Traditional agents for controlling the levels of glucose in the blood remain important therapies but have their downside from the point of view of tolerability and side effects. Moreover, they appear not to be able to counter the natural history deterioration of the disease in terms of the onset of diabetic-related complications.

Recent years have seen an influx of new treatment therapies and technologies aimed at achieving better glycaemic control for diabetic patients such as liraglutide, saxagliptin and insulin pumps, away from the more traditional therapies such as classic insulin therapy and oral hypoglycaemics.

Advanced Technologies and Treatment for Diabetes 3rd Edition brings together and critically analyses the last year’s most important articles published in the world’s leading medical journals on this topic. Chapters are focused on the most current hot topic areas such as:

– New methods of insulin delivery
– Internet and IT use in treatment of diabetes
– Closing the loop-artificial pancreas
– Immunotherapy for type 1 diabetes

Each chapter will include abstracts of the published articles, scientific conclusions made, as well as annotations and a comments and analysis section from the relevant chapter editor, each of whom is a well-known expert in the field.

Advanced Technologies and Treatment for Diabetes 3rd Edition will be essential reading for research scientists in diabetes, endocrinology and metabolism, as well as specialist endocrinologists involved with the frontline care of diabetic patients.
ATTD 2011 Yearbook
ATTD 2011 Yearbook
Advanced Technologies & Treatments for Diabetes
Third Edition

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Preface

This is the third ATTD Yearbook and by now we already know that the book makes its way to the hands of many clinicians, diabetes educators and researchers in academic institutes and to the members of the diabetes industry as well as many others interested in changing the life of people with diabetes all over the world. The availability of the book on the ATTD webpage and in PubMed facilitates access to anybody in the world interested in new technologies and therapies in diabetes. Also this year, the book consists of short summaries of selected papers published in peer-reviewed journals, between July 2010 and June 2011, with comments from the associate editors and editors bringing their expert insight to the reader.

The improvement in quality of life and life expectancy of people with diabetes increasingly depends on the success of innovative people in academia and industry to develop new technologies. This accomplishment is in turn crucially related to the interaction between different disciplines of research collaborating in the endeavour to solve the challenges diabetes presents to patients, caregivers, researchers and the industry. Professional interactive relationships between academia and industry will facilitate progress in the field and will lead not only to great innovations but also to their availability for routine clinical care.

We hope that the ATTD meeting and the present ATTD Yearbook will help to raise the attention and facilitate the communication of all interested parties in the field of diabetes for the ultimate benefit of our patients.

Moshe Phillip
Tadej Battelino
CHAPTER 1

Self-Monitoring of Blood Glucose

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INTRODUCTION

Diabetes prevalence is increasing globally especially in the Asian subcontinent. It is expected that by the year 2030 there may be close to 400 million people with diabetes. All of the research in the past 25 years has clearly documented the effectiveness of improving glucose control in reducing long-term complications of diabetes, both microvascular and macrovascular. The improvement in glucose control usually requires continuous intensive diabetes management, particularly in insulin-requiring patients, which \textit{must} include home self-monitoring of blood glucose (SMBG). Despite the convincing evidence, the role of SMBG in diabetes management is still being debated even though its availability in the past 35 years has revolutionised diabetes care, especially at home.

The International Diabetes Federation (IDF) recently published guidelines for SMBG use in non-insulin-treated diabetic patients, recommending that SMBG should be used only when patients and/or their clinicians possess the ability, willingness and knowledge to incorporate SMBG and therapy adjustment into their diabetes care plan. The IDF also recommends that structured SMBG be performed with the choice of applying different defined blood glucose testing algorithms to patients’ individual diabetes care plans. These defined blood glucose testing algorithms give SMBG a medically meaningful structure to collect high quality glucose information and are called structured SMBG. Former SMBG studies have demonstrated SMBG to be beneficial when patients receive feedback regarding the impact of their behaviours on SMBG.
results. Other studies which did not link SMBG results to these principal behaviours have shown no SMBG benefit. A new wave of clinical studies performed after the release of the IDF guideline have recently been published and have proved the success of the new application of SMBG.

The reasons for this ongoing debate may in part be due to rising healthcare costs globally, lack of convincing data in non-insulin-requiring patients with type 2 diabetes in randomised controlled clinical trials and multiple controversial meta-analyses performed on several studies. Sometimes the decisions are extended to insulin-requiring patients, even those with type 1 diabetes. For example, last year in the state of Washington in the USA, legislators were going to stop reimbursing glucose test strips for children with type 1 diabetes. After much debate with committee members (who were not diabetologists and or endocrinologists) and law makers, not only SMBG but even in some cases continuous glucose monitoring (CGM) is now reimbursed. The issue was simply educating non-understanding but well-meaning people whose main concern is saving money. In the end, no one, even those not familiar with paediatric type 1 diabetes, can disagree about the need for SMBG in this age group.

It seems to us that we should instead be spending our time and effort in advancing the field and improving diabetes management for patients through newer technologies like CGM and closed-loop systems. As discussed in the section on CGM (Chapter 2) there is ample data from both non-randomised and randomised clinical trials showing the efficacy in reducing time spent in hypoglycaemia and hyperglycaemia along with improvement in glucose control without introducing any additional medication. We hope that the future will be spent in advancing the care rather than useless meta-analyses or going back in time. It is worthwhile to review existing evidence about SMBG to learn, transfer and apply knowledge about the core requirement for good diabetes management, glucose information.

Non-coding glucometers among paediatric patients with diabetes: looking for the target population and an accuracy evaluation of no-coding personal glucometer

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Pediatr Endocrinol Diabetes Metab 2011; 17: 57–63
Background
SMBG is one of the major components of diabetes management.

Aims
To evaluate the potential for miscoding of a personal glucometer, to define a target population among paediatric patients with diabetes for a non-coding glucometer and to assess the accuracy of the Contour TS non-coding system.

Methods
Potential for miscoding during SMBG was evaluated by means of an anonymous questionnaire, with worst and best case scenarios evaluated depending on the response pattern. Testing of the Contour TS system was performed according to the national committee for clinical laboratory standards guidelines.

Results
The estimated frequency of individuals prone to non-coding ranged from 68.21% [95% confidence interval (CI) 60.70%–75.72%] to 7.95% (95% CI 3.86%–12.31%) for the worse and best case scenarios, respectively. Factors associated with increased likelihood of non-coding were a smaller number of tests per day, a greater number of individuals involved in testing and self-testing by the patient. The Contour TS device showed intra-and inter-assay accuracy of –95%, a linear association with laboratory measurements ($R^2 = 0.99$, $p < 0.0001$) and small bias of –1.12% (95% CI –3.27% to 1.02%). Clarke error grid analysis showed 4% of values within the benign error zone (B) with the other measurements yielding an acceptably accurate result (zone A).

Conclusions
The Contour TS system showed sufficient accuracy to be safely used in the monitoring of paediatric patients with diabetes. Patients from families with a high throughput of test-strips or multiple individuals involved in SMBG using the same meter are candidates for clinical use of such devices due to an increased risk of calibration errors.

COMMENT
This study further highlights the role of making SMBG simpler and easier so that patients can monitor the glucose more effectively. The current study used the Contour TS system which does not require coding by the patient and thus removes the barrier of mis-coding of SMBG. We personally think that all meters going forward must be non-coding meters.
Effect of ambient temperature on analytical performance of self-monitoring blood glucose systems

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Background
Analytical quality of SMBG can be affected by environmental conditions.

Aims
To determine the influence of a shift in the ambient temperature immediately before measurement and taking measurements in the lower and upper part of the operating temperature range.

Methods
Different SMBG systems (n = 9) available on the Norwegian market were tested with heparinised venous blood (4.8 and 19.0 mmol/l). To test the effect of a shift in ambient temperature, the glucometer and strips were equilibrated for 1 h at 5 °C or 30 °C before the meter and strips were moved to room temperature, and measurements were performed after 0, 5, 10, 15 and 30 min. To test the lower and upper temperature range, measurements were performed at 10 °C and at 39 °C after 1 h for temperature equilibration of the glucometer and strips. All the measurements were compared with measurements performed simultaneously on a meter and strips kept the whole time at room temperature.

Results
Six of nine SMBG systems overestimated and/or underestimated results by more than 5% after moving meters and strips from 5 °C or 30 °C to room temperature immediately before the measurements. Two systems underestimated the results at 10 °C. One system overestimated and another underestimated the results by more than 5% at 39 °C.

Conclusions
A rapid shift in the ambient temperature affects analytical performance. Therefore patients need to wait at least 15 min for temperature equilibration of affected meters and strips before measuring blood glucose.
### COMMENT

This study highlights the importance of ambient temperature on analytical performance of SMBG. The study shows that rapid shift in ambient temperature may affect the accuracy and bias in SMBG measurement and highlights the need for 15 min temperature equilibration. In addition to what has been highlighted in the study, future studies also need to assess the accuracy of existing meters (especially the one using glucose oxidase) at higher altitudes (10,000 feet or higher). It is known that many of these meters do not perform well at high altitudes.

### Association between self-monitoring of blood glucose and diet among minority patients with diabetes


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*J Diabetes* 2011; 3: 147–52; Comment in *J Diabetes* 2011; 3: 93–4

### Background

It is unknown whether SMBG can motivate adherence to dietary recommendations.

### Aims

To evaluate if patients who used more SMBG would also report lower fat and greater fruit and vegetable consumption.

### Methods

This was a cross-sectional study of primarily minority individuals living with diabetes in East Harlem, New York ($n = 401$). Fat intake and fruit and vegetable consumption were measured with the Block Fruit/vegetable/fiber and Fat Screeners.
Self-Monitoring of Blood Glucose

Results
Greater frequency of SMBG was associated with lower fat intake \[ r(s) = -0.15; p < 0.01 \], but not fruit and vegetable consumption. The effects of SMBG were not moderated by insulin use. A significant interaction was found between frequency of SMBG and changing one’s diet in response to SMBG on total fat intake.

Conclusions
The frequency of SMBG was associated with lower fat intake. The data suggest that participants who use SMBG to guide their diet do not have to monitor multiple times a day to benefit.

COMMENT
This study further highlights the importance of SMBG in daily lifestyle changes. Subjects with higher frequency of SMBG consumed less fat, in part related to overall education and seeing the impact from making dietary changes on SMBG levels.

Accuracy and precision evaluation of seven self-monitoring blood glucose systems
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Diabetes Technol Ther 2011; 13: 596–600

Background
SMBG systems should at least meet the minimal requirement of the World Health Organization’s ISO 15197:2003. For tight glycaemic control, a tighter accuracy requirement is needed.

Methods
Seven SMBG systems were evaluated for accuracy and precision: Bionime Rightest\textsuperscript{TM} GM550 (Bionime Corp., Dali City, Taiwan), Accu-Chek\textsuperscript{®} Performa (Roche Diagnostics, Indianapolis, IN, USA), OneTouch\textsuperscript{®} Ultra\textsuperscript{®} 2 (LifeScan Inc., Milpitas, CA, USA), MediSense\textsuperscript{®} Optium\textsuperscript{TM} Xceed
Satish K. Garg and Irl B. Hirsch

(Abbott Diabetes Care Inc., Alameda, CA, USA), Medisafe (TERUMO Corp., Tokyo, Japan), Fora® TD4227 (Taidac Technology Corp., Wugu Township, Taiwan) and Ascensia Contour® (Bayer HealthCare LLC, Mishawaka, IN, USA). The 107 participants were 23–91 years old. The analytical results of seven SMBG systems were compared with those of plasma analysed with the hexokinase method (Olympus AU640, Olympus America Inc., Center Valley, PA, USA).

**Results**
The imprecision of the seven blood glucose meters ranged from 1.1% to 4.7%. Three of the seven blood glucose meters (42.9%) fulfilled the minimum accuracy criterion of ISO 15197:2003. The mean absolute relative error value for each blood glucose meter was calculated and ranged from 6.5% to 12.0%.

**Conclusions**
More than 40% of evaluated SMBG systems meet the minimal accuracy criterion requirement of ISO 15197:2003. However, considering a tighter criterion for accuracy of ±15%, only the Bionime Rightest GM550 meets this requirement. Manufacturers have to try to improve accuracy and precision and to ensure the good quality of blood glucose meters and test strips.

**COMMENT**

This study further highlights the need for more accurate SMBG systems. Their data concluded that more than 40% of the evaluated SMBG systems meet the minimum ISO criteria. Since patients use blood glucose information for adjusting their insulin dose and/or treating hypoglycaemia, the accuracy of the glucose meters has to be consistent and improved.

**Self-monitoring of blood glucose: the use of the first or the second drop of blood**

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Self-Monitoring of Blood Glucose

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Diabetes Care 2011; 34: 556–60

Background
There is no agreement regarding the use of the first or second drop of blood for glucose monitoring.

Aims
To investigate whether capillary glucose concentrations, as measured in the first and second drops of blood, differed ≥10% compared with a control glucose concentration in different situations.

Methods
Capillary glucose concentrations were measured in two consecutive drops of blood in 123 patients with diabetes in the following circumstances: without washing hands, after exposing the hands to fruit, after washing the fruit-exposed hands, and during application of different amounts of external pressure around the finger. The results were compared with control measurements.

Results
Not washing hands led to a difference of ≥10% in glucose concentration in the first and in the second drops of blood in 11% and 4% of the participants, respectively. In fruit exposed fingers, these differences were found in 88% and 11% of the participants, respectively. Different external pressures led to ≥10% differences in glucose concentrations in 5%–13% of the participants.

Conclusions
Washing hands with soap and water, drying them, and using the first drop of blood for SMBG is recommended. If washing hands is not possible, it is acceptable to use the second drop of blood after wiping away the first drop. External pressure may lead to unreliable readings.

COMMENT
Over the years we have probably under-emphasised the importance of technique with SMBG. One has to wonder how much iatrogenic hypoglycaemia has occurred due to unintended exposure to glucose on the hands, and how often CGM devices are inaccurate due to poor technique with SMBG use.
**Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, non-insulin-treated type 2 diabetes: results from the Structured Testing Program study**

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*Diabetes Care* 2011; **34**: 262–7

**Aim**

To assess the effectiveness of structured blood glucose testing in poorly controlled patients with type 2 diabetes without insulin treatment.

**Methods**

A 12-month prospective, randomised, multicentre study recruited insulin-naive patients with type 2 diabetes (\(n = 483\)) and poor glycaemic control (A1C ≥ 7.5%) from 34 primary care practices in the USA. Practices were randomised to an active control group (ACG) with enhanced usual care or a structured testing group (STG) with enhanced usual care and at least quarterly use of structured SMBG. STG patients and physicians were trained to use a paper tool to collect/interpret seven-point glucose profiles over three consecutive days. The primary endpoint was HbA1c level measured at 12 months.

**Results**

The 12-month intent-to-treat analysis (ACG, \(n = 227\); STG, \(n = 256\)) showed significantly greater reductions in mean (SE) HbA1c in the STG compared with the ACG \([-1.2\% (0.09) \text{ vs. } -0.9\% (0.10); \Delta = -0.3\%; p = 0.04]\). Per-protocol analysis (ACG, \(n = 161\); STG, \(n = 130\)) showed even greater mean (SE) HbA1c reductions in the STG compared with the ACG \([-1.3\% (0.11) \text{ vs. } -0.8\% (0.11); \Delta = -0.5\%; p < 0.003]\). Significantly more STG patients received a treatment change recommendation at the first month visit compared with ACG patients, regardless of the patient’s initial baseline HbA1c level (75.5% vs. 28.0%; \(p < 0.0001\)). Both STG and ACG patients displayed significant (\(p < 0.0001\)) improvements in general well-being.
Conclusions

Appropriate use of structured SMBG significantly improves glycaemic control and facilitates more timely/aggressive treatment changes in insulin-naive patients with type 2 diabetes without decreasing general well-being.

COMMENT

It is clear that, with an engaged healthcare team, using a structured glucose testing strategy can improve glucose control in non-insulin-treated patients. Potential benefits are many, including cost of care. Whether this can be repeated in a non-study setting with the more typical time limits encountered in a primary care setting remains to be seen.

Estimates of total analytical error in consumer and hospital glucose meters contributed by haematocrit, maltose and ascorbate

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Aims

To estimate analytical error in consumer and hospital glucose meters contributed by variations in haematocrit, maltose, ascorbate and imprecision.

Methods

The influences of haematocrit (20\%–60\%), maltose and ascorbate were tested alone and in combination with each glucose meter and with a reference plasma glucose method at three glucose concentrations. Precision was determined by consecutive analysis ($n = 20$) at three glucose levels. Multivariate regression analysis was used to estimate the bias associated with the interferences, alone and in combination.

Results

Three meters demonstrated haematocrit bias that was dependent upon glucose concentration. Maltose had profound concentration-dependent