**JPC Recommendations (as approved April 2010 and Updated September 2012):**

Advice on SMBG monitoring in patients with Type 2 diabetes (not receiving insulin).

- Type 2 patient not on insulin & stable, no symptoms, HbA1c normal, and urinalysis normal – no blood glucose monitoring required – no strips for prescription. Patients on sulphonylureas should be educated to recognize the symptoms of hypoglycaemic attacks when on sulphonylureas. No SMBG testing was needed as this would not help their management. However, patients should report suspected hypoglycaemic attacks to their health professional. SMBG would be helpful in patients with a previous history of hypoglycaemic attacks.

- Type 2 patient not on insulin but either newly diagnosed, has symptoms or changing clinical picture – test 3-6 times a week. This is equivalent to 12-25 strips a month (1 pack of 50 every 2-4 months). Patients with any of the changing clinical picture (medication titrated, intercurrent illness, concurrent medication / conditions e.g. steroid, or pregnant/pre-pregnancy), testing 3-6 times/wk is inadequate. Some of these patients will need to be testing up to 3x/day, particularly when rapid titration of OHA (e.g. symptomatic or steroid treated), or very tight/close monitoring (e.g. pregnancy) is required.

Local diabetes specialists have confirmed that stable patients would not include anyone where:

- the diabetes medication is being titrated (increased, decreased or changed)
- those with intercurrent illness, concurrent medical conditions / medication (e.g. steroids) that has or potentially can upset previously stable control, or
- pregnant diabetic (known pre-pregnant Type 2 on diet / metformin only or gestational diabetics on diet/metformin only)
- patients undergoing significant lifestyle modification (e.g. diet/exercise) where SMBG can facilitate self management (e.g. encourage correct food choices/motivate physical activity) and monitor risk of hypoglycaemia which may require medication modification.
In addition to the above criteria, the JPC recommends that prescribers should follow the advice issued by the DVLA with respect to self-monitoring of blood glucose in patients with non-insulin treated diabetes mellitus holding group 1 and group 2 driving licences.

The summary recommendations below relate only to self blood glucose monitoring for people with diabetes who are not on treatment with insulin.

For the full list of other requirements / needs of notification etc and detailed guidance, please refer to the DVLA document: “At a glance guide to the current medical standards of fitness to drive” (May 2012) available at http://www.dft.gov.uk/dvla/medical/ataglance.aspx

Group 1 Licences (car/motorbike)
- To recommend that those who take tablets that carry a risk of hypoglycaemia (such as sulfonylureas and glinides e.g. repaglinide, nateglinide) and who have or are applying for a Group 1 driving licence should be advised that “It may be appropriate to monitor blood glucose regularly and at times relevant to driving to enable the detection of hypoglycaemia”. The DVLA guidance also states that these patients “Must be under regular medical review”.

- In addition, the JPC recommend that the decision as to which patients fit this criteria should be made on a case by case basis, by the prescriber, taking individual circumstances into consideration.

- The DVLA does not make any recommendations regarding blood glucose monitoring for patients who take tablets other than those which carry a risk of hypoglycaemia or use non-insulin injectable medication.

- Blood Glucose Testing Strips to be issued by GPs in line with the formulary.

Group 2 Licences (Lorry/bus/taxis)
- To recommend that those who take tablets that carry a risk of hypoglycaemia (such as sulfonylureas and glinides e.g. repaglinide,nateglinide) and who have or are applying for a Group 2 driving licence should be advised that they “Must regularly monitor blood glucose at least twice daily and at times relevant to driving”.

- To recommend that patients who take tablets other than those that carry a risk of hypoglycaemia or use non-insulin injectable medication are advised to monitor their blood glucose regularly and at times relevant to driving. The DVLA guidance also states that these patients “Must be under regular medical review”.


• Blood Glucose Testing Strips to be issued by GPs in line with the formulary.

**Bulletin Update (May 2012)**

The Driver and Vehicle Licensing Agency (DVLA) issued guidance entitled “At a Glance Guide to Current Medical Standards of Fitness to Drive” (Dec 2011, updated May 2012) which detailed the requirements and advice for the monitoring of blood glucose in people with diabetes. (1)

This publication specifies the requirements and advice from the DVLA in relation to patients with diabetes who are 1) insulin-treated, 2) managed by tablets which carry a risk of inducing hypoglycaemia (this includes sulphonylureas and glinides, 3) managed by tablets other than those specified in point 3, or by non-insulin injectable medication, 4) managed by diet alone and 5) those with impaired awareness of hypoglycaemia.

This purpose of this bulletin update is to incorporate the DVLA guidance and advice with relation to **non-insulin treated type 2 diabetic patients**. The DVLA requirements for insulin treated patients differs and is not covered in this bulletin.

The DVLA guidance and advice for **non-insulin** treated diabetic patients is as follows below. (Extract from DVLA document (1).)

<table>
<thead>
<tr>
<th>DIABETES MELLITUS</th>
<th>GROUP 1 ENTITLEMENT ODL - CAR, M/CYCLE</th>
<th>GROUP 2 ENTITLEMENT VOC – LGV/PCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANAGED BY TABLETS WHICH CARRY A RISK OF INDUCING HYPOGLYCAEMIA. THIS INCLUDES SULPHONYLUREAS AND GLINIDES (e.g. nateglinide, repaglinide)</td>
<td>Must not have had more than one episode of hypoglycaemia requiring the assistance of another person within the preceding 12 months. It may be appropriate to monitor blood glucose regularly and at times relevant to driving to enable the detection of hypoglycaemia. Must be under regular medical review. If the above requirements and all of those set out in the attached information on INF188/2 are met, DVLA does not require notification. This information leaflet can be printed and retained for future reference. Alternatively, if the information indicates that</td>
<td>Must satisfy the following criteria:</td>
</tr>
<tr>
<td>(to read additional appendix, see DVLA guidance document (1))</td>
<td></td>
<td>• No episode of hypoglycaemia requiring the assistance of another person has occurred in the preceding 12 months.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Has full awareness of hypoglycaemia.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Regularly monitors blood glucose at least twice daily and at times relevant to driving.</td>
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</tbody>
</table>
Medical enquiries will need to be undertaken, DVLA should be notified.

- Must demonstrate an understanding of the risks of hypoglycaemia.
- There are no other debarring complications of diabetes such as a visual field defect.

If meets the medical standards 1, 2 or 3 year licence will be issued.

<table>
<thead>
<tr>
<th>DIABETES MELLITUS</th>
<th>GROUP 1 ENTITLEMENT ODL - CAR, M/CYCLE</th>
<th>GROUP 2 ENTITLEMENT VOC – LGV/PCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANAGED BY TABLETS OTHER THAN THOSE ON THE PREVIOUS PAGE OR BY NON-INSULIN INJECTABLE MEDICATION (to read additional appendix, see DVLA guidance document (1))</td>
<td>If all the requirements set out in the attached information on INF188/2 are met, and they are under regular medical review, DVLA does not require notification. This information leaflet can be printed and retained for future reference. Alternatively, if the information indicates that medical enquiries will need to be undertaken, DVLA should be notified.</td>
<td>Drivers will be licensed unless they develop relevant disabilities e.g. diabetic eye problem affecting visual acuity or visual fields, in which case refusal, revocation or short period licence. Drivers are advised to monitor their blood glucose regularly and at times relevant to driving. They must be under regular medical review.</td>
</tr>
<tr>
<td>MANAGED BY DIET ALONE</td>
<td>Need not notify DVLA unless develop relevant disabilities e.g. Diabetic eye problems affecting visual acuity or visual field or if insulin required.</td>
<td>Need not notify DVLA unless develop relevant disabilities e.g. Diabetic eye problems affecting visual acuity or visual field or if insulin required.</td>
</tr>
<tr>
<td>Impaired awareness of Hypoglycaemia</td>
<td>If confirmed, driving must stop. Driving may resume provided reports show awareness of hypoglycaemia has been regained, confirmed by consultant/GP report.</td>
<td>See previous page for \textit{insulin treated}. Refusal or revocation. (see DVLA guidance document (1))</td>
</tr>
</tbody>
</table>
**Re: Taxi Licensing:** The DVLA document states that “Responsibility for determining the standards, including medical requirements, to be applied to taxi drivers, over and above the driver licensing requirements, rest with the Transport for London in the Metropolitan area and the Local Authority in all other areas. Current best practise advice is contained in the booklet “Fitness to drive”: A guide for Health Professional published on behalf of the department. (2006). This recommends that the Group 2 medical standards applied by DVLA in relation to bus and lorry drivers should also be applied by local authorities to taxi drivers.

**Re: Police, Ambulance and Health Service Vehicle Driver Licensing:**
The DVLA document states that “Responsibility for determining the standards, including medical requirements, to be applied to the police, ambulance and health service vehicle drivers, over and above the driving licensing requirements rests with the individual police force, within the NHS Trust, Primary Care Trust or Health Service body in each area. The Secretary of State’s honorary Medical Advisory Panel on Diabetes and Driving have issued advice regarding insulin treated diabetes and the driving of emergency vehicles.

**Summary**

Group 2 Licences cover bus and lorry drivers. It is also recommended that the same rules are applied to taxi drivers.

**Group 2 Licence ((LGV /PCV)**
With regards blood glucose monitoring, the DVLA specifies that diabetic patients who are managed by tablets which carry a risk of inducing hypoglycaemia (includes sulfonylurea and glinides) must regularly monitor their blood glucose at least twice daily and at times relevant to driving. The DVLA specifies that patients who are managed by tablets other than those which carry a risk of hypoglycaemia or by non-insulin injectable medication are advised to monitor their blood glucose regularly and at times relevant to driving and that the patient must be under regular medical review.

**Group 1 Licence (Car / Motorcycle)**
With regards blood glucose monitoring, the DVLA specifies that in diabetic patients who are managed by tablets which carry a risk of inducing hypoglycaemia (includes sulfonylurea and glinides), it may be appropriate to monitor blood glucose regularly and at times relevant to driving to enable the detection of hypoglycaemia and that patients must be under regular medical review. The DVLA does not make any recommendations regarding blood glucose monitoring for patients who are managed by tablets other than those which carry a risk of hypoglycaemia or by non-insulin injectable medication.

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**Introduction**
Self-monitoring of Blood Glucose (SMBG) is a widespread practice amongst diabetes patients and whilst there is some evidence to suggest that this may
benefit patients in maintaining good glycaemic control there is very little evidence and guidance to support the optimal frequency of testing. This paper focuses on Type 2 diabetes patients not on insulin therapy. In Bedfordshire 90% of diabetic patients have Type 2 diabetes.

Key Points

- A Cochrane systematic review in 2005 and more recently a CADTH systematic review in May 2009 concluded that there may be some benefit in the use of SMBG in Type 2 Non-insulin dependent diabetes mellitus (NIDDM) patients.
- NICE guidance CG66 on Type 2 Diabetes, states routine SMBG in people with Type 2 diabetes who are not being treated with insulin is not usually recommended.
- SMBG should inform lifestyle and treatment change and patients should receive the necessary education to support this action.
- A multi-centre RCT by W. A. Scherbaum, et al., found that SMBG once a week is as sufficient and safe as four times a week in T2D patients with stable metabolic control.
- A financial impact analysis based on UK primary care identified that on average NIDDM patients were testing three times a week.
- Prescribing expenditure on blood glucose test strips over the 12 month period from December 08 to November 09 for Bedfordshire and Luton was £1.4m which is about 60% of the expenditure on oral antidiabetic drugs.
- Studies have shown insignificant differences in glycaemic control when comparing blood glucose and urine glucose monitoring. This should be recommended to appropriate patients. Glycosuria detection strips are considerably cheaper than blood glucose test strips.

Cost and Estimated Impact to NHS

Prescribing expenditure in NHS Bedfordshire and Luton

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

The UK financial impact analysis found that about half of the prescriptions issued for blood glucose test strips was to NIDDM patients. On the basis of this data, reducing the frequency of SMBG could generate savings of £472,401 across the two PCTs.
SUPPORTING EVIDENCE:

Diabetes type 2 – Management

When should self monitoring of blood glucose be carried out?

**NICE CG 66 recommends that SMBG should be made available to:**
- People on insulin treatment.
- People on oral antidiabetic drugs to provide information to help avoid hypoglycaemia.
- Assess changes in glucose control resulting from medication and lifestyle changes.
- Monitor changes in glucose control during intercurrent illness.
- Ensure safety during such activities as driving.
- Newly diagnosed Type 2 diabetes only as an integral part of their self-management education.

- **Assess SMBG at least once a year.** Assessment should include:
  - Self-monitoring skills.
  - The quality and frequency of testing.
  - The use made of the results obtained.
  - The impact on quality of life.
  - The continued benefit.
  - The equipment used.

- **Routine SMBG in people with Type 2 diabetes who are not being treated with insulin is not usually recommended.**
- If blood glucose monitoring is not acceptable, consider urine glucose monitoring.

Clarification / Additional information

- If the person is self monitoring their blood glucose levels and their pre-meal levels are well controlled (less than 7 mmol/L) but their HbA\(_1c\) remains high, advise checks after meals to detect post-prandial hyperglycaemia (greater than 8.5 mmol/L).

Basis for using self monitoring of blood glucose (SMBG) in specific circumstances:

- For people with Type 1 diabetes (i.e. on insulin treatment), SMBG is widely acknowledged as an essential part of management, enabling individuals to refine and adjust their insulin dose, resulting in improved glycaemic control [DTB, 2007]. This is supported by good evidence from both observational and interventional studies. Although there is less evidence for people with Type 2 diabetes treated with insulin, the effects of SMBG are potentially similar to those with Type 1
diabetes.

- Intercurrent illness may interfere with glycaemic control, generally increasing blood glucose levels but occasionally lowering them. In addition, high-dose corticosteroid therapy (such as that used for an exacerbation of asthma or chronic obstructive pulmonary disease) may impair carbohydrate tolerance, increasing the requirement for antidiabetic treatment. Although there are no published trials to support it, current opinion, supported by NICE, is for increased self monitoring during intercurrent illness and for those people who do not routinely self monitor to do so [DTB, 2007].

**Basis for not recommending routine self monitoring of blood glucose in people not treated with insulin:**

- There has been much debate whether SMBG is appropriate in the management of people with Type 2 diabetes not treated with insulin. SMBG might improve adherence to oral antidiabetic drug treatment and motivate people to make appropriate lifestyle changes. However, the evidence in this group of people is generally poor, with conflicting results, and SMBG has considerable cost implications.

- Evidence from two recent randomized controlled trials reinforces the view that SMBG is unlikely to be beneficial in people with Type 2 diabetes not treated with insulin; it may worsen quality of life and is not cost effective.

**Relevant Studies:**

1. Two articles published early online in the Canadian Medical Association journal (CMAJ) examine this topic. The first article describes the findings of a study examining the benefits and costs of SMBG by patients with type 2 diabetes not using insulin. Researchers carried out an incremental cost-effectiveness analysis using the United Kingdom Prospective Diabetes Study (UKPDS) model to forecast diabetes-related complications, corresponding quality-adjusted life years and costs. Clinical data were obtained from a systematic review by the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), comparing self-monitoring with no self-monitoring. The systematic review had identified 7 RCTs of 2270 patients managed with oral antidiabetic agents or lifestyle measures alone. The pooled difference in HbA1c was statistically significant in favour of self-monitoring (weighted mean difference –0.25%, 95% CI, –0.36% to –0.15%). The primary outcome measure was quality-adjusted life-years (QALYs).

The following results were reported:

- The HbA1c benefit of self-monitoring from the systematic review when analysed using the UKPDS Outcomes Model, translated into small differences (ranging from 0.08% to 0.40%, depending on the outcome) in
The numbers of patients who would need to perform self-monitoring to avert 1 diabetes-related complication over a 40-year period ranged from 228 to 1299.

SMBG at a frequency ≥7 times per week was associated with an additional 0.024 QALYs and increased lifetime costs of $2711, resulting in an incremental cost-utility ratio of $113,643 per QALY gained.

The results did not change substantially with changes to a number of inputs, including the type of anti-diabetes therapy, degree of glycaemic control at baseline and history of diabetes-related complications, although the incremental cost per quality-adjusted life year fell within widely cited cost-effectiveness thresholds when testing frequency or the price per test strip was substantially reduced from the current levels.

The researchers conclude that SMBG was associated with a modest reduction in HbA1C in patients with type 2 diabetes not treated with insulin, but within the limitations of modelling and the available clinical data, frequent use of self-monitoring (≥7 times per week) in this population was associated with unfavourable cost-effectiveness estimates and was unlikely to represent an efficient use of finite health care resources. However, reduced frequency (e.g., 1 or 2 times per week) or a reduction in the price of test strips would likely improve the cost-effectiveness of routine self-monitoring in this population.

The second article examined options to reduce usage of blood glucose test strips. Researchers conducted a cross-sectional analysis of annual prescription claims for test strips between 1997 and 2008 for patients in Ontario aged 65 years and older with diabetes, stratified into 1 of 4 groups according to the most intensive glucose-lowering treatment received during each calendar year. Test strip use was calculated annually for each group over the study period, and the effects of 5 hypothetical policy scenarios of more selective test strip use were assessed.

The following findings were reported:

• Test strip use increased by almost 250% from 1997 to 2008, with 52.6% (n = 263,513) of included patients receiving a prescription during 2008, and almost half of these patients were at low risk for drug-induced hypoglycaemia.

• In 2008, over 117 million test strips were dispensed in Ontario; however, more focused policy scenarios could have reduced this number by between 9.5 million and 74.5 million test strips.

The researchers conclude that “Even modest changes in the frequency of self-monitoring of blood glucose among selected patients with type 2 diabetes through focused policy decisions could lead to substantial reductions in test strip use. Any associated cost reductions could be used to
improve diabetes care in ways that are better supported by evidence, without limiting reimbursement for blood glucose test strips for patients at risk of drug-induced hypoglycaemia."

2. A Multi-centre randomised control trial by Werner A. Scherbaum, C Ohmann, et al, the authors concluded that “one SMBG per week is as sufficient and safe as four SMBG per week to maintain HbA1c in non-insulin treated T2D close to metabolic target”.

This study was conducted in Germany and the aim was to investigate two testing regimen of SMBG in patients with stable metabolic control.

Patients with T2D treated with oral antidiabetic drugs were randomized to two groups: either one SMBG (low) or four SMBG (high) per week. Subjects were followed up after 3, 6 and 12 months. Primary outcome parameter was the change in HbA1c between baseline and 6 months. Primary outcome criterion was tested by a one-sided t-test for non-inferiority. Secondary outcome parameters were safety, compliance and HbA1c at 3 and 12 months (however the secondary outcomes were not covered in the paper).

Results: There were no differences in the 202 subjects for demographic and sociodemographic parameters and drug treatment. HbA1c at baseline was similar in both groups (7.2±1.4 vs. 7.2±1.0) Non-inferiority was demonstrated for the low group (p=0.0022) with a difference from baseline to 6 months of 0.24 in the low and 0.16 in the high group. Compliance with the testing regimen was 82-90% in both groups. There were no statistically significant differences for compliance, HbA1c at 3 and 12 months and serious adverse events.

3. A financial impact analysis based on UK primary care performed an analysis on the usage of and costs associated with SMBG in type 2 diabetes (non-insulin dependent) according to treatment regimen. Prevalence data for diabetes were assessed using UK QoF returns for 2006/07 and data on the prescribing expenditure of blood glucose test strips were extracted from UK Prescription Pricing Agency data. Prescribing data for 40,651 patients with diabetes were also extracted from the IMS Disease Analyzer database. The information was combined to arrive at mean usage and expenditure data per patient, broken down by treatment type.

Summary table

<table>
<thead>
<tr>
<th>Mean national expenditure on SMBG</th>
<th>£73.64 /patient /year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expenditure per treatment type ranged from £9.83 for diet therapy to 37.87 for triple therapy and £191.18 for insulin therapy</td>
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</table>

<table>
<thead>
<tr>
<th>Estimated mean weekly test strip usage / therapy group</th>
<th>2.5 – diet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.6 – glitazone monotherapy</td>
</tr>
<tr>
<td></td>
<td>3.1 – Metformin monotherapy</td>
</tr>
<tr>
<td></td>
<td>3.5 – sulphonyl urea monotherapy</td>
</tr>
</tbody>
</table>
Findings:

- There was an increased use of SMBG in patients with T2D as treatment regimen is stepped up
- Many patients are currently using SMBG more frequently than recommended by UK consensus guidelines, at substantial cost to the NHS
- If SMBG was used in accordance with guidelines, the authors estimate potential annual savings of around £17 million.

Limitations:

- The data sources did not identify the reasons underlying individual decisions to prescribe blood glucose monitoring strips nor identify the educational support provided.

(Please note: This paper makes reference to a ‘UK consensus guidelines’ for monitoring blood glucose, however we cannot comment on this as the information is not readily accessible.)

This study is gives a very good insight to the actual usage of blood glucose testing strips in the UK by diabetic patients in the various therapy groups.

Conclusions

There is insufficient evidence available to make clear recommendations on the optimal frequency of self-monitoring of blood glucose in non-insulin dependent Type 2 diabetes patients. However based on the findings from the studies cited in this paper, we recommend that SMBG should be used no more than once a week for this group of patients and that this practice should be supported with appropriate education to inform lifestyle and treatment changes.

Additional Points for Consideration – for discussion and comment

- What criteria should be used to identify patients at high risk of hypoglycaemia in order to recommend more intense monitoring of blood glucose?
- How are patients expected to use the information from their blood tests to make changes to their treatment and lifestyle?

Systematic Review of Use of Blood Glucose Test Strips for the Management of Diabetes Mellitus, COMPUS Vol3, Issue 2, May 09


National Institute for Health and Clinical Excellence (NICE) guideline Type 2 diabetes: the management of type 2 diabetes (update) [National Collaborating Centre for Chronic Conditions, 2008; NICE, 2008a].

Cost-effectiveness of self-monitoring of blood glucose in patients with type 2 diabetes mellitus; CMAJ; December 2009; Chris Cameron, Doug Coyle, Ehud Ur, Scott Klarenbach

Blood glucose test strips: options to reduce usage
Tara Gomes, David N Juurlink, Baiju R Shah, J Michael Paterson, Muhammad M Mamdani


June 2012 Update References: