Case study:
*Adult who is newly diagnosed with type 2 diabetes and at risk of hypoglycaemia*

Authored by Lawrence Leiter and Edward Horton 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 an adult who is newly diagnosed with type 2 diabetes and at risk of hypoglycaemia.

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

*The management of any patient 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.
Adult who is newly diagnosed with type 2 diabetes and at risk of hypoglycaemia

- Jean is aged 75 and lives alone
- Recently, she has experienced episodes of extreme lethargy, thirst and an increased need to urinate
- Jean has severe arthritis in her hip and borderline osteopenia (managed via dietary modification)
- Jean’s daughter encourages her to visit the doctor for a check-up
First visit with the doctor

• Jean outlines her symptoms to the doctor who tells her she has put on 3 kg in 6 months
• Jean says she finds it difficult to stand long enough to prepare regular, healthy meals and she usually snacks on ready-made meals
• She explains that both the tiredness and arthritis make exercise almost impossible

Clinical chemistry†

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
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<tbody>
<tr>
<td>FPG</td>
<td>10.5 mmol/l</td>
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<tr>
<td>HbA₁c</td>
<td>8.7%</td>
</tr>
<tr>
<td>LDL-cholesterol</td>
<td>2.8 mmol/l</td>
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<tr>
<td>HDL-cholesterol</td>
<td>1.2 mmol/l</td>
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<tr>
<td>Triglycerides</td>
<td>1.3 mmol/l</td>
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<td>eGFR</td>
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Blood pressure*

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<tr>
<td>Systolic/diastolic</td>
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BMI: 25.5 kg/m²

†Additional testing for ketone body, anti-GAD antibody and C-peptide may be performed subject to regional variation and patient presentation. *Confirmed on subsequent visits.

BMI, body mass index; FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA₁c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; eGFR, estimated glomerular filtration rate.
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BMI, body mass index; FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; HbA₁c, glycosylated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; eGFR, estimated glomerular filtration rate.
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A comprehensive approach to type 2 diabetes management

• Jean is diagnosed with type 2 diabetes. Establishing glycaemic control is a priority for all newly diagnosed individuals, but should be pursued within a multifactorial risk-reduction framework that includes appropriate lifestyle interventions.

In addition to antihyperglycaemic medication, consider the following for all people newly diagnosed with type 2 diabetes:

• ACE inhibitors/ARBs (or alternative if contraindications exist) if SBP ≥140 mmHg, DBP >80 mmHg or if ACR is ≥2.5 mg/mmol (≥30 mg/g)
• Statin drugs for those:
  – With LDL-cholesterol >2.6 mmol/l (>100 mg/dl) OR
  – With overt CVD (LDL-cholesterol target <1.8 mmol/l; <70 mg/dl) OR
  – Who are aged >40 years with at least one additional CVD risk factor*
• ASA for secondary prevention of CVD or for those with high CV risk

Baseline examinations to be performed in all people newly diagnosed with type 2 diabetes:

• Eye exam (refer to ophthalmologist): for signs of retinopathy
• Serum creatinine (to calculate eGFR) and 24 hour urine test:† to assess kidney function
• Comprehensive foot exam: for signs of neuropathy

*Family history of CVD, hypertension, smoking, dyslipidaemia or albuminuria.
†24 hour urine test may not always be required. ACR could also be obtained to assess kidney function.

ACE, angiotensin-converting enzyme; ACR, albumin:creatinine ratio; ARB, angiotensin II receptor blocker; CVD, cardiovascular disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; LDL, low-density lipoprotein; SBP, systolic blood pressure.

Setting a glycaemic target

- Jean is diagnosed with type 2 diabetes with a FPG of 10.5 mmol/l and an HbA$_{1c}$ of 8.7% (72 mmol/mol)
- The doctor tells Jean that in addition to lifestyle interventions, it will be necessary to start medication to reduce her BG levels, and they discuss her glycaemic target

**Question**
What is the most appropriate HbA$_{1c}$* target for Jean?

- <6.0%
- 6.0–6.5%
- 6.5–7.0%
- 7.0–7.5%
- 7.5–8.0%

BG, blood glucose; FPG, fasting plasma glucose; HbA$_{1c}$, glycosylated haemoglobin.

*Equivalent values: 6.0% = 42 mmol/mol; 6.5% = 48 mmol/mol; 7.0% = 53 mmol/mol; 7.5% = 58 mmol/mol; 8.0% = 64 mmol/mol.
Setting a glycaemic target

What is the most appropriate HbA$_{1c}$* target for Jean?

- <6.0%
- 6.0–6.5%
- 6.5–7.0%
- 7.0–7.5%
- 7.5–8.0%

- The recommended target for most people with type 2 diabetes is <7.0%; however, glycaemic targets should always be individualized.

- The doctor is alerted to Jean’s increased risk of hypoglycaemia, owing to:
  - Older age: risk of hypoglycaemia increases exponentially with age.
  - Irregular eating pattern: increases risk, particularly when taking hypoglycaemic agents.
  - Lives alone: self-treating or seeking of medical attention may be significantly delayed.
  - Poor mobility: increases susceptibility to falls (a particular issue in Jean’s case given her osteopenia).

- The glycaemic target for patients at risk of hypoglycaemia should be 7.0–7.5% or even up to 8.5% in patients at the highest risk, in the elderly or those who live alone$^1$.

- A glycaemic target of 7.0–7.5% is set. Jean will be monitored closely and the target reassessed if its attainment proves difficult or if safety becomes a concern.

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

*Equivalent values: 7.0% = 53 mmol/mol; 7.5% = 58 mmol/mol; 8.0% = 64 mmol/mol; 8.5% = 69 mmol/mol.

Initial medication

- The doctor tells Jean that in addition to lifestyle interventions, she will require antihyperglycaemic medication to reduce and maintain her BG within the agreed target range.

**Question**

*In addition to lifestyle interventions*, which of the following is appropriate first-line antihyperglycaemic medication for Jean?

- Metformin
- Basal insulin
- Metformin + sulphonylurea
- Metformin + DPP-4 inhibitor
- Sulphonylurea
**Initial medication**

**In addition to lifestyle interventions**, which of the following is appropriate first-line antihyperglycaemic medication for Jean?

- Metformin
- Basal insulin
- Metformin + sulphonylurea
- Metformin + DPP-4 inhibitor
- Sulphonylurea

- Unless contraindicated, metformin is the first-line agent of choice for most people with type 2 diabetes:¹ metformin would not be appropriate if renal insufficiency was present, a common co-morbidity in elderly individuals.
- Metformin carries a low risk of hypoglycaemia, is weight neutral and lowers HbA₁c by an average of 1–2%¹,²
- Initial therapy with a combination of drugs or insulin should be reserved for those presenting with a high HbA₁c (e.g. ≥9.0%; 75 mmol/mol)¹

HbA₁c: glycosylated haemoglobin.

Further instructions and additional medication

- As metformin can cause GI symptoms,\(^1\) the doctor recommends a gradual upwards titration of metformin – beginning with 500 mg bid and titrating to 850 mg b.i.d after 4 weeks
  - Jean was advised to always take the medication with meals/food
- In addition to medications for her hyperglycaemia, Jean was prescribed an ARB to reduce her BP and a statin to lower her LDL-cholesterol
- She was also referred to a diabetes education centre to develop a diet and exercise plan and learn about self monitoring of blood glucose
- A 3-month follow-up appointment was then made for Jean

<table>
<thead>
<tr>
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<tr>
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</tr>
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ARB, angiotensin receptor blocker; b.i.d., twice daily; BP, blood pressure; GI, gastrointestinal; HbA\(_{1c}\), glycosylated haemoglobin.
3-month follow-up appointment: BG and BP target levels not achieved

- Jean reports that, apart from an occasional stomach upset, she feels well
- She has been trying to eat more regularly and has lost a small amount of weight
- Jean also reports good adherence to her medication and is able to explain her regimen to the doctor
- Despite these factors, however, Jean’s BG and BP remain above their targets

**Current status/assessments**
- FPG: 9.0 mmol/l (162 mg/dl)
- HbA1c: 8.1% (66 mmol/mol)
- BP: 142/86 mmHg
- BMI: 25.0 kg/m²

**Question**
Which is the most appropriate next course of action for Jean in response to inadequate glycaemic and BP control?

- Re-assess in a further 3 months to see whether the problem persists
- Intensify antihyperglycaemic and antihypertensive medications
- Re-assess factors other than medication that might result in failure to respond

BG, blood glucose; BMI, body mass index; BP, blood pressure; FPG, fasting plasma glucose; HbA1c, glycosylated haemoglobin.
Response to not achieving targets: Re-assess in 3 months

- The benefit : risk ratio must always be considered when designing individualized treatment regimens
- Although a less-intensive approach to glycaemic control is appropriate for Jean (given her increased hypoglycaemia risk), the combination of hyperglycaemia and hypertension increases her risk of vascular complications
  - Measures should be taken immediately to minimize this risk
- Opting for a sensible combination of antihyperglycaemic medications will help to ensure that intensification of therapy improves glycaemia without enhancing the risk of hypoglycaemia
Response to not achieving targets: Immediately intensify treatment

- The combination of hyperglycaemia and hypertension increases the risk of vascular complications, and measures should be taken to limit this risk
- It is important to explore all possible reasons for the lack of glycaemic and BP control
- Jean reports improved dietary habits and good adherence to medication, suggesting that lifestyle factors/poor adherence do not contribute to the lack of glycaemic and BP control
  - People with type 2 diabetes often require combination therapy to meet glycaemic and BP targets
- Opting for a sensible combination of antihyperglycaemic medications will help to ensure that intensification of therapy improves glycaemia without enhancing the risk of hypoglycaemia

BP, blood pressure.
Response to not achieving targets:
Re-assess factors other than medication

- The combination of hyperglycaemia and hypertension increases the risk of vascular complications
- Exploring all the possible factors behind lack of glycaemic and BP control is important; re-assessing lifestyle factors/adherence issues alone is not sufficient to minimize this risk
- Jean reports improved dietary habits and good adherence to medication, suggesting that lifestyle factors/poor adherence do not contribute to the lack of glycaemic and BP control
  - People with type 2 diabetes often require combination therapy to meet glycaemic and BP targets
- Opting for a sensible combination of antihyperglycaemic medications will help to ensure that intensification of therapy improves glycaemia without enhancing the risk of hypoglycaemia

BP, blood pressure.
Jean’s medication requires intensifying and as part of this, the doctor increases the dose of antihypertensive medication. As Jean has already reported some GI symptoms with her current dose of metformin, the doctor decides to combine metformin with another agent, and to reduce the metformin dose to 500 mg b.i.d.

Question

In addition to lifestyle interventions, which of the following is an appropriate combination of antihyperglycaemic medication for Jean?

- Metformin + sulphonylurea
- Metformin + basal insulin
- Metformin + DPP-4 inhibitor
- Metformin + thiazolidinedione
- Metformin + GLP-1 receptor agonist

b.i.d, twice daily; DPP, dipeptidyl peptidase; GI, gastrointestinal; GLP, glucagon-like peptide.
Second-line therapy chosen (alongside lifestyle interventions): Metformin + sulphonylurea

- Sulphonylureas can lower BG rapidly and carry a moderate risk of hypoglycaemia
  - Although not contraindicated in those at risk of hypoglycaemia, sulphonylureas should be used with caution in this patient population
    - To reduce the risk of hypoglycaemia, incretin agents can be used before secretagogues
- As Jean does not require a large reduction in HbA\textsubscript{1c}, an alternative combination that lowers HbA\textsubscript{1c} with a lower risk of hypoglycaemia may be more appropriate
- Sulfonylureas may also cause weight gain and due to her immobility, Jean is reluctant to use this medication

### Metformin\textsuperscript{1,2}
- \(\downarrow\)HbA\textsubscript{1c} efficacy: High
- Hypoglycaemia risk: Low
- Weight effect: Neutral/loss
- Major side effects: GI, Lactic acidosis
- Cost: Low

### Sulphonylurea\textsuperscript{1,2}
- \(\downarrow\)HbA\textsubscript{1c} efficacy: High
- Hypoglycaemia risk: Moderate
- Weight effect: Gain
- Major side effects: Hypoglycaemia
- Cost: Low

BG, blood glucose; GI, gastrointestinal; HbA\textsubscript{1c}, glycosylated haemoglobin.

Second-line therapy chosen (alongside lifestyle interventions): Metformin + DPP-4 inhibitor

- DPP-4 inhibitors reduce BG levels to a similar extent as sulphonylureas and have a lower risk of hypoglycaemia¹
  - DPP-4 inhibitors are well tolerated and do not cause weight gain; Jean is relatively immobile and therefore susceptible to gaining weight
  - Many of the DPP-4 inhibitors can be taken once daily, minimizing the risk of non-adherence due to complicated medication regimens
- The doctor and Jean decide on a combination of metformin and a DPP-4 inhibitor as the most appropriate for Jean’s individual circumstances

Patients with hyperglycaemia despite metformin therapy were randomized to receive either sitagliptin or glipizide as add-on therapy.¹ †By week 52; *p<0.001 compared with metformin + sitagliptin.

BG, blood glucose; DPP, dipeptidyl peptidase HbA₁c, glycosylated haemoglobin.

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Second-line therapy chosen (alongside lifestyle interventions): Metformin + basal insulin

- Insulin lowers BG rapidly and carries a high risk of hypoglycaemia
- Although not contraindicated in those at risk of hypoglycaemia, a less intensive approach to lowering HbA1c should be taken in this patient population
- Insulin therapy is generally recommended for patients with more marked hyperglycaemia (HbA1c >9%; 75 mmol/mol), or when dual therapy is insufficient at achieving glycaemic control
  - In addition, insulin requires good motor skills and can be particularly difficult for elderly patients to administer; insulin can also cause weight gain
- Insulin may be considered for Jean if glycaemic control is not achieved with oral agents or if glycaemic control worsens over time
- A pre-mixed insulin preparation is often preferred for elderly patients if bedtime basal insulin is insufficient, as this can minimize dosing errors

**Metformin**

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BG, blood glucose; GI, gastrointestinal; HbA1c, glycosylated haemoglobin.


**Please select another option**
Second-line therapy chosen (alongside lifestyle interventions): Metformin + thiazolidinedione

• Thiazolidinediones carry a low risk of hypoglycaemia

• However, they are associated with increased risk of heart failure and higher numbers of bone fractures,¹ particularly in women
  – It is important to minimize the likelihood of CV events in patients at risk of hypoglycaemia
  – The increased risk of bone fractures is also not optimal; Jean is elderly with severe arthritis in her hip and diagnosed osteopenia

• Thiazolidinediones may also cause weight gain

• The doctor and Jean decide that this is not the best option for her personal circumstances

CV, cardiovascular.
Second-line therapy chosen (alongside lifestyle interventions): Metformin + GLP-1 receptor agonist

• GLP-1 receptor agonists carry a risk of hypoglycaemia when combined with other antihyperglycaemic agents\(^1\)
• An advantage with these agents is weight loss; Jean is borderline overweight and fairly immobile, making weight loss difficult
• However, these agents are injectable, and common side-effects include nausea and vomiting\(^1\)
• After discussing her options, the doctor and Jean decide that this is not the most appropriate combination for her individual circumstances

### Metformin\(^1,2\)
- \(\downarrow\)HbA\(_{1c}\) efficacy: High
- Hypoglycaemia risk: Low
- Weight effect: Neutral/loss
- Major side effects: GI
- Cost: Low

### GLP-1 receptor agonist\(^1,2\)
- \(\downarrow\)HbA\(_{1c}\) efficacy: High
- Hypoglycaemia risk: Low
- Weight effect: Neutral/loss
- Major side effects: GI
- Cost: Moderate

GI, gastrointestinal; GLP, glucagon-like peptide; HbA\(_{1c}\), glycosylated haemoglobin.

Please select another option
Why is hypoglycaemia an important consideration?

- In patients with type 2 diabetes:
  - Hypoglycaemic events (HE) have been shown to increase risk for acute cardiovascular events (ACVE)\(^1\)
  - A strong association between severe hypoglycaemia (SH) and adverse clinical outcomes has been demonstrated\(^2\)

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Hypoglycaemia is associated with increased risk of acute CV events\(^1\)

Severe hypoglycaemia is associated with increased risk of adverse clinical events\(^2\)

*\(^p<0.001\) compared with patients with no HE

\(^*\)\(^p<0.001\) compared with patients with no SH

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\(^a\)See slide 35 in deck for copyright acknowledgement.

Why is hypoglycaemia an important consideration?

- In addition to serious CV and other health outcomes, hypoglycaemia can have a negative impact on several aspects of an individual’s life.

**Question**
Which of the following are associated with mild hypoglycaemia?

- Anxiety
- Poor adherence to medication
- Reduced independence
- Time away from work

*CV, cardiovascular.*
Why is hypoglycaemia an important consideration?

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**Question**
Which of the following are associated with mild hypoglycaemia?

- Anxiety
- Poor adherence to medication
- Reduced independence
- Time away from work

✓ Those who experience hypoglycaemia often report feelings of anxiety.¹ Not only does this impact on an individual’s well being, but stress may also be a cause of hypoglycaemia¹

Why is hypoglycaemia an important consideration?

- In addition to serious CV and other health outcomes, hypoglycaemia can have a negative impact on several aspects of an individual’s life.

**Question**

Which of the following are associated with mild hypoglycaemia?

- Anxiety
- Poor adherence to medication
- Reduced independence
- Time away from work

✓ Those who experience hypoglycaemia may become reluctant to take their medication,\(^1\) exposing patients to the consequences of poor glycaemic control.

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Why is hypoglycaemia an important consideration?

- In addition to serious CV and other health outcomes, hypoglycaemia can have a negative impact on several aspects of an individual’s life.

- Hypoglycaemia can have a significant impact on an individual’s quality of life, since normal day-to-day activities such as driving may need to be restricted.

Why is hypoglycaemia an important consideration?

- In addition to serious CV and other health outcomes, hypoglycaemia can have a negative impact on several aspects of an individual’s life.

### Question
Which of the following are associated with mild hypoglycaemia?

- Anxiety
- Poor adherence to medical treatment
- Reduced independence
- Time away from work

- ✔ Even mild hypoglycaemic events occurring at, or outside of, work lead to a significant number of hours away from the workplace¹

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## Awareness of hypoglycaemia and how to treat

- Jean’s medication was selected to minimize her risk of hypoglycaemia.
- However, elderly patients with diabetes often fail to recognize the symptoms of hypoglycaemia\(^1\) and this is something Jean needs to learn as part of managing her condition.

### Question
If Jean becomes hypoglycaemic/experiences hypoglycaemic symptoms and is able to self treat, what should she be advised to do?

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<td>Ingest 15 g of glucose/sucrose, wait 15 minutes then take another 15 g glucose/sucrose if BG is &lt;4.0 mmol/l; once hypoglycaemia is reversed have a meal or snack to prevent recurrence</td>
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<tr>
<td>Administer 1 mg glucagon intramuscularly or subcutaneously; once hypoglycaemia is reversed have a meal or snack to prevent recurrence</td>
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BG, blood glucose.
Awareness of hypoglycaemia and how to treat

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1. Ingest 15 g of glucose/sucrose then call the emergency services.
2. Administer 1 mg glucagon intramuscularly or subcutaneously; once hypoglycaemia is reversed have a meal or snack to prevent recurrence.
3. Ingest 15 g of glucose/sucrose, wait 15 minutes then take another 15 g glucose/sucrose if BG is <4.0 mmol/l; once hypoglycaemia is reversed have a meal or snack to prevent recurrence.

**Symptoms of hypoglycaemia**

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<thead>
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<th>Neuroglycopenic</th>
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<tbody>
<tr>
<td>Trembling</td>
<td>Difficulty concentrating</td>
</tr>
<tr>
<td>Palpitations</td>
<td>Confusion</td>
</tr>
<tr>
<td>Sweating</td>
<td>Weakness</td>
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<tr>
<td>Anxiety</td>
<td>Drowsiness</td>
</tr>
<tr>
<td>Hunger</td>
<td>Vision changes</td>
</tr>
<tr>
<td>Nausea</td>
<td>Difficulty speaking</td>
</tr>
<tr>
<td>Tingling</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
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</tbody>
</table>

Awareness of hypoglycaemia and how to treat

**Question**
If Jean becomes hypoglycaemic/experiences symptoms and feels able to self treat, what should she be advised to do?

Ingest 15 g of glucose/sucrose, wait 15 minutes then take another 15 g glucose/sucrose if BG is <4.0 mmol/l; once hypoglycaemia is reversed have a meal or snack to prevent recurrence

**Show examples of 15 g glucose/sucrose**

- Ingestion of 15 g glucose raises BG levels by approx. 2.1 mmol/l within 20 minutes
- In cases of severe hypoglycaemia, where a person requires assistance to treat, 20 g of glucose/sucrose should be given in the first instance to a conscious person\(^1,2\)
- Glucagon should be administered by a friend or caregiver in the case of severe hypoglycaemia with unconsciousness; the emergency services should also be called\(^1,2\)
- Even if Jean feels able to self treat, it is good practice for Jean to inform somebody who lives nearby that she is feeling unwell, so they can check for full recovery
- A family member, friend or caregiver who lives nearby should be trained in treating hypoglycaemia, so that Jean can be assisted if necessary

BG, blood glucose.
Awareness of hypoglycaemia and how to treat

**Question**

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**Hide examples of 15 g glucose/sucrose**

**Examples of 15 g of glucose/sucrose for treatment of mild to moderate hypoglycaemia**

- 15 g of glucose in the form of glucose tablets
- 15 ml (3 teaspoons) of table sugar dissolved in water
- 175 ml (3/4 cup) of juice or regular soft drink
- 15 ml (1 tablespoon) of honey

6-month follow-up since initial diagnosis

• 3 months after starting combination therapy (6 months since initial diagnosis), Jean’s $\text{HbA}_{1c}$ is within the target range.
• Her BP is still above target, however, and the doctor adds a second antihypertensive (a CCB) to Jean’s regimen.
• Jean’s therapy has not caused any weight gain.
• The doctor stresses the importance of regular meals and adherence to medication.

**Current assessments**
- FPG: 4.4 mmol/l (80 mg/dl)
- $\text{HbA}_{1c}$: 7.2% (55 mmol/mol)
- BP: 135/85 mmHg
- BMI: 24.5 kg/m²

BMI, body mass index; BP, blood pressure; CCB, calcium channel blocker; FPG, fasting plasma glucose; $\text{HbA}_{1c}$, glycosylated haemoglobin.
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*Slide 24*

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.
