Self monitoring in DIABETES

Self monitoring of blood glucose is an important component of diabetes management for some people. But, which people?

Any component of a treatment plan that is both invasive and expensive needs to result in an improved clinical outcome.[1] Gathering information about blood glucose levels is only useful when it can be used to improve clinical outcomes.

Clinical outcomes in diabetes are improved when glycaemic control is improved. Measurement of the concentration of glycated haemoglobin (HbA1c) is the most appropriate and accurate way to monitor glycaemic control. When then, does self monitoring of blood glucose provide additional benefit?

TYPE 1 DIABETES

Self monitoring of blood glucose (SMBG) is mandatory for people with type 1 diabetes. The information gained is essential for patients to adjust the type and amount of food and exercise, document hypo and hyperglycaemia and select appropriate dosages of insulin. People with type 1 diabetes usually test three to four times a day and are educated to act on the result to bring about improved control (i.e. a lower HbA1c result).

TYPE 2 DIABETES

Self monitoring is required for people with type 2 diabetes on insulin

Advice regarding the use of SMBG for people with type 2 diabetes treated with insulin is essentially the same as for people with type 1 diabetes. These people however, may be on insulin regimens with less frequent dosing, and so may only need to test twice a day.

Advice for people with type 2 diabetes who are not using insulin needs individual consideration (includes those on oral medication)

There is no doubt that for the vast majority of people with diabetes, measurement of the concentration of glycated haemoglobin (HbA1c) remains the most appropriate and accurate way to monitor glycaemic control.

Evidence of benefit for SMBG in non-insulin treated type 2 diabetes

There is now an abundance of published research in this area. However the designs of the studies, the outcomes and ultimately the conclusions reached, have varied widely.[2] There is still a lack of consensus.[3,4] A conclusion reached in a recent commentary article was that for people with non-insulin treated type 2 diabetes, SMBG "is an expensive and popular procedure without an evidence base".[5] The author suggests that the only way to answer the question of whether to advocate routine SBMG would be through "properly designed, randomised clinical trials."

Do the guidelines help us?

The current New Zealand guideline states that "self-monitoring of blood glucose is well-established in clinical practice, but the literature in this area is limited and difficult to assess".[6] The recommendation is that SMBG "should be considered in conjunction with appropriate therapy as a part of integrated self-care. The purpose of blood glucose self-monitoring should be clear and agreed with the person with diabetes." A similar recommendation is included in the NICE guideline.[7] However, a new draft of this guideline is under consultation at present.[8]

When does SMBG produce benefit for people with non-insulin type 2 diabetes?

The key message is that the aim of using SMBG is to improve glycaemic control, i.e. a lower HbA1c, and to ultimately reduce long term complications. Measuring blood glucose gives immediate information for the patient, but to give any benefit, this information must be acted upon.[9]

If HbA1c is already satisfactory without SMBG, adding it may not be associated with any further improvement.[2]

Therapeutic benefit is more likely to be obtained when:

- There are special circumstances such as new diagnosis, starting or changing medication, illness, pregnancy and frequent hypoglycaemia[10]
- The patient knows how and when to test and how to interpret or act on the results[2]
- Patient education is individually tailored and ongoing[11]
- Patients are "sufficiently literate and numerate"[10]
- Patients are motivated to make changes to diet or lifestyle[2,10]
- A clear goal is negotiated and agreed with patients[11]
- There is an understanding of the relationship between SMBG and HbA1c results[11]

When used appropriately, SMBG can increase disease awareness and compliance[10], it can empower[9,12] and reassure.[11]

Conversely, the continual reminder of less than ideal control can lead to uncertainty, frustration, guilt and high levels of anxiety.[9,11] If GPs and practice nurses take little notice of self monitoring results and don't use the readings as a chance for further education, it tends to reinforce the idea that test results are not important.[11] The patient will often become discouraged and lose motivation. GPs can end up spending a lot of time dealing with the anxiety arising from unexpected or poor results.

In patients who are receiving no benefit from SMBG, it is appropriate to stop.

The recent Diabetes Glycaemic Education and Monitoring (DiGEM) trial has concluded that "routine self monitoring of blood glucose for patients with reasonably controlled non-insulin treated type 2 diabetes seems to offer, at best, small advantages, is not well accepted, and the cost, effort and time involved in the procedures may be better directed to supporting other health related behaviours."[13] It is thought that studies such as this may encourage clinicians to talk to their patients about the usefulness of SMBG and give them "confidence to discontinue it if it is providing no benefit."[14]

A pragmatic approach to the use of SMBG is recommended

If we are faced then with contradictory evidence and very broad recommendations, how do we make choices that will benefit our patients? The decision comes down to an individual patient level and relies upon the doctor and patient reaching agreement on the best course of action.

Andrew Moore, the editor of Bandolier, has been involved in a systematic review of the current evidence.[10] He states that:

"It is sobering to remember that where doctors make their own decisions, the results have been terrific, especially in clinical outcomes with major consequence. They did it by deciding which patients with type 2 diabetes would benefit from self-monitoring and prescribing self-monitoring in those patients. Simple, really". [16]

Further reading

For more information on the DiGEM trial, refer to the following articles in the BMJ (requires subscription)

http://www.bmj.com/cgi/content/full/335/7611/132

http://www.bmj.com/cgi/content/full/335/7611/105

The issue of cost

Healthcare providers worldwide are struggling with the difficulties of who should get the healthcare dollars. A huge multi-billion dollar industry has developed to supply meters and strips and there is ongoing spending, with companies trying to produce increasingly fast and easy to use devices.[15]

The largest group of people using SMBG are those with non-insulin treated type 2 diabetes. The routine use of SMBG in this group can have a major cost impact and the expense can be justified only if it leads to savings in the future.[15]

Who to test and why to test have become major issues. In the United Kingdom, some primary care organisations now restrict access to blood testing strips causing debate between doctors, patients and suppliers. Diabetes UK (a charity for people with diabetes) has launched a national online campaign to try and reintroduce unrestricted access to home blood glucose testing equipment.[3] Similar financial dilemmas face those working in primary health care in New Zealand.

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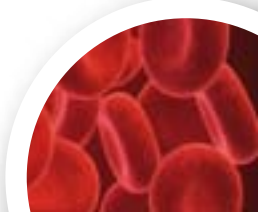

GLUCOSE METERS

– different meters, different results

The way that blood glucose results are presented varies depending on the type of meter used. There is a danger that these variations could be falsely attributed to poor control.

WHOLE BLOOD VERSUS PLASMA GLUCOSE

Plasma glucose results measure approximately 15% higher than whole blood glucose results. This is often called the 'matrix effect' and is due to the higher protein and lipid content of red cells than the liquid portion of the blood. This results in glucose (which is water soluble) being unequally distributed between the intracellular and the extracellular space.

VARIATION IN THE WAY BLOOD GLUCOSE METERS REPORT RESULTS

The difference is significant because glucose meters currently available in New Zealand report results as either whole blood or as a "plasma equivalent" while laboratory results are reported as plasma results.

The "plasma equivalent" result is calculated from the whole blood glucose reading using an equation built into the glucose meter. This allows GPs and patients to easily compare laboratory test results with glucose results obtained at home. The International Federation of Clinical Chemistry and the American Diabetes Association has also recommended home glucose analysers should report results as "plasma equivalent".

If however, the meter is reporting results as "whole blood equivalent", both **GP and patient have to know that the whole blood equivalent result is approximately 15% lower than the plasma result,** and is therefore not directly comparable with results obtained from the laboratory.

Table 1 indicates the method of reporting for glucose meters currently available in New Zealand.

As of the 1 July 2008, PHARMAC will no longer be funding test strips for Accu-check Advantage, therefore patients currently using these meters will need to change to either the Abbott Optium Xceed or the Roche Accu-Chek Performa system. Following this change results throughout New Zealand will be consistently reported as "plasma equivalent".

Table 1: methods of reporting for glucose meters currently available in New Zealand.

Analyser	Reported as:
Abbott Optium Xceed	Plasma equivalent
Roche Accu-Chek Advantage	Whole blood equivalent
Roche Accu-Chek Performa	Plasma equivalent

GLUCOSE METERS – common problems

Probably the greatest concern when using glucose meters is false results. All users should be educated about factors contributing to false results.

The Office of In Vitro Diagnostics (OIVD), a service of the FDA, evaluates glucose meters. They evaluate long term safety and effectiveness of the analysers and how devices are used. OIVD, in consultation with manufacturers and users, have produced a table of common problems encountered when using glucose meters (Table 2).

Causes of false results may be patient/sample based or user/device based. Probably the most important advice for any user of a blood glucose meter is to question any result not consistent with the clinical picture. This needs to be investigated and, at a minimum, the test repeated.

Table 2: Common problems with glucose meter results.

Results	Problem	Recommendation
Falsely low results	Sensor strips not fully inserted into meter	Always be sure strip is fully inserted in meter
	Not enough blood applied to strip	Repeat test with a new sample
	Patient in shock	Treat appropriately. Venous sample should be sent immediately to a laboratory
	Squeezing fingertip too hard because blood is not flowing	Repeat test with a new sample from a new stick
	Polycythaemia/increased haematocrit	Venous sample should be sent to a laboratory
Falsely high results	Patient sample site (for example the fingertip) is contaminated with sugar	Always clean test site before sampling
	Patient is dehydrated	Treat appropriately. Venous sample should be sent immediately to a laboratory
	Anemia/decreased haematocrit	Venous sample should be sent to a laboratory
Variable results	Test strips/controls stored at temperature extremes	Store kit according to directions
	Sites other than fingertips	Results from alternative sites may not match finger stick results
	Test strips/controls damaged	Always inspect package for cracks, leaks, etc.
	Dirty meter	Even small amounts of blood, grease, or dirt on a meter's lens can alter the reading
Error codes	Batteries low on power	Change batteries and repeat sample collection
	Test will not complete	Check package details, calibration code, and expiry dates are all compatible

Further reading

FDA diabetes website: http://www.fda.gov/diabetes/

The Office of In Vitro Diagnostics: http://www.fda.gov/cdrh/oivd/labsafetytips.html#tip4