NHS Bedfordshire Clinical Commissioning Group

NHS Luton Clinical Commissioning Group

BEDFORDSHIRE & LUTON JOINT PRESCRIBING COMMITTEE

June 2016

Review: June 2019

Bulletin 241 : Guidelines on self-monitoring of blood glucose (SMBG) in non-insulin treated Type 2 diabetic patients for maintaining glycaemic control.

JPC Recommendations :

- **Clinicians to note the following recommendations are applicable to non-insulin treated TYPE 2 adult patients only.**

  Previous JPC guidance (as per Bulletin 124) on the self-monitoring of blood glucose (SMBG) in non-insulin TYPE 2 adult diabetic patients has been updated in accordance with NICE Clinical Guidelines, and with local modification as a result of Specialist input. As a consequence, Bulletin 124 has now been superseded and the following recommendations were approved:

1) Take the Driver and Vehicle Licensing Agency (DVLA)'s document Assessing fitness to drive - a guide for medical professionals into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes.

2) Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:-
   - there is evidence of or concern about hypoglycaemic episodes **or**
   - the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or undertaking a high risk activity **or**
   - the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on diabetes in pregnancy.

3) Consider **short-term** self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):
   - when starting treatment with oral or intravenous corticosteroids or
   - to confirm suspected hypoglycaemia.
   - when assessing the effectiveness of treatment.
   - patients presenting with symptomatic hyperglycaemia.

4) Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Healthcare professionals should test blood glucose and review treatment as necessary.

5) If adults with type 2 diabetes are self-monitoring their blood glucose levels, a structured assessment of the patient should be carried out at least annually.

6) Blood Glucose Testing Strips to be issued by GPs in line with BCCG and LCCG Primary Care Formularies.

7) **Frequency of Monitoring**
The NICE Guideline Development Group (GDG) (Type 2 Diabetes in adults, NG 28) noted a lack of evidence concerning the frequency of SMBG and specific target values when SMBG is used. The GDG was unable to make any recommendations on these issues and chose instead to draft 2 research recommendations. The GDG (Diabetes in pregnancy: management from preconception to the postnatal period, NG3) did make specific recommendations on frequency of testing.

The following recommendations are based on national guidance, where available and local guidance (agreed with local specialists):-

NICE Clinical Guideline 28 recommendations	JPC guidance / national guidance regarding frequency of monitoring
There is evidence of hypoglycaemic episodes	*Up to 3 x daily*
The person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or undertaking a high risk activity.	As per DVLA guidance or as appropriate
The person is planning to become pregnant)	If a woman with diabetes who is planning to become pregnant needs intensification of blood glucose-lowering therapy, advise her to increase the frequency of self-monitoring of blood glucose to include fasting levels and a mixture of pre-meal and post-meal levels.
The person is pregnant *	4 x daily (**fasting sample and samples at 1 hour after meals**)
Consider short-term self-monitoring of blood glucose levels (and review treatment as necessary): ➢ when starting treatment with oral or IV corticosteroids, **OR** ➢ to confirm suspected hypoglycaemia **OR** ➢ when assessing the effectiveness of treatment. ➢ In patients presenting with symptomatic hyperglycaemia	Up to 3 x daily (short term use only)

*Recommendations apply to treatment of gestational diabetes in addition to type 2 diabetes.

In addition to the bulletin, a patient information leaflet was also updated, available on the 'Advice and Guidance' section of the JPC page on the GP Ref website . http://www.gpref.bedfordshire.nhs.uk/referrals/bedfordshire-and-luton-joint-prescribing-committee-(jpc).aspx

1.0 Introduction/Background

The JPC produced guidelines on the frequency of self-monitoring of blood glucose in non-insulin treated type 2 diabetics in February 2010, revised in April 2010 and September 2012 (JPC Bulletin 124).[i]

Following the issue of updated NICE Guidelines relating to diabetes, the JPC agreed to update a number of local guidelines relating to the management of diabetes including bulletin 124, to incorporate the information contained in the NICE Guidelines.

Self-monitoring is a direct method by which a person with diabetes can be made aware of their level of blood glucose control. It is useful in people on drug treatments that require dose adjustments (such as insulin), have erratic effects or increase in risk of hypoglycaemia. There is, however, ongoing debate surrounding the routine use of self-monitoring in people with type 2 diabetes as part of an overall educational package designed to enhance self-care and provide feedback on the impact of lifestyle measures on blood glucose control. There is also very little information and guidance to support the optimal frequency of testing. With the growing number of patients being diagnosed with Diabetes, it is important to ensure that Health Care resources are optimised. This bulletin focuses on self-monitoring of blood glucose (SMBG) in patients with Type 2 Diabetes not on insulin therapy and seeks to give guidance (based where possible on the relevant NICE Guidelines) on which patients should undertake SMBG and the frequency of testing. Although current Formulary choices of blood glucose testing strips and meters are included in this document, detailed information on how these choices were agreed, is the subject of another bulletin.

Key Points:-

- NICE Guidelines 3 and 28 make recommendations on SMBG.
- NICE Guideline (NG) 28 has an **overall, a strong 'do not do' recommendation made for the majority of people with type 2 diabetes,** because the Guidelines Development Group (GDG) agreed that self-monitoring would not be of sufficient benefit for most people. However, **exception groups** were added to this recommendation, because the GDG agreed it was important to **offer targeted self-monitoring to people at higher risk of experiencing hypoglycaemic events.** This included people who are taking insulin therapy, oral antidiabetic medicines that increase the risk of hypoglycaemia, or if there was evidence of hypoglycaemic episodes. The GDG also added a further recommendation for healthcare professionals to refer to the DVLA's document Assessing fitness to drive - a guide for medical professionals to ensure that targeted self-monitoring was carried out in accordance with legislative guidance.
- The NICE GDG for NG 28 noted a lack of evidence concerning the frequency of SMBG and specific target values when SMBG was used and was unable to make any specific recommendations on these issues and chose instead to draft 2 research recommendations.
- NG 28 referred to NG 3 for consideration of the use of SMBG for use in people who were pregnant or planning to become pregnant. The GDG noted that, overall, the evidence supported the view that more frequent testing of blood glucose (and subsequent adjustment of treatment) led to better outcomes and that the frequency of monitoring should reflect the severity of the disease. The GDG noted that the optimum frequency of blood glucose

testing in pregnancy in women with pre-existing diabetes, not taking insulin was unknown and therefore included a research recommendation on this issue.

- The NICE recommendations on SMBG differ from the current JPC recommendations. The overall 'do not use' recommendation excludes a number of patient groups e.g. patients having diabetes medicines titrated; patients with intercurrent illness; patients undergoing significant lifestyle changes.
- The cost impact resulting from the change in recommendations is difficult to elucidate due to the multiple recommendation changes. It should be noted however that that despite a significant increase in expenditure relating to the treatment of diabetes, the costs associated with blood glucose testing strips has remained largely unchanged. The costs in this area have been managed by:-

    - Cost effective formulary choices of blood glucose meters and testing strips. *(Refer to 'Appendix 4' to see the formulary list of blood glucose test strips available to prescribe that meet ISO guidelines (May 2016).)*
    - Appropriate self-monitoring of blood glucose (SMBG) in accordance with JPC Bulletin 124.

2. NICE Guidance

A number of NICE Guidelines relating to the treatment of Diabetes have been published recently. The two most relevant guidelines which inform this bulletin are:-

- Type 2 Diabetes in adults: management, NICE guideline 28, published December 2015 https://www.nice.org.uk/guidance/ng28[ii]
- Diabetes in pregnancy: management from preconception to the postnatal period. NICE Guideline 3, published February 2015, last updated August 2015. https://www.nice.org.uk/guidance/ng3[iii]

2.1 Type 2 Diabetes in adults: management, NICE guideline 28, published December 2015[ii]

The NICE Guideline states the following with respect to SMBG (new 2015 recommendations are annotated):-

1.6.12 Take the Driver and Vehicle Licensing Agency (DVLA) At a glance guide to the current medical standards of fitness to drive into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes. **[new 2015] (See below for more detailed information)**

1.6.13 Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:

1. the person is on insulin **or**
2. there is evidence of hypoglycaemic episodes **or**
3. the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery **or**
4. the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on diabetes in pregnancy. **[new 2015]**

1.6.14 Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):

- when starting treatment with oral or intravenous corticosteroids **or**
- to confirm suspected hypoglycaemia. **[new 2015]**

1.6.15 Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Review treatment as necessary. **[new 2015]**

1.6.16 If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include:

- the person's self-monitoring skills
- the quality and frequency of testing
- checking that the person knows how to interpret the blood glucose results and what action to take
- the impact on the person's quality of life
- the continued benefit to the person
- the equipment used. **[2015]**

Research recommendations:-

What is the effectiveness of short-term self-monitoring of blood glucose during acute intercurrent illnesses in adults with type 2 diabetes?

Why this is important
There is an increased risk of hyperglycaemia during acute intercurrent illnesses in adults with type 2 diabetes. However, there is little evidence on the clinical and cost effectiveness of short-term self-monitoring of blood glucose levels during acute illnesses. Robust evidence from randomised controlled trials is needed to determine the comparative effectiveness of self-monitoring with no self-monitoring during episodes of acute illnesses. Outcomes should include change in treatment and prevention of hospital admissions.

What is the optimal frequency for self-monitoring of blood glucose in adults with type 2 diabetes?
What are the optimal blood glucose targets for self-monitoring in adults with type 2 diabetes?

Why this is important
It is widely recognised that self-monitoring of blood glucose is a multicomponent intervention. As well as being educated about how to use a self-monitoring device to assess blood glucose levels, adults with type 2 diabetes need to be able to understand their results and act on the observed readings. In adults for whom self-monitoring is appropriate, there is limited evidence to guide clinical practice in prescribing self-monitoring regimens, in terms of frequency of testing and optimal blood glucose targets. Given the inconvenience and expense of self-monitoring, robust

evidence from randomised controlled trials is needed to guide the optimal use of this intervention. Type 2 diabetes in adults Blood glucose management

2.2 Diabetes in pregnancy: management from preconception to the postnatal period. NICE Guideline 3, published February 2015, last updated August 2015.[iii]

The NICE Guideline states the following with respect to SMBG (new 2015 recommendations are annotated):-

1.1.13 Offer women with diabetes who are planning to become pregnant a meter for self-monitoring of blood glucose. **[2008]**

1.1.14 If a woman with diabetes who is planning to become pregnant needs intensification of blood glucose-lowering therapy, advise her to increase the frequency of self-monitoring of blood glucose to include fasting levels and a mixture of pre-meal and post-meal levels. **[2008]**

1.1.16 Agree individualised targets for self-monitoring of blood glucose with women who have diabetes and are planning to become pregnant, taking into account the risk of hypoglycaemia. **[2008]**

1.2.12 Teach women with gestational diabetes about self-monitoring of blood glucose. **[2015]**

1.2.13 Use the same capillary plasma glucose target levels for women with gestational diabetes as for women with pre-existing diabetes (see recommendations 1.3.5 and 1.3.6). **[2015]**

1.3.3 Advise pregnant women with type 2 diabetes or gestational diabetes to test their fasting and 1-hour post-meal blood glucose levels daily during pregnancy if they are:

- on diet and exercise therapy **or**
- taking oral therapy (with or without diet and exercise therapy) or single-dose intermediate-acting or long-acting insulin. **[new 2015]**

1.3.4 Agree individualised targets for self-monitoring of blood glucose with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia. **[2008]**

1.3.5 Advise pregnant women with any form of diabetes to maintain their capillary plasma glucose below the following target levels, if these are achievable without causing problematic hypoglycaemia:

- fasting: 5.3 mmol/litre

  and

- 1 hour after meals: 7.8 mmol/litre **or**
- 2 hours after meals: 6.4 mmol/litre. **[new 2015]**

1.3.6 Advise pregnant women with diabetes who are on insulin or glibenclamide to maintain their capillary plasma glucose level above 4 mmol/litre. **[new 2015]**

Research recommendations

Post-meal blood glucose testing in women with diabetes in pregnancy: is the 1 hour test more acceptable than the 2 hour test?

Why this is important

Self-monitoring of blood glucose is an important tool in the management of diabetes in pregnancy. Many studies have shown that post prandial hyperglycaemia is a predictor for fetal macrosomia and may contribute to neonatal hypoglycaemia. Current recommendations state that tests should be performed at either one or two hours post meals. Studies have demonstrated however, that the 1hour post prandial test is more likely to detect abnormal values which may require treatment and helps the person understand the relationship between food and blood glucose levels. Identifying acceptability of blood monitoring regimes using qualitative studies may improve both compliance and accuracy of testing and optimise pregnancy outcomes.

What is the optimum frequency of blood glucose testing in pregnancy in women with pre-existing diabetes who are not taking insulin?

The optimum frequency of blood glucose testing in pregnancy in women with pre-existing diabetes who are not taking insulin is unknown. While daily fasting blood glucose values in women on insulin are required to optimize the basal insulin dose and avoid nocturnal hypoglycaemia for women not taking insulin a daily fasting glucose is less informative as there is little day-to-day variability. Unlike women taking insulin there is no need to perform a pre-bedtime glucose value to lessen the risk of nocturnal hypoglycaemia. The frequency of blood glucose tests for other times in the day are currently recommended to be the same as for women on insulin. Randomised control trials are required to inform on the optimum frequency of blood glucose testing in pregnancy in women who are not taking insulin

3.0 Clinical and Cost-effectiveness Evidence Reviewed by NICE

Detailed information from the full NICE Guideline 28[iv] –Type 2 diabetes in adults: management (relating to self-monitoring of blood glucose) is included as appendix 1.

N.B. – The information reviewed by NICE looks at the use of SMBG to manage glycaemic control in people with type 2 diabetes treated with diet alone, or in combination with any blood glucose lowering therapies including insulin. In addition, the review looked at whether the use of self-monitoring should be restricted to specific sub-groups of the population, how often and when people should self-monitor, and where on the body tests should be carried out. The review also looked at the comparative effects of different types of SMBG.

Key points to note:-

- The quality of evidence varied from high to very low, but overall the quality was low.
- When comparing the evidence presented for SMBG compared to no SMBG, a statistically significant difference was observed in HbA1c levels in favour of SMBG. However, the small reduction at less than 5 mmol/mol (0.5%; the threshold for a minimal important difference) was not clinically meaningful.
- There was generally no difference in HbA1c levels and hypoglycaemic events between enhanced SMBG (education, telecare, automated glucometer) and conventional SMBG.

- **There was little evidence on frequency and location of SMBG testing**, but findings from the 3 included studies showed no difference in HbA1c levels and hypoglycaemic events between the groups comparing more frequent (every 2 weeks or 4 times a week) and less frequent (monthly or once a week) SMBG and different sites of testing (forearm or fingertip). **The lack of evidence concerning the frequency of SMBG and specific target values when SMBG is used meant that the NICE Guideline Development Group (GDG) was unable to make any recommendations on these issues** and chose instead to draft 2 research recommendations. (see Section 2.1 above).
- No evidence had been identified to indicate that short-term SMBG would be beneficial during intercurrent illnesses. Therefore, the GDG agreed that it would be useful to make clinicians aware of the potential risk of worsening hyperglycaemia during intercurrent illnesses in people with type 2 diabetes and to draft a research recommendation (see section 2.1 above) on this issue. Treatment should be reviewed and individuals should be reminded about what action to take when they are unwell.
- Overall, the NICE GDG considered the economic evidence did not make it possible to state conclusively that self-monitoring is or is not likely to be cost-effective compared with no self-monitoring, but the most applicable evidence with least limitations suggested that **self-monitoring is not likely to be cost-effective compared with no self-monitoring.**
- **When making recommendations for the use of self-monitoring, the GDG considered the following points:-**
    - Overall, the evidence showed a small reduction in HbA1c levels that was not clinically important.
    - There was uncertainty around whether self-monitoring was cost effective, but the GDG considered that it was unlikely to be at the magnitude of HbA1c changes reported.
    - Some medications have been shown to increase the risk of hypoglycaemia.

Overall, a strong 'do not do' recommendation was made for the majority of people with type 2 diabetes, because the GDG agreed that self-monitoring would not be of sufficient benefit for most people. However, **exception groups** were added to this recommendation, because the GDG agreed it was important to **offer targeted self-monitoring to people at higher risk of experiencing hypoglycaemic events.** This included people who are taking insulin therapy, oral antidiabetic medicines that increase the risk of hypoglycaemia, or if there was evidence of hypoglycaemic episodes. The GDG also added a further recommendation for healthcare professionals to refer to the DVLA's document Assessing fitness to drive - a guide for medical professionals to ensure that targeted self-monitoring was carried out in accordance with legislative guidance.

Detailed information from the full NICE Guideline 3 – Diabetes in pregnancy: management from preconception to the postnatal period is included in appendix 2.[v]

NB – The aim of the NICE Guideline review (of this issue) was to evaluate the effectiveness of monitoring blood glucose in pregnant women with type 1, type 2 or gestational diabetes. The review does not examine the evidence available for the performance of self-monitoring, but specifically focuses on the frequency of monitoring blood glucose and timing relative to meals.

Key points to note:-

- The quality of the evidence ranged from moderate to very low.
- The guideline development group noted that, overall, the evidence supported the view that more frequent testing of blood glucose (and subsequent adjustment of treatment) led to better outcomes.
- Intermittent glucose monitoring requires pricking a finger for a capillary blood sample several times during the day and using a meter to measure blood glucose. This is disruptive and requires a significant commitment from the woman. The group believed that self-monitoring of blood glucose would be especially helpful to women who are more likely to experience hypoglycaemic episodes (such as those who experience wide variability in their glucose regulation, or who are on insulin or glibenclamide, or who may have hypoglycaemia unawareness). The 2008 guideline on diabetes in pregnancy recommended this as the standard method of glucose monitoring for all women with type 1 and those with type 2 diabetes on insulin therapy.
- The guideline development group was of the view that the frequency of monitoring should reflect the severity of the disease and its treatment and to improve compliance in women with less severe disease. Hence they felt that it would be reasonable to write recommendations for 3 different categories of women with diabetes in pregnancy in decreasing order of severity: women with type 1 diabetes; women with type 2 or gestational diabetes on a multiple insulin dose regimen; and women with type 2 or gestational diabetes who were on diet and exercise therapy only, or taking oral therapy or a single daily dose of intermediate-acting or long-acting insulin.
- The guideline development group concluded that for all women with diabetes both pre- and postprandial testing was important during pregnancy and that it should be performed 7 times a day for women with type 1 or insulin-requiring type 2 or gestational diabetes.
- **Women who achieved glucose regulation using diet or oral therapy or single dose intermediate or long-lasting insulin did not need to test preprandially and testing could be limited to a fasting sample and samples at 1 hour after meals every day.**
- No health economic evidence was identified that considered blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy. De novo analysis was not undertaken for this question as it was not considered as high priority as other issues within the guideline.
- The guideline development group noted that self-monitoring of blood glucose is part of standard NHS treatment for people with diabetes. Any increase in frequency of testing during pregnancy will incur an additional cost. However, because tight blood glucose control is particularly important for improving pregnancy outcomes, the benefits of additional testing are likely to outweigh testing costs.

4.0 Driving

The Driver and Vehicle Licensing Agency (DVLA) has issued updated guidance entitled 'Assessing fitness to drive: a guide for medical professionals', published 11 March 2016, updated 18th April 2016 and 27th May 2016. https://www.gov.uk/government/publications/assessing-fitness-to-drive-a-guide-for-medical-professionals[vi]

This publication specifies the requirements and advice from the DVLA on monitoring of blood glucose in people with diabetes who are/have:-

1) Insulin-treated diabetes
2) Impaired awareness of hypoglycaemia

3) Diabetes complications
4) Temporary insulin treatment
5) Diabetes treated by medication other than insulin
6) Diabetes managed by diet/lifestyle alone
7) Hypoglycaemia due to other causes
8) Pancreas transplant
9) Islet cell transplantation.

The DVLA guidance and advice for **non-insulin treated diabetic** patients is summarised below. (Extract from DVLA document).

DIABETES MELLITUS	GROUP 1 Car and motorcycle	GROUP 2 Bus and lorry
Managed by tablets carrying hypoglycaemia risk. This includes Sulfonylureas And Glinides (e.g. Nateglinide , Repaglinide)	! - May drive and need not notify the DVLA, provided: ■ no more than 1 episode of severe hypoglycaemia in the last 12 months ■ **if needed, detection of hypoglycaemia is by appropriate blood glucose monitoring at times relevant to driving and clinical factors, including frequency of driving** ■ under regular review. **It may be appropriate to monitor blood glucose depending on a number of factors including frequency and/or duration of driving, in which case monitoring should be carried out at times relevant to driving.** If the above requirements and those set out in Appendix D of the DVLA Guidance are met, the DVLA need not be informed. The DVLA must be notified if clinical information indicates the agency may need to undertake medical enquiries.	! - May drive but must notify the DVLA. All the following criteria must be met for the DVLA to issue a licence for 1, 2 or 3 years: ■ no episode of severe hypoglycaemia in the last 12 months ■ full awareness of hypoglycaemia ■ **regular self-monitoring of blood glucose – at least twice daily and at times relevant to driving** ■ demonstrates an understanding of the risks of hypoglycaemia ■ has no disqualifying complications of diabetes that mean a licence will be refused or revoked, such as visual field defect.

DIABETES MELLITUS	GROUP 1 Car and motorcycle	GROUP 2 Bus and lorry

Managed by medication, including non-insulin injectables (excluding sulfonylureas and glinides) (See also Appendix 4)	! - May drive and need not notify the DVLA, provided the requirements set out in Appendix D* of the DVLA guidance are met and the driver is under regular medical review. ! - May drive but must notify the DVLA if clinical information indicates the agency may need to undertake medical enquiries.	! - May drive but must notify the DVLA. The DVLA may issue a licence if the requirements set out in Appendix D* to the DVLA guidance are met and the driver is under regular medical review. A licence is refused or revoked if relevant disqualifying complications have developed, such as diabetic retinopathy affecting visual acuity or visual fields. A short-term licence may be issued if diabetes complications have developed but the required medical standards have been met.
Managed By Diet/lifestyle alone	✓- May drive and need not notify the DVLA. ✗- Must not drive and must notify the DVLA if, for example: ■ relevant disqualifying complications develop such as diabetic retinopathy affecting visual acuity or visual fields ■ insulin treatment is required (see the requirements for insulin-treated diabetes).	✓- May drive and need not notify the DVLA. ✗- Must not drive and must notify the DVLA if, for example: ■ relevant disqualifying complications develop such as diabetic retinopathy affecting visual acuity or visual fields ■ insulin treatment is required (see the requirements for insulin-treated diabetes).

*See Appendix 4

Re: Taxi Licensing:

The DVLA Guidance states that responsibility for determining any higher standards and medical requirements for taxi drivers, over and above the driver licensing requirements, rests with Transport for London in the Metropolitan area, or the Local Authority in all other areas.

Advice on best practice for local authorities issuing taxi licences is given by the booklet, ‘Fitness to drive: a guide for health professionals’, published in 2006 by The Royal Society of Medicine (RSM) on behalf of the Department for Transport (ISBN reference 9781853156519).

This guide for local authorities recommends that taxi drivers should meet the same medical standards that Group 2 bus and lorry drivers must meet under the DVLA’s requirements.

Re: Police, Ambulance and Health Service Vehicle Driver Licensing:

The DVLA Guidance states that the same medical standards apply for drivers of police, fire, coastguard, ambulance and health service vehicles as they do for all drivers holding Group 1 and 2

licences. Any responsibility for determining higher medical standards, over and above these licensing requirements, rests with the individual force, service or other relevant body.

Note, however, that the Secretary of State's Honorary Medical Advisory Panel on Diabetes and Driving has recommended that drivers with insulin-treated diabetes do not drive emergency vehicles. This takes account of the difficulties for an individual, regardless of whether they may appear to have exemplary glycaemic control, in adhering to the monitoring processes required when driving in response to an emergency.

5.0 Expenditure in Bedfordshire and Luton/Cost Impact to the NHS

The information outlined below shows that despite a significant increase in expenditure relating to the treatment of diabetes, the costs associated with blood glucose testing strips has remained largely unchanged. The costs in this area have been managed by:-

- Cost effective formulary choices of blood glucose meters and testing strips.

(Refer to 'Appendix 4' to see the formulary list of blood glucose test strips available to prescribe that meet ISO guidelines (May 2016).)

- Appropriate self-monitoring of blood glucose (SMBG) in accordance with JPC Bulletin 124.

December 2008 – November 2009	NHS Bedfordshire PCT	NHS Luton PCT
Prescribing expenditure for all anti-diabetic therapy	£4,308,782	£2,368,856
Prescribing expenditure for oral anti-diabetics agents	£1,508,041	£933,060
Prescribing expenditure for blood glucose testing strips	£957,819	£459,386
Prescribing expenditure for urine glucose test strips	£6,732	£2737

March 2015 – February 2016	BCCG	LCCG
Prescribing expenditure for all anti-diabetic therapy	£6,177,052.04	£3,265,842.53
Prescribing expenditure for oral anti-diabetics agents	£2,800,159.55	£1,677,277.68
Prescribing expenditure for blood glucose testing strips	£1,044,346.01[a]	£479,496.99[a]
Prescribing expenditure for urine glucose test strips	£1,429.29	£700.47

[a]Includes estimated rebate.

The impact of the proposed change in recommendations are difficult to elucidate due to multiple changes as outlined below:-

- DVLA Guidance – now no longer recommends that people with a group 2 licence managed by medication including non –insulin injectables (excluding sulfonylureas and glinides) are not advised to monitor their blood glucose regularly.
- Diabetes medication being titrated – SMBG – no longer recommended.
- Patients with intercurrent illness – SMBG – no longer recommended.
- Patients undergoing significant lifestyle changes – SMBG – no longer recommended.
- Pregnant diabetic patient (type 2) – SMBG recommended 4 instead of 3 times per day.
- To confirm hypoglycaemia – Short term SMBG now recommended.
- Hypoglycaemic episodes -SMBG now recommended. (this recommendation is likely to include Type 2 patients receiving insulin)

Appendix 1

The following information is an excerpt from NICE Guideline 28 (Full Guideline) – Type 2 diabetes in adults: management.[iv] The evidence presented below relates to Self-monitoring of blood glucose.

https://www.nice.org.uk/guidance/ng28/evidence/full-guideline-2185320349

Clinical evidence

None of the studies reported evidence on diabetes-related complications.

SMBG versus no SMBG

Evidence from a meta-analysis of 17 trials showed a small, clinically unimportant reduction in HbA1c levels with SMBG compared to no SMBG at up to 1 year. None of the subgroup analyses based on existing treatment (that is diet alone or combined with oral antidiabetic and/or insulin medicines), type of SMBG (standard or enhanced) or overall prescribed frequency of SMBG testing (that is less than once a day, 1 to 2 times a day or more than twice a day) showed a clinically important reduction in HbA1c levels. The quality of the evidence was low.

Evidence from a meta-analysis of the 6 trials reporting data on fasting blood glucose showed no significant changes in the 5 trials that included people who were treated with diet and/or oral antidiabetic medicines up to 1 year, but a significant reduction at 6 months in a trial of older adults who were on insulin therapy and undertaking SMBG (standard or enhanced) compared to no SMBG. Subgroup analyses based on overall prescribed frequency of SMBG testing showed no significant differences in fasting blood glucose in people undertaking SMBG compared to no SMBG. The quality of the evidence was low.

The low-quality trial including older adults on insulin therapy also reported data on postprandial blood glucose levels and found a significant reduction in those undertaking SMBG (standard or enhanced) compared to no SMBG at 6 months.

A meta-analysis of 6 trials that reported any hypoglycaemic event showed a significantly increased risk in those undertaking SMBG compared to no SMBG for people on diet and/or oral antidiabetic medicines (4 studies), but no difference in risk for people on diet alone (1 low-quality study) or on diet, oral antidiabetic and/or insulin medicines (1 low-quality study) up to 1 year. Subgroup analyses based on overall prescribed frequency of SMBG testing only showed a significantly increased risk in those undertaking SMBG less than once a day compared to no SMBG (2 studies). Overall, the quality of the evidence was low. A meta-analysis of the 3 trials that reported severe hypoglycaemic events showed low event rates and no significant difference in risk in those undertaking SMBG compared to no SMBG. One moderate-quality trial showed no significant difference in risk in adverse events in people undertaking SMBG compared to no SMBG. The quality of the evidence was low.

Different forms of SMBG

SMBG plus education versus conventional SMBG

Overall, 2 meta-analyses were conducted on HbA1c levels and any hypoglycaemic events for 3 studies that examined SMBG plus education compared to standard SMBG on people treated with diet and/or oral antidiabetic and/or insulin medicines up to 1 year. Overall, no significant differences in HbA1c levels and hypoglycaemic events were observed in people undertaking SMBG plus

education compared to SMBG alone. However, 1 very-low-quality trial showed a significant clinically relevant reduction in HbA1c levels at 3 months in people on oral antidiabetic and/or insulin medicines who were undertaking SMBG plus education compared to SMBG alone. Overall, the quality of the evidence was low.

SMBG plus telecare versus conventional SMBG

A meta-analysis of 5 trials showed a non-significant reduction in HbA1c levels up to 44 weeks in people on diet, oral antidiabetic and/or insulin undertaking SMBG plus telecare compared to SMBG only (3 studies), but a significant and clinically important reduction in HbA1c levels was observed in favour of SMBG plus telecare compared to SMBG alone in 2 trials that did not specify the diabetes treatment that people were receiving. Overall, the quality of the evidence was low. Two low-quality trials also reported data on fasting blood glucose up to 44 weeks which showed no significant differences in people on diet, oral antidiabetic medicines and/or insulin undertaking SMBG plus telecare compared to SMBG. One low-quality trial additionally reported data on postprandial blood glucose levels and any hypoglycaemic events, and showed no significant differences at 26 weeks between people on diet, oral antidiabetic and/or insulin undertaking SMBG plus telecare compared to SMBG alone in either of these outcomes.

Automated mobile telephone glucometer versus standard glucometer

One small, low-quality trial showed no significant differences in blood glucose measures (HbA1c, fasting and postprandial blood glucose) at 3 months in SMBG using an automated glucometer compared to a standard glucometer in people with unspecified current diabetes treatments.

SMBG plus continuous glucose monitoring (CGM) versus conventional SMBG

Overall, a meta-analysis of 2 trials showed a significant and clinically important reduction in HbA1c levels in people on insulin undertaking SMBG plus CGM compared to those on SMBG alone up to 12 months. The quality of the evidence was very low. One low-quality trial reported no significant differences in fasting and postprandial blood glucose at 3 months in people on insulin undertaking SMBG plus CGM compared to those on SMBG alone.

Frequency and location of SMBG testing

Two moderate-to-low-quality trials showed no clinically important differences in HbA1c levels in people treated with oral antidiabetic medicines undertaking monthly versus fortnightly self-monitoring or 4 times weekly versus once weekly monitoring. There was an increased risk of any hypoglycaemic event with increased monitoring.

High-to-moderate-quality evidence from 1 trial in people with type 2 diabetes treated with insulin showed that there were no clinically important differences in HbA1c levels or hypoglycaemia associated with forearm versus fingertip testing.

Health economic evidence

Two directly applicable Cost Utility Analyses (CUAs) with minor limitations found that, for people with type 2 diabetes treated with diet or oral antidiabetic drugs, SMBG was more costly and produced less QALYs than no SMBG.

Four partly applicable CUAs with potentially serious limitations that based their treatment effect on the same US observational study found SMBG to be cost effective, though there was substantial uncertainty in their results.

Appendix 2

The following information is an excerpt from NICE Guideline 3 (Full Guideline) – Diabetes in pregnancy: management from preconception to the postnatal period.[v] The evidence presented below relates to self-monitoring of blood glucose.

https://www.nice.org.uk/guidance/ng3/evidence/full-guideline-3784285

Review question

What is the effectiveness of blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy?

The aim of this review was to evaluate the effectiveness of monitoring blood glucose in pregnant women with type 1, type 2 or gestational diabetes.

In the previous guideline on diabetes in pregnancy, 2 recommendations were made to inform how self monitoring of intermittent capillary blood glucose should be performed. During pregnancy, women with diabetes were to be advised to test fasting blood glucose levels and blood glucose levels 1 hour after every meal and women with insulin-treated diabetes were to be advised to additionally test blood glucose levels before going to bed at night.

The review question in this update does not examine the evidence available for the performance of self monitoring, but specifically focuses on the frequency of monitoring blood glucose and timing relative to meals.

Evidence statements

Monitoring versus no monitoring

One study (n=68) found no difference in the number of vaginal births (relative risk [RR] 1.0, 95% confidence interval [CI] 0.7 to 1.4) or caesarean sections (RR 1.0, 95% CI 0.5 to 2.1) when comparing women with type 1, type 2 or gestational diabetes who had their blood glucose monitored with those who did not. There was also no difference between groups whose HbA1c values were measured at 28 weeks (MD −0.6, 95% CI −1.5 to 0.3), 32 weeks (MD 0.2, 95% CI 0.5 to 0.9), 36 weeks (MD −0.3, 95% CI −0.8 to 0.2)), 38 weeks (MD −0.2 95% CI −0.7 to 0.3) or at term (MD −0.4, 95% CI −1.2 to 0.4). The evidence for this outcome was of moderate quality.

One study (n=68) found no difference in the number of neonates born large for gestational age (RR 1.3, 95% CI 0.5 to 3.2), the incidence of shoulder dystocia (RR 0.4, 95% CI 0.0 to 8.9) or the incidence of neonatal hypoglycaemia (RR 0.4, 95% CI 0.1 to 1.7) when comparing women who had their blood glucose monitored with those who did not. The quality of this evidence was low.

One study (n=123) found no difference in the risk of large for gestational age neonates born to women with type 1, type 2 or gestational diabetes between groups associated with monitoring compared with no monitoring of blood glucose. The quality of this evidence was very low.

Monitoring strategies

Two studies (n=990; n=116) found no difference between groups in the number of vaginal births (including births with forceps) associated with women with type 1, type 2 or gestational diabetes who received blood glucose monitoring compared to those who did not (RR 0.94, 95% CI 0.85 to 1.04; RR 1.40, 95% CI 0.56 to 3.50, respectively). The quality of the evidence was very low.

Two studies (n=116; n=990) found no difference between groups in the number of vaginal births with forceps associated with women with type 1, type 2 or gestational diabetes who received blood glucose monitoring compared to those who did not (odds ratio [OR] 2.77, 95% CI 0.9 to 8.4; RR 0.6, 95% CI 0.3 to 1.4, respectively). The quality of the evidence was very low.

One study (n=116) found no difference between groups for vaginal births without forceps (OR 0.49, 95% CI 0.24 to 1.04) when comparing women with type 1, type 2 or gestational diabetes who monitored their blood glucose daily with women who had weekly monitoring of their blood glucose. The quality of the evidence was very low.

Three studies (n=116; n=990; n=28) found no difference between groups for the risk of caesarean sections when comparing women with type 1, type 2 or gestational diabetes (respectively OR 1.41, 95% CI 0.6 to 3.2; RR 1.12 95% CI 0.9 to 1.3; RR 0.78, 95% CI 0.39 to 1.54). The quality of the evidence was very low.

One study (n=990) found a lower risk of neonates large for gestational age (on the 90th centile or above) being born to women with type 1, type 2 or gestational diabetes who monitored their blood glucose daily compared with women who performed weekly monitoring of their blood glucose (RR 0.7, 95% CI 0.5 to 0.9). The quality of the evidence was very low.

One study (n=116) found a reduced risk of neonatal hypoglycaemia (OR 0.19, 95% CI 0.08 to 0.5), while 2 studies (n=990; n=28) found no difference in the risk of neonatal hypoglycaemia (RR 1.6, 95% CI 1.0 to 2.8; RR 0.57, 95% CI 0.20 to 1.59 respectively) when comparing women with type 1, type 2 or gestational diabetes. The quality of the evidence for this outcomes was very low.

One study (n=990) found no difference in the risk of shoulder dystocia between groups (RR 0.8, 0.3 to 2.3) when comparing women with type 1, type 2 or gestational diabetes. The quality of the evidence for this outcome was very low.

Preprandial versus postprandial monitoring

Two studies (n=61; n=66) found no difference between groups in the risk of caesarean section associated with women with type 1, type 2 or gestational diabetes who received preprandial monitoring compared with those who did not (RR 1.45, 95% CI 0.9 to 2.3; RR 1.63, 95% CI 0.8 to 3.4). The evidence for this outcome was low quality.

One study (n=61) found no difference in the final HbA1c value between groups (MD 0.3, 95% CI −0.1 to 0.7) or in the change in HbA1c value from booking (MD 0.1, 95% CI −0.5 to 0.7) between women with type 1, type 2 or gestational diabetes who received postprandial monitoring compared with preprandial measurements to monitor their blood glucose. The evidence for this outcome was of moderate quality.

One study (n=66) found an increased risk of neonates large for gestational age (greater than 90th centile) associated with the group of women who underwent preprandial compared with postprandial measurements to monitor their blood glucose (RR 1.2, 95% CI 0.7 to 1.9). The quality of evidence for this outcome was low.

One study (n=66) found an increased risk of large for gestational age (greater than 90th percentile) neonates associated with the group of women who underwent preprandial compared with postprandial measurements to monitor their blood glucose (RR 3.5, 95% CI 1.3 to 9.5). The quality of evidence for this outcome was moderate.

One study (n=66) found no increased risk of shoulder dystocia associated with the group of women who underwent preprandial compared with postprandial measurements to monitor their

blood glucose (RR 6.0, 95% CI 0.8 to 47.1). The quality of evidence for this outcome was moderate.

Two studies (n=61; n=66) found no difference between groups in the risk of neonatal hypoglycaemia in women with type 1, type 2 or gestational diabetes who underwent preprandial compared with postprandial measurements to monitor their blood glucose (RR 1.1, 95% CI 0.5 to 2.5; RR 7.0, 95% CI 0.9 to 53.8, respectively). The quality of evidence for this outcome was low.

Two studies (n=62; n=66) found no difference between groups in the risk of neonatal hypoglycaemia in women with type 1, type 2 or gestational diabetes who underwent preprandial compared with postprandial measurements to monitor their blood glucose (RR 2.8, 95% CI 0.1 to 66.6; RR 3, 95% CI 0.1 to 71.1, respectively). The quality of evidence for this outcome was low.

One hour postprandial versus 2 hours postprandial monitoring

One study (n=112) found no difference between groups in the risk of caesarean section in women with type 1, type 2 or gestational diabetes who received 1 hour postprandial monitoring compared with 2 hour postprandial measurements to monitor their blood glucose (RR 0.8, 95% CI 0.4 to 1.4). The quality of evidence for this outcome was very low.

One study (n=112) found no difference between groups in the risk of large for gestational age neonates in women with type 1, type 2 or gestational diabetes who received 1 hour postprandial monitoring compared with 2 hour postprandial measurements to monitor their blood glucose (RR 0.5, 95% CI 0.2 to 1.5). The quality of evidence for this outcome was very low.

Four daily (fasting and 3 post prandial measurements) versus 7 daily measurements

One study (n=2461) found an increased risk of caesarean section in women with type 1, type 2 or gestational diabetes associated with 4 daily measurements compared with 7 daily measurement of blood glucose (RR 1.4, 95% CI 1.2 to 1.7). The quality of this evidence was very low.

One study (n=2461) found an increased length of neonatal intensive care unit (NICU) length of stay associated with women with type 1, type 2 or gestational diabetes who had 4 daily measurements compared with 7 daily measurements of blood glucose (MD 1.7, 95% CI 1.5 to 1.9). The quality of this evidence was very low.

One study (n=2461) found an increased risk of large for gestational age (greater than 90th centile) neonates in women with type 1, type 2 or gestational diabetes associated with 4 daily measurements compared with 7 daily measurements of blood glucose (RR 1.5, 95% CI 1.3 to 1.9). The quality of this evidence was very low.

One study (n=2461) found an increased risk of shoulder dystocia in the neonates of women with type 1, type 2 or gestational diabetes who had 4 daily measurements compared with 7 daily measurement of blood glucose (RR 3.1, 95% CI 1.2 to 8.4). The quality of this evidence was very low.

One study (n=2461) found an increased risk of neonatal hypoglycaemia associated with women with type 1, type 2 or gestational diabetes who had 4 daily measurements compared with 7 daily measurements of blood glucose (RR 5.2, 95% CI 3.8 to 7.1). The quality of this evidence was very low.

One study (n=2000) found no difference between groups of women with type 1, type 2 or gestational diabetes who had 4 daily measurements compared with 7 daily measurements of blood glucose for the outcomes of stillbirth (per 1000) (RR 4, 95% CI 0.5 to 35.7) or neonatal death (per 1000) (RR 0.7, 95% CI 0.1 to 4.0). The quality of this evidence was very low.

Health economics profile

No health economic evidence was identified that considered blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy.

De novo analysis was not undertaken for this question as it was not considered as high priority as other issues within the guideline.

Appendix 3– Appendix D to the DVLA Guidance – Assessing fitness to drive – a guide for medical professionals, issued March/April 2016[vi]

INF188/2 leaflet 'Information for drivers with diabetes' and DIABNF leaflet 'A guide to insulin treated diabetes and driving'

2/16INF188/2Information for drivers with diabetes treated by non insulin medication, diet, or both.

Please keep this leaflet safe so you can refer to it in the future

Drivers do not need to tell us if their diabetes is treated by tablets, diet, or both and they are free of the complications listed over the page.

Some people with diabetes develop associated problems that may affect their driving.

Ref: Tab115684

Hypoglycaemia (low blood sugar)

Hypoglycaemia (also known as a hypo) is the medical term for a low blood glucose (sugar) level.

Severe hypoglycaemia means the assistance of another person is required. The risk of hypoglycaemia is the main danger to safe driving and can occur with diabetes treated with insulin or tablets or both. This may endanger your own life as well as that of other road users. Many of the accidents caused by hypoglycaemia are because drivers carry on driving even though they get warning symptoms of hypoglycaemia. If you get warning symptoms of hypoglycaemia while driving you must stop as soon as safely possible – **do not ignore the warning symptoms.**

Early symptoms of Hypoglycaemia include:

n Sweating, shakiness or trembling, feeling hungry, fast pulse or palpitations, anxiety, tingling lips.

If you don't treat this it may result in more severe symptoms such as:

n Slurred speech, difficulty concentrating, confusion, disorderly or irrational behaviour, which may be mistaken for drunkeness.

If left untreated this may lead to unconsciousness.

What you need to tell us about

By law you must tell us if any of the following applies:

n You suffer more than one episode of severe hypoglycaemia within the last 12 months. You must also tell us if you or your medical team feel you are at high risk of developing severe hypoglycaemia. For Group 2 drivers (bus/lorry), one episode of severe hypoglycaemia must be reported immediately.

n You develop impaired awareness of hypoglycaemia. (Difficulty in recognising the warning symptoms of low blood sugar).

n You suffer severe hypoglycaemia while driving.

n You need treatment with insulin.

n You need laser treatment to both eyes or in the remaining eye if you have sight in one eye only.

n You have problems with vision in both eyes, or in the remaining eye if you have sight in one eye only. By law, you must be able to read, with glasses or contact lenses if necessary, a car number plate in good daylight at 20 metres. In addition, the visual acuity (with the aid of glasses or contact lenses if worn) must be at least 6/12 (0.5 decimal) with both eyes open, or in the only eye if monocular.

n You develop any problems with the circulation, or sensation in your legs or feet which makes it necessary for you to drive certain types of vehicles only, for example automatic vehicles, or vehicles with a hand operated accelerator or brake. This must be shown on your driving licence.

n An existing medical condition gets worse or you develop any other condition that may affect your driving safely.

In the interests of road safety, you must be sure that you can safely control a vehicle at all times.

How to tell us

If your doctor, specialist or optician tells you to report your condition to us, you need to fill in a Medical Questionnaire about diabetes (DIAB1). You can download this from **www.gov.uk/driving-medical-conditions**

Phone: 0300 790 6806.

Write to: Drivers Medical GroupDVLASwanseaSA99 1TU

Useful address

Diabetes UK Central Office Macleod House10 ParkwayLondonNW1 7AA
Diabetes UK Website: www.diabetes.org.uk

Find out about DVLA's online services

Go to: www.gov.uk/browse/driving

-The applicant or licence holder must notify DVLA unless stated otherwise in the text

DIABINF

A Guide to Insulin Treated Diabetes and Driving

Drivers who have any form of diabetes treated with any insulin preparation must inform DVLA
(Caveat: See Temporary Insulin Treatment)

HYPOGLYCAEMIA

Hypoglycaemia (also known as a hypo) is the medical term for a low blood glucose (sugar) level.

Severe hypoglycaemia means the assistance of another person is required.

The risk of hypoglycaemia is the main danger to safe driving and this risk increases the longer you are on insulin treatment. This may endanger your own life as well as that of other road users. Many of the accidents caused by hypoglycaemia are because drivers carry on driving even though they get warning symptoms of hypoglycaemia. If you get warning symptoms of hypoglycaemia whilst driving, you must always stop as soon as safely possible – **do not ignore the warning symptoms**.

EARLY SYMPTOMS OF HYPOGLYCAEMIA INCLUDE:

Sweating, shakiness or trembling, feeling hungry, fast pulse or palpitations, anxiety, tingling lips.
If you don't treat this it may result in more severe symptoms such as:
Slurred speech, difficulty concentrating, confusion, disorderly or irrational behaviour, which may be mistaken for drunkenness.

If left untreated this may lead to unconsciousness.

DRIVERS WITH INSULIN TREATED DIABETES ARE ADVISED TO TAKE THE FOLLOWING PRECAUTIONS.

- You should **always** carry your glucose meter and blood glucose strips with you. You should check your blood glucose no more than 2 hours before the start of the first journey and every two hours whilst you are driving. If driving multiple short journeys, you do not necessarily need to test before each additional journey as long as you test every 2 hours while driving. More frequent testing may be required if for any reason there is a greater risk of hypoglycaemia for example after physical activity or altered meal routine. The intention is to ensure that blood glucose is always above 5.0mmol/l while driving.
- In each case if your blood glucose is **5.0mmol/l or less, take a snack**. If it is less than **4.0mmol/l or you feel hypoglycaemic, do not drive.**
- If hypoglycaemia develops while driving, stop the vehicle as soon as possible.
- You should switch off the engine, remove the keys from the ignition and move from the driver's seat.
- You should not start driving until 45 minutes after blood glucose has returned to normal (confirmed by measuring blood glucose). It takes up to 45 minutes for the brain to recover fully.
- Always keep an emergency supply of fast-acting carbohydrate such as glucose tablets or sweets within easy reach in the vehicle.
- You should carry personal identification to show that you have diabetes in case of injury in a road traffic accident.
- Particular care should be taken during changes of insulin regimens, changes of lifestyle, exercise, travel and pregnancy.
- You must take regular meals, snacks and rest periods on long journeys. Always avoid alcohol.

EYESIGHT

All drivers are required by law to read, in good daylight (with glasses or corrective lenses if necessary), a car number plate from a distance of 20 metres. In addition, the visual acuity (with the aid of glasses or contact lenses if worn) must be at least 6/12 (0.5 decimal) with both eyes open, or in the only eye if monocular.

LIMB PROBLEMS

Limb problems/amputations are unlikely to prevent driving. They may be overcome by driving certain types of vehicles e.g. automatics or one with hand controls.

YOU MUST INFORM DVLA IF:

- You suffer more than one episode of severe hypoglycaemia (needing the assistance of another person) within the last 12 months. For Group 2 drivers (bus/lorry) one episode of severe hypoglycaemia must be reported immediately. You must also tell us if you or your medical team feels you are at high risk of developing hypoglycaemia.
- You develop impaired awareness of hypoglycaemia. (difficulty in recognising the warning symptoms of low blood sugar)
- You suffer severe hypoglycaemia while driving.
- An existing medical condition gets worse or you develop any other condition that may affect you driving safely.

CONTACT US

Web site: www.gov.uk/browse/driving
Tel: 0300 790 6806 (8.00am. to 5.30pm. Mon – Fri) & (8.00 am. to 1pm. Saturday)
Write: Drivers' Medical Group, DVLA, Swansea SA99 1TU
For further informations on diabetes visit www.diabetes.org.uk

Appendix 4 : Formulary Options (BCCG and LCCG) For Blood Glucose Test Strips Available on Prescription (International Organisation for Standardisation {ISO} Standard {May 2016} compliant):

Blood Glucose Test Strip	Image	Pack Size
MyLife Pura		50
TRUEresult		50

BCCG and LCCG recognise that patients from areas outside, but bordering on Bedfordshire and Luton, may be prescribed alternative blood glucose testing strips and meters agreed by other CCGs. BCCG and LCCG would not seek to change these meters as long as they are costed at £10/meter or less.

Bedfordshire and Luton Joint Prescribing Committee (JPC)
Assessment against Ethical and Commissioning Principles

Treatment assessed : June 2016

JPC Recommendations :

- **Clinicians to note the following recommendations are applicable to non-insulin treated TYPE 2 adult patients only.**

  Previous JPC guidance (as per Bulletin 124) on the self-monitoring of blood glucose (SMBG) in non-insulin TYPE 2 adult diabetic patients has been updated in accordance with NICE Clinical Guidelines, and with local modification as a result of Specialist input. As a consequence, Bulletin 124 has now been superseded and the following recommendations were approved:

7) Take the Driver and Vehicle Licensing Agency (DVLA)'s document Assessing fitness to drive - a guide for medical professionals into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes.

8) Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:-
   - there is evidence of or concern about hypoglycaemic episodes **or**
   - the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or undertaking a high risk activity **or**
   - the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on diabetes in pregnancy.

9) Consider **short-term** self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):
   - when starting treatment with oral or intravenous corticosteroids or
   - to confirm suspected hypoglycaemia.
   - when assessing the effectiveness of treatment.
   - patients presenting with symptomatic hyperglycaemia.

10) Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Healthcare professionals should test blood glucose and review treatment as necessary.

11) If adults with type 2 diabetes are self-monitoring their blood glucose levels, a structured assessment of the patient should be carried out at least annually.

12) Blood Glucose Testing Strips to be issued by GPs in line with BCCG and LCCG Primary Care Formularies.

7) **Frequency of Monitoring**

The NICE Guideline Development Group (GDG) (Type 2 Diabetes in adults, NG 28) noted a lack of evidence concerning the frequency of SMBG and specific target values when SMBG is used. The GDG was unable to make any recommendations on these issues and chose instead to draft 2 research recommendations. The GDG (Diabetes in pregnancy: management from preconception to the postnatal period, NG3) did make specific recommendations on frequency of testing.

The following recommendations are based on national guidance, where available and local guidance (agreed with local specialists):-

NICE Clinical Guideline 28 recommendations	JPC guidance / national guidance regarding frequency of monitoring
There is evidence of hypoglycaemic episodes	*Up to 3 x daily*
The person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or undertaking a high risk activity.	As per DVLA guidance or as appropriate
The person is planning to become pregnant)	If a woman with diabetes who is planning to become pregnant needs intensification of blood glucose-lowering therapy, advise her to increase the frequency of self-monitoring of blood glucose to include fasting levels and a mixture of pre-meal and post-meal levels.
The person is pregnant *	4 x daily (**fasting sample and samples at 1 hour after meals**)
Consider short-term self-monitoring of blood glucose levels (and review treatment as necessary): ➢ when starting treatment with oral or IV corticosteroids, **OR** ➢ to confirm suspected hypoglycaemia **OR** ➢ when assessing the effectiveness of treatment. ➢ In patients presenting with symptomatic hyperglycaemia	Up to 3 x daily (short term use only)

*Recommendations apply to treatment of gestational diabetes in addition to type 2 diabetes.

1) Clinical Effectiveness
From NICE CG 28 :-

- When comparing the evidence presented for SMBG compared to no SMBG, a statistically significant difference was observed in HbA1c levels in favour of SMBG. However, the small reduction at less than 5 mmol/mol (0.5%; the threshold for a minimal important difference) was not clinically meaningful.
- There was generally no difference in HbA1c levels and hypoglycaemic events between enhanced SMBG (education, telecare, automated glucometer) and conventional SMBG.
- There was little evidence on frequency and location of SMBG testing, but findings from the 3 included studies showed no difference in HbA1c levels and hypoglycaemic events between the groups comparing more frequent (every 2 weeks or 4 times a week) and less frequent (monthly or once a week) SMBG and different sites of testing (forearm or fingertip). The lack of evidence concerning the frequency of SMBG and specific target values when SMBG is used meant that the NICE Guideline Development Group (GDG) was unable to make any recommendations on these issues and chose instead to draft 2 research recommendations.

From NICE CG 3:-

- The guideline development group noted that, overall, the evidence supported the view that more frequent testing of blood glucose (and subsequent adjustment of treatment) led to better outcomes.

2) Cost Effectiveness

From NICE CG 28:-

- Overall, the NICE GDG considered the economic evidence did not make it possible to state conclusively that self-monitoring is or is not likely to be cost-effective compared with no self-monitoring, but the most applicable evidence with least limitations suggested that self-monitoring is not likely to be cost-effective compared with no self-monitoring.

From NICE CG 3:-

- No health economic evidence was identified that considered blood glucose monitoring in predicting adverse outcomes in women with type 1, type 2 or gestational diabetes during pregnancy. De novo analysis was not undertaken for this question as it was not considered as high priority as other issues within the guideline.
- The guideline development group noted that self-monitoring of blood glucose is part of standard NHS treatment for people with diabetes. Any increase in frequency of testing during pregnancy will incur an additional cost. However, because tight blood glucose control is particularly important for improving pregnancy outcomes, the benefits of additional testing are likely to outweigh testing costs.

3) Equity

Not applicable

4) Needs of the community

Information from The National Diabetes Audit 2014-15 indicates that there were 18,866 patients in 51 (out of a total of 55) BCCG GP practices were Type 2 diabetics during 2014/15. (Information from LCCG is awaited).
It is not clear how many of these patients would be treated with insulin.

5) Need for healthcare (incorporates patient choice and exceptional need)

See NICE Guidelines.

6) Policy drivers

- Type 2 Diabetes in adults: management, NICE guideline 28, published December 2015. https://www.nice.org.uk/guidance/ng28
- Diabetes in pregnancy: management from preconception to the postnatal period. NICE Guideline 3, published February 2015, last updated August 2015. https://www.nice.org.uk/guidance/ng3

7) Disinvestment

SMBG is no longer recommended for the following patient groups:-

- DVLA Guidance – now no longer recommends that people with a group 2 licence managed by medication including non –insulin injectables (excluding sulfonylureas and glinides) are not advised to monitor their blood glucose regularly.
- Diabetes medication being titrated – SMBG – no longer recommended.
- Patients with intercurrent illness – SMBG – no longer recommended.

The JPC agreed the following sections within the PCT Ethical and Commissioning Framework were not relevant to JPC discussions: Health Outcomes, Access, and Affordability.

References

[i] Bulletin 124 (Updated): Guidelines on the frequency of self-monitoring of blood glucose in non-insulin treated Type 2 diabetic patients for maintaining glycaemic control, Bedfordshire & Luton Joint Prescribing Committee, February 2010, revised April 2010 & September 2012. http://www.gpref.bedfordshire.nhs.uk/media/88960/ADVGUID_BloodGlucosSelfMonitoring.pdf

[ii] Type 2 Diabetes in adults: management, NICE Guideline 28, issued 2 December 2015. https://www.nice.org.uk/guidance/ng28

[iii] Diabetes in pregnancy: management from preconception to the postnatal period, NICE Guideline 3, issued 25 February 2015. https://www.nice.org.uk/guidance/ng3

[iv] Type 2 diabetes in adults: management (full guideline), NICE Guideline 28, issued 2 December 2015. https://www.nice.org.uk/guidance/ng28/evidence/full-guideline-2185320349

[v] Diabetes in pregnancy: management from preconception to the postnatal period (full guideline), NICE Guideline 3, issued 25 February 2015. https://www.nice.org.uk/guidance/ng3/evidence/full-guideline-3784285

[vi] Assessing fitness to drive: a guide for medical professionals', DVLA, published 11 March 2016, updated 18th April 2016 and 27th May 2016. https://www.gov.uk/government/publications/assessing-fitness-to-drive-a-guide-for-medical-professionals