trend UK
TRAINING, RESEARCH AND EDUCATION FOR NURSES IN DIABETES

Blood Glucose Monitoring Guidelines

Consensus Document [Version 2.0] January 2017

RATIONALE AND REMIT:

This document has been updated from version 1 *(TREND-UK, 2014)* which was developed to update the blood glucose monitoring consensus guidelines published in 2004 *(Owens et al, 2004)*. The prevalence of diabetes and the treatment choices for people with the condition has increased significantly in the last decade, resulting in escalating costs. The pressure on the NHS to keep up with demand and meet expectations has led to increasing consideration in ensuring resources are good value for money. Initiatives to save money have included reducing access to blood glucose monitoring for some people depending upon their glycaemic therapy. There has been a variation in the way this advice has been interpreted and implemented locally, resulting in inequalities and confusion.

This document is intended to serve as a helpful resource for healthcare professionals (HCPs) working with adults with diabetes, those who prescribe self-monitoring equipment, and for commissioners and designers of services.

This guidance was written by Training, Research and Education for Nurses in Diabetes (TREND-UK).

When implementing this guidance, full account should be taken of the local context and any action taken should be in line with statutory obligations required of the organisation and individual. No part of this guidance should be interpreted in a way that would knowingly put anybody at risk.

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INTRODUCTION:

The importance of blood glucose control in reducing the risk of complications in people with type 1 and type 2 diabetes is well established *(DCCT 1993; DCCT/EDIC 2005; UKPDS [UK Prospective Diabetes Study] 1998; Holman et al, 2008; Stratton et al, 2000)*. Both HbA1c and daily blood glucose variability influence this risk *(Ceriello and Kilpatrick, 2013)*. The use of self-monitoring of blood glucose (SMBG) to facilitate the achievement of evidence-based blood glucose targets has increasingly been incorporated into routine management for many people with diabetes. Indeed, SMBG has been described as possibly the most important advance in controlling diabetes since the discovery of insulin *(Tonyushkina and Nichols, 2009)*.

History

The first visual blood glucose monitoring strip was Dextrostix, developed in 1963, and the first blood glucose meter became available in 1970, weighing 3 lbs and costing $650 *(Tonyushkina and Nichols, 2009)*. Today in the UK, there are approximately 40 different prescribable blood glucose (BG) testing strips for use with a wide range of meters which are small, light in weight, take only a few seconds to deliver a BG result with a small drop of capillary blood, and may have a variety of additional features including test results memory, insulin dose calculators, and the facility to alert the user to results which fall below or above pre-set targets. The BG meters are relatively low cost but may also be provided at no cost to the individual by their diabetes or primary care team. However, the cost to the NHS of prescribing the BG strips is significant: £186.6 million was spent on diagnostics and monitoring devices in England between 2015 and 2016 *(NHS Digital, 2016)*.

Cost

The rapidly increasing prevalence of diabetes in the UK *(Diabetes UK, 2015)* is consuming a significant proportion of NHS resources. For example, the diabetes prescribing costs alone for primary care in England increased from £458.6 million in 2004/5 to £956.7 million in 2015/16 *(NHS Digital, 2016)*. Despite the financial constraints the NHS faces, there is a requirement to maintain quality, afford newer higher cost treatments, meet public expectations and increase capacity to deliver healthcare services to all who need them, which has led to a consideration of how and where precious healthcare resources are used. Reviewing the routine prescribing of BG testing strips for people with type 2 diabetes who do not use insulin was recommended a number of years ago by Quality, Innovation, Productivity and Prevention (QIPP) as an area where considerable financial savings could be made to the NHS.

Who should test?

The interpretation of this recommendation resulted in restrictions in some areas on SMBG for all people who have type 2 diabetes and who do not use insulin *(Diabetes UK, 2014)*. This has resulted in considerable debate between those who see SMBG as an empowerment tool for people to self-manage their diabetes even if managed by lifestyle alone, others who have concerns about people who are at risk of hypoglycaemia from particular oral hypoglycaemic agents (OHAs) , and those who draw on the lack of robust evidence that SMBG can facilitate a reduction in HbA1c that is clinically significant. This had led to confusion about who should test blood glucose, with restrictions on SMBG making it difficult even for some people with type 1 diabetes to obtain sufficient strips in some areas *(Diabetes UK, 2014)*.

The challenges

Twelve years ago, consensus guidelines for SMBG for people with type 1 and type 2 diabetes were published, at a time when £90 million was being spent annually on blood glucose testing strips, 40% more than was spent on oral hypoglycaemic agents *(Owens et al, 2004)*. The concerns regarding inappropriate use of NHS resources remain but much has changed in the NHS and in diabetes management since 2004. A significant number of new but costly diabetes therapies are now available with lower risk of hypoglycaemia, there have been changes in driving regulations, there is an increasing awareness of the risk of hypoglycaemia in an ageing population and those with renal impairment, and there is varied availability of structured education to improve self-management skills. These are some of the issues that may increase demand for SMBG, in an environment of much tighter financial constraint and significant organisational change.

THE AIMS OF THIS DOCUMENT ARE TO:

- Summarise the evidence available on where SMBG can be effective
- Briefly review the existing UK and key international guidelines
- Provide a simple guide on who could benefit from access to SMBG
- Describe how to maximise the effectiveness of SMBG in those who use it
- List some areas to consider when developing a limited formulary of meters
- Recognise the responsibilities of the people with diabetes who self monitor, the HCPs who support them, and the organisations which control the commissioning and funding of diabetes services

WHY SHOULD PEOPLE USE SMBG?

The landmark trials for type 1 and type 2 diabetes *(DCCT, 1993; UKPDS, 1998)* related the level of HbA1c achieved to the risk of developing complications, providing evidence that better glycaemic control reduced risk. HbA1c reflects the exposure to prevailing blood glucose levels during the lifespan of red blood cells (approximately 120 days, but 50% of the value reflects the last 30 days). However, HbA1c does not reflect the variations in blood glucose levels during that period of time *(Ceriello and Kilpatrick, 2013)* and, depending on the type of treatment, activity levels, state of general health and diet consumed, SMBG can provide additional valuable information for a variety of situations:

1. **Safety:**
   - To identify and confirm hypoglycaemia in people using insulin, sulphonylureas or glinides to facilitate appropriate treatment. Although awareness of the risk of hypoglycaemia in those using insulin is well recognised, awareness of the risk with the use of sulphonylureas may not be. People treated with sulphonylureas had similar levels of hypoglycaemia as those with type 2 diabetes in the first 2 years of insulin treatment *(UK Hypoglycaemia Study Group, 2007)*. All people using insulin or OHAs with an increased risk of hypoglycaemia should be advised about the symptoms and treatment of hypoglycaemia. However, symptoms may not always be a reliable indicator of biochemical hypoglycaemia *(Pramming et al, 1990)* and episodes may be missed. Click here to access the patient leaflet *Why do I sometimes feel shaky, dizzy and sweaty?*
   - To confirm safety to drive, and before commencing other activities such as climbing or swimming if using insulin or OHAs with a risk of hypoglycaemia.
   - To inform management to optimise glycaemic control in women planning or during pregnancy (foetus safety).
   - To inform management of intercurrent illness and stress in order to reduce risk of acute metabolic decompensation (diabetic ketoacidosis and hyperosmolar hyperglycaemic state) and avoid unplanned admission to hospital. Click here to access the patient leaflet *Diabetes: What to do when you are ill.*
   - To reduce risk of hypoglycaemia in those using insulin or OHAs with a risk of hypoglycaemia during fasting (e.g. Ramadan).
2. **Empowering lifestyle changes:**

   Can give objective feedback to the person with diabetes about the success or otherwise of lifestyle changes such as dietary modification and increased activity, as well as effectiveness of their medication dose.
3. **Supporting decision making:**

   Can provide data to support people with diabetes and their HCPs in providing tailored advice for individuals with diabetes about lifestyle and blood glucose lowering medications.
4. **Reducing complications:**

   Reduction of costly acute and long-term complications may be achieved if SMBG is used to make behavioural changes, facilitate medication concordance and make effective use of medication.
5. **Special circumstances:**

   Can inform medication management to facilitate appropriate adjustments of insulin or OHA dose with steroid use, or when commencing antipsychotic medication. Click here to access the patient leaflet *Diabetes and steroids* and here to access the JBDS-IP 2014 guideline *Management of hyperglycaemia and steroid (glucocorticoid) therapy.*

EVIDENCE FOR AND AGAINST SMBG IN TYPE 2 DIABETES:

The usefulness of SMBG, coupled with structured education in self-management, for people using insulin is generally accepted and the QIPP agenda and NICE recommendations for reviewing blood glucose testing strip usage does not include insulin users. The concern with providing this facility for people with type 2 diabetes who are not using insulin is that the evidence that it gives clinical benefit or is cost-effective is either not available or is conflicting. Indeed, the focus on glycaemic control alone may be inappropriate in people with type 2 diabetes, and a more holistic approach including blood pressure and lipid management to reduce cardiovascular risk is more beneficial *(Yudkin et al, 2010)*. Encouraging very tight glycaemic control (e.g. HbA1c <53 mmol/mol [<7%]) in people using medications with a risk of hypoglycaemia may be harmful, especially in those with long-standing diabetes or in frail older people *(Currie et al, 2010)*.

A brief summary of some of the evidence for SMBG in type 2 diabetes is given below:

"A German-Austrian trial incorporated meal-related SMBG to empower patients to make medication and lifestyle adjustments. This resulted in lower HbA1c with an increase in general well-being and less depression *(Schwedes et al, 2002)*. However, a qualitative study by Peel et al (2004) found that although SMBG could increase awareness of diabetes, empower, reassure and motivate people, it could also increase anxiety and depression, and lead to self-blame.

DiGEM (Diabetes Glycaemic Education and Monitoring) compared three groups of people with type 2 diabetes using OHAs only: those who did not SMBG, those using SMBG three times a day on 2 days a week and instructed to contact an HCP for interpretation and advice on action, and those who used SMBG at the same frequency but who were trained to interpret and initiate their own response. After 4 years, the trial concluded there was no significant difference between the three groups *(Farmer et al, 2007)*.

In the ESMON (Efficacy of self monitoring of blood glucose in patients newly diagnosed with type 2 diabetes) trial, people with newly diagnosed type 2 diabetes who SMBG were compared with those who did not monitor. The HbA1c fell in both groups with no statistical difference between them. However, depression scores were higher in the group who monitored their blood glucose. No difference was found in hypoglycaemia, body mass index or use of OHAs *(O'Kane et al, 2008)*.

DINAMIC-1 assessed the contribution of SMBG as part of evaluating safety, efficacy and tolerability of modified-release gliclazide *(Barnett et al, 2008)*. The SMBG group achieved a 0.24% greater reduction in HbA1c than the control group who did not SMBG. However, as SMBG results guided changes in gliclazide dose, this may have influenced HbA1c. More episodes of hypoglycaemia were reported in the SMBG group (8.7% vs 7.0%) but asymptomatic episodes were identified in this group, confirming evidence that relying on symptoms for hypoglycaemia is not infallible *(Pramming et al, 1990)*.

A 12-month trial by Polonsky et al (2011) followed 483 people with poorly controlled type 2 diabetes (HbA1c >7.5%) and not using insulin, and encouraged them to use structured profiles of SMBG to make lifestyle changes. The HCPs supporting them were trained to interpret the BG results to adjust medication. The SMBG group had a 1.2% reduction in HbA1c compared with a 0.9% reduction in the control group. No loss of general well-being was noted in the SMBG group.

Reviews summarising the numerous trials and observational studies are useful. An early review of six randomised controlled trials (RCTs) in 2005 found that SMBG groups had a 0.39% greater reduction in HbA1c than non-SMBG groups. The authors compared this to a 14% reduced risk of developing microvascular complications achieved by the same reduction of HbA1c in the UKPDS, but suggested the reduction achieved in the SMBG groups should be considered with caution as there were so many other variables within the six trials that made it difficult to consider the effect of SMBG alone *(Welschen et al, 2005)*."

A more recent health technology assessment (HTA) report on SMBG in type 2 diabetes considered whether SMBG is worth its cost and effort by looking at glycaemic control, incidence of hypoglycaemia, quality of life, and cost per quality-adjusted life-year (QALY). Thirty RCTs were reviewed but very few were noted to be of high quality. A reduction in HbA1c of 0.21% was found in those who tested BG but had no education or support in how to use the results compared with those who did not test (but this was not thought to be clinically significant). A reduction of 0.52% in HbA1c was achieved in the enhanced group where patients and HCPs received education or feedback *(Clar et al, 2010)*.

There was no consistent effect on hypoglycaemia episodes or medication changes. The reviewers concluded that SMBG has limited clinical effectiveness in people with type 2 diabetes using OHAs or diet alone and is unlikely to be cost-effective. However, the HTA does suggest SMBG may improve glycaemic control if used in conjunction with education for both patients and HCPs to enable them to use the results to make changes to medication and lifestyle. A common complaint from patients however, is that HCPs do not show any interest in their results *(Diabetes UK, 2013a)*.

More research is needed to identify what type of education is effective, which patients may benefit, what are the ideal testing times and frequencies, and when SMBG may cause depression or anxiety *(Clar et al, 2010)*. More recent reviews and meta-analyses of the evidence confirm these findings *(Farmer et al, 2012; Malanda et al, 2013)*.

WHAT DOES NICE SAY?

NICE guidelines for blood glucose monitoring in type 1 diabetes:

- Advise routine self-monitoring of blood glucose levels for all adults with type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed
- Support to test up to 10 times a day if any of the following apply:
  - The desired target for blood glucose control measured by HbA1c is not achieved
  - The frequency of hypoglycaemia episodes increases
  - In relation to driving as per DVLA requirements. Click here to access the DVLA *Assessing fitness to drive – a guide for medical professionals*
  - During periods of illness
  - Before, during and after sport
  - When planning pregnancy, during pregnancy and while breastfeeding
  - If there is a need to know blood glucose levels more than 4 times a day for other reasons (e.g. impaired awareness of hypoglycaemia, high-risk activities)

(NICE NG17, 2015a)

NICE guidelines for blood glucose monitoring in type 2 diabetes:

Take the DVLA *Assessing fitness to drive – a guide for medical professionals* into account when offering SMBG for adults with type 2 diabetes. Click here to access this document.

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

Self-monitoring of plasma glucose should be offered if:

- The person is on insulin
- There is evidence of hypoglycaemic episodes
- On oral medication that may increase their risk of hypoglycaemia while driving or operating machinery
- Is pregnant or planning a pregnancy
- Starting treatment with oral or intravenous corticosteroids

Assess annually in a structured way:

- Self-monitoring skills
- The quality and appropriate frequency of testing
- The use made of the results obtained
- The impact on quality of life
- The continued benefit
- The equipment used

(NICE NG28, 2015b)

Scottish Intercollegiate Guidelines Network:

- SMBG is recommended for patients with type 1 or type 2 diabetes who are using insulin where patients have been educated in appropriate alterations in insulin dose
- Routine SMBG in people with type 2 diabetes who are using oral glucose lowering drugs (with the exception of sulphonylureas) is not recommended
- Motivated patients with type 2 diabetes using sulphonylureas may benefit from routine use of SMBG to reduce risk of hypoglycaemia
- SMBG may be considered in the following groups of patients who are not using insulin: those at increased risk of hypoglycaemia, those experiencing acute illness, those undergoing significant changes in pharmacotherapy, those fasting (e.g. during Ramadan), those with unstable or poor glycaemic control (e.g. HbA1c >64 mmol/mol [8%]), and women during or planning pregnancy

(SIGN 116, 2014)

WHAT DOES THE DVLA SAY?

The following information assumes there are no other circumstances that affect the ability of a person with diabetes to drive safely, particularly regarding risk of, and ability to detect, hypos (low blood glucose levels). If a patient is unsure what a hypo is, or which category their diabetes medication is in, they should ask their pharmacist or diabetes HCP. Click here to access the patient leaflet *Diabetes: Safe Driving and the DVLA.*

DVLA guidance for driving and blood glucose monitoring

Diabetes treatment	Group 1	Group 2
Diet alone	–	–
Treatment by tablets or injections with no hypoglycaemia risk	–	–
Tablets carrying a risk of hypoglycaemia (sulphonylureas and glinides)	If needed, detection of hypoglycaemia is by appropriate BGM at times relevant to driving and clinical factors including frequency of driving. It is appropriate to offer SMBG at times relevant to driving to enable the detection of hypoglycaemia	Regular SMBG – at least twice daily and at times relevant to driving (e.g. no more than 2 hours before the start of the first journey and every 2 hours while driving)
Insulin	Test blood glucose no more than 2 hours before the start of the first journey. Test every 2 hours while driving. More frequent SMBG may be required with any greater risk of hypoglycaemia (e.g. physical activity, altered meal routine)	Must use a meter with sufficient memory to store 3 months of readings. Carry out regular BGM at least twice daily on days when not driving. Test no more than 2 hours before the start of the first journey and every 2 hours while driving. More frequent monitoring may be required with any greater risk of hypoglycaemia (e.g. physical activity, altered meal routine)
Continuous glucose monitoring systems: Because these systems measure interstitial glucose, drivers must also monitor blood glucose levels as outlined above		
Adapted from: *Diabetes mellitus: Assessing fitness to drive (DVLA, 2016).*		

If all group 1 drivers using sulphonylureas were to test as regularly as insulin users, this would result in a considerable increase in cost to the NHS. However, the DVLA recommends that for drivers using tablets which carry a risk of hypoglycaemia that "it is appropriate to offer SMBG at times relevant to driving to enable the detection of hypoglycaemia" *(DVLA, 2016)*.

The **Association of British Clinical Diabetologists (ABCD)** recommend targeted testing for patients who are starting treatment with sulphonylureas (the greatest risk of hypoglycaemia is in the first 3 months of therapy), those who are experiencing hypoglycaemia, and those with reduced hypoglycaemia awareness. The highest risk for people with type 2 diabetes prior to insulin occurs during late afternoon *(Gallen et al, 2012)*.

WHAT DO OTHER BODIES SAY?

The **International Diabetes Federation (IDF)** Task Force on Clinical Guidelines and the Self-Monitoring Blood Glucose international working group *(IDF, 2008)* make the following recommendations:

- SMBG should only be used when the patient has the knowledge and willingness to incorporate SMBG and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals
- It can be used by newly diagnosed patients to enhance their understanding of diabetes as part of their education programme, and to facilitate timely treatment initiation and dose optimisation
- The frequency of SMBG monitoring should be individualised depending on education, behavioural and clinical requirements (i.e. to identify/prevent/manage hyperglycaemia and hypoglycaemia)
- It can also be used where it will provide HCPs with the data to inform therapeutic decisions

Diabetes UK updated their position statement on SMBG monitoring in April 2013, endorsed by the ABCD. They emphasise that SMBG is not a stand-alone intervention and should be incorporated into the diabetes care plan, accompanied by education to interpret the results and adjust treatment. It should be available to all insulin users but also for those taking sulphonylurea and prandial glucose regulators (glinides) because of the risk of hypoglycaemia. They call for the removal of blanket policies that deny access to BG monitoring equipment to people not using these agents or insulin, and recommend SMBG availability should be based on individual assessment. Diabetes UK identifies the responsibilities of all involved in SMBG monitoring: the person with diabetes, the HCP, the pharmacist, the strip manufacturer, and the commissioners of services *(Diabetes UK, 2013a)*. The organisation also provides advice for patients who are finding it difficult to obtain test strips on prescription *(Diabetes UK, 2013b)*.

The **American Association of Diabetes Educators (AADE)** advises SMBG can be a key component of the treatment regimen, giving immediate information about current blood glucose levels. Unlike HbA1c, SMBG provides the person with diabetes a means to distinguish fasting, preprandial and postprandial blood glucose levels, allowing them to monitor the immediate effects of food, physical activity and medications on glycaemic control. Beyond improving clinical outcomes, SMBG data can improve quality of life. It must be integrated into a self-management plan *(AADE, 2014).*

WHO SHOULD TEST AND HOW OFTEN?

The following table draws from national and international guidelines to suggest who may benefit from SMBG. Rather than a blanket approach determined by therapy alone, it attempts to identify individual circumstances which may make SMBG useful, albeit for a short period of time. Concerns about risks of hypoglycaemia in vulnerable groups (e.g. the elderly, those with renal impairment) may be better addressed by a review of medication choice rather than increased SMBG.

Table 1: Diabetes blood glucose monitoring

Typical self-monitoring regimens	Recommendation
A	Periodic testing to meet needs at that time
B	1–2 tests daily, varying times of testing
C	4 tests per day x 2 days a week
D	4 tests per day each day
E	7 tests per day pre and postmeals and before bed

Type 2 diabetes – diet and lifestyle management only	HbA1c monitoring
SMBG is not recommended as part of routine care if HbA1c is within target, but may be useful as an educational tool to understand lifestyle interventions. If SMBG is considered appropriate	Measure HbA1c 3 monthly until target is reached, then monitor 6 monthly Possible regimen: A
Type 2 diabetes – oral therapy	
If HbA1c is out of target or if there is a risk of hypoglycaemia using oral therapies consider SMBG. The frequency of testing should be agreed with the patient and adequate training provided. Some patients benefit from blood testing for short periods of time, e.g. when oral medication is changed or adjusted.	Continue to measure HbA1c 3–6 monthly Possible regimens: A, B, C
Type 2 diabetes – Insulin with/without oral agents	
SMBG is recommended. Regular testing is required at initiation and during adjustment of doses. Frequency may be reduced when glycaemic target reached. Increased testing may be required during intercurrent illness and when there is risk of hypoglycaemia. Adequate training must be provided.	HbA1c should be measured 3–6 monthly Possible regimens: B, C, D
Type 1 diabetes	
It is recommended that all people with type 1 diabetes monitor their BG levels. SMBG may be used to adjust insulin doses prior to meals (e.g. basal bolus therapy and carbohydrate counting, pump therapy, DAFNE patients) and so frequent daily testing will be required. In more stable type 1 diabetes less frequent monitoring may be acceptable depending on patients daily routine.	HbA1c should be measured 3–6 monthly in all type 1 diabetes patients. Possible regimens: B, C, D, E

Table 1: Diabetes blood glucose monitoring (continued)

Pregnant women	
Type 1 and type 2 diabetes: • Required to test at least 2–4 times daily pre and one hour postprandial (up to 7 times a day) Gestational diabetes: • Not requiring insulin – will need to test 4 times per day premeal and one hour postmeal • Treated with insulin – will need to test as for type 1 diabetes	Possible regimens: D, E
Steroids and SMBG	
Without pre-existing diagnosis of diabetes, with high risk or with symptoms suggestive of hyperglycaemia: Check HbA1c before commencement of steroids Blood glucose test at least once daily (preferably before or 1 to 2 hours post lunch or evening meal) If BG >12 mmol/L, increase to 4 times daily (before meals and at bedtime) As dose reduces or ceases, continue testing until blood glucose normalises (4 to 7 mmol/L). Check HbA1c no earlier than 3 months following cessation of steroids	
With pre-existing diabetes: Four times daily before or after meals, and at bedtime As dose reduces or ceases, continue testing until blood glucose normalises (4 to 7 mmol/L). Check HbA1c no earlier than 3 months following cessation of steroids	
Adapted from the *Leicestershire Diabetes Management Guidelines*	

When auditing BG strip usage in a given population (usually the diabetes population in an individual GP practice), there may be more useful areas to investigate rather than total BG strips being prescribed per se. Identifying people using insulin but who are not requesting BG strips, especially if they are drivers; people who are requesting a significant number of strips but who have poor glycaemic control; those who use a large number of BG strips and have very tight glycaemic control, should all trigger concern. Investigation may identify safety issues, fear of hypoglycaemia, and poor use of resources.

GETTING THE MOST OUT OF TESTING:

People with diabetes (and HCPs and carers using BG meters) should know their BG targets and understand what action is required if the result is out of target range (i.e. the detection and correction of hypo- and hyperglycaemia).

Other issues to consider:

- Correct user technique is critical.
- Hands should be washed and dried before commencing the procedure.
- BG testing strips should be in date.
- Strips should be stored at the correct temperature and in manufacturer's packaging.
- The lid should be replaced on the container promptly after removing a strip to keep the contents in the correct condition.
- A sufficient blood sample should be obtained (using an appropriate finger pricking device and technique).
- The BG meter should show results in *mmol/L not mg/dL*.
- The user should be aware of the degree of error especially in the low BG range.
- The user should know to re-check if symptoms do not tally with BG reading.
- Quality assurance (both internal and external) is mandatory for HCPs *(MHRA, 2013).*
- Patients should not have abnormalities with haematocrit or interferences that would give inaccurate readings.
- Only specific meters are suitable for patients on peritoneal dialysis, so the HCP needs to check with the manufacturers' guidance.

QUALITY STANDARDS FOR BLOOD GLUCOSE METERS:

ISO (International Organization for Standardization) 15197:2013 (E) describes the requirements for blood glucose monitoring systems using capillary blood *(ISO, 2013)*.

Originally developed in 2003, the standards have been revised, made more stringent, and were published in 2013. All capillary blood glucose monitoring systems must have met the 2013 ISO standards (not the 2003 standards) by 2016. The standards cover the following areas:

- Ease of operation, maintenance, cleaning. Ensuring the visual display is clear and there is no likelihood of misinterpretation of the result.
- Safety and reliability (e.g. no risk of electric shocks to the user, resistance to shock, vibration and heat).
- Precision, accuracy and influence by abnormalities in haematocrit and other interferences.
- User performance evaluation, including ease of understanding instructions.
- 95% of blood glucose results should reach the following standard (using 600 test strips, 200 from 3 different lots):
  - Either within ±0.83 mmol/L of the reference value at a glucose concentration of <5.55 mmol/L.
  - Or within ±15% of the reference value at a glucose concentration of ≥5.55 mmol/L.

  99% of individual glucose measured values should fall within zones A and B of the Consensus Error Grid for type 1 diabetes.

Haematocrit affects the fluid content of blood, where the glucose is carried. Therefore abnormalities of haematocrit can result in erroneous blood glucose results. High haematocrit (common in chronic respiratory conditions, high triglycerides, shock, dehydration) can give falsely low BG readings (less fluid in the blood sample volume), whereas conditions with low haematocrit (e.g. pregnancy) give falsely high BG results *(Tonyushkina and Nichols, 2009)*.

Although the ISO standards are important, the skill of the user, not the meter, is the most significant source of BG errors, accounting for 91–97% of overall inaccuracies.

TOP TIPS FOR DEVELOPING A TEST STRIP FORMULARY:

Although QIPP did not recommend reducing patient choice of BG meter, many health organisations made the decision to develop a restricted formulary for preferred BG strips that can be prescribed in their area. Diabetes UK is concerned about the effect this has on patient choice. However, restricting choice to a small number of strips from the forty or so prescribable BG strips available in the UK is attractive: it may enable HCPs to get to know a few meters very well.

It is essential to involve all stakeholders in this decision, including user representation and community pharmacists. It is important that meters which are not included in the formulary are not promoted locally as strips may not be available. Quality performance (including meeting the 2013, not the 2003, ISO requirements), meter features (for example, blood ketone testing and insulin calculators are features to consider if the restricted formulary will apply to people with type 1 diabetes as well), quality assurance, user support services, shelf-life after opening (for infrequent testers), patient feedback, and not just the cost, will need to be considered.

BLOOD GLUCOSE MONITORING: EVERYBODY'S RESPONSIBILITY

Diabetes UK's position statement on SMBG *(Diabetes UK, 2013a)* identifies the responsibilities of the providers and users of blood glucose strips for people with type 2 diabetes. The key points are summarised below:

The person with diabetes:

- Should ensure correct technique is followed, know what to do with the results, use the resource wisely and consider whether testing frequency and timing is optimal.
- Should understand that the results reflect the success, or otherwise, of their day-to-day management of their diabetes, so SMBG without adherence to a healthy eating plan and concordance with medication has limited value

The HCP:

- Should work in partnership with the person with diabetes to agree whether SMBG is appropriate, recognising the need for cost-effective use of NHS resources. If so, agree the frequency, timing, BG targets and the period of time testing should be done.
    - SMBG is a tool for providing feedback on diabetes management, so it should always be incorporated into an individual's education programme.
    - HCPs should review the results of testing and discuss the implications with the person with diabetes.
    - HCPs should be trained in correct SMBG technique, self-management education, and interpretation of BG result.

Manufacturers of BG testing strips:

- Should review the cost of BG testing strips and work with the Department of Health to agree the most affordable price for the NHS.

Community pharmacists:

- Should advise customers considering purchasing a BG meter to discuss with their diabetes HCP whether SMBG is appropriate for them.

Commissioners:

- Should ensure education in self-management of diabetes is available for all people with diabetes. SMBG should be available to all who would benefit, using a meter suitable for their needs.

NEW TECHNOLOGIES IN GLUCOSE MONITORING:

Technology is moving so fast in many areas of diabetes care, not least in glucose monitoring, with many new meters which are either updates of existing systems with new functionality or new meters which do two things at once. For example, one meter has a 2-in-1 test strip. If elevated ketones are detected, the meter immediately alerts the user through colour-coded alerts (green, amber or red) relating to the level of ketones in the blood.

Abnormal haematocrit levels can result in incorrect BG results *(Tonyushkina and Nichols, 2009)*. There is a meter now available which utilises haematocrit correction technology: it measures the user's haematocrit and BG, then modulates the BG result according to haematocrit value to increase accuracy. There is an option to turn an iPhone into this same meter system, measuring BG, ketones, haematocrit and haemoglobin. A meter for android and iOS smartphones enables users to track glucose, insulin, carbohydrates and weight to help visualise trends.

The finger-prick-free system measures interstitial glucose levels. A small sensor attached to the upper arm automatically measures and continuously stores glucose readings over 24 hours for up to 14 days. With every scan of the sensor (which can even be made through clothing), the current glucose reading and the last 8 hours of glucose data is available, with an arrow to indicate in which direction the glucose level is heading. This system is not available on prescription.

SHARPS DISPOSAL:

Every person who is asked to perform BG monitoring should be provided with the correct means of safe disposal of their sharps, i.e. lancets.

- There are a number of devices that enable the safe disposal of sharp equipment.
- Sharps disposal boxes are available on prescription.
- Each local council may have a different collection service; this should be clearly communicated to each person with diabetes who is asked to monitor their BG levels.
- The EU Directive 2010/32, which became UK Law in May 2013, focuses on the need to provide greater protection to all healthcare workers, downstream workers and others who are at risk of sharps injury *(European Union, 2010)*.
    - The directive sets out to protect patients and workers at risk by ensuring the safest possible working environment. People with diabetes who are monitoring their own BG levels, at home or whilst they are out and about, should be aware of the dangers of disposing of their sharps inappropriately and be encouraged to use the correct equipment provided.

CONCLUSIONS:

- Self-monitoring of glucose is essential for people with diabetes who use insulin therapy. The evidence for its value in those who do not use insulin is less clear.
- For some people with type 2 diabetes who treat the condition with lifestyle measures and oral blood glucose lowering medication, SMBG may not be a good use of NHS resources (cost of strips, HCP time for training the user) especially given the financial constraints on healthcare services.
- Potentially, savings made on reducing unnecessary SMBG can finance the use of newer glucose-lowering therapies and structured education programmes.
- However, for some people with type 2 diabetes who do not use insulin but who are at risk of hypoglycaemia from using oral therapies such as sulphonylureas, the cost is justified in certain situations for safety such as driving, managing intercurrent illness and facilitating appropriate medication adjustment. It may also motivate lifestyle improvements.
- HbA1c alone will not provide information on trends and glucose variation. When used in combination with regular SMBG, it enables people with diabetes and HCPs to make appropriate and timely decisions when making treatment changes.
- However, SMBG is not a stand-alone intervention: it should be used in combination with structured education to empower the individual to use the results effectively.
- Regular review of the quality, benefits and frequency of testing should be incorporated into the annual diabetes review.

REFERENCES

AADE (2014) *Position statement: Self-monitoring of blood glucose using glucose meters in the management of type 2 diabetes.* Available at: https://www.diabeteseducator.org/docs/default-source/default-document-library/self-monitoring-of-blood-glucose-using-glucose-meters-in-the-management-of-type-2-diabetes.pdf?sfvrsn=0 (accessed 23.11.2016)

Barnett A, Krentz A, Strojek K et al (2008) The efficacy of self-monitoring of blood glucose in the management of patients with type 2 diabetes treated with gliclazide modified-released based regimen. A multicentre, randomised parallel-group, 6 month evaluation (DINAMIC-1). *Diabetes Obes Metab* 10: 1239–47

Ceriello A, Kilpatrick ES (2013) Glycemic variability: Both sides of the story. *Diabetes Care* 36 (Supplement 2): S272–5

Clar C, Barnard K, Cummins E et al (2010) Self-monitoring of blood glucose in type 2 diabetes: systematic review. In: NIHR Health Technology Assessment programme: Executive Summaries. Southampton (UK): NIHR Evaluation, Trials and Studies Coordinating Centre. Available at: www.ncbi.nlm.nih.gov/books/NBK56887 (accessed 23.11.2016)

Currie CJ, Peters JR, Tyman A et al (2010) Survival as a function of HbA1c in people with type 2 diabetes: a retrospective cohort study. *Lancet* 375: 481–9

DCCT (Diabetes Control and Complications Trial Research Group) (1993) The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 329: 977–86

DCCT/EDIC (2005) Intensive Diabetes Treatment and Cardiovascular Disease in patients with type 1 diabetes. *N Engl J Med* 353: 2643–53

Diabetes UK (2013a) *Position statement: Self monitoring of blood glucose (SMBG) for adults with type 2 diabetes.* Available at: http://www.diabetes.org.uk/Documents/Position%20statements/Diabetes-UK-position-statement-SMBG-Type2-0413.pdf (accessed 23.11.2016)

Diabetes UK (2013b) *Advocacy pack: Availability of blood glucose test strips.* Available at: www.diabetes.org.uk/Document/Advocacy/test-strips-advocacy-pack-0613.pdf (accessed 23.11.2016)

Diabetes UK (2014) *People with diabetes not allowed vital prescriptions.* Available at: www.diabetes.org.uk/About_us/News/People-with-diabetes-not-allowed-vital-prescriptions/ (accessed 23.11.2016)

Diabetes UK (2015) *Diabetes: Facts and stats.* Available at: https://www.diabetes.org.uk/Documents/Position%20statements/Facts%20and%20stats%20June%202015.pdf (accessed 23.11.2016)

DVLA (2016) *Diabetes mellitus: assessing fitness to drive: guide for medical professionals.* Available at: www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive (accessed 23.11.2016)

European Union (2010) *Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU.* Available at: https://osha.europa.eu/en/legislation/directives/council-directive-2010-32-eu-prevention-from-sharp-injuries-in-the-hospital-and-healthcare-sector (accessed 23.11.2016)

Farmer A, Wade A, Goyde E et al (2007) Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. *BMJ* 335: 132

Farmer A, Pererar R, Wade A et al (2012) Meta-analysis of individual patient data in randomised trials of self-management of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ* 344: e486

Gallen I, Amiel S, Robinson A, McKnight J (on behalf of the Association of British Clinical Diabetologists [ABCD] committee) (2012) Driving and hypoglycaemia: questions and answers. *Practical Diabetes* 29: 13–4

Holman RR, Paul SK, Bethel MA et al (2008) 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med* 359: 1577–89

IDF (2008) *Guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes.* Available at: www.idf.org/guidelines/self-monitoring (accessed 23.11.2016)

ISO (2013) ISO 15197:2013(en): *In vivo diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.* International Organization for Standardization, Geneva

Malanda UL, Bot SD, Nijpels G (2013) Self-monitoring of blood glucose in noninsulin-using type 2 diabetic patients: it is time to face the evidence. *Diabetes Care* 36:176–8

MHRA (2013) *Management and use of IVD point of care test devices.* Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf (accessed 23.11.2016)

NHS Digital (2016) *Prescribing for diabetes, England 2005/06 to 2015/16.* Available at: www.digital.nhs.uk/pubs/presdiab0516 (accessed 23.11.2016)

NICE (2015a) *NG17. Type 1 diabetes in adults: diagnosis and management.* Available at: http://bit.ly/2a1FEnU (accessed 23.11.2016)

NICE (2015b) *NG28. Type 2 diabetes in adults: management.* Available at: http://bit.ly/1ZGtvbA (accessed 23.11.2016)

O'Kane MJ, Bunting B, Copeland M, Coates VE (2008) Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. *BMJ* 336: 1174–7

Owens D, Barnett A, Pickup et al (2004) Blood glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus. *Diabetes & Primary Care* 6: 8–16

Peel E, Parry O, Douglas M et al (2004) Blood glucose monitoring in non-insulin treated type 2 diabetes: a qualitative study of patients' perspectives. *British Journal of General Practice* 54: 183–8

Polonsky WH, Fisher L, Schikman CH et al (2011) Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled, non-insulin treated type 2 diabetes. Results from the Structured Testing Program Study. *Diabetes Care* 34: 262–7

Pramming S, Thorsteinsson B, Bendtson I, Binder C (1990) The relationship between symptomatic and biochemical hypoglycaemia in insulin-dependent diabetic patients. *J Intern Med* 228: 641–6

Schwedes U, Siebolds M, Mertes G (2002) Meal-related structured self-monitoring of blood glucose: Effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care* 25: 1928–32

SIGN (2014) *SIGN 116: A national clinical guideline*. Scottish Intercollegiate Guidelines Network, Edinburgh. Available at: www.sign.ac.uk/pdf/sign116.pdf (accessed 23.11.2016)

Stratton IM, Adler AI, Neil HA et al (2000) Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35) prospective observational study. *BMJ* 321: 405–12

Tonyushkina K, Nichols JH (2009) Glucose meters: A review of the technical challenge to obtaining accurate results. *J Diabetes Sci Technol* 3: 971–80

TREND-UK (2014) *Blood Glucose Monitoring Guidelines: Consensus Document V1* Available at: www.trend-uk.org (accessed 23.11.2016)

UK Hypoglycaemia Study Group (2007) Risk of hypoglycaemia in types 1 and 2 diabetes: effects of treatment modalities and their duration. *Diabetologia* 50: 1140–7

UK Prospective Diabetes Study (UKPDS) Group (1998) Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352: 837–53

Welschen LM, Bloemendal E, Nijpels G et al (2005) Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. *Diabetes Care* 28:1510–7

Yudkin JS, Richter B, Gale EAM (2010) Intensified glucose lowering in type 2 diabetes: time for reappraisal. *Diabetologia* 53: 2079–85

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