal outcomes\(^2,3\)

- Women with GDM should receive multidisciplinary care including advice/education on glycaemic control and diet, and fetal risks
  - The doctor makes an appointment for her to see the diabetes nurse, with the aim of developing a management programme

CVD, cardiovascular disease; FPG, fasting plasma glucose; GDM, gestational diabetes; HbA$_{1c}$, glycosylated haemoglobin; OGTT, oral glucose tolerance test.

Blood glucose monitoring and diet

- Julia is commenced on a stricter diet and asked to monitor her BG levels
  - She tests herself 4 times/day
  - Pre-meal/fasting and 2 hours after each meal
- Target range for BG\(^1\)
  - Pre-meal: <5.3 mmol/l (95 mg/dl)
  - 2 hours post-meal: <6.7 mmol/l (121 mg/dl)

In addition to monitoring BG levels, measuring HbA\(_{1c}\) can also be used to quantify glycaemic control in patients with GDM (measured at baseline and every 6–8 weeks)
- Julia’s HbA\(_{1c}\) target should be <5.5% (37 mmol/mol) to minimize the risk of perinatal complications

BG, blood glucose; GDM, gestational diabetes; HbA\(_{1c}\), glycosylated haemoglobin.

Blood glucose monitoring: Week 28

- After a week during which Julia’s BG levels were maintained in a healthy range she returned for further evaluation of her progress.

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<tr>
<th>Fasting BG (mmol/l)</th>
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<th>2 hours post-lunch (mmol/l)</th>
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<tbody>
<tr>
<td>4.3</td>
<td>6.2</td>
<td>6.3</td>
<td>7.4</td>
</tr>
<tr>
<td>4.5</td>
<td>6.9</td>
<td>7.1</td>
<td>6.9</td>
</tr>
<tr>
<td>4.5</td>
<td>6.3</td>
<td>7.3</td>
<td>6.8</td>
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<tr>
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<td>5.9</td>
<td>7.4</td>
<td>6.9</td>
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<td>6.7</td>
<td>7.3</td>
<td>6.8</td>
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**Question**
Given the measures shown above, are the diet and lifestyle adjustments sufficient as a means of controlling Julia’s BG?
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<td>112</td>
<td>114</td>
<td>133</td>
</tr>
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<td>81</td>
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<td>133</td>
<td>124</td>
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<td>83</td>
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<td>124</td>
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**Question**

Given the measures shown above, are the diet and lifestyle adjustments sufficient as a means of controlling Julia’s BG?
Diet and lifestyle adjustment: an essential part of management

- Maintaining an active lifestyle, including a healthy diet,\(^1\) is essential to help prevent excess weight gain and its associated risk of CV complications
- In GDM, MNT is well known as the cornerstone of treatment\(^2\)
- Solely relying on diet and exercise risks leaving Julia exposed to episodes of hyperglycaemia
  - Increasing the risk of complications for herself and her baby
- To reduce Julia’s BG a more intensive strategy is required

**Clinical chemistry**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-hour BG (average)</td>
<td>6.8 mmol/l</td>
</tr>
<tr>
<td></td>
<td>(123 mg/dl)</td>
</tr>
<tr>
<td>HbA(_{1c}):</td>
<td>5.4%*</td>
</tr>
<tr>
<td>Ketone body:</td>
<td>Negative</td>
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**Blood pressure**

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BG, blood glucose; CV, cardiovascular; GDM, gestational diabetes; HbA\(_{1c}\), glycosylated haemoglobin; MNT, medical nutritional therapy.

*36 mmol/mol.

Management of hyperglycaemia

**Question**
Given Julia’s BG measurements, which one of the following options do you think would be appropriate as a management strategy?

- SU + lifestyle adjustment
- Insulin + lifestyle adjustment
- Metformin + lifestyle adjustment

BG, blood glucose; SU, sulphonylurea
Treatment selected: Sulphonylurea plus lifestyle adjustment

- Use of oral anti-hyperglycaemic agents in pregnant women remains an issue of debate
- The sulphonylurea glyburide (glibenclamide) has minimal transfer across the placenta and is not associated with excess neonatal hypoglycaemia\(^1,2\)
  - Glyburide action must be balanced with meals and snacks to prevent maternal hypoglycaemia\(^1\)
  - Less successful in obese patients or those with hyperglycaemia early in pregnancy\(^1\)
- Although glyburide is an option for Julia, following discussion with her doctor she decides on an alternative therapeutic regimen

Glyburide has been shown to provide similar BG and HbA\(_{1c}\) control to insulin when used in conjunction with MNT\(^2\)

<table>
<thead>
<tr>
<th>Blood glucose</th>
<th>Glyburide (mg/dl)*</th>
<th>Insulin (mg/dl)*</th>
<th>p value</th>
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<tbody>
<tr>
<td>Fasting</td>
<td>98±13</td>
<td>96±16</td>
<td>0.17</td>
</tr>
<tr>
<td>Preprandial</td>
<td>95±15</td>
<td>97±14</td>
<td>0.17</td>
</tr>
<tr>
<td>Postprandial</td>
<td>113±22</td>
<td>112±15</td>
<td>0.60</td>
</tr>
<tr>
<td>Mean</td>
<td>105±16</td>
<td>105±18</td>
<td>0.99</td>
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<tr>
<td>HbA(_{1c}) (%)</td>
<td>5.5±0.7</td>
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BG, blood glucose; HbA\(_{1c}\), glycosylated haemoglobin; MNT, medical nutritional therapy.

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<td>5.4±0.8</td>
<td>0.17</td>
</tr>
<tr>
<td>Postprandial</td>
<td>6.3±1.2</td>
<td>6.3±0.8</td>
<td>0.60</td>
</tr>
<tr>
<td>Mean</td>
<td>5.9±0.9</td>
<td>5.9±1.0</td>
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BG, blood glucose; HbA\(_{1c}\), glycosylated haemoglobin; MNT, medical nutritional therapy.

Treatment selected:
Insulin plus lifestyle adjustment

- Lifestyle intervention and insulin have been demonstrated to improve perinatal outcomes\(^1\)
  - Insulin is recommended for glycaemic control during pregnancy\(^2\)
- Insulin resistance is a particular issue in the third trimester; however, this normally improves during the day
  - Rapid-acting insulin pre-meals is useful
  - Obese pregnant women require more basal insulin
- The right insulin regimen is the one that targets hyperglycaemia
- Following explanation of insulin use, Julia is started on 4 units per day of insulin lispro before breakfast

Use of insulin analogues in pregnancy

- Minimal differences between conventional insulins and insulin analogues in GDM management\(^3\)
  - No significant difference in HbA\(_{1c}\) control\(^3\)
- Human insulin is the least immunogenic; however, analogues lispro and aspart have similar profiles\(^4\)
- Lispro and aspart: effective, minimal placental transfer, no teratogenesis\(^4\)
  (no data on glulisine)
- Safety data on long-acting analogues is lacking (glargine, detemir)\(^3,4\) – glargine not likely to cross the placenta at therapeutic doses\(^5\)


GDM, gestational diabetes; HbA\(_{1c}\), glycosylated haemoglobin.
Treatment selected: Metformin plus lifestyle adjustment

- Reported outcomes for the use of metformin in pregnancy have generally been favourable\(^1\)
  - However, metformin crosses the placenta\(^2\) and could affect fetal physiology directly\(^1\)
- Trial results have suggested metformin is sometimes preferred to insulin by patients\(^1\)
  - However, insulin (plus MNT or lifestyle measures) is generally recommended for glycaemic control in pregnancy\(^3\)
- Julia’s doctor suggests that metformin therapy may not be the most appropriate treatment for her

In the Metformin in Gestational Diabetes trial\(^1\)
- Primary outcome (composite of neonatal complications) did not differ between women treated with metformin or those administered insulin (32% vs. 32.2%, respectively)
- 46.3% of women administered metformin required additional insulin to achieve their glycaemic targets
  - Although no significant effect on the primary outcome
- Severe hypoglycaemia was less common in metformin-treated women
- Preterm birth was more common in the metformin-treated group
- Serious adverse events (affecting either mother or child) were not significantly different between treatment groups

MNT, medical nutritional therapy.

Glycaemic control in pregnancy

- Therapy to manage excess BG levels should be initiated in addition to standard antenatal care
  - Target HbA\(_{1c}\) <5.5\% (37 mmol/mol) or FPG <5.3 mmol/l (95 mg/dl) to minimize risk of perinatal complications
- Dietary and lifestyle advice plus insulin is generally required/recommended
  - Individual needs/preferences may necessitate an alternative to insulin, e.g. metformin
- Dietary regulation, home BG monitoring and insulin/oral anti-hyperglycaemic drugs reduce the risk of serious perinatal morbidity in the infant
- Lifestyle changes also reduce risk of developing true diabetes following childbirth

At 32 weeks Julia’s BG levels were not adequately controlled with the initial insulin regimen
  - Dosage increased to 6 units before breakfast and 4 before lunch
  - Further increases were necessary at Week 34: 18 units/day (split: 10/4/4)
- By Week 36 Julia required 22 units*/day to control her BG levels: split 12/6/4

*Maximum insulin dose: 26 units/day.


BG, blood glucose; FPG, fasting plasma glucose; HbA\(_{1c}\), glycosylated haemoglobin.
Gestational diabetes: management issues around delivery

• Unless evidence of maternal or fetal compromise is observed, delivery before 38 weeks is not advised:¹
  – Although the frequency of spontaneous preterm birth is increased in women with GDM¹
• BG monitoring during labour may be used in women with GDM treated with insulin or glyburide¹
  – Manage potential hyperglycaemia, fetal hypoxia and neonatal hypoglycaemia¹

• Delivery of a large-for-gestational-age fetus is associated with an increased risk of birth injury compared with the non-diabetic population:¹
  – Measures to reduce birth injury include a more liberal approach to caesarean delivery when fetal over-growth is suspected
  – Ultrasound estimation of fetal weight may assist in reducing rates of shoulder dystocia

BG, blood glucose; GDM, gestational diabetes.
Birth and long-term follow up

• On her regimen of 22 units insulin/day Julia’s FPG was 5.1 mmol/l (within the acceptable target)\(^1\)
• 3 weeks later (Week 39) she gave birth to a healthy girl
  – 3.3 kg (7.3 lbs)/no neonatal complications/breastfeeding
• Julia’s insulin regimen was halted at onset of labour
• 12 weeks post-partum, 75 g OGTT revealed BG levels of 5.2/7.9/6.9 mmol/l (94/142/124 mg/dl)
  – Julia is advised to aim for her pre-pregnancy weight and to evenly distribute meals with moderate carbohydrate/low fat content throughout the day
• A further 75 g OGTT 2 years later revealed BG levels of 5.3/8.6/7.9 mmol/l (95/155/142 mg/dl)
  – Her doctor advises her that this could be suggestive of impaired glucose tolerance or pre-diabetes
• Women who have had GDM and who are found to have pre-diabetes should receive lifestyle interventions or metformin to prevent diabetes development\(^1\)
• Annual review to determine whether type 2 diabetes has developed is advised

BG, blood glucose; FPG, fasting plasma glucose; GDM, gestational diabetes; OGTT, oral glucose tolerance test.

Gestational diabetes: management issues post-partum

• A post-delivery health plan should be developed that includes surveillance for, and prevention of, diabetes\(^1\)
  – Following GDM, 35–60% of women will develop type 2 diabetes within 10 years\(^1\)
• A significant proportion of women with GDM remain diabetic or continue to have impaired glucose tolerance following birth\(^1\)
• All women with GDM should have a postnatal OGTT\(^2\) to eliminate the presence of continued hyperglycaemia\(^1\)
  – Elevated values should be confirmed by FPG or postprandial glucose measures\(^1\)

In patients with elevated BG, MNT and insulin should be continued to maintain glycaemic control\(^1\)
  – Provides sufficient calories for lactation and infant well-being\(^1\)
• Women who had GDM should continue to be tested for diabetes development at least every 3 years\(^3\)

BG, blood glucose; FPG, fasting plasma glucose; GDM, gestational diabetes; MNT, medical nutrition therapy; OGTT, oral glucose tolerance test.

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*Slides 11 and 12*

10 Steps to get more people with type 2 diabetes to goal:

- Aim for an appropriate individualized glycaemic target, e.g. HbA$_{1c}$ 6.5–7% (48–53 mmol/mol) (or fasting/preprandial plasma glucose 110–130 mg/dL [6.0–7.2 mmol/L] where assessment of HbA$_{1c}$ is not possible) when safe and appropriate.
- Monitor HbA$_{1c}$ every 3 months in addition to appropriate glucose self-monitoring.
- Appropriately manage all cardiovascular risk factors.
- Refer all newly diagnosed patients to a unit specializing in diabetes care where possible.
- Address the underlying pathophysiology of diabetes, including the treatment of β-cell dysfunction and insulin resistance.
- Treat to achieve appropriate target HbA$_{1c}$ within 6 months of diagnosis.
- After 3 months, if patients are not at the desired target HbA$_{1c}$, consider combination therapy.
- Consider initiating combination therapy or insulin for patients with HbA$_{1c}$ ≥9% (≥75 mmol/mol).
- Use combinations of antihyperglycaemic agents with complementary mechanisms of action.
- Implement a multidisciplinary team approach that encourages patient self-management, education and self-care, with shared responsibilities to achieve goals.

HbA$_{1c}$, glycosylated haemoglobin.
