Recommendations:
People with Type 2 diabetes not on insulin

- Glycated haemoglobin (HbA1c) is the recommended measure of glycaemic control, not self-monitoring of blood glucose (SMBG).
- Those with new onset of Type 2 diabetes not on insulin, should be discouraged from using SMBG.
- Current users of SMBG with T2 diabetes not on insulin, should be advised to stop testing where there is mutual agreement that there is little or no benefit.
- SMBG may be beneficial in people known to have recurrent or severe hypoglycaemia, in people on sulphonylureas when fasting or drivers of LGV/PSV.
- People requiring SMBG should be adequately trained and supported in line with NICE guidance.
- The use of meters and test strips should be standardised and audited.
- Staff training and procedures for testing in the practice or at home should be reviewed.
- Urine glucose testing is not advised.
Current evidence on SMBG in people not on insulin was reviewed by

The recommendations represent a consensus view and not necessarily the views of any one individual. The guidance is advisory and is intended as an aid to, but not a replacement, for the clinical judgement of the responsible clinician.

It is not intended for use in pregnancy, and the improvement in quality of self-testing by patients and point of care testing by staff will be the subject of separate reviews.

Tower Hamlets PCT

T Chowdhury: Consultant physician
M Coughlan: Head of Medicine Management
S Fernandez: Diabetes nurse specialist specialist
I Hodkinson: General practitioner
F Oluboyede: Prescribing advisor
D Petersen: Consultant physician
J Robson: General practitioner
L Vincent: Diabetes programme manager
A Wignal: Diabetes nurse specialist

City and Hackney PCT

B Brese: Prescribing advisor
S Ambrose-Wilson: Consultant nurse

The following commented on the review

S Hull: General practitioner
A Livingstone: General practitioner
K Boomla: General practitioner
P Bennett-Richards: General practitioner
C Highton: General practitioner

Richard Bull Public Health Strategist
Abigail Knight Public health Strategist

Comments or questions can be addressed to the corresponding author
j.robson@qmul.ac.uk

Further copies or information can be obtained from:

Clinical Effectiveness Group
Centre for Health Sciences
Institute of Health Sciences Education
Barts & the London
Abernethy Building
2 Newark Street
London E1 2AT

Tel: 020 7882 2553
Fax: 020 7882 2552

Website: http://ceg.ihse.qmul.ac.uk
evidence review

Self-monitoring of blood glucose (SMBG) for people with type 2 diabetes not on insulin:

The NHS is currently reviewing the management of Type 2 diabetes. In doing so, it has a duty to use available resources where they will provide most benefit, on the basis of the best evidence, in a cost-effective, evidence-based, acceptable, safe and equitable manner.

This guidance concerns people with Type 2 diabetes not on insulin who are unlikely to benefit from SMBG. Separate guidance will follow on SMBG in people on insulin or oral treatment who do need testing as well as testing by staff at the point of care. This guidance does not relate to women who are pregnant. This guidance is consistent with “Self monitoring of blood glucose in non-insulin-treated Type 2 diabetes: A report prepared by an NHS Diabetes Working Group. 2010” based on Clar C. Health Technology Assessment 2010; 12: 1-140.

SUMMARY

Since 2006 when NICE guidance was last formulated, major new trials of SMBG have been conducted in people with Type 2 diabetes not using insulin. Some earlier studies were of poor quality or biased and their inclusion in meta-analysis has been controversial. Of the three more recent studies of HbA1c control, two studies (DIGEM, ESMON) lasting one year showed no significant benefit in glycaemic control. One study of 6 months duration (DINAMIC1) showed a small benefit of doubtful clinical relevance. In all three studies there was no difference in hypoglycaemic episodes or in weight. A cost-effectiveness analysis showed that the reduction of one quarter of one percent in HbA1c level (0.25%) found in DINAMIC1 was not cost effective, costing £67,000 per QALY gained.

National reviews in the UK, New Zealand and Canada recommend that SMBG should not be routinely used in people with T2 diabetes not on insulin because the evidence shows....

SMBG results in little or no improvement in glycaemic control or other outcomes
SMBG is associated with discomfort and reduces the quality of life
SMBG is not cost effective
SMBG is expensive, the resources would be better used for more effective interventions

We recommend that
• Glycated haemoglobin (HbA1c) is the recommended measure of glycaemic control
• Those with new onset of T2 diabetes not on insulin, should be discouraged from using SMBG.
• Current users of SMBG with T2 diabetes not on insulin, should be advised to stop testing where there is mutual agreement that there is little or no benefit.
• SMBG may be beneficial in people known to have recurrent or severe hypoglycaemia, people on sulphonylureas who are fasting or drivers of LGV/PSV.
• People requiring SMBG should be trained and supported in line with NICE guidance.
• The use of meters and test strips should be standardised and audited.
• Staff training and procedures for testing in the practice or at home should be reviewed.
• Urine glucose testing should not be advised.
evidence review

Current local policy

Current local guidance is based on NICE evidence up to 2006 and is now outdated. This guidance is so broad it is often interpreted as a recommendation to routinely use SMBG in almost all people with treated T2 diabetes.

New patients are routinely given or may obtain themselves, a diverse array of glucose meters. There are concerns that the ‘free’ supply of meters by commercial companies may lead to product promotion rather than optimal testing quality. This has led to a confusing array of kit for which both staff and patients may be poorly trained and quality standards are variable.

Existing users are encouraged to continue monitoring with little coherent support. Testing often becomes a ritual activity unconnected with changes in treatment. In people not requiring insulin, there is no evidence that such meters improve diet, physical activity, hypoglycaemia or wellbeing. In other words many people are unnecessarily monitored while those that need monitoring may be inadequately supported.

Recent UK, New Zealand or Canadian recommendations based on new evidence conclude (1) “... SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents or diet alone, and is therefore unlikely to be cost-effective.” (HTA UK)

For people not on insulin, current practice therefore is poorly targeted. For the few who may benefit from SMBG, the quality of current procedures and training is poor.

Why does the new evidence differ from earlier NICE guidance?

Recommendations differ because the evidence up until 2006 was contested, with advocates of SMBG claiming some benefit, whilst sceptics claimed that good quality trials showed no evidence of benefit. This debate has been influenced by an international testing industry worth $4 billion in the USA alone. This has promoted a large number studies, some of poor quality or with methodological bias.

The 2008 NICE review was based upon studies only up to 2006. The 2005 Cochrane review identified only 6 studies of assessable quality(2). Of these only two reported a beneficial effect on glycaemic control. One of these two trials should be discounted as it was an on-treatment analysis (3) and the other was of doubtful quality because of a high and differential drop-out rate (30% in controls and 40% in intervention) which makes it likely that the “remaining responders” (with lower HbA1c) were more likely to report positive results(4). In other words up until 2006, none of the high quality trials showed evidence of benefit (with one doubtful exception).

Since 2005 when NICE reviewed the evidence, three new high quality trials have reported.; the DiGEM(5) and ESMON studies(6) found no benefit from SMBG, they both demonstrated a lower quality of life and DiGEM demonstrated a lack of cost effectiveness. The DINAMIC1 study(7) showed a small 0.25% reduction at 6 months in HbA1c. A German trial of once weekly versus 4 times weekly testing showed no difference in glycaemic control(8). The 2010 UK and 2009 Canadian cost effectiveness reviews (1, 9-11) confirmed lack of benefit in more intensive testing. Similar conclusions were reached in New Zealand(12).

These national and international reviews concluded that SMBG shows little or no benefit and is not cost-effective in monitoring of people with T2 diabetes not on insulin. They considered SMBG should be ended as a routine method to assess glycaemic control, except in those at high risk of hypoglycaemia.
**Evidence Review**

**How should we stop testing?**

Patients can be reassured glycaemic control is best assessed with regular HbA1c blood tests as part of the diabetes care package; 6 monthly if the diabetes control is good and every 3 months if the control is less good. Changes in treatment will be based on the results of these tests. Trial evidence has confirmed that testing can be reduced by 40% without any compromise in quality(13).

Stopping or reducing a procedure previously recommended is always difficult – there may be individual clinical circumstances where the clinician or patient feels there is benefit. But in most instances patients will be relieved to stop or reduce a procedure that is unpleasant, time consuming and largely ineffective. Disinvestment requires the support of patients and community staff, dieticians, pharmacists, nurses and doctors in both primary and secondary care. Where patients elect to continue despite explanation, the frequency of testing should be no more than weekly unless risk of hypoglycaemia is an issue.

EMIS Access allows patients to view their own records including HbA1c results. More widespread use of this in the future will allow sharing of care plans and treatment goals. IT staff can advise practices on the use of this facility.

**Hypoglycaemia**

Hypoglycaemia is an unusual complication of treatment in people not on insulin. Most people are at low risk of hypoglycaemia and there is no reason for routine monitoring.

Sulphonylureas are associated with higher risk of hypoglycaemia than metformin, particularly in the elderly on polypharmacy. Short acting sulphonylureas such as tolbutamide or gliclazide are less likely to cause hypoglycaemia than longer acting drugs such as glibenclamide and glimepiride.

Patients starting sulphonylureas should be educated about the risks, symptoms and management of hypoglycaemia. Arrangements for professional monitoring may be needed where there is serious acute illness. There may be special clinical circumstances where SMBG may be appropriate; for example in people with proven recurrent hypoglycaemia.

Those who have prolonged fasts may also be at risk. Drivers with LGV or PSV licences on long journeys taking sulphonylureas need advice on avoidance of hypoglycaemia – including regular meals and snacks at least every two hours – and SMBG.

**Ramadan:** people with type 2 diabetes who decide to fast during Ramadan should discuss this with their medical team

- Fasting is not recommended for people on insulin, and is not recommended for people on tablets who have poor diabetic control HbA1c>9%, or if they have other medical problems such as heart, kidney or eye disease, are pregnant or acutely ill.
- Higher doses of metformin alone may need reduction.
- Sulphonylureas may need a reduction in dose, particularly the early morning dose.
- Consider changing to repaglinide during fasting (but change back after Ramadan). SMBG may be required for people who remain on sulphonylureas during Ramadan, but can stopped afterwards.

Detailed information on management during Ramadan can be found on the Leicester website [http://www.leicestershirediabetes.org.uk/display/templatedisplay1.asp?sectionid=244](http://www.leicestershirediabetes.org.uk/display/templatedisplay1.asp?sectionid=244)
Further considerations

Point of care testing: Many community staff – doctors, practice or district nurses – may be called on infrequently to test blood glucose using meters. Equipment may be unavailable or poorly maintained and skills and quality of testing variable. Agreed procedures for testing on practice premises and at home need to be set out to assure quality, including procedures for training.

Further consideration should be given to standardisation of meters/strips and for improvement in staff training, procedures and quality standards in the use of SMBG. This will be a subject for further review.

Frequently asked questions:

Does SMBG improve glycaemic control?
In people who do not require insulin, there is little or no evidence of improved glycaemic control. Some studies have shown small benefit, as have some reviews, however the standard of some studies included in these reviews are poor. High quality studies show little or no improvement and this is not a cost-effective use of resources. Monitoring using HbA1c is agreed as the best method of monitoring for people not on insulin.

How can my diabetes be monitored if blood glucose isn’t tested?
HbA1c is the best measure of control of diabetes. Patients can be informed that they can check their own HbA1c levels on-line if they have access to the internet. They can ask the practice for details of how to do this through EMIS Web Access. The patients leaflet also gives details of HbA1c monitoring. HbA1c should be measured 6 monthly.

Is this just another cut in services?
This is not a cut in services. The NHS and PCT has substantially increased, not decreased investment in diabetes services, with extensive new local services in local communities and new care pathways. The measurement of blood glucose is outdated as a way of measuring diabetes control which is better done by measuring HbA1c.

Does SMBG help people manage their diet?
There is no evidence that SMBG helps motivate people with improvement in their diet or weight. In the DiGEM trial reported diets were better in people monitored with HbA1c than in those using SMBG.

Does SMBG make people feel better?
There is no evidence that SMBG improves quality of life or controls symptoms but there is evidence that it makes them feel worse.

Policy considerations

Test strips cost about £14 for 50 strips and average around £60 annually per patient not on insulin. Nationally strips cost £145 million per annum in England. In Tower Hamlets PCT £600,000 is spent on testing strips compared to £700,000 on oral drugs for diabetes (PACT 2010). If the use of strips in people not on insulin were to be halved, about £100,000 could be saved locally and devoted into more effective uses such as the employment of more staff, staff training and patient education. It would be reasonable to view reductions in SMBG over a 3 year time frame, reducing use in people with non-insulin requiring diabetes by around 20% per annum with the aim of reducing current spending in people not on insulin, by half in 3 years.
**evidence review**

**Current use**

In August 2010 the prescribing of testing sticks to patients with Type 2 diabetes in Tower Hamlets was as follows...

Of a total of 10,596 people with Type 2 diabetes, 44% (4662) used SMBG in the past year.

Of the 4662 people using SMBG, 34% (1604) were on insulin and 66% (3058) were not on insulin.

1058 use SMBG with metformin or diet alone

2000 use SMBG with a sulphonylurea or other oral agent.

The cost of strips to the 3000 people on oral medication is about £200,000

If this were reduced by half, about £100,000 per year would be saved per PCT and some 1500 people could stop an unnecessary and unpleasant task.

**References**

15% CHD risk = 20% CVD risk

**Primary prevention**
- Smoking cessation
- Improve diet and physical activity
- BP control < 140/90mmHg

**Secondary Prevention**
- Smoking cessation
- Improve diet and physical activity
- Optimal BP control < 130/80mmHg
- Optimal total cholesterol < 4mmols/l OR LDL < 2mmols/l
- MI, ACS, Angina, stent/ CABG
- Statin
- Beta blocker + aspirin 75mg
- ACE inhibitors
- Clopidogrel after ACS/stent
- Stroke/ TIA, PA D
- Statin
- Aspirin + dipyridamole 200mg bd

**Type 2 Diabetes**
- Age > 40 yrs + Statin
- BP control < 140/80mmHg

**Acute coronary syndrome**
- Treat with higher intensity statin any of the following:
  - Simvastatin 80mg
  - Atorvastatin 80mg

**Stable CHD/angina, stroke, TIA, diabetes or peripheral arterial disease**
- Simvastatin 40mg

**Cholesterol ≥ 4mmols/l or LDL cholesterol ≥ 2mmols/l**
- Simvastatin 80mg

ISBN 0 902238 70 1