# The continuing debate on self-monitoring of blood glucose in diabetes

David Owens, John Pickup, Anthony Barnett, Brian Frier, Joan Allwinkle, Lesley Lowes, Roger Gadsby, Phyllis Bushby, Debbie Hicks

April 2004 saw the publication of a much-needed consensus statement (Owens et al, 2004) on the use of self-monitoring of blood glucose (SMBG) by people with diabetes. Since the publication of the original document, the authors have attempted to obtain a wider consultation by involving healthcare professionals across the UK. This article aims to describe the measures taken to widen the debate in an attempt to provide as clear statements as possible in support of appropriate use of SMBG in people with diabetes.

he need for clarification regarding the utility of self-monitoring of blood glucose (SMBG) was initially addressed in a position statement published in April 2004 (Owens et al, 2004). This need was heightened because of the suggestion by some UK primary care trusts (PCTs) – on the recommendation of their pharmaceutical advisors – to restrict patients with diabetes to one blood glucose test per day irrespective of diabetes type or therapeutic regimen. Some authorities in the UK have since developed local guidelines for SMBG based on the

original position statement (Owens et al, 2004), aimed at clarifying the requirements for blood glucose test strips in the different categories of persons with diabetes (Rhondda Cynon Taff Local Health Board, 2004; Wycombe PCT, 2005). The National Institute for Clinical Excellence (NICE) guidance (NICE, 2002), while emphasising the need for SMBG did not prescribe the necessary frequency of blood glucose testing required by the different patient groups, or how it should relate to specific situations. There is evidence available that the more

#### Article points

- 1. The need for clarification regarding the utility of self-monitoring of blood glucose (SMBG) was initially addressed in a consensus statement published in April 2004.
- A wider consultation on the document was sought by involving additional diabetes-related healthcare professionals from around the UK.
- 3. Most of the initial recommendations/ statements were well understood and accepted but some needed further clarification.
- 4. Where there was a low level of consensus with the original statements alternative wordings were proposed.
- 5. The revised recommendations on SMBG are outlined at the end of this article.

frequent the SMBG, the better the  $HbA_{1c}$  regardless of diabetes type or therapy (Karter et al, 2001).

Since the original multidisciplinary consensus statement was published (Owens et al, 2004), we have further attempted to obtain a wider consultation by involving 292 additional diabetes-related healthcare professionals from across the UK. The subsequent discussions confirmed that most of the initial recommendations/statements were well understood and accepted but that some needed further clarification. In this article, we aim to describe the measures taken to widen the debate based on the original proposals in an attempt to provide as clear statements as possible in support of the appropriate use of SMBG in persons with diabetes (see Appendices 1 and 2).

# Consensus position: widening the debate

In order to evaluate the level of agreement amongst the diabetes care multidisciplinary team regarding the original 32 consensus statements, a number of workshops were conducted across the UK. These were held at six different locations (Birmingham, Cardiff, Glasgow, London, Manchester and York) during 2004 in an attempt to accommodate any possible regional differences in opinion and practice. Delegates included diabetes specialist nurses (DSNs), pharmaceutical advisors, general practitioners (GPs), hospital clinicians, practice nurses, primary care trust (PCT)/local health board (LHB) personnel and a small number of patients.

These workshops provided participants with the opportunity to express and record their responses to any of the original statements and also provide alternative proposals. The term 'consensus' was initially defined as >50% agreement for each statement when discussed at the regional meetings. Only two statements failed to achieve this level of agreement, with 17 out of

the 32 statements (53%) achieving >90% agreement after debate. Where there was a low level of consensus with the original statements alternative wordings were proposed. The feedback from the workshops resulted in the construction of a number of proposed alternative statements, which were returned to the participants in the form of a questionnaire to elicit preferences. The responses were then analysed and discussed by the 'consensus group' to arrive at the final statements included in *Appendix 2*. Key elements in the various discussions are presented below.

# Issues for clarification The relationship between different indices of glycaemic control

Although the two most widely used measures of diabetes control – blood glucose and glycated haemoglobin ( $HbA_{1c}$ ) concentrations – are well known to healthcare practitioners, there is still considerable confusion about the most appropriate use of these glycaemic indices. Understanding the relationship between these indicators is central to the recommendations relating to their use in the management of a given person with diabetes.

#### Blood glucose

In diet-treated type 2 diabetes, both the basal and the postprandial blood glucose concentrations are elevated compared to persons without diabetes, and the pattern is generally predictable from day to day (Pickup, 2003). For this reason, a single fasting or random blood glucose test is a fairly good measure of the 'diabetic control' and the average blood glucose concentration (Holman and Turner, 1981). Both fasting and single glucose values throughout the day correlate with HbA<sub>1c</sub> (which is a measure of mean blood glucose level - see below) in type 2 diabetes (Gonen et al, 1979; Avignon et al, 1997; Bonora et al, 2001).

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- Where there was a low level of consensus with the original statements alternative wordings were proposed.
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There has been a divergence of views as to whether the fasting/preprandial or the postprandial blood glucose test relates best to overall control and HbA<sub>1c</sub> in type 2 diabetes. Some authors have found the best correlation with HbA<sub>1c</sub> for non-fasting (postprandial) glucose (Avignon et al, 1997), while others found the best relationship between HbA<sub>1c</sub> and fasting blood glucose levels (Bonora et al, 2001). This discrepancy may be explained by a recent study (Monnier et al, 2003), which showed that the relative contribution of fasting blood glucose concentration to overall glycaemia increases as control worsens (HbA<sub>1c</sub> increasing). Thus, a fasting blood glucose test is likely to be a better measure of overall control in the poorly-controlled type 2 patient (with an HbA<sub>1c</sub> above about 7.5%) and a postprandial blood glucose test the better index in the better-controlled patient (HbA<sub>1c</sub> <7.5%). One should therefore consider determining the postprandial blood glucose wherever the fasting blood glucose is normal or near normal but the HbA<sub>1c</sub> remains elevated (>7.5 %).

The progression from lifestyle measures alone (diet, weight management and physical exercise) to the additional requirement for insulin secretagogues (sulphonylureas, metaglinides) or insulin therapy in type 2 diabetes is accompanied by an increased risk of hypoglycaemia. This increased risk is more apparent with insulin therapy, which therefore demands greater frequency of blood glucose testing during the transition (Owens et al, 2004).

In type 1 diabetes, however, the blood glucose level often varies widely throughout the day, ranging from hypoto hyperglycaemia, and the pattern is often unpredictable both within and between days (Pickup, 2003). This has been amply demonstrated by recent continuous in vivo blood monitoring using a glucose sensor (Sachedina and Pickup, 2003). It is for this reason that one or two clinic or home blood

glucose tests give only limited information about such variations in persons with type 1 diabetes. Therefore, a timed series of blood glucose measurements during the day is essential to assess the quality of glycaemic control in this type of diabetes. The more erratic the blood glucose oscillations in a given patient, the more frequent the necessary testing. As expected in type 1 diabetes, there is no correlation between a single blood glucose test and  $HbA_{1c}$  (McCance et al, 1988).

#### Glycated haemoglobin and HbA<sub>1c</sub>

Glycated haemoglobin is a measure of the average blood glucose control over the preceding two-to-three months. This arises because, over the lifetime of the red blood cell (about 120 days), glucose and sugar phosphates slowly attach (glycate) by a covalent but non-enzymatic mechanism to sites (N-terminal and ε-amino groups) on the haemoglobin molecule (Pickup, 2003). HbA<sub>1c</sub> is the glycated haemoglobin component present in largest amount and the one measured most often in clinical practice; it is formed by the attachment of glucose to the N-terminal of the  $\beta$ -chain of haemoglobin. As the rate of glycation is proportional to the ambient glucose concentration, the percentage of haemoglobin glycated thus reflects average preceding glucose levels. In fact, the HbA<sub>1c</sub> concentration is weighted towards glycaemia in the month preceding testing (Tahara and Shima, 1995).

Many studies show that glycated haemoglobin correlates strongly with the mean blood glucose concentration over the previous months (e.g. Paisey et al, 1980; Bonora et al, 2001; Rohlfing et al, 2002; Derr et al, 2003), even in type 1 diabetes where the glucose levels show wide oscillations. There is no evidence that HbA<sub>1c</sub> is influenced by glycaemic oscillations (Derr et al, 2003) and therefore the HbA<sub>1c</sub> cannot distinguish between a mean level of glycaemia with little variation and one with wide variation around

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- 3. Glycated haemoglobin is a measure of the average blood glucose control over the preceding twoto-three months.

5.5%, for example, may therefore either represent excellent control with a mean blood glucose concentration of 5 mmol/l or poor control with the same mean blood glucose concentration of 5 mmol/l but frequent

HbA<sub>1c</sub> is incapable of assessing hour-byglucose unpredictable levels hypoglycaemia is a significant risk, e.g. type 1 type 2 patients taking insulin secretagogues. (metformin and glitazones) when used without the concomitant use of insulin secretagogues or insulin.

In view of the well recognised limitations with the use of HbA<sub>1C</sub> it is surprising that the UK National Prescribing Centre (2002) has made a general statement that:

Measuring  $HbA_{1c}$  levels is, therefore, likely to provide more information about glycaemic control than day-to-day monitoring of blood glucose' (National Prescribing Centre, 2002).

Moreover, we note that many clinical trials and surveys continue to evaluate diabetes control utilising a variety of different indices and frequencies of monitoring. The continued use of HbA<sub>1c</sub> as the only outcome measure thus ignores the well recognised glycaemic oscillations that occur from day to day, which are a more accurate representation of the individual patient's glycaemic status (e.g. Faas et al, 1997; Evans et al, 1999; Coster et al, 2000).

# the average blood glucose level. An HbA<sub>1c</sub> of

episodes of hypo- and hyperglycaemia. hour changes in blood glucose level, which is often necessary for optimising insulin dosage for the different insulin preparations. It is for this reason that HbA<sub>1c</sub> is unsuitable as a solitary measure of glycaemic control in diabetes patients with highly variable and and type 2 patients on insulin therapy and also HbA<sub>1c</sub> is an important index of long-term control in both type 1 and type 2 patients and can be the sole measure in persons with type 2 diabetes on diet and oral agents that are not normally associated with hypoglycaemia

Fructosamine

Fructosamine is essentially glycated serum protein, mainly albumin, and is formed in an analogous manner to the glycation of haemoglobin (Austin et al, 1999). Since albumin has a half-life of about 17 days, fructosamine is an index of integrated glycaemic control over a much shorter time than HbA<sub>1c</sub>, i.e. over the preceding two weeks or so. In clinical practice, fructosamine has been used as an alternative measure of 'longterm' control, particularly when there is interference with HbA<sub>1c</sub> assays in persons with haemoglobinopathies and when glycaemic control is changing rapidly, such as during pregnancy in people with diabetes (Kilpatrick, 1997; Pickup, 2003). As a measure of long-term control in diabetes, it has the same provisos as HbA<sub>1c</sub>, being insensitive to blood glucose variations.

The measurement of fructosamine is now less often used than HbA<sub>1c</sub>. HbA<sub>1c</sub> has a wellestablished place in the assessment of overall diabetes control (Diabetes Control and Complications Trial [DCCT] Research Group, 1993; United Kingdom Prospective Diabetes Study [UKPDS] Group, 1998) and is regarded as the primary indicator for assessing risk of developing diabetes-related complications due to dysglycaemia.

#### Urine glucose

Urine glucose testing used to be the routine method of assessing diabetes control before the advent of SMBG. It is an extremely unreliable measure of blood glucose levels (Tattersall and Gale, 1981) and has largely been abandoned.

Glycosuria occurs when the renal threshold for glucose is exceeded, which is usually 10 mmol/l. The threshold varies between individuals and to a lesser extent within the same person from day to day. Therefore, marked hyperglycaemia may well occur without the presence of glycosuria. The presence of a high threshold, or marked

- 1. HbA<sub>1c</sub> is incapable of assessing hour-by-hour changes in blood glucose level, which is often necessary for optimising insulin dosage for the different insulin preparations.
- 2. It is for this reason that HbA<sub>1c</sub> is unsuitable as a solitary measure of glycaemic control in diabetes patients with highly variable and unpredictable glucose levels when hypoglycaemia is a significant risk.
- 3. The continued use of HbA<sub>1c</sub> as the only outcome measure thus ignores the well recognised glycaemic oscillations that occur from day to day, which are a more accurate representation of the individual patient's glycaemic status.

glycosuria may be evident during periods of normal blood glucose due to a reduced renal threshold for glucose, e.g. during pregnancy. The urine glucose can also be affected by fluid intake by concentrating or diluting the urine. The urine glucose result does not reflect the blood glucose concentration at the time of testing and only approximates over the time that the urine has been produced (American Diabetes Association [ADA], 2003).

Therefore, urine glucose concentration is a very crude indicator of glycaemic control in persons with diabetes. It has largely been abandoned and replaced by  $HbA_{1c}$  measurements, supplemented by SMBG as deemed necessary in the circumstance (Owens et al, 2004).

### The new General Medical Services (nGMS) Contract and SMBG: A surprising deficiency

The new GP contract was introduced in the UK in April 2004 (British Medical Association, 2004). It has a Quality and Outcomes Framework, which rewards GPs for achieving levels of process and outcome in various domains. There are 99 points that can be achieved through the fulfilment of 18 indicators in the clinical sphere of diabetes. None specifically mentions blood glucose monitoring. However, 27 of the points relate to HbA<sub>1c</sub> levels, of which 16 points will be awarded for achieving an HbA<sub>1c</sub> of 7.4% or less in 50% of the people with diabetes on the practice register, and 11 points for obtaining a HbA<sub>1c</sub> of 10% or less in 85%.

SMBG is an essential procedure in any attempt to achieve these important treatment goals (HbA<sub>1c</sub> targets). It can enable those with poor overall glycaemic control to monitor their day-to-day blood glucose levels, and understand the relationship between their prescribed treatment, food intake and physical activity. It also enables concordance between these various factors to achieve near normoglycaemia while avoiding

hypoglycaemia. For people with diabetes who require insulin treatment, blood glucose monitoring is mandatory to enable appropriate insulin dose adjustments to be made to optimise glycaemic control and achieve the  $HbA_{1c}$  targets stated in the Quality and Outcomes Framework.

# Differences in patterns of glycaemic control in type 1 and type 2 diabetes

As has been discussed, in patients with type 2 diabetes, blood glucose levels tend to be more predictable on a day-to-day basis, with no wide swings in blood glucose concentration, as are so commonly seen in patients with type 1 diabetes (Pickup, 2003).

There other well-recognised are differences between these two major types of diabetes which are relevant to these discussions. The UKPDS showed clearly that type 2 diabetes is a progressive disease, with gradual and almost inevitable deterioration in glycaemic control over time (UKPDS Group, 1998) requiring adjustments to be made in therapy and accompanying monitoring. In contrast, patients with type 1 diabetes have essentially similar monitoring requirements to achieve satisfactory levels of diabetes control, based on HbA<sub>1c</sub> and SMBG over many years, even decades.

In patients with type 2 diabetes, disease progression has not been shown to be influenced by commonly used hypoglycaemic agents, i.e. metformin, sulphonylureas or even insulin (UKPDS Group, 1998). Preliminary studies with insulin sensitisers (e.g. glitazones) suggest that preservation of glycaemic control in subjects with type 2 diabetes may be more feasible. The future involvement of other agents such as GLP-1 analogues or DPPIV inhibitors may be important, although much more work needs to be done in this 2004; Serdy (Campbell,

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- It has largely been abandoned and replaced by HbA<sub>1c</sub> measurements, supplemented by SMBG as deemed necessary.
- 3. None of the clinical indicators in the nGMS contract specifically mentions blood glucose monitoring. However, 27 of the points available in diabetes relate to HbA<sub>1c</sub> levels.
- 4. SMBG is an essential procedure in any attempt to achieve these important treatment goals.
- 5. It can enable those with poor overall glycaemic control to monitor their day-to-day blood glucose levels and understand the relationship between their prescribed treatment, food intake and physical activity.

Table 1. Location of workshops and attendance		
Location	Number of attendees	
Birmingham	41	
London	48	
Manchester	44	
York	50	
Cardiff	53	
Glasgow	56	
Total	292	

Abrahamson, 2004; Habener, 2001).

For the above reasons, particularly in the context of primary care, management of glycaemic control should be considered differently for persons with type 1 and the majority of people with type 2 diabetes.

## Opportunistic testing two weeks prior to a clinic visit

When the person with diabetes is unable or unwilling to perform regular SMBG, consideration should be given to requesting the patient to carry out monitoring during the two weeks prior to a clinic visit. In the absence of more comprehensive data, this option, although limited, could form some basis for discussion with the patient during the clinic appointment.

Table 2. Distribution by role of attendee		
Role	Number of attendees	%
DSN	130	44.5
GP	13	4.5
PCT	13	4.5
Hospital Clinician	7	2.4
Other Primary Care	13	4.5
Other Secondary Care	43	14.7
District/Practice Nurse	42	14.4
Other	24	8.2
Hospital Nurse	7	2.4
Total	292	100

#### Frequency of testing in pregnancy

In type 1 diabetes, poor glycaemic control at the time of conception and during pregnancy adversely influences the outcome (Temple et al, 2002; Evers et al, 2004, Jensen et al, 2004). Daily SMBG is associated with lower HbA<sub>1c</sub> values and a lower incidence of adverse outcomes such as congenital malformation (de Veciana et al, 1995; Jensen et al, 2004). The optimal frequency and timing of blood glucose testing in pregnancy has yet to be established (Homko and Reece, 2002). Current recommendations on the frequency of SMBG during pregnancy are therefore based largely on expert opinion rather than trial evidence (Homko and Reece, 2002). The recommended frequency of testing is similar in gestational diabetes treated with diet, as for those on insulin.

Diabetes UK advises that pregnant women should measure their blood glucose frequently (Diabetes UK, 2004). More specifically, however, guidance from the Scottish Intercollegiate Guidelines Network (SIGN) recommends maintaining blood glucose within the range of 4-7 mmol/l, and suggests that this will require carrying out SMBG 4-6 times daily (SIGN, 2001). The ADA does not stipulate the frequency of SMBG, but suggests aiming preprandial values for 3.9-5.6 mmol/l and two-hour postprandial values of <7.8 mmol/l during the preconceptual period (ADA, 2002). The risk of hypoglycaemia is greatest in the first trimester (Evers et al, 2002), so more frequent testing may be necessary at this and other times during pregnancy to improve glycaemic control whilst avoiding hypoglycaemia.

# SMBG in patients with type 2 diabetes on diet and exercise

It is widely recognised that  $HbA_{1c}$  measurements in type 2 diabetes treated by diet and exercise alone, and by metformin and glitazones, are a good guide to the status of diabetes control, and the recommended

frequency of this test is 3-6 monthly (UKPDS Group, 1998). This, however, may not always be carried out routinely in primary care, and in other circumstances where HbA<sub>1c</sub> testing is not available, SMBG is the preferred substitute for monitoring glycaemic control. Patients may be exposed to increasing blood glucose levels without much change in HbA<sub>1c</sub> during the early phase of type 2 diabetes. Bonora et al (2001) found that many type 2 patients had a postprandial blood glucose >8.9 mmol/l even when HbA<sub>1c</sub> was below 7%. It is therefore important to recognise not only the relentless progression of type 2 diabetes but also perhaps the subtle changes in glycaemic control that can be detected by SMBG.

Educating patients on the principles of SMBG should not be in isolation but as an integral part of the patient's self-care plan, taking into consideration the individual's knowledge, abilities, needs and fully informed choice (Department of Health, 2002).

Diabetes education includes motivating the patient to carry out lifestyle changes such as increased activity, improved diet and weight management to avoid obesity. There is plenty of evidence to suggest that newly diagnosed type 2 patients can achieve substantial improvement in their HbA<sub>1c</sub> levels initially, but unfortunately this is not sustained in the medium- to long-term due to the lack of adherence and motivation (UKPDS, 1998). SMBG may have a role in educating the patient about the impact of certain foods and exercise patterns. Knowing the pre- and postexercise blood glucose level allows an individual to recognise the benefits of increased activity, and to achieve these safely. For the obese person with diabetes, a reduction in weight will result in lower blood glucose, which in the self-monitored patient may increase motivation and encourage the individual to continue to improve. In the patient who is empowered but indulges in occasional dietary indiscretions, SMBG may

Table 3. Distribution by healthcare sector			
Sector	Number of attendees	%	
Primary care	69	23.6	
Secondary care	178	61.0	
Other	45	15.4	
Total 292 100			

alert them to the adverse consequences on blood glucose levels and the need to 'come back on track'.

Evidence in this area is currently sparse, but there is support for the notion that mealrelated SMBG can improve at least some patients with type 2 diabetes (Schwedes et al, 2002).

# SMBG in children and adolescents with diabetes

NICE guidelines state that children and young people with diabetes should be encouraged to perform frequent blood glucose monitoring because this is associated with improved HbA<sub>1c</sub> levels (NICE, 2004). Unfortunately, optimal glycaemic control is rarely achieved in children and young people with diabetes (Mortensen and Hougaard, 1997). Variable eating habits and exercise patterns (particularly in younger children), insulin resistance during puberty (Raine et al, 2001) and psychosocial problems during adolescence can contribute to erratic blood glucose control.

Table 4. Levels of agreement with the original 32 consensus statements

	Beginning of session	After debate
Mean (proportion agreement	81 %	85 %
with with original 32 statements)		
Number of statements where	30/32	31/32
consensus was greater than 50 %		
Number of statements where	22/32	25/32
consensus was greater than 75 %		

Table 5. Staten	nents requiring review
Number	Original statement
6	'For patients with type 1 diabetes, monitoring
	should take place four or more times per day to
	prevent hypoglycaemia and control
	hyperglycaemia'
14	'Glycaemic control is generally less stable in
	people with type 1 diabetes than those with type
	2 diabetes'
16	'Frequent testing during the two weeks prior to a
	clinic visit will provide the patient and the
	clinician with detailed data from which to better
	assess current glycaemic control'
17	'Pregnant women who can achieve glycaemic
	control through diet alone should monitor their
	blood glucose at least once every two days
	including fasting and 1 h postprandial'
22	'Stable glycaemic control in people with type 2
	diabetes managed through diet and exercise does
	not require routine blood glucose monitoring'

Page points

- 1. During 2004, a series of six workshops were held across the UK, attended by diabetes care professionals to debate the original 'Consensus Guidelines'.
- At each workshop, two identical questionnaires relating to SMBG were issued to all attendees, one at the beginning of the session and one after the debate.
- 3. The questionnaires were designed to assess the level of agreement with the 32 original 'consensus' statements.

In childhood diabetes, poor glycaemic control has many consequences over and above those applicable to the adult population. In addition to the increased risk of complications in later life, poor diabetes control can adversely affect children's growth and development. Although the relationship between abnormal growth and development and metabolic control is difficult to define (Dunger, 1994), inadequate insulin therapy can cause delayed puberty and impaired growth (Raine et al, 2001).

Therefore, children and young people with diabetes should adjust their insulin dosage requirements according to their blood glucose measurements (NICE, 2004). The recommendations for blood glucose monitoring for adult people with type 1 diabetes equally apply to the paediatric population.

# Regional meetings to debate the 'Consensus Guidelines'

During 2004, a series of six workshops were

held across the UK, attended by diabetes care professionals to debate the original 'Consensus Guidelines' (Owens et al, 2004). A total of 307 delegates from several diabetes-related disciplines attended the meetings (see below). Feedback from the regional meetings revealed that 96% of delegates felt they had benefited from the discussions during the workshops and that 88% planned to make changes to their working practice as a direct result.

The workshop programme also allowed discussion of both local and national issues relating to diabetes care, providing input to the debate for the purpose of achieving a consensus on SMBG. At each workshop, two identical questionnaires relating to SMBG were issued to all attendees, one at the beginning of the session and one after the debate. The questionnaires were designed to assess the level of agreement with the 32 original 'consensus' statements (Owens et al, 2004). Out of 307 participants, the final sample consisted of 292 participants who submitted completed questionnaires.

*Table 1* demonstrates that there were a similar number of participants at each meeting.

Distribution of attendees by role and healthcare sector is shown in *Tables 2* and *3*. The majority of workshop attendees were DSNs, who are the most actively involved professional group in the day-to-day practice of SMBG (*Table 2*).

Following discussion at the workshops, it was observed that for half of the original 'consensus' statements there was agreement of greater than 90 % (+/- 3.4 %, 95 % CI) and for over three quarters, agreement of greater than 70 % (+/- 5.2 %, 95 % CI) was observed.

The debate concerning SMBG resulted in a higher level of agreement (*Table 4*). Further evaluation of the dataset revealed significant differences in levels of agreement between DSNs and PCT staff who attended the debating sessions.

The difference of opinion, demonstrated across the different professional groups

supports the need for continuing dialogue between the clinical and managerial arms of each PCT/LHB. As a basis for such discussion, a policy statement would serve to ensure that there is equity of care with respect to SMBG nation-wide.

The questionnaires provided the participants with the facility to record their objections to any of the original statements and provide alternative wordings. Following a thorough review of the comments, it was found that most of the disagreements were semantic, rather than conceptual, although a number of suggested changes and amendments were proposed. A structured approach was adopted to finalise the five statements which were in the bottom quartile with regard to level of agreement, and for which the respondents registered the greatest number of objections (*Table 5*).

A third questionnaire was mailed to the 292 participants, who were asked to rank their preference for proposed new wordings for each of the five statements by scoring each new wording from 1-5 according to preference. One-hundred-and-thirty-eight (47.3%)completed questionnaires were received. The responses were analysed by summating the ranking for each statement, so that if a respondent gave two or more options the same ranking, analysis would reflect the equal standing of these options. The frequency distribution for each option with respect to the different ranks was used to assess the level of consensus and indicate the most preferred wording for each of the statements.

This 'consensus' group reviewed all of the suggested alternatives and amended where felt necessary the wording of the original statements (*Table 6*).

The revised consensus guidelines are contained in *Appendix 2*, where they are presented and expanded into a table to include the full 32 position statements. These are intended as recommendations to healthcare professionals on SMBG in persons with diabetes.

Table 6. Amen	ded wordings for statements
Number	Amended statement
6	'The majority of patients with type 1 diabetes
	should consider SMBG four or more times
	per day to prevent hypoglycaemia and control
	hyperglycaemia'
14	'In general, blood glucose concentrations
	fluctuate more widely in people with type 1
	diabetes than those with type 2 diabetes'
16	'In the absence of regular testing by the patient,
	more frequent blood glucose measurements
	during the two weeks before a clinic visit may
	provide the patient and the clinician with more
	information to assess current glycaemic control'
17	'Pregnant women with type 1 diabetes, plus those
	with type 2 diabetes requiring insulin and
	diet-treated patients with gestational diabetes or
	those requiring insulin should monitor their blood
	glucose at least four times per day to include both
	fasting and postprandial blood glucose
	measurements'
22	'Patients with type 2 diabetes managed only on
	diet and exercise do not normally require routine
	blood glucose monitoring. Informed patients
	may choose SMBG as a means of monitoring
	lifestyle changes'

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- American Diabetes Association (2003). Test of glycemia in diabetes. *Diabetes Care* **26**: S106–8
- American Diabetes Association (2002) Position Statement: Preconception care of women with diabetes. *Diabetes Care* **25** (Suppl 1): S82–S84
- Austin GE, Wheaton R, Nanes MS, Rubin J, Mullins RE (1999) Usefulness of fructosamine for monitoring outpatients with diabetes. *American Journal of Medical Sciences* **318**: 316–23
- Avignon A, Radauceanu A, Monnier L (1997). Nonfasting plasma glucose is a better marker of diabetic control than fasting plasma glucose in type 2 diabetes. *Diabetes Care* 20: 1822–26
- British Medical Association (2004) Investing in general practice: the new general medical services contract. Available at http://www.bma.org.uk/ap.nsf/Content/investinggp (accessed 17.03.05)
- Bonora E, Calcaterra F, Lombardi S, Banfante N, Formentini G, Bonadona RC, Muggeo M (2001). Plasma glucose levels throughout the day and HbA1c interrelationships in type 2 diabetes. *Diabetes Care* 24: 2023–29
- Campbell IW. (2004) Long-term glycaemic control with pioglitazone in patients with type 2 diabetes. *International Journal of Clinical Practice* **58**(2): 192–200
- Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R (2000). Self-monitoring in type 2 diabetes mellitus: a meta-analysis. *Diabetic Medicine* 17: 755–61
- de Veciana M. Major CA. Morgan MA. Asrat T. Toohey JS. Lien JM. Evans AT (1995) Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy. New England Journal of Medicine 333(19): 1237–41
- Derr R, Garrett E, Stacy GA, Saudek CD (2003). Is HbA1c affected by glycemic instability? *Diabetes Care* **26**: 2728–33
- Department of Health (2002) National Service Framework for Diabetes. DoH, London. Available at: http://www.publications.doh.gov.uk/nsf/diabetes/(accessed 17.03.05)
- 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. *New England Journal of Medicine* **329**: 977–86
- Diabetes UK (2004) Care Recommendation: Recommendation for the management of pregnant women with diabetes (including gestational diabetes). Diabetes UK, London. Available at www.diabetes.org.uk/ infocentre/carerec/preg4.doc. (accessed on 17.03.05)
- Dunger DB (1994) Endocrine evolution, growth and puberty in relation to diabetes. In Kelnar C J H (ed) Childhood and Adolescent Diabetes. Chapman & Hall Medical, London: 75–87
- Evans JMM, Newton RW, Ruta DA, MacDonald TM, Stevenson RJ, Morris AD (1999). Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. *British Medical Journal* 319: 83–68
- Evers IM, de Valk HW, Visser GH. (2004) Risk of complications of pregnancy in women with type 1 diabetes: nationwide prospective study in the Netherlands. *British Medical Journal* 328: 915–19
- Evers IM, ter Braak EW, de Valk HW, van der Schoot B, Janssen N, Visser GH. (2002) Risk indicators predictive for severe hypoglycemia during the first trimester of type 1 diabetic pregnancy. *Diabetes Care* **25**: 554–59
- Faas A, Schellevis FG, van Eijk JT (1997). The efficacy of self-monitoring of blood glucose in NIDDM subjects: A criteria-based literature review. *Diabetes Care* 20:

- 1482-86
- Gonen B, Rochman H, Rubenstein AH (1979). Metabolic control in diabetic patients: assessment by hemoglobin A1 values. Metabolism 28(4 Suppl 1): 448–52
- Habener J (2001) Glucagonlike peptide-1 agonist stimulation of ß-cell growth and differentiation. *Current Opinion in Endocrinology and Diabetes* **8**: 74–81
- Holman RR, Turner RC (1981). The basal plasma glucose: a simple index of maturity-onset diabetes. Clinical Endocrinology 14: 275–86
- Homko CJ, Reece EA. (2002) Self-monitoring of blood glucose in gestational diabetes. *Journal of Maternal and Neonatal Medicine* 12: 389–95
- Jensen DM, Damm P, Moelsted-Pedersen L, Ovesen P, Westergaard JG, Moeller M, Beck-Nielsen H (2004) Outcomes in type 1 diabetic pregnancies: A nationwide, population-based study. *Diabetes Care* 27: 2819–23
- Karter AJ, Ackerson LM, Darbinian JA, D'Agostino RB Jr,
   Ferrara A, Liu J, Selby JV (2001) Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry.
   American Journal of Medicine 111: 1–9
- Kilpatrick ES (1997). Problems in the assessment of glycaemic control in diabetes mellitus. *Diabetic Medicine* 14: 819–31
- McCance DR, Ritchie CM, Kennedy L (1988). Is HbA1 measurement superfluous in NIDDM? *Diabetes Care* 11: 512–14
- Monnier L, Lapinski H, Colette C (2003) Contributions of fasting and postprandial plasma glucose increments to the overall diurnal hyperglycemia of type 2 diabetic patients. *Diabetes Care* **26**: 881–85
- Mortensen HB, Hougaard P (1997). Comparison of metabolic control in a cross-sectional study of 2,873 children and adolescents with IDDM from 18 countries. The Hvidore Study Group on Childhood Diabetes. *Diabetes Care* **20**(5): 714–20
- National Institute for Clinical Excellence (NICE) (2004)

  Type 1 diabetes: diagnosis and management of type 1 diabetes in children and young people. NICE, London.

  Available at www.nice.org.uk/page.aspx?o=213902 (accessed 17.03.05)
- NICE (2002) Management of type 2 diabetes Managing blood glucose levels (Guideline G). NICE, London. Available at http://www.nice.org.uk/page.aspx?o=36738 (accessed 17.03.05)
- National Prescribing Centre (2002) When and how should patients with diabetes mellitus test blood glucose? MeReC Bulletin 13(1). Available at http://www.npc.co.uk/MeReC\_Bulletins/2002Volumes/vol13no1.pdf (accessed 17.03.05)
- Owens D, Barnett AH, Pickup J, Kerr D, Bushby P, Hicks D et al (2004). Blood glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus. *Diabetes and Primary Care* **6**: 8–16
- Paisey RB, Macfarlane DG, Sherriff RJ, Hartog M, Slade RR, White DA (1980) The relationship between blood glycosylated haemoglobin and home capillary blood glucose levels in diabetics. *Diabetologia* **19**(1): 31–4
- Pickup JC (2003). Diabetic control and its measurement. In: Pickup JC and Williams G (Eds), *Textbook of Diabetes*, 3rd Edition. Blackwell Publishing, Oxford: 34.1–34.17
- Raine JE, Donaldson MDC, Gregory JW, Savage MO (2001) *Practical endocrinology and diabetes in children*. Blackwell Science, Oxford
- Rhondda Cynon Taff Local Health Board (2004) *Diabetes Desktop Guidelines*. Rhondda Cynon Taff Local Health Board, Treforest
- Rohlfing CL, Wiedmeyer H-M, Little RR, England JD,

- Tennill A, Goldstein DE (2002). Defining the relationship between plasma glucose and HbA1c in the Diabetes Control and Complications Trial. *Diabetes Care* **25**: 275–78
- Sachedina N, Pickup JC (2003) Performance assessment of the Medtronic-MiniMed Continuous Glucose Monitoring System and its use for measurement of glycaemic control in type 1 diabetic subjects. *Diabetic Medicine* **20**: 1012–15
- Scottish Intercollegiate Guidelines Network (SIGN) (2001) Section 8: Management of diabetes in pregnancy In: SIGN Publication No 55: Management of diabetes. SIGN, Edinburgh: 34–38
- 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
- Serdy S, Abrahamson MJ (2004) Durability of glycemic control: a feature of the thiazolidinediones. *Diabetes Technology & Therapeutics* **6**(2): 179–89.

- Tahara Y, Shima K (1995). Kinetics of HbA1c, glycated albumin and fructosamine and analysis of their weight functions against preceding plasma glucose level. Diabetes Care 18: 440–47
- Tattersall RB, Gale E (1981). Patient self monitoring of blood glucose and refinements of conventional insulin treatment. *American Journal of Medicine* **70**: 177–82
- Temple R, Aldridge V, Greenwood, R, Heyburn P, Sampson M, Stanley, K. (2002) Association between outcome of pregnancy and glycaemic control in early pregnancy in type 1 diabetes: population based study. *British Medical Journal* 325: 1275-76
- UK Prospective Diabetes Study 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
- Wycombe PCT Diabetes Testing Steering Group (2005) Now You Are Monitoring Blood Glucose – What Next? Wycombe PCT, High Wycombe

#### Appendix 1. General advice regarding self-monitoring of blood glucose (SMBG)

- The most important principles for establishing SMBG in patients with type 1 or type 2 diabetes must be to improve the quality and stability of glycaemic control and the avoidance of hypoglycaemia
- In general, blood glucose concentrations fluctuate more widely in people with type 1 diabetes than those with type 2 diabetes
- Appropriate training and education is required so that people with diabetes can through SMBG understand their diabetes and safely adjust their lifestyle and insulin doses according to their SMBG results
- Good glycaemic control is essential to minimise the risk of short-term (hyper- and hypoglycaemia) and long-term (vascular) complications relating to diabetes
- Individual patients should be made aware of the importance of SMBG in recognition of the evidence emanating from the DCCT (type 1 diabetes) and UKPDS (type 2 diabetes)
- SMBG has an essential role to play in ensuring the safety and efficacy of blood glucose lowering therapies
- The provision of materials for SMBG is key to patient empowerment and to ensure the achievement of good glycaemic control safely
- Drivers with diabetes should SMBG before commencing any journey and at regular intervals on long journeys
- Depending on the treatment regimen, knowledge of actual pre-meal and/or post-meal blood glucose levels is needed to avoid hyperglycaemia and prevent hypoglycaemia
- Any change in blood glucose lowering therapy requires SMBG to ensure safety (avoidance of hypoglycaemia) while optimising effectiveness
- Reliance on subjective assessment of blood glucose levels is unhelpful
- Patients receiving terminal care will require monitoring to ensure that they avoid hypoglycaemia and/or periods of excessive hyperglycaemia
- People with diabetes who are in coronary care units should be monitored using hospital laboratory facilities
- All people with type 1 diabetes should have access to SMBG at least four times per day as required
- People with type 2 diabetes have different SMBG requirements depending on their treatment regimen (see Appendix 2)
- In the absence of regular testing by the patient, more frequent SMBG measurements during the two weeks before a clinic visit may provide the patient and the clinician with more information to assess current glycaemic control

Diabetes type	Treatment group	Monitoring regimen
Type 1 diabetes	All people with type 1 diabetes	<ul> <li>SMBG should be regarded as an integral part of treating all people with type 1 diabetes</li> <li>People with type 1 diabetes should be educated to SMBG and adjust treatment appropriately</li> <li>The majority of patients with type 1 diabetes should consider SMBG four or more times per day to prevent hypoglycaemia and control hyperglycaemia</li> <li>To avoid metabolic emergencies such as diabetic ketoacidosis may require frequent SMBG</li> </ul>
Diabetic pregnancy	Diabetic pregnancy	<ul> <li>Pregnant women with type 1 diabetes, plus those with type 2 diabetes requiring insulin and patients with gestational diabetes requiring insulin should SMBG at least four times per day to include both fasting and postmeal blood glucose measurements</li> <li>In diet-treated patients it may be necessary to SMBG with the same frequency as insulin-treated patients to ensure strict glycaemic control</li> <li>In insulin-treated patients increased frequency of testing may be necessary in the first trimester when the risk of hypoglycaemia is greatest</li> </ul>
Type 2 diabetes	Intensive insulin therapy	<ul> <li>People who adopt intensive insulin therapies require regular feedback regarding SMBG levels</li> <li>People with type 2 diabetes who use a multiple daily insulin regimen should SMBG in the same way as those with type 1 diabetes</li> <li>Fasting blood glucose should be tested daily during basal insulin dose titration</li> </ul>
Type 2 diabetes	Conventional insulin therapy	• People with type 2 diabetes who are using a conventional insulin regimen and who have stable control should SMBG two or three times a week
continues on page 2	21	

Appendix 2 (continued). Recommendations regarding self-monitoring of blood glucose (SMBG)		
Diabetes type	Treatment group	Monitoring regimen
Type 2 diabetes	Conventional insulin therapy (continued)	<ul> <li>People with type 2 diabetes who are using a conventional insulin regimen and who have less stable control should SMBG at least once daily, varying the time of testing between fasting, premeal and postmeal</li> <li>Fasting blood glucose should be tested daily during basal insulin dose titration</li> </ul>
Type 2 diabetes	Combined insulin and oral antidiabetic therapy	<ul> <li>Fasting blood glucose should be tested daily during basal insulin dose titration</li> <li>People with type 2 diabetes who use insulin or oral hypoglycaemic agents should SMBG at least once daily, varying the time of testing between fasting, premeal and postmeal</li> </ul>
Type 2 diabetes	Diet and exercise	<ul> <li>People with type 2 diabetes who have good control on diet and exercise, metformin or glitazone treatment do not need SMBG monitoring, unless they are destabilised by other factors</li> <li>Glycaemic control managed through diet and exercise in people with type 2 diabetes is best monitored through HbA<sub>1c</sub> testing</li> <li>Patients with type 2 diabetes managed only on diet and exercise do not normally require routine SMBG. Informed patients may choose SMBG as a means of monitoring lifestyle changes</li> </ul>
Type 2 diabetes	Metformin (+/- glitazone)	As for diet and exercise
Type 2 diabetes	Glitazone (+/- metformin)	As for diet and exercise
Type 2 diabetes	Sulphonylurea alone (or in combination with other oral antidiabetic agents)	• Hypoglycaemia may be more common than assumed in people with type 2 diabetes on sulphonylureas and SMBG will reveal this situation