Social, political and economic implications of self-blood glucose monitoring in type 2 diabetes management.

A qualitative study of how Australian health care professionals form their convictions – viewed through the lens of self-blood glucose monitoring in patients with non-insulin treated diabetes mellitus

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

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I hope I got the balance right.

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ABSTRACT

Background: Globally the burden of diabetes is increasing. Self-monitoring of blood glucose (SMBG) has been recommended as part of diabetes management, irrespective of treatment, for 50 years. There is evidence that SMBG does not clinically improve glycaemic control in all patients with non-insulin treated type 2 diabetes (NITT2DM). Funding and practice models are influenced by stakeholders, including industry and patient advocacy groups. Yet how Australian HCPs formulate their views regarding SMBG has not been studied.

Aim: This research is designed to inform our understanding of the factors that influence Australian HCP's perceived value of SMBG for patients with NITT2DM and to review the evidence for SMBG analysing social, political and economic trends influencing recommendations.

Method: Following a review of evidence and detailed review of policy documents, using a Qualitative Descriptive method, qualitative semi-structured interviews were undertaken with Australian HCPs to obtain insight into their beliefs and practices relating to SMBG in patients with NITT2DM. The perceptions about the value of monitoring, why and how HCPs form these views, and the ways they use the results were examined. Moreover, the type and source of the education and training of HCPs were identified.

Results: A qualitative approach thematic analysis of the data resulted in key insights from 25 interviews with diabetes educators, pharmacists, endocrinologists, general practitioners, dietitians and primary care nurses. Seven main themes emerged from the analysis: (1) The perceived value of SMBG in people with diabetes varies within and between health professional groups; (2) The information patients receive about SMBG is limited; (3) SMBG is not a benign activity and can have negative consequences; (4) The health care professionals most likely to use the results in a purposeful manner are diabetes educators and dietitians; (5) the capacity to provide specialised training to patients is limited; (6) Professional training does not address SMBG; and (7) HCPs want impartial information about SMBG.

Conclusions: This thesis demonstrated that the views of HCPs are varied and largely based on inconsistent information, training as well as the influence of marketing, and other key stakeholder groups. The consequences of these actions have implications for the health care system, provider and patients. Inconsistent recommendations to patients contribute to adverse health care outcomes and rising health care costs. These findings provide an empirical basis to inform educational and policy interventions to help ensure that training and recommendations regarding SMBG are standardised and evidence-based.

Definition of terminology

Blood glucose meter: Portable, hand-held, battery operated instruments used in conjunction with blood glucose test strips (BGTS) to measure glucose concentration rapidly in a small sample of whole blood.

HbA1c (Haemoglobin A1c or glycosylated haemoglobin): The HbA1c assay reflects glucose control over the three months prior to obtaining the blood sample. It is the only measure of glycaemic control that has been shown to be associated with long-term complications of diabetes.

Self-monitoring of blood glucose (SMBG): The act of obtaining a blood sample – usually by the finger-stick method, placing the sample on a strip that is inserted into the blood glucose meter. The meter will give a result usually within several seconds, displaying the current blood glucose level.

Type 1 diabetes mellitus: An autoimmune condition that usually develops in childhood and results in the destruction of insulin-producing β-cells in the pancreas and absolute insulin deficiency.

Type 2 Diabetes Mellitus: A chronic condition that commonly develops in late adulthood. Type 2 diabetes results from increasing insulin resistance, a reduction in β-cell function, and declining β-cell mass.

ADEA: Australian Diabetes Educators Association. The leading Australian organisation for health care professionals providing diabetes education and care.

ADS: Australian Diabetes Society. The peak medical and scientific body in Australia for diabetes consisting of predominantly endocrinologists, basic science researchers and health administration members.

APNA: Australian Practice Nurse Association. The peak professional body for nurses working in primary health care including general practice.

DA: Diabetes Australia. Diabetes Australia is the national body for people affected by all types of diabetes and those at risk.

DAA: Dietitian's Association of Australia. The national association of the dietetic profession, with branches in each state and territory.

NDSS: National Diabetes Services Scheme. An initiative of the Australian Government and administered by Diabetes Australia. The scheme delivers diabetes-related products, information and support services to almost 1.1 million Australians with diabetes.

NPS: National Prescribing Service. NPS MedicineWise is an independent, not-for-profit and evidence-based organisation that provides practical tools such as medicines with the aim to improve the way health technologies, medicines and medical tests are prescribed and used.

PBS: Prescription Benefit Scheme. A program of the Australian Government that provides subsidised prescription drugs to residents of Australia.

PSA: Pharmaceutical Society of Australia. PSA is the major provider of continuing professional development programmes for pharmacists in Australia.

RACGP: Royal Australian College of General Practitioners. Australia's largest professional general practice organisation.

Chapter 1

Introduction

Diabetes

Both globally (Herman & Zimmet 2012b) and nationally (Australian Institute of Health and Welfare 2015), the prevalence of diabetes mellitus is rapidly increasing as a result of population ageing, urbanisation, and lifestyle factors such as physical inactivity, improved nutrition and obesity (Nolan, Damm & Prentki 2011). Prevalence estimates suggest 6.4% of adults (285 million) worldwide have diabetes, with this figure predicted to rise to around 7.7% (439 million) by 2030 (Shaw, Sicree & Zimmet 2010).

Nationally, the picture is equally dismal. In 2004-05, an estimated 700,000 Australians had been diagnosed with diabetes. By 2011-12, this had risen to one million (Australian Institute of Health and Welfare 2015). Currently, 4.2% of Australians have been diagnosed with diabetes with projections suggesting that this will double to 8.4% by 2030 (Shaw, Sicree & Zimmet 2010). Type 2 diabetes accounts for at least 90% of these cases (Chen, Magliano & Zimmet 2012).

The healthcare costs associated with diabetes are staggering. In the United Kingdom (UK), diabetes currently accounts for approximately 10% of the total health budget, and this is projected to rise to 17% in 2035/2036 (Hex et al. 2012). In Australia, recent data on costs are lacking, but direct health care costs for diabetes were $1,507 million in 2008-09, 43% of which were hospital care expenses (Australian Institute of Health and Welfare 2015). Findings from the Fremantle Diabetes Study suggest the costs of diabetes in Australia are likely to quadruple over the next 40 years (Davis, Bruce & Davis 2013) and, if Australia follows trends in the United Kingdom (UK), intensive self-monitoring of blood glucose - the use of a glucose meter to enable a patient to recognise glycaemic variations, will account for a major component of these costs (Simon et al. 2008).

Problem statement

Achieving tight glycaemic control in people with diabetes reduces the risk of mcrovascular disease and the chronic diabetes complications (Diabetes Control and Complications Trial Research Group 1993; UK Prospective Diabetes Study (UKPDS) Group 1998). Further follow-up studies have demonstrated that interventions that result in a period of tight glycaemic control

reduce the risk of macrovascular complications. These benefits may become evident ten or more years after the intervention (Chalmers & Cooper 2008; Holman et al. 2008).

SMBG is promoted as a tool to improve glycaemic control. As part of diabetes self-management education (DSME), self-monitoring of blood glucose (SMBG) has been widely recommended as an intervention that can contribute to improved glycaemic control for people with non-insulin treated type 2 diabetes mellitus (NITT2DM).

However, there is now growing evidence that this practice does not improve glycaemic control to a level of clinical significance (Allemann et al. 2009; Clar et al. 2010; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009), and importantly, may result in higher levels of distress, depressive symptoms and anxiety in some patients who do self-monitor (Beverly et al. 2012; Franciosi et al. 2001; O'Kane 2008; Rubin & Payrot 2001; Simon et al. 2008). These studies are discussed in more detail in Chapter 3. Further, studies have not identified an optimal blood glucose monitoring schedule for this group of people.

Despite the paucity of strong clinical evidence supporting the use of SMBG in people with NITT2DM, self-monitoring of blood glucose is still endorsed as part of diabetes self-management and widely recommended by HCPs. For some sectors involved in this aspect of diabetes management, there is a strong financial interest in patients engaging in this activity despite the limited evidence of its benefit. Of note, in June 2015, the Australian Federal Government announced restrictions on the period of time people with NITT2DM will be able to access subsidised blood glucose test strips (BGTS). These changes have resulted in objections by some stakeholder groups (Klein 2015).

People with NITT2DM have reported feeling confused about why and when to perform SMBG (Bermaci Consulting 2012). They also have indicated that they feel HCPs frequently do not review their SMBG results or make recommendations based on the data they diligently collect (Peel, Douglas & Lawton 2007). It is not surprising that many of those who do start to perform SMBG choose not to continue, presumably due to lack of perceived benefit.

Various clinical guidelines inform health care professionals about the importance of SMBG for people with NITT2DM (American Diabetes Association 2014; International Diabetes Federation 2009; National Health and Medical Research Council 2009; National Institute for Clinical Excellence 2009). There has been a criticism of these guidelines as they appear to be more in favour of SMBG in NITT2DM than the evidence that they reference (Aakre et al. 2012).

That there are doubts about the usefulness of SMBG for people with NITT2DM after so many decades of use suggests that there is no overwhelming benefit.

Statement of purpose

In Australia and internationally, various governments introduced federally-funded schemes to subsidise the cost of BGTS. The Prescription Benefit Scheme (PBS) and later the National Diabetes Services Scheme (NDSS) in Australia have been subsidising urine and BGTS since 1969. Given the high level of government expenditure on blood glucose monitoring (NDSS/Diabetes Australia 2015), one would expect that this self-management strategy provides significant benefits to the person with diabetes.

Blood glucose monitoring has been a feature of clinical management for diabetes for over 50 years. More recently the evidence supporting the use of SMBG in people with NITT2DM has been strongly questioned. Further, some studies have indicated SMBG has adversely impacted some people, and yet many Australian HCPs continue to recommend blood glucose monitoring to this cohort of patients.

To date, there has been only limited attempts to understand the Australian HCP's perception the value of SMBG in patients with NITT2DM and how this is influenced by social, political and economic factors (Australian Diabetes Educators Association 2009 page 4; Henderson et al. 2013). Further, there have been no studies investigating the factors that contribute to these perceptions.

This study has investigated, in a select sample, how Australian HCPs' caring for people with diabetes came to form their views on this specific component of diabetes management. Twenty-five Australian HCPs from a variety of professional backgrounds were interviewed. They provide detailed accounts of the factors that have influenced their views, including the training the have received and the resources they turn to for guidance.

This study has two purposes. Firstly, the study asks on a pragmatic level: "What are Australian HCPs' perceptions of the value of SMBG for people with NITT2DM?" Secondly, highlighting the subjective nature of these perceptions, this study asks "How did you form your views?"

Research Questions

1. What perceptions do Australian health care professionals hold about the value of self-monitoring for people with NITT2DM?
2. Why and how do Australian health care professionals make recommendations for self-monitoring in patients with NITT2DM, and what are the ways they use the results?

3. What are the factors that have contributed to these perceptions?
4. What education and training do Australian HCPs receive about self-blood glucose monitoring, and how do they identify and access trusted sources of information?

Overview of Methodology

As the aim of the study was to gain insight into HCPs' perceptions of SMBG in the Australian context, a qualitative approach was chosen for this study. Conceptual underpinnings for this study involved challenging traditional views and questioning the origin of beliefs and values. The study is contextualised within a review of existing evidence and a review of key stakeholder groups operating within the Australian health care system.

Interviews of twenty-five HCPs from the central and northern Sydney area typically involved in the care of people with type 2 diabetes were conducted. This group included general practitioners, diabetes educators, dietitians, endocrinologists and pharmacists. HCPs from both the public and private sectors participated.

A 13 question interview guide was developed, guided by relevant literature to examine four core areas:

1. Beliefs, recommendations and practices in relation to SMBG
2. The ways in which the HCP might use the results of blood glucose monitoring
3. Factors influencing the HCP's recommendations regarding blood glucose monitoring
4. The sources of information HCPs access or are exposed to in relation to blood glucose monitoring

The duration of the interviews ranged from 12 – 32 minutes and were conducted in the HCP's place of work or by phone. The interviews were conducted as per the interview guide and recorded. The recorded interviews were subsequently transcribed. The contents of these transcripts then underwent content analysis where common themes were identified to help identify similarities and differences within groups and between groups of the different HCPs.

A qualitative description approach was used for analysing the data. Qualitative description is a minimally interpretive approach to analysing the data which allows for a description of the participants experience more or less in their own language (Neergaard et al. 2009).

Significance of this study

Globally, diabetes is now one of the most common non-communicable diseases. As part of diabetes education self-management, SMBG has been routinely recommended for people with NITT2DM as a way to improve glycaemic control and to gain confidence in self-managing diabetes (Diabetes Australia 2015b; International Diabetes Federation 2009).

However, there is now growing evidence that this practice does not improve glycaemic control to a level of clinical significance, and importantly, may result in higher levels of distress, depressive symptoms and anxiety in some patients who do self-monitor (Allemann et al. 2009; Farmer et al. 2012; Malanda et al. 2012). Moreover, it may distract from the importance of important measures of outcome, such as HbA1C.

Health care professionals form their views as a consequence of multiple complex factors, including peer recommendations, marketing, evidence-based guidelines and patient expectations (Dobrow, Goel & Upshur 2004; Timmermans & Berg 2010). Considering context is of importance in determining how views develop or are acquired. Most current guidelines recommend that people with diabetes be encouraged to perform SMBG and be instructed how to utilise the data to enhance their diabetes self-care practice.

However, there are limited data on who provides this information and self-management support to people with diabetes or what instructional information is provided. Driven by marketing pressures, ownership of the meters is growing as more people purchase blood glucose meters over the internet where there is even less opportunity for people with diabetes to receive education in the clinical practice setting. Also, HCPs involved in the care of people with diabetes in Australia may not be accessing the training necessary to help people interpret blood glucose results and incorporate them into management plans.

This study is unique in the Australian context and helps us to understand how health care professionals from a range of professional backgrounds form their opinions regarding treatment strategies through the lens of blood glucose monitoring in type 2 diabetes. As there is a shift from professional, hierarchical models to person-centered models of care, such a focus is increasingly important (Asimakopoulou & Scambler 2013; Funnell & Anderson 2004). Moreover, as diabetes management occurs commonly in the community, it is important to consider the views of the range of providers that the patient interacts with and their motivations. The emphasis on retail outlets in the community as the vehicle of health care delivery is important (Bachrach et al. 2015).

There have been many quantitative randomised control trials and meta-analyses that have investigated whether SMBG can improve glycaemic control in people with NITT2DM (Allemann et al. 2009; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009). The conclusions from the meta-analyses are very similar and suggest that the use of SMBG is associated with a statistically significant, but not clinically significant, improvement in glycaemic control in people with non-insulin treated type 2 diabetes, particularly where the HbA1c values < 8.0% - (<64mmol/mol).

There have been relatively few qualitative studies that have explored the experience of people with NITT2DM in relation to SMBG. The studies that have been conducted demonstrate mixed results. Several studies indicate that although some people with NITT2DM found blood glucose monitoring to be beneficial and reassuring, there remained a lack of clarity for many about how to relate the results to lifestyle (Farmer et al. 2009; Mathew et al. 2012; Peel et al. 2004).

Moreover, other studies indicate that people with NITT2DM often experience a lack of understanding about SMBG, which leads to worry and fear. If health care professionals are perceived to provide inadequate support, this was considered to be a demotivating experience (Bond & Hewitt-Taylor 2014; Peel, Douglas & Lawton 2007).

To date, there has been only limited attempts to understand the Australian HCP's perception of the value of SMBG in patients with NITT2DM (Henderson et al. 2013) and no studies investigating the factors that contribute to these perceptions. It is becoming increasingly difficult to ignore a practice that follows tradition, despite a mounting body of evidence that challenges established practice and as a consequence uptake of recommendations by patients.

In an environment of increasing demands on the health dollar and workforce, the use of SMBG in people with NITT2DM provides a potentially useful study that may have implications for other areas of health management and government subsidy. Taking such an approach requires a critical approach, questioning entrenched views and considering the motivation of stakeholder groups (Dhandapani, Sony & Kumaran 2014; Rouse 2008).

This study comes at a critical time of change in relation to the ongoing subsidisation of BGTs in Australia. The Australian Government in June 2015 announced their intention to end unrestricted access to BGTs for people with NITT2DM. The findings of this study support change to access and are discussed more fully in the recommendations. The findings of this study will inform educational and/or policy interventions to ensure self-monitoring of blood glucose is conducted by those most likely to benefit.

Organisation of the thesis

The thesis begins with a summary of the available literature that provides a critical context for the study described in chapters 4 and 5. The literature review is divided into two chapters.

Chapter two: Literature review Part 1. The history of blood glucose monitoring.

This chapter sets the scene by exploring the history of blood glucose monitoring from the earliest days of development in the 1960s through to the current day. This history includes an investigation into the changing political landscape of SMBG including the introduction of, and the removal of, government subsidies for BGTS. There is a discussion about the costs of subsidising BGTS in Australia and an attempt at analysing who the major financial beneficiaries of SMBG are, as well as the experience of the consumer. This chapter also discusses the social, political and economic factors driving the community health care management of diabetes.

Chapter three: Literature review. Part 2.

This chapter examines the importance of glycaemic control in patients with NITT2DM. Following on from that is a review of the recent evidence in relation the effectiveness of SMBG in improving glycaemic control and current clinical practice guidelines. There is a review of literature relating to how health care professionals from around the globe view the value of SMBG and how they use the results. The literature review helps to determine a gap in the current literature between clinical practice guidelines and clinical practice and identifies how this study will augment our knowledge on the topic.

Chapter four: Conceptual Framework.

The conceptual framework is employed to synthesise the information found in the literature review and serve as a link to the research approach.

The conceptual framework highlights four elements that help the health care professional form their perceptions of the value of SMBG for people with NITT2DM. Specifically the context in which the decision is made, the knowledge that exists about the treatment options, the socioeconomic environment and the effectiveness of the facilitator in explaining treatment options.

Chapter five: The research approach.

This chapter provides the reasons for choosing a qualitative approach and how the interview guide was developed. This chapter outlines how the data was gathered and analysed and how issues around ethical behaviour and trustworthiness of research data were managed.

Chapter six: Findings.

This chapter outlines the study's main findings, providing a presentation of the qualitative data.

Chapter seven: Discussion.

This chapter discusses the findings in relation to the research questions, conceptual underpinnings and contextualises this within the existing literature.

Chapter eight: Conclusions and recommendations.

This final chapter provides a number of statements and recommendations based on the conclusions drawn from the study.

Chapter 2

Literature review: Part 1

Introduction

As discussed in Chapter 1, discussing health care within a broader context is important. This chapter sets the scene for the study by outlining the history of blood glucose monitoring and also discusses the social, political and economic factors driving the community health care management of diabetes.

The history of blood glucose monitoring

Anton Clemens, an employee of the United States based Miles – Ames Laboratory is credited with developing the first blood glucose meter, the Ames Reflectance Meter (ARM) in the late 1960s. Although considered to be reasonably accurate compared to laboratory methods, it was neither portable nor convenient, weighing 1.2kg. It was also very dependent on the user negotiating numerous exacting steps to obtain a result (Clarke & Foster 2012).

Blood glucose meters were initially developed for screening for diabetes or used in the Emergency Departments to help confirm hypoglycaemia. The manufacturers, Miles – Ames Laboratory, restricted their availability for the exclusive use of doctors.

The first reported personal use of a blood glucose meter was by American, Dick Bernstein, in 1969. Mr Bernstien had been diagnosed with type 1 diabetes, and his wife was a doctor. She was able to purchase a meter on his behalf. He was the first to demonstrate how they may be of benefit to individuals self-adjusting insulin therapy (Mendosa 2006).

Throughout the 1970s, new companies began to manufacture and market blood glucose meters. The “Eyetone” was marketed by Kyoto-Daiichi and later the “Reflomat” by Boehringer Mannheim. However, they were mains powered and expensive, thus remaining out of reach of the general public.

The first portable battery operated blood glucose meter was developed in Sydney Australia by Mr Stan Clarke for the use of his daughter who was diagnosed with type 1 diabetes. Mr Clarke demonstrated his meter on the 1978 ABC television program the “What'll They Think of Next?” (Love 2011).

Mr Clarke’s invention generated great interest, and he subsequently formed a company that manufactured and marketed blood glucose meters primarily for the use of children with type 1 diabetes.

Other medical device companies such as Ames, Lifescan and Boehringer Mannheim soon followed launching a growing variety of portable battery operated blood glucose meters in the early 1980s (Rizzoni et al. 2001).

Self-monitoring of blood glucose in people with NITT2DM

As more blood glucose meters entered, the market prices fell, and people with insulin-treated diabetes increasingly purchased them. Continued improvements in technology allowed more frequent monitoring, giving an indication of blood glucose response and providing a convenient method to determine the adequacy of an insulin dose (Jones et al. 2011).

Blood glucose meters came to be advertised and sold to the general public. To this day, there remains no restriction in Australia on who can purchase a blood glucose meter. Meters are easily obtained by people with diabetes irrespective of the type of diabetes they have or whether they are treated with insulin, oral glucose-lowering agents or lifestyle modification alone. Thus, there is limited control of the marketing and purchasing of these devices.

Approximately 80% of Australians with non-insulin treated diabetes own and have used a blood glucose meter (Henderson et al. 2013).

Self-monitoring of blood glucose is promoted as an intervention that can contribute to improved glycaemic control in patients not treated with insulin (Diabetes Australia 2015b; International Diabetes Federation 2009; National Institute for Clinical Excellence 2009). It is suggested this can contribute to improved glycaemic control in two ways. Firstly, it may reinforce positive lifestyle behaviours. Secondly, SMBG may also help to establish blood glucose patterns and, with appropriate education, assist people with diabetes to make day-to-day decisions regarding their self-management and proper use of medication (Australian Diabetes Educators Association 2015; International Diabetes Federation 2007, 2009).

In more recent years there have been challenges to these assertions and been debate as to whether owning and using a blood glucose meter results in improved glycaemic control, particularly for those with NITT2DM (Allemann et al. 2009; Farmer et al. 2012; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009).

How is glycaemic control determined?

In the 1970s, a relationship between long-term diabetes complications and glycated haemoglobin was identified. Glycosylation of haemoglobin occurs slowly and is not significantly affected by acute changes in blood glucose levels. A variety of methods were developed to measure glycated haemoglobin, and there was significant inter-laboratory

variation with results dependent upon the variety of blood components measured (Goodall et al. 2007).

From the late 1970s to the early 1980s glycated haemoglobin assays took several days to perform. HbA1c analysers were not very precise and measured the glycosylation of a range of proteins HbA1a, HbA1b and HbA1c as well as other interfering substances. It was only by the mid to late 1980s the Haemoglobin A1c (HbA1c) assay became refined and used in the routine monitoring of glycaemic control (Jones et al. 2011).

The HbA1c assay reflects glucose control over the three months prior to obtaining the blood sample. It is the only measure of glycaemic control that has been shown to be associated with long-term complications of diabetes (Colagiuri et al. 2009). The HbA1c is now standardised and conducted around the world (Goodall et al. 2007). It is considered to be the 'gold standard' method for determining glycaemic control (Colagiuri et al. 2009; Hanas & John 2010).

Guidelines established by professional bodies and their health care professionals recommend that people with diabetes be set individualised HbA1c targets (Australian Diabetes Society 2009; International Diabetes Federation 2009).

The widespread availability of blood glucose meters pre-dated the adoption of the HbA1c assay as a way of determining glycaemic control. SMBG remains considered by many as a substitute for, or complement to, Hba1c analysis (American Diabetes Association 2015; Colagiuri et al. 2009).

The National Diabetes Services Scheme

Prior to 1987, pharmacies were the sole distributors of BGTS in Australia. As demand for blood glucose monitoring grew, Diabetes Australia Limited (DAL) successfully negotiated with the Australian Federal Government for the establishment of the National Diabetes Supplies Scheme - NDSS (National Diabetes Services Scheme / Diabetes Australia 2015).

Registration with the scheme is free for Australian Medicare cardholders diagnosed with diabetes. NDSS registrants receive access to insulin pen needles and syringes at no cost as well as subsidised BGTS. Although most people purchasing BGTS pay a co-payment, these costs are largely subsidised by the taxpayer (National Diabetes Services Scheme 2015b).

The National Diabetes Supplies Scheme became the National Diabetes Services Scheme in 1995 when the Australian Government determined that the successful tender for administering the scheme should provide information and other services to Registrants.

The number of people registered with the NDSS has also grown by an average of 13.49% since 1990 (National Diabetes Services Scheme / Diabetes Australia 2015). There was a total of 1,074,368 NDSS Registrants as at 31 January 2012. This figure is very similar to those reported to have been diagnosed with diabetes (Australian Institute of Health and Welfare 2015), suggesting that the majority of people diagnosed with diabetes in Australia are NDSS Registrants.

The NDSS is a resource for statistical information related to diabetes. Recent NDSS statistics indicate that the majority of NDSS registrants (two-thirds) are people with NITT2DM. The majority of registrants have at one time or another purchased BGTS confirming that most people with diabetes in Australia own and have used a blood glucose meter (National Diabetes Services Scheme / Diabetes Australia 2015). Test strip sales represent approximately 82% of the product sold in the scheme (Department of Heath and Ageing 2012; Speight et al. 2011).

Today the NDSS costs the Australian taxpayer a substantial amount to maintain. The Australian Government expenditure on the NDSS for the 2012-13 financial year was $218.0 million, an increase of $11.5 million over the previous financial year (Prescription Benefit Scheme 2013). Utilisation of test strips is growing by 6.3% per annum (Department of Heath and Ageing 2012).

In 2011, a five-year agreement was signed between the Commonwealth and Diabetes Australia. The agreement is expected to cost $1 billion AUD over five years (Dept of Health 2015).

The cost of blood glucose monitoring for the individual with diabetes

Blood glucose monitoring is very affordable for most people in Australia. The average Australian weekly wage as of November 2012 was $1,115.40 (Australian Bureau of Statistics 2013).

Blood glucose meters are very inexpensive and typically priced between $0 and $50.00. The actual average cost of 100 test strips is $39.29. However, NDSS registrants purchase the same strips at a subsidised price of $16.20 and a concessional rate of $2.60 and for pensioners, it is $1.20 (National Diabetes Services Scheme 2015a).

In 2006 that the annual cost per patient was $162.00, excluding the cost of the meter for each person with diabetes. SMBG, therefore, represents an annual cost nationally of $51million (Davis, Bruce & Davis 2006).

The real dollar amount, however, is difficult to ascertain but is certainly higher as some people purchase BGTS through the PBS as they reach Safety Net thresholds that allow them to obtain them at an even cheaper rate.

The worldwide market for blood glucose meters

Since the 1970s blood glucose meters have become smaller, more accurate and far less expensive (Rizzoni et al. 2001). The international market for blood glucose meters and test strips has grown at an enormous rate, driven by the obesity epidemic and explosion in the number of people with diabetes.

Worldwide, the market for blood glucose meters and BGTS was estimated to be worth US $8.8 billion dollars in 2008 (Hughes 2009). It is expected to grow to US $15 Billion dollars by 2017 (Global Industry Analysts 2011).

The bulk of the global market share for blood glucose monitoring systems is divided between Switzerland's Roche Holding, Johnson & Johnson, Abbott and Bayer. Roche and Johnson & Johnson have a combined worldwide market share of more than 52%. Internationally, the blood glucose meter manufacturer Roche Holdings is the overall market leader, with a 35% share of the market (Hughes 2009).

As the cost of manufacturing meters has fallen, companies have been ensuring their market share by providing blood glucose meters at ever reduced costs and in many instances, they are now given away. Consequently, the widespread subsidisation of BGTS has resulted in a blood glucose meter market supported mostly by BGTS sales.

The subsidisation of BGTS in Australia ensures they are available at the same price to consumers no matter what meter they choose. This situation has resulted in companies advertising meters on the basis of features such as speed and memory capacity. Underlying the promotion of the meters has been an assertion that they will benefit the user (Abbott Diabetes Care 2011, 2015; Accuchek 2012; Diabetes Australia 2015b).

Worldwide removal of the subsidies for blood glucose monitoring

Since blood glucose monitoring became widely available, many national governments established schemes that subsidised the cost of BGTS. However, as doubts have emerged about the effectiveness of SMBG in improving glycaemic control and in the face of escalating health costs, international governments have moved to restrict subsidies.

In the United Kingdom, (UK) Local Health Boards, in an attempt at reducing costs, are limiting the number of BGTS available on prescription (INPUT 2013). The NHS is also driving costs down by using formularies to identify preferred budget blood glucose meters (Accuchek 2012).

The New Zealand Government has moved to restrict access to only one brand of meter, the South Korean based company "Caresens". Caresens won the tender to supply test strips at the cheapest rates (PHARMAC 2012). From March 2013, only the Caresens brand of BGTS has been subsidised. People who choose to use other branded meters must pay the manufacturer's set price for the BGTS. These changes have been shown to save the New Zealand Government around $10 million NZD per annum (Holman et al. 2008).

The German Federal Ministry of Health has chosen to eliminate reimbursement for urine and BGTS for people with NITT2DM with strips prescribed only in exceptional cases (Danne 2011). In the US, the Centers for Medicare & Medicaid Services announced that reimbursements for BGTS will be reduced by up to 72 percent (CMS Media Relations 2013).

In Australia, the Department of Health Care and Ageing launched a review of the blood glucose meter subsidies in 2012 (Department of Heath and Ageing 2012). The objective of this study is to evaluate the body of clinical evidence regarding diabetes interventions to ensure people with diabetes are using the most appropriate medicines and products.

As part of the review, a stakeholder forum was convened by the Department of Health Care and Ageing in November 2012. This forum allowed interested stakeholders from the manufacturers, consumers, and professional bodies to provide input into the review of the use of BGTS in people with NITT2DM (Pharmaceutical Benefits Scheme 2012b).

The Department of Health and Ageing received 32 written public submissions, representative of a cross-section of interests– individuals, consumer advocates, peak bodies and industry. An examination of the submissions is provided in Appendix C.

In June 2015, the Australian Federal Government announced that unrestricted access to BGTs will end from 1st July 2016. The changes are expected to save $146 million AUD over four years. These changes are in line with the Post - Market Review of Products Used in the Management of Diabetes Report to the Pharmaceutical Benefits Advisory Committee Part 1: Blood Glucose Test Strips July 2013 (Pharmaceutical Benefits Advisory Committee 2013) and the "Choosing Wisely Australia" program conducted by the National Prescribing Service Medicine Wise and the Royal Australian College of General Practitioners (Choosing Wisely Australia 2015).

From that date, people with NITT2DM will be entitled to six a month supply from diagnosis. Prescribers will be given the discretion to extend this period if they believe that it is necessary for the patient due to a change in medication, illness or co-prescribed medication that adversely impacts glycaemic control.

Protests against the proposed changes to blood glucose testing subsidies

There are numerous examples of passionate opposition to the threat of the removal of subsidies for BGTS in people with NITT2DM.

The former Chief Executive of the Australian Diabetes Council, Nicola Stokes, was quoted as saying that "removing the subsidy could have detrimental health effects for more than a million people Australia-wide". In the same newspaper report, Toongabbie doctor Shanthini Seelan was quoted as saying that "at least 500 of his diabetic patients would be worse off if the test strips were removed from the subsidy scheme, and further: ''I think, for a lot of people on pensions or unemployment, if this (treatment) is not completely subsidised then they're going to have difficulty treating their condition" (Lawrence 2013).

Diabetes UK has published a position statement protesting against any restriction on the prescription of BGTS and advising patients how to escalate the matter should they feel they have not been dealt with fairly (Diabetes UK 2013).

These comments are in line with a recent online survey of members of the Australia Diabetes Educators Association (ADEA). The survey found that 87% of those who took part voted 'No' when asked if access to subsidised BGTS should be restricted. ADEA members also argued that to move to restrict access to BGTS would result in a blowout of the health care budget due to the fallout of poorly managed type 2 diabetes cases (Aubusson 2013).

In the online newsletter "Diabetes Educators", the news regarding the change to restrict BGTs in Australia was criticised by several diabetes educators: "You need to be able to use self-blood glucose monitoring as a problem-solving tool", and that it ignores the recommendations from the "STeP" study (Worsely 2015a).

Impact of worldwide reductions in blood glucose testing reimbursements

The international reductions in reimbursements and increasing competition have impacted the profits of major blood glucose companies. In 2014, Roche Holdings noted that internationally blood glucose test strip sales had declined by 6% in North America and Japan (Roche Group 2014).

In March 2013, Reuters reported that Roche Holding AG was exploring a sale of its blood glucose meter business due to increased competition and reimbursement pressure. However by September 2013 they had abandoned these plans as they could not elicit a competitive bid (Toonkel 2013). In 2012, Bayer AG, Germany's biggest drug maker, attempted to sell its blood glucose meter business for around $1.5 billion USD. Bayer abandoned the sale early in 2012 after failing to find sufficient buyer interest (Varnholt 2013).

With the threat of reduced profits from BGT sales in traditional markets, companies are now turning to developing markets. The regions of South Asia, Latin America and the Caribbean, and Central Asia, North Africa, and the Middle East are experiencing growth as westernisation is contributing to rapid increases in the rates of diabetes (World Health Organisation 2015).

For example, Roche Holdings, despite noting weak worldwide sales of BGTS, did experience an increase in sales in the Middle East, Africa, Latin America and the Asia-Pacific markets (Roche Group 2014).

With an estimated 40 million patients with diabetes, India is emerging as a major market for blood glucose meters. The pharmaceutical company Omron expects the Indian medical devices and diagnostics market to reach Rs 275 billion ($4.8 billion AUD). The country is fast emerging as the diagnostic capital of the world (Omron 2013; Tomoda 2013).

In addition to this, the Asia-Pacific and South and Central American markets are forecast to grow annually at a rate of 15.2% and 13% respectively. China, Brazil, India, Taiwan, Korea and Japan are forecast to grow faster than the market rate of 10.8% for the next seven years (INPUT 2013).

The Australian market for blood glucose testing

There are several companies importing and selling blood glucose meters in Australia. Market leaders Roche Diagnostics, which maintains approximately 55% of the market, and Abbott Diabetes Care, who enjoys 35% market share, were joined by US medical supplies company Johnson and Johnson. The Japanese based company Nipro has also recently joined a plethora of smaller companies in the market and have become very active using an aggressive campaign to provide meters free of charge through major pharmacies (Lui 2010).

Currently, there are 33 different test strips available through the NDSS that can be used in 49 meters distributed by some 17 different manufacturers in Australia (National Diabetes Services Scheme / Diabetes Australia 2015).

The growth in the number of available BGTS and meters distributed by the less established manufacturers is having an impact on the Australian market. People are purchasing meters more and more from online mail-order suppliers rather than retail pharmacies (Hughes 2009).

Larger meter manufacturers rely on saturating the market to protect their share of sales by producing a variety of meters. For example, the two major blood glucose meter companies in Australia, Roche Diagnostics and Abbott Diabetes Care between them manufacture 14 different meters.

Historically, companies have sought to influence the market by the use of advertising to both consumers and HCPs. Pharmaceutical companies must now abide by a stringent set of guidelines when advertising products (Medicines Australia 2013).

In Australia, medical devices that are advertised directly to consumers must comply with the Therapeutic Goods Advertising Code 2007. The purpose of the Code is to ensure that the marketing of therapeutic goods to consumers is conducted in a manner that promotes the quality use of the products, is socially responsible and does not mislead or deceive the consumer.

These guidelines are quite specific in regards the need to substantiate any claims about the efficacy of any treatment modality.

Self -blood glucose meters are advertised to all people with diabetes irrespective of treatment highlighting the accuracy and precision of the products. Online advertisements are common and commercials have appeared on television (Abbott Diabetes Care 2011) and online (Nipro 2015).

Blood glucose meter company websites feature promotions of their products. The Accuchek Website features this quote: “The more often you check your blood glucose, the better you will understand it and the easier it will be for you to manage your diabetes. It doesn’t matter if you have type 1 or type 2 diabetes, or if you are taking insulin or not, self-monitoring can help you, and your doctor manage your therapy”(Accuchek 2012).

The Abbott Diabetes Care website features a ”brand ambassador” Mr. Rob Palmer, a popular television presenter, talking about the speed and accuracy of a particular blood glucose meter. He states that these features are important to him (Abbott Diabetes Care 2015).

These advertisements do not claim that monitoring blood glucose levels will result in improvements in glycaemic control. However, they are similar in not differentiating between insulin-treated and non-insulin treated diabetes in regards to any potential benefits.

The industry lobby in Australia

In 2012, the Australian Department of Health Care and Ageing launched a review of the blood glucose meter subsidies (Pharmaceutical Benefits Scheme 2012a, 2012b). The objective of this review was to evaluate the body of clinical evidence regarding diabetes interventions to ensure people with diabetes are using the most appropriate medicines and products.

In particular, the review focused on the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) and the clinical outcomes and benefits of SMBG for people with type 2 diabetes not treated with insulin.

A report by the Veterans Medicines Advice and Therapeutic Education Services and the University of South Australia was generated from the review detailing the number of BGTS supplied to patients in Australia.

This report is entitled: Pharmaceutical Benefits Scheme Products Used in the Treatment of Diabetes

– Report to the Pharmaceutical Benefits Advisory Committee December 2012

As part of the review, a stakeholder forum was convened by the Department of Health Care and Ageing in November 2012. The forum allowed interested stakeholders from the health care industry, health professional bodies and consumers to provide input into the review of the use of BGTS in type 2 diabetes (Pharmaceutical Benefits Scheme 2012b).

As part of this process, submissions were called from stakeholders. Ultimately 32 submissions were received from various consumer organisations, health care professional bodies, medical societies, pharmaceutical societies, industry and individuals. The majority of these submissions have been published online and are freely accessible to the public.

The submissions are largely in favour of the ongoing subsidisation of BGTS. More than half of the submissions were from organisations that could be said to have a financial stake in the industry, and it was likely that those who responded are more motivated for the continuing subsidisation.

Many of the submissions pointed to limitations of the evidence questioning the value of SMBG in people with non-insulin treated diabetes. There is criticism of the varied nature of the study methods, the lack of information in relation to any educational components and that some studies examined the effects of SMBG in people who already enjoyed relatively acceptable glycaemic control.

Numerous submissions point to a more recent study that integrated a greater educational component regarding the use of SMBG data (Polonsky et al. 2011). This education included not only the patient with diabetes but the treating physician. They demonstrated that this more structured approach resulted in greater reductions in glycaemic levels. However to date, these studies are few and may not reflect what is happening in the real world.

Other arguments put forward in the submissions outlined possible negative consequences of removing the subsidy on BGTS. Blood glucose testing has been recommended as being an essential component of diabetes self-management for many years and removing the subsidies may be construed as a removal of a fundamental right by those who practise it.

Some studies have highlighted the risk of hypoglycaemia in those treated with sulfonylurea medication. Hypoglycaemia would be dangerous in high-risk activities such as driving and working in areas such as mining and child care. Hypoglycaemia can be asymptomatic when it occurs and may jeopardise cognitive function. It is suggested that SMBG may help identify episodes of hypoglycaemia.

It becomes apparent when reviewing the submissions that some respondents have used the opportunity to comment to drive their political agendas. For example, responses from two pharmaceutical companies who do not supply sulfonylurea medications suggest that a greater reliance on alternative diabetes medications may reduce the risk of hypoglycaemia, thereby reducing the need for SMBG.

The Pharmacy Guild of Australia suggests integration of a more structured approach to the education of patients regarding SMBG into pharmacy practice. Currently, pharmacists are eligible for government rebates for conducting Home Medicine Reviews and Diabetes Medschecks performed within the pharmacy. They argue that a structured approach to SMBG which would involve initial education and annual assessment could attract an even greater government payment to their members. They also argue for the transfer of the supply of NDSS products to pharmacy wholesalers.

The Australian Medical Association (AMA) argues that doctors are best placed to advise patients about how and when to monitor blood glucose levels. They argue for continued subsidisation through the PBS where patients are compelled to visit the general practitioner to obtain a prescription for test strips.

The least surprising of the submissions were from the blood glucose monitoring companies and the largest manufacturer of BGTS internationally and in Australia, Roche Diagnostics. Roche is the sponsor of the "Structured Testing Program Study" (Polonsky et al. 2011), which is the most often quoted study into structured blood glucose monitoring.

The Australian Diabetes Educators Association (ADEA) argues for the continued subsidisation of BGTS while also arguing for greater access to diabetes educators.

There is little evidence in the literature that defines when patients should perform SMBG. Some of the submissions draw attention to this issue and suggest that people should be given individualised instructions by their treating HCP, which will be reviewed annually.

The submissions generally do not address the issue that providing an individual assessment, annual review as well as up-skilling those people who already own a blood glucose meter to use it in a more structured way would require a substantial increase in resources. Such changes would include funding to employ additional diabetes educators or other privately employed health care professionals who would demand additional money for providing an enhanced service.

The consumer experience of blood glucose meter promotion

One promotional activity involves blood glucose meter companies inviting people to bring their old blood glucose meter (often a competitor brand) to the pharmacy and providing a free meter in exchange. The implication is that the new meter on offer has more advanced features than their existing meter.

While many people believe that they are getting a 'good deal' others have questioned the activities as this anonymous US man's online protest illustrates:

"My wife, a diabetic, was given a new blood glucose meter by her doctor. Even though, she had just refilled her prescription for test strips. We found out later that all diabetics when at appointments were issued new meters. We found out later that the Doctor got about $50,000 as a bonus for dispensing these meters, even though the old meters were completely

functional. The graft and corruption in health care is shameful and underlies the reason that the health care industry is against universal health care. First do no harm "my a$$" (Yahoo Answers 2015).

Participation in one such promotion by a pharmacy in Western Sydney, Australia was evaluated by the consulting firm, Bernaci Consulting. The consulting firm concluded that many people with type 2 diabetes who are with NITT2DM remain confused about the purpose of SMBG (Bermaci Consulting 2012).

Through informal interviewing the consulting firm found that people with NITT2DM were confused about the following:

1. How often they should test their glucose levels?
2. Why they should test their glucose levels?
3. When they should test their glucose levels?
4. How old their glucose meter is?
5. How often they should check their glucose meter is functioning correctly

The consulting firm concluded that this confusion was the result of a lack of education provided to the consumer. They found that people using insulin were more likely to have attended a diabetes centre and have received education regarding SMBG.

Bernaci asserts that high competition between suppliers has created an environment where people with diabetes are given free meters in the hope of generating increased business. This situation has resulted in many people owning multiple meters with subsequent confusion and uncertainty about which meter to use and what to do when they obtain differing results. They also question the appropriateness of the pharmacy setting for training in the use of SMBG.

Bernaci identified that the lack of education on the use of SMBG resulted in a corresponding reduction in the use of SMBG. These findings echo those of an Australian study that examined the role of education in SMBG. This study indicated that patients who were attending diabetes education or diabetes-related clinics were more likely to use SMBG (Davis, Bruce & Davis 2006).

Also, it has been reported that people who monitored blood glucose levels more frequently found it to be a burden and that half of people with diabetes do not receive the information they needed from their diabetes health care team (Speight et al. 2011).

Patterns of blood glucose monitoring usage: Australian statistics

In Australia, approximately 35% of all BGTS dispensed are for people with NITT2DM (Department of Heath and Ageing 2012).

The NDSS spends about $44 million per year on providing BGTS to the 363,000 patients diagnosed as having NITT2DM (Department of Heath and Ageing 2012). This figure equates to about 1.1 million boxes of BGTS per year or an average of three boxes per year. Each packet of BGTS must be discarded three to six months after opening.

In 2011, 12% of those with NITT2DM received, at least, one test strip dispensed during the year via the PBS. Also, approximately 50% of those with NITT2DM received BGTS via the NDSS.

People with NITT2DM, who received, at least, one test strip dispensed in 2011/12 received on average 300 test strips per year or less than one per day (Department of Heath and Ageing 2012).

Hence, each NITT2DM patient uses an average of slightly less than one strip per patient per day at a cost of around $120 per patient per year (Department of Heath and Ageing 2012).

This data further indicate that a significant proportion (up to 38%) of people with NITT2DM did not access any test strips for a 12-month period.

It can be concluded that cost is not a significant barrier to blood glucose monitoring in Australia. The most likely reason people with NITT2DM choose not to perform SMBG frequently, or at all, is that either they have not received adequate instruction regarding monitoring in a beneficial way or they have started monitoring and found that the experience did not provide any significant or lasting benefit.

Who are the major financial beneficiaries of self-monitoring of blood glucose type 2 diabetes?

Blood glucose monitoring generates substantial revenue in Australia. While the primary beneficiaries of this revenue are the blood glucose test strip manufacturers, other beneficiaries include distributors of BGTS.

These groups include pharmacies who benefit through the direct sale of medication, insulin, blood glucose monitoring products and other over the counter supplies as well as the incidental purchases that people with diabetes make when they come into a pharmacy (Zhuo et al. 2015).

The member organisations of the Diabetes Australia group include the state and territory consumer arms and the ADEA and the Australian Diabetes Society (ADS). These arms collectively receive approximately $140 million dollars of funding through the National Diabetes Services Scheme agreement (Cheung 2012).

Medical prescribers such as general practitioners, endocrinologists and nurse practitioners in private practice can potentially generate income by charging for the appointment if people come to have their prescriptions for BGTS obtained through the PBS.

Costs associated with self-monitoring of blood glucose

In 1987, Diabetes Australia signed an arrangement with the Federal Government to provide Australian Medicare cardholders who have diabetes, irrespective of their mode of treatment, to register with the NDSS. As a result, registrants are eligible to obtain subsidised diabetes-related products including BGTS (National Diabetes Services Scheme / Diabetes Australia 2015).

While the costs of subsidising self-monitoring by the Australian Federal Government can be readily determined, there is little in the literature that addresses the additional cost of training patients to make the best use of the results. Klonoff et al. (2008) identified the following skills that a patient would need to perform, interpret, and act on blood glucose information appropriately:

- Accurately perform self-monitoring of blood glucose according to a prescribed regimen
- Recognise confounding factors that can degrade monitor performance
- Understand appropriate timing and testing sites for monitoring
- Interpret self-monitoring of blood glucose results relative to predetermined target levels
- Appreciate the link between abnormal blood glucose levels and acute risks
- See a connection between out-of-range results and lifestyle (e.g., eating, exercise, stress) or medication dosing

- Know how to modify diet, exercise, stress, and medication dosing to alter the level of glycaemia
- Possess the knowledge to make adjustments in therapy based on self-monitoring of blood glucose results
- Act upon an agreed action plan for responding to deviant glucose levels
- Accurately record self-monitoring of blood glucose test results on paper or electronically
- For electronic recording, precisely program date, time, and events into the monitor
- Rely more on self-monitoring of blood glucose readings than subjective sensations of well-being

These additional costs are generally not considered.

Conclusion

Blood glucose monitoring for people with diabetes has a history stretching back some 50 years. Originally designed for the use of endocrinologists to confirm the diagnosis of diabetes, it was an individual with type 1 diabetes who first demonstrated that SMBG could help with the adjustment of insulin doses and stabilise his condition.

Blood glucose monitoring pre-dated the routine use of HbA1c analysis to determine glycaemic control and became an accepted method for this purpose. In the decades that followed, blood glucose meters became widely available and inexpensive due to improvements in technology and manufacturing. Many national governments including the Australian Federal Government introduced federally-funded schemes to subsidise the cost of BGTs.

A substantial industry has developed around blood glucose monitoring both in Australia and internationally. Blood glucose monitoring is promoted as a way of improving glycaemic control in all people with diabetes irrespective of their treatment. Recently the effectiveness of SMBG in improving glycaemic control in people with NITT2DM has been investigated. These studies have brought into question the value of SMBG as a component of diabetes management in this cohort.

While clinical guidelines have largely recommended the practice, some studies and reports suggest patients receive limited instruction regarding SMBG and are uncertain as to why and when they should self-monitor their blood glucose levels.

There are many HCPs who remain convinced of the value of SMBG, and there are those in the industry who have lobbied for the continuation of the subsidies for BGTS stating that SMBG is of significant benefit in NITT2DM. However, the evidence suggests that many people with NITT2DM do not benefit substantially from the practice and for various reasons choose not to perform SMBG.

This chapter identifies an apparent gap between the claims and expectations of many of those involved in the diabetes health industry and the consumer's experience in the real world.

Chapter 3

Literature Review Part 2

Introduction

This chapter begins with an overview of diabetes and the importance of glycaemic control and provides a justification for the research questions. The epidemiology of type 2 diabetes is summarised as well as an historical profile of the use of blood glucose monitoring.

A review of existing literature in this area has demonstrated that three topics, in particular, have been the focus of research in relation to SMBG. Firstly, whether the use of a blood glucose meter can improve glycaemic control in patients with NITT2DM. Secondly, can SMBG reinforced by education regarding a structured approach to monitoring, result in greater improvements in glycaemic control in patients NITT2DM? Thirdly, what are the positive or negative experiences of performing SMBG?

The following questions guided this literature review:

1. Many people in Australia are advised to perform SMBG by using a blood glucose meter with a reasonable expectation that they will benefit from the practice. Does the act of blood glucose monitoring result in an intrinsic positive benefit that will assist the patient with diabetes improve glycaemic control?

2. Can SMBG utilising a structured approach, enhanced by additional education, provide greater benefits to the patient than the standalone act of performing SMBG? Are their examples of patients receiving this additional training? If so what form does this additional training take and what are the results?

3. What are the experiences of people with NITT2DM? Are the experiences positive or negative?

Two additional questions relevant to the study were included in the literature search.

4. What are the perceived values of HCPs in regards to the use of SMBG for people with NITT2DM?

5. What do current guidelines recommend about SMBG in people with NITT2DM?

A search of the electronic databases, including Medline and CINAHL, was undertaken using key words "blood glucose self-monitoring" [MeSH Terms] OR ("blood" [All Fields] AND

"glucose" [All Fields] AND "self-monitoring" [All Fields]) OR "blood glucose self-monitoring" [All Fields] OR ("self" [All Fields] AND "monitoring" [All Fields] AND "blood" [All Fields] AND "glucose" [All Fields]) OR "self-monitoring of blood glucose" [All Fields] ("diabetes mellitus" [MeSH Terms] OR ("diabetes" [All Fields] AND "mellitus" [All Fields]) OR "diabetes mellitus" [All Fields] OR ("diabetes" [All Fields] AND self-monitoring [All Fields].

A search of the grey literature was also undertaken, and findings synthesised to address the study questions. Given the focus of the study, both experimental and non-experimental study designs were considered. Also, opinion pieces, policy documents and clinical guidelines were reviewed.

The importance of glycaemic control

The term diabetes mellitus is used to describe several conditions where an absolute or relative lack of effective circulating insulin inhibits the uptake of glucose by the body's cells. This results in elevated blood glucose levels (hyperglycaemia) (Alberti & Zimmet 1998).

There are two predominant types of diabetes, type 1 diabetes mellitus and type 2 diabetes. Type 1 diabetes is less common, representing approximately 10% of people with diabetes (AIHW 2015).

Type 1 diabetes is an autoimmune condition that results in the destruction of insulin-producing β-cells in the pancreas and absolute insulin deficiency. Type 1 diabetes develops as a result of the interaction of multiple genes and environmental factors; however, what triggers the destructive process is not fully understood (Craig et al. 2011).

Type 1 diabetes mellitus usually develops in children or young adulthood (Catanzariti et al. 2009). Symptoms often develop quickly leading to prompt diagnosis. Type 1 diabetes is always treated with insulin replacement therapy (NHMRC 2005b).

In contrast, type 2 diabetes mellitus is a chronic condition that commonly develops in late adulthood. Type 2 diabetes results from increasing insulin resistance, a reduction in β-cell function, and declining β-cell mass (Colagiuri et al. 2009; Karaca, Magnan & Kargar 2009). Type 2 diabetes is often diagnosed on the basis of a coincidental finding of hyperglycaemia (Colagiuri et al. 2009; Dunstan et al. 2002).

If diabetes is undiagnosed and blood glucose levels are sub-optimally controlled, its complications can be devastating to the individual and costly to the community (Colagiuri 2003). Hyperglycaemia contributes to the development of microvascular diseases including

retinopathy, blindness and renal disease requiring dialysis or transplantation as well as neuropathy leading to foot ulceration, lower limb amputation, and erectile dysfunction (International Diabetes Federation 2007; National Health and Medical Research Council 2009).

The metabolic changes associated with type 2 diabetes include hypertension and dyslipidaemia result in accelerated atherosclerosis (Dobesh 2006; Solano & Goldberg 2006) and increased risk of cardiovascular and cerebrovascular disease (Goff Jr et al. 2007; Morrish et al. 2001). Mortality rates from cardiovascular disease are two to four times higher for persons with diabetes (Ferdinand 2006).

Type 2 diabetes is initially treated by the adoption of a healthier diet and regular exercise (Diabetes Australia 2009). However, the majority of people with T2DM will also require oral glucose-lowering agents and many progress to insulin therapy due to a further decline in endogenous insulin production (Colagiuri et al. 2009). As of 30th September, 2013 approximately 23% of people with type 2 diabetes were being treated with insulin in Australia (National Diabetes Services Scheme / Diabetes Australia 2015).

Both type 1 and type 2 diabetes are complex conditions that require the person's active involvement in the day-to-day management if complications are to be avoided, and clinical outcomes, health status, and quality of life are to be preserved (Funnell et al. 2010).

Currently, a number of guidelines stipulate that self-monitoring of blood glucose (SMBG) in people with insulin-treated diabetes is essential in order safely to adjust insulin doses often on a daily basis (Craig et al. 2011; Wong & Yue 2004). Frequent blood glucose monitoring is necessary for people using insulin pumps - continuous subcutaneous insulin infusion (National Institute for Clinical Excellence 2008). SMBG is also considered mandatory for monitoring the rapidly changing blood glucose levels in women with diabetes during pregnancy (Nankervis et al. 2012).

However, in people with non-insulin requiring type 2 diabetes, the benefits of self-monitoring of blood glucose do not relate to the daily adjustment of oral medication. Authors and guidelines have suggested that SMBG provides benefits to patients with NITT2DM by:

- Providing information on blood glucose levels at a specific point in time (e.g., postprandial) (Clark 2012; International Diabetes Federation 2009)
- Contributing to increased patient empowerment and an improved sense of wellbeing (O'Kane & Pickup 2009)
- Reinforce positive lifestyle behaviours (Klonoff et al. 2008)

- Helping to establish blood glucose patterns that, with appropriate education, may assist people with diabetes to make day-to-day decisions regarding their therapy (Australian Diabetes Educators Association 2015).

Does self-monitoring of blood glucose in patients not treated with insulin improve glycaemic control?

To review search strategies and findings see Appendix D.

The long-term clinical impact of self-monitoring of blood glucose is difficult to evaluate. The microvascular complications of diabetes such as retinopathy, nephropathy and nerve disease tend to develop over years and are impractical for use in prospective controlled trials due to the need for long follow-up periods.

Consequently, most clinical studies/randomised controlled trials measure the impact of self-monitoring on glycaemic control using the HbA1c assay that reflects glucose control over the previous three months (Colagiuri et al. 2009).

The HbA1c is now standardised and employed around the world for the monitoring of glycaemic control. The usual range for a person without diabetes is considered to be 4.0 – 6.0% (20 - 42 mmol/mol) (Cheung et al. 2009). An individualised target range for people with diabetes is highly recommended. However, the recommended target range is slightly higher than the normal range, i.e. 6.0 - 7.0% (42 – 53 mmol/mol). For patients with gestational diabetes mellitus, a lower target of ≤ 6.7% (50 mmol/mol) is recommended (Nankervis et al. 2012). For patients with recurrent hypoglycaemia or reduced lifespan, a slightly higher range of up to ≤ 8.0% (64 mmol/mol) is suggested (Cheung et al. 2009).

Any improvement in HbA1c may be considered desirable. Each reduction of 1.0% (11mmol/mol) HbA1c above 7.0% (53 mmol/mol) is associated with a decrease in risk of diabetes complications by 35% (Saul 2002). The significance of a reduction depends on the magnitude of the improvement. A reduction in HbA1c from 15% (140 mmol/mol) to 14% (129.5 mmol/mol) is very different to a fall of 7% (53 mmol/mol) to 6.8% (50.8 mmol/mol).

It is also easier to achieve a fall in HbA1c if it is significantly elevated, i.e. > 8.0% (64mmol/mol), than where the HbA1c is relatively well controlled < 7.0% (53mmol/mol) (Clark & Pawlson

2006). A reduction in HbA1c is considered clinically significant when it achieves the magnitude of 0.5% (Little & Rohlfing 2011).

Some randomised controlled trials and meta-analyses have demonstrated statistically significant reductions in HbA1c between those who self-monitor their blood glucose and those who do not. However, most improvements are typically modest ranging from -0.24% (Poolsup, Suksomboon & Rattanasookchit 2009) to -0.31% (Allemann et al. 2009).

In a recent Cochrane review (Malanda et al. 2012), the authors noted a relatively small improvement in glycaemic control HbA1c at 6-months after the commencement of SMBG (-0.3%; [95% CI: -0.4 to -0.1]). However, this difference disappeared after 12 months.

Interestingly this result was similar to another Cochrane review investigating the effectiveness of diabetes education. This review noted an improvement in glycaemic control HbA1c (-0.1% (95% (CI) -0.3 to 0.1, P = 0.33) over a 12 month period (Duke, Colagiuri & Colagiuri 2009).

It is important to note the improvements in HbA1c observed in randomised controlled trials of self-monitoring of blood glucose can involve additional training on how to interpret and act on the results. This additional training introduces an unavoidable bias potentially influencing the study results (Minichiello et al. 2003).

Further, by virtue of their willingness to participate in a study assessing self-monitoring of blood glucose, participants may also be motivated in other areas of diabetes self-management that may influence the study results (O'Kane 2008). Given the improvements achieved within a controlled study setting have been small, it is unlikely people living with diabetes who self-monitor their blood glucose would achieve clinically meaningful reductions in HbA1c through this self-management practice alone.

In summary, the evidence for SMBG improving glycaemic with NITT2DM is not convincing.

Does the introduction of a structured approach to SMBG improve glycaemic control?

The number of studies that specifically incorporate education regarding a structured approach to SMBG are limited. However several studies have demonstrated that where DSME includes

instructions on how to incorporate SMBG into the diabetes management plan to both patients with NITT2DM and HCPs, greater improvements in HbA1c can be achieved (Polonsky et al. 2011; Schwedes, Siebolds & Mertes 2002).

In a 24-week observation study, 250 people with NITT2DM were randomised to receive a blood glucose meter with standardised counselling (intervention group) or non-standardised counselling with no blood glucose meter. The study demonstrated an overall improvement in HbA1c 1.0 ± 1.08% in the intervention group compared with 0.54 ± 1.41%, P = 0.0086, for the control group (Schwedes, Siebolds & Mertes 2002). The study incorporated four weekly visits with nurses trained in the study protocol. It is noted that 24% of the intervention group were found to have not responded to the readings or act on their findings.

In 2011, a structured program of blood glucose monitoring was reported in the USA. The study training randomised 483 patients to receive usual care, or additional training in the use of a structured blood glucose monitoring tool (Polonsky et al. 2011). In this study, the treating physicians were provided training in the interpretation and use of this tool. Participants in the enhanced care arm achieved a statistically significant improvement in HbA1c of -0.3%, P = 0.04.

The use of a structured approach as described by Polonsky is the use of a paper or computer based recording system that requires the patient to plot their SMBG results fasting, and pre or post prandial times in relation to meal sizes and exercise over a number of days. In addition patients were given training in how to identify patterns in blood glucose control to correct high and low blood glucose levels by changing exercise patterns or meal size and composition. Treating physicians also receive training in how to interpret SMBG data presented in this manner and how to apply treatment strategies including lifestyle and pharmacological options to address problem areas.

Polonsky demonstrated that when participants who adhered to the intervention protocol are compared to the control group they had achieved an even greater reduction of HbA1c, which achieved a clinically significant of -0.5%, P < 0.003. However, it is of note there was a higher attrition rate in the intervention group than the control group. The authors suggested that following the structured SMBG intervention was too burdensome for some and may have biased the findings.

Both of these studies demonstrated that greater improvements in glycaemic control may be achieved when additional training regarding the structured use of SMBG is provided to both the person with NITT2DM and their treating HCPs.

Psychological outcomes associated with self-monitoring of blood glucose

For a review of search strategy and results see Appendix E and Appendix F.

Patients with NITT2DM have been shown to experience positive, negative or no discernable effect on well-being or quality of life associated with SMBG (Malanda et al. 2012; Welschen et al. 2005).

Where a focused, collaborative patient/physician intervention using a structured approach to SMBG is used, improvements in the symptoms of distress and depression have been demonstrated (Fisher et al. 2011; Schwedes, Siebolds & Mertes 2002). It is acknowledged that these improvements may be in part related to the additional education and care the intervention groups received.

Other studies have linked SMBG to adverse psychological outcomes. Several studies noted a relationship between SMBG and increasing levels of anxiety (Beverly et al. 2012; Franciosi et al. 2001; O'Kane 2008) and depression in some people with diabetes (Rubin & Payrot 2001; Simon et al. 2008).

There are various reasons why people with diabetes would dislike blood glucose monitoring. It is an invasive technique that can be painful or uncomfortable, and the finding of high blood glucose values may cause anxiety and contribute to a negative experience of diabetes management (O'Kane & Pickup 2009). It is suggested that many patients blame themselves for not achieving better metabolic control, directing their frustration and disappointment inwardly through self-deprecating comments (Beverly et al. 2012). These negative experiences must be balanced or exceeded by a perceived benefit to the individual if they are to continue to perform SMBG.

While newer more modern blood glucose meters are easier to use and require smaller blood samples, the very act of lancing and drawing blood is unnatural and proves emotionally challenging for many people. Also, while meters can provide results in as little as five seconds, people still have to find the time and place to conduct the test. SMBG may prove difficult or

inconvenient in certain situations. For many people, it is yet another task to comply with during this life-long condition.

Polonsky suggests people find blood glucose monitoring frustrating and difficult because it makes them feel bad about themselves, checking blood glucose reminds them that they have diabetes, the blood glucose meter 'controls their life', serves as an opportunity for people's friends and family to bother them and seems pointless when the results are not acted on (Polonsky 1999).

In relation to this last point, Peel, Douglas and Lawton interviewed people with NITT2DM diabetes about their SMBG practices over a three-year period (Peel, Douglas & Lawton 2007). The study found that self-monitoring tended to decrease over time and that the HCPs' attitudes to self-monitoring results are crucial to this. Participants in the study indicated that they had received no education about self-monitoring in the years following initial diagnosis. Further, most noted a lack of interest in the results of their self-monitoring from their health care professionals, leading some participants to question the value of continuing this practice.

There appears to be a lack of clarity for many about how to relate the results to lifestyle (Farmer et al. 2009). At best, patients report using the results of SMBG to guide lifestyle choices (Bond & Hewitt-Taylor 2014). At worst, patients with NITT2DM describe how a lack of understanding about SMBG can lead to worry and fear (Mathew et al. 2012). Some patients held a view that the meters were judging whether they had been "good" or "bad" regarding their diabetes management (Peel, Douglas & Lawton 2007). If health care professionals are perceived to provide inadequate support, this was reported to be a demotivating experience (Bond & Hewitt-Taylor 2014).

Thus, it is easy to understand why people feel despondent or anxious when performing self-monitoring, particularly if health professionals do not act on the blood glucose results. There is a risk people may become discouraged from continuing efforts to maintain lifestyle changes when their blood glucose results remain elevated: "Sometimes I get so frustrated I just say 'to hell with it' and for a few days I don't bother testing or doing much of anything to care for my diabetes" (Rubin & Payrot 2001).

Conclusion: Studies report differing effects on emotional well-being and levels of distress in people with NITT2DM, who perform SMBG. It appears that those people in studies who receive enhanced training and contact with their HCPs fare better than those who do not receive this additional attention. It is reasonable to conclude that SMBG is not always a benign process, and some people will be negatively impacted emotionally – especially if it is not supported by education on how to use the results in a structured manner, or where health care professionals appear to be uninterested in the results.

Health care professionals perceived value of SMBG

Searches of databases revealed few studies that examined the views of HCPs in relation to SMBG in patients with NITT2DM.

In a qualitative study of seven community nurses in the UK (Abbott et al. 2007) study participants felt that patients should be encouraged to perform self-monitoring. They indicated that those who did would be more aware of their condition and, therefore, empowered to manage it effectively. The nurses did not question the evidence to support self-monitoring, nor investigate it for themselves. Although they understood that guidelines for performing SMBG were available from their local hospital, they were rarely accessed.

More recently, a study in Canada investigated the role of SMBG from the perspective of General Practitioners, pharmacists, nurse practitioners and diabetes educators (Latter et al. 2011). Participants were asked to discuss their recommendations regarding SMBG for patients with NITT2DM, who had adequate glycaemic control. Further, they were asked if and how they used the records generated by patients, and how they accessed information regarding self-monitoring.

The authors found that although there was variability about the recommendations regarding when and how often self-monitoring should be performed, all HCPs recommended the practice. Most HCPs recommended patients monitor before meals and bed while some suggested testing after meals. There was significant within-specialty variation in the responses in this group. The reasons cited for SMBG included enabling the person to understand the impact of exercise and food intake.

Physicians' recommendations varied from once or twice a week to twice daily. Some reported they recommended patients to use diabetes medications that promoted insulin secretion monitor levels frequently and to watch for signs of hypoglycaemia.

Pharmacists tended to suggest more frequent testing with readings taken up to four times per day. Reasons for the more regular monitoring of blood glucose levels included gaining a picture of blood glucose control, identification of hypoglycaemia, and fostering self-management skills.

Although an accepted indication for self- monitoring is to see how exercise and dietary changes impact on blood glucose levels, in Latter et al.'s (2011) study, HCPs did not describe how they explained this to their patients. The authors suggested healthcare professionals believed blood glucose monitoring would benefit all who perform it, which conflicts with findings from clinical trials and meta-analyses (Farmer et al. 2012; Malanda et al. 2012).

Conclusion: There is little in the literature that directly examines HCPs' attitudes or perceptions about SMBG. There appears to be a widespread belief that SMBG is beneficial for people with NITT2DM.

Clinical practice guideline recommendations

Clinical practice guidelines relevant to Australian HCPs were identified by a search for position statements from the relevant professional bodies. These included the Australian Diabetes Educators Association, Australian Diabetes Society, the International Diabetes Federation, and the National Institute for Clinical Excellence and the American Diabetes Association. Also, guidelines developed by the National Health and Medical Research Council, The Royal Australian College of General Practitioners, National Prescribing Service and the consumer organisation, Diabetes Australia, were examined.

The International Diabetes Federation (International Diabetes Federation 2009), the National Institute for Health and Care Excellence (National Institute for Clinical Excellence 2009), the American Diabetes Association (American Diabetes Association 2014) and the National Health and Medical Research Council (National Health and Medical Research Council 2009) have developed clinical practice guidelines that recommend self-monitoring of blood glucose for patients with NITT2DM where they possess the willingness and ability to incorporate the results into their clinical and self-management plans.

The Australian Diabetes Educators Association's (Australian Diabetes Educators Association 2015) Position Statement on this issue advises that the decision to undertake SMBG in people with NITTDM should be considered on an individual basis. Interestingly the Position Statement recommends that those HCPs involved in teaching SMBG be accredited directly for each meter they provide by a company representative or diabetes resource person (for example, a diabetes educator). The process of this accreditation is not defined.

The Royal Australian College of General Practice (RACGP) published a handbook on diabetes management for the use of General Practitioners (Royal Australian College of General Practitioners / Diabetes Australia 2014–2015). The 2014 - 15 edition does not support the routine use of SMBG by people with NITT2DM not using sulphonylureas.

In contrast, Diabetes Australia (Diabetes Australia 2015b) and the National Prescribing Service (National Prescribing Service 2015) both recommend SMBG for patients with NITT2DM.

In 2012, members of the European Federation of Clinical Chemistry and European Union of Medical Specialists examined to what extent current clinical practice guideline recommendations about SMBG in patients with NITT2DM were evidenced-based (Aakre et al. 2012). This paper identified many of the same guidelines that appear in this literature review.

Their findings suggest clinical practice guidelines are more in favour of self-monitoring in patients with NITT2DM than the systematic reviews and other evidence cited by them. Further, industry funding seemed to lead to a more positive attitude toward self-monitoring of blood glucose. The authors concluded that the principles of evidence-based medicine were not adhered to in the 18 clinical practice guidelines evaluated.

In summary, a review of currently available guidelines that apply to Australian HCPs demonstrates that they favour SMBG in people with NITT2DM. However, they also recommend that the patient is able and willing to incorporate the results into their management plan. This review indicates that there is an important role for the HCP to provide some form of assessment about the suitability of a patient to perform SMBG. Further, if the decision to perform SMBG is made they should then provide the patient with training around structured blood glucose monitoring.

It is interesting that at least one recent Australian resource - the RACGP Handbook on diabetes management - has indicated that people with NITT2DM should not routinely be recommended to perform SMBG. This new development possibly points towards a 'tipping point' as the amount of evidence indicating that SMBG does not result in substantial improvements in glycaemic control comes into conflict with the economic realities of health care.

Summary

Elucidating the interactions of the various competing factors that determine an individual's right to autonomous, informed decision making is highly aligned with qualitative methodology (Stewart 2001). Appreciating and understanding these factors is critical in intervening in the practice setting.

In legal terms, the right to informed, autonomous decision making reflects the process by which a health care provider informs a consumer of their treatment options, associated risks and benefits and supports them to make a decision (Consumers Health Forum of Australia 2013).

A range of disparate views and opinions have been identified. Interestingly, systematic reviews and meta-analyses fail to support the use of self-monitoring of blood glucose in achieving clinically significant and sustained improvements in glycaemic control in patients with NITT2DM (Allemann et al. 2009; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009). Furthermore, evidence suggests that self-monitoring may lead to an increase in anxiety and depression, and reduce the quality of life and well-being in some people (Beverly et al. 2012; Franciosi et al. 2001; O'Kane 2008; Rubin & Payrot 2001; Simon et al. 2008).

From a socioeconomic point of view, it is clear that SMBG is easily affordable in Australia and widely available to all but the most disadvantaged of people. This situation makes Australia unusual in the world context. The government subsidies of BGTS have further reinforced the view that SMBG is an important component of diabetes self-management.

People with diabetes see a range of health care professionals to receive education and advice on managing their conditions and SMBG is endorsed as an important component of diabetes self-management. Yet there has been little investigation to date that helps us to understand

the HCPs' perceptions regarding the value of SMBG in patients with NITT2DM and even less about how they formed these views.

Thus, this research is important to help us fill this gap in our knowledge and help us understand how Australian diabetes HCPs, from a range of professional backgrounds, form their opinions regarding treatment strategies through the lens of blood glucose monitoring in type 2 diabetes.

Chapter 4

Conceptual Framework

Introduction

This study has considered that clinical practice decisions are made in a complex milieu of factors: such as available evidence (Allemann et al. 2009; Farmer et al. 2009; Polonsky et al. 2011; Poolsup, Suksomboon & Rattanasookchit 2009), reports , policies (Australian Diabetes Educators Association 2015; International Diabetes Federation 2009) and funding models (National Diabetes Services Scheme 2015a).

As shown in the literature review there is a range of factors that have resulted in the view held by many HCPs that most, if not all, people with NITT2DM will benefit from the practice of SMBG. However, it is undeniable that a very different range of factors moderates any individual's behaviors in respect of blood glucose monitoring. The conceptual framework helps to distill the information contained within the literature review and serve as a link to the research approach applied in this research project.

Kitson and colleagues have undertaken a range of conceptual studies about implementing evidence into practice (Kitson, Harvey & McCormack 1998; Rycroft-Malone et al. 2002). They have identified three key elements that form the basis of a framework required for the successful integration of new treatment options – evidence, context and facilitation. In addition to these three elements, I have included a fourth: socioeconomic factors which are an expansion of the context, underscoring economic drivers.

Together, these four elements form the pillars necessary to support appropriate clinical practice decisions. This relationship is characterised in figure 1 in which the four elements are equal and provide a solid platform on which a patient may make appropriate choices. For a patient to make an appropriate and informed choice about SMBG, it can be assumed that all of these four pillars are present and equal in strength and integrity.

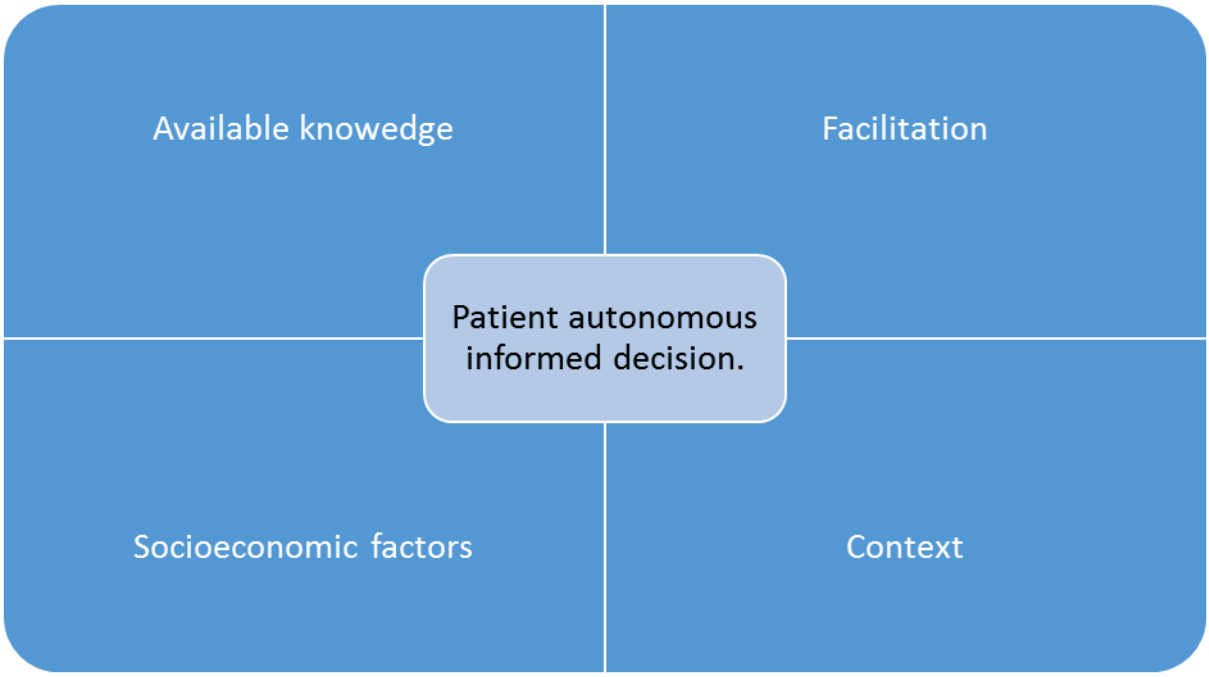

Figure 1. Conceptual Framework

These components of the conceptual framework are discussed in turn.

The patient: Informed appropriate clinical practice.

The ultimate value of any health intervention must ultimately be for the benefit of the person with the medical condition rather than the health care professional. This research is designed to help understand the perceived value of SMBG for the patient as seen through the HCP's eyes. Blood glucose meters are sold to the consumer on the basis that using one will enhance their understanding of their diabetes self- management practices and improve glycaemic control. Therefore the ultimate value of this intervention rests with the consumer who remains the central component of the conceptual framework.

Diabetes self-care is complex as it requires the person to balance lifestyle choices against the possibility of future potential diabetes-related complications. The empowerment model of diabetes education recognises that people have an inherent drive towards health (Funnell & Anderson 2004).

The goal of the empowerment model is to exploit this inherent drive by providing the patient with the skills and tools necessary to optimise self-care practices. Blood glucose monitors are advertised to patients with NITT2DM on the premise that SMBG will provide a compass to guide them on the road to better health.

Empowerment has much in common with patient-centred care, although some have criticised the concept of empowerment for implying that the patient has to take control even if their preference is not to (Asimakopoulou et al. 2012). Both patient-centered care and patient empowerment differ from the more traditional medical model where the patient is a passive consumer of medical advice provided by the more knowledgeable and powerful health care professional. In the medical model, the patient is simply expected to comply with instructions rather than take an active role in their self-care.

However, if the patient is to be truly at the centre of the decision-making process then the health professional – patient relationship is shared more evenly. Decisions are determined in partnership (Holmström & Röing 2010). The patient is given the best information available about the possible benefits and costs associated with the suggested practice or treatment and can then make an informed decision about whether to adopt the practice or not. In this scenario, a range of factors is considered by both parties. The HCP shares expertise and knowledge and allows the patient to determine the most appropriate course of action.

If any of the pillars supporting the patient in their decision are not equal and robust, then the decision itself will be unbalanced leaving the patient vulnerable to making less informed choices.

For example, Funnell and her team acknowledge that many HCPs are concerned about the limited time they have with patients and revert to the medical model of health to ensure they cover all the information that they feel it is important to convey (Funnell & Anderson 2004). If a HCP takes this approach, then the patient will only be given the recommendation to perform SMBG (or not) and will have limited information upon which to base their decision.

Pillar one: Facilitation

In relation to blood glucose monitoring, any HCP involved in the care of people with diabetes would be considered to be a “facilitator”. An effective facilitator will focus on helping and enabling the patient rather than telling a person or persuading them to take a particular course of action. The facilitator is concerned with addressing the whole person by matching their role and skills to the situation (Rycroft-Malone et al. 2002).

The facilitator will help the patient make the decision whether to perform SMBG based on their assessment of the patient's capacity to understand and act on the results (Australian Diabetes Educators Association 2015). If the patient makes the decision to perform SMGB, the role of the facilitator includes helping them to do so in a purposeful manner.

The repertoire of skills and attributes needed by an effective facilitator include respect and empathy for the patient, ease of access, supportiveness, self-confidence and the ability to think non-judgmentally (Kitson, Harvey & McCormack 1998).

The ADEA National Standards of Practice for Credentialled Diabetes Educators stresses the importance of defining goals in relation to blood glucose monitoring in collaboration with the patient (Australian Diabetes Educators Association 2014a).

The Facilitation pillar will be weakened if the facilitator is insensitive to the need of the patient or has a poor knowledge of the subject. Further, the support will be limited by the HCP's personal beliefs about what choices the patient "should" make, especially if this belief influences what information and resources are provided to the patient (Asimakopoulou & Scambler 2013).

Pillar two: Available knowledge

For interventions such as blood glucose monitoring to be sustained and successful, there must be evidence of its effectiveness. The evidence to support the intervention must be of high standard and include rigorous systematic (quantitative or qualitative) evaluation or be based on high levels of expert consensus (Kitson, Harvey & McCormack 1998).

The choice of term "Available Knowledge" is deliberate. No matter how good the evidence is, it is of no value on its own. This evidence should be disseminated or easily obtained and understood by all those on whom it impacts. In matters relating to health, this will necessarily relate to the scope of practice of the health care provider. For example, a podiatrist might have a limited understanding of blood glucose monitoring whereas a diabetes educator would be expected to have a deeper and thorough understanding of the topic.

Although the depth of understanding is different between HCPs, if the available information is based on good evidence and widely disseminated as in this example, the overall messages should be consistent.

The Evidence pillar will be weakened if evidence is of poor quality or is inconsistent. Further, the Evidence pillar will be weakened if the available evidence is not widely disseminated or understood by those it impacts.

Pillar three: Socioeconomic factors

For any intervention to be successful, it must be affordable for the patient and easily accessible. Another factor is how socially acceptable is the proposed practice? No matter how important an intervention is to the health of a patient, if they feel uncomfortable with the practice, they will be disinclined to commence or continue with it.

Several factors may be important here – for example, the social perspective. If the patient and their HCPs are familiar with an intervention and it is seen to be common practice then they may be less inclined to question recommendations. In relation to blood glucose monitoring, this may result in the perception that the person should also carry out the activity. The patient may then feel obliged to perform SMBG due to pressure from their family or their health care providers.

Critical social theory involves the critique of society and consideration of perspectives and actions in the social environment. According to critical social theory, the identity of any individual in the post-modernist phase is shaped through the commodities they purchase and use (Dant 2003). For many HCPs, the recommendation for patients with NITT2DM to conduct SMBG has moved beyond simple endorsement to expectation. There exists a view that a person who does not perform SMBG cannot be said to be fully committed to self-managing their condition, leaving them open to criticism. It also signals that health care is highly contextually driven and influenced beyond merely health care professional's recommendations.

In this instance, the characterisation of diabetes has become synonymous with owning and using a blood glucose meter and visa-versa. Therefore, for many HCPs, they view individuals as non-adherent who do not perform SMBG as this conflicts with their perceptions on how they

understand people with diabetes should act. This is in spite of limited evidence to support this value proposition.

Subsequently, when a person is diagnosed with diabetes, they are frequently directed to obtain a blood glucose meter. The person carries out this instruction with an expectation that it will be of benefit to them. This is emphasised by marketing and often health education material. Despite, or because of this expectation, there appears to be limited opportunity for training in its use and even less consistency in the way that education is provided. The majority of patients obtain their blood glucose meters over the counter at pharmacies where the likelihood of receiving comprehensive education about how to use the device is limited. Recently an increasing number of patients have purchased the meters online where the likelihood of receiving any substantive education is virtually non-existent.

Advertising plays a significant role in the promotion of blood glucose monitoring. There is a multitude of ways that blood glucose monitoring is promoted. Through direct advertising in print and visual media to in-store promotions at pharmacies. Such promotions necessarily highlight the apparent benefits of an intervention with scant mention of any negative consequences, compelling the person with diabetes to perform SMBG. Consequently, the views of both HCP and the patient could be based on biased information.

The Socioeconomic pillar will be weakened if the intervention is too expensive or not readily available. In contrast, the strength of the pillar can be over inflated due to expectation rather than fact or if belief in the validity of the intervention is based on biased information. By making blood glucose meters very cheap or free, patients are more likely to accept one. Any potential negative considerations are discounted as there is little or no financial penalty.

The strength of the pharma lobby advocacy group is important in this equation. Blood glucose monitoring is worth a significant amount of money to the companies involved, but their viability depends very much on the ongoing subsidisation of BGTS. By creating an expectation that patients need a blood glucose meter to manage their condition effectively, and by ensuring as many people as possible own one, a compelling argument for subsidisation is established.

Pillar four: Context Local contextual factors

Kitson defines context as the forces at work that gives the environment character and feel (Kitson, Harvey & McCormack 1998). Of importance here are the impact of leadership and the approach to monitoring of systems and services. Rycroft-Malone takes the definition of "context" further by noting it to be a dynamic process' patterns of power and authority, resources and feedback systems (Rycroft-Malone et al. 2002).

Within the context of diabetes self-management, nearly all policies support the practice of SMBG in people with NITT2DM. The Australian Federal Government due to its long-term subsidisation of BGTS appears to represent a powerful argument for people with NITT2DM to perform SMBG. There would be an expectation that the practice over time has been reviewed and found to be of benefit.

The context pillar can be weakened by relying too much on tradition – simply doing it because it has always been done this way- and a lack of ongoing evaluation and consideration of any feedback. In addition power relationships and hierarchical models of practice can influence health care delivery.

Summary

The conceptual framework highlights four elements that need consideration when determining the health care professionals perception of SMBG for people with NITT2DM. Specifically the context in which the decision is made, the knowledge that exists about the treatment options, the socioeconomic environment and the effectiveness of the facilitator in explaining treatment options.

The literature review indicates via the conceptual framework that the platform on which the patient's autonomous decision about blood glucose monitoring is not balanced. See figure 2. The framework in figure 2 is dominated by socioeconomic factors and context both of which make it easy to obtain and use a blood glucose meter in Australia. However, the available knowledge does not support the practice in such a robust way, and the facilitation pillar is diminished by the HCP's limited capacity to assist people to use SMBG in a meaningful manner.

Nevertheless, the recommendation to perform SMBG by health professionals as part of diabetes self-management appears to persist and most guidelines and resources related to the issue continue to support the practice. The research approach should therefore involve a

sample of health care professionals from a variety of professional backgrounds to gain insight into what perceptions they hold and how they were formed.

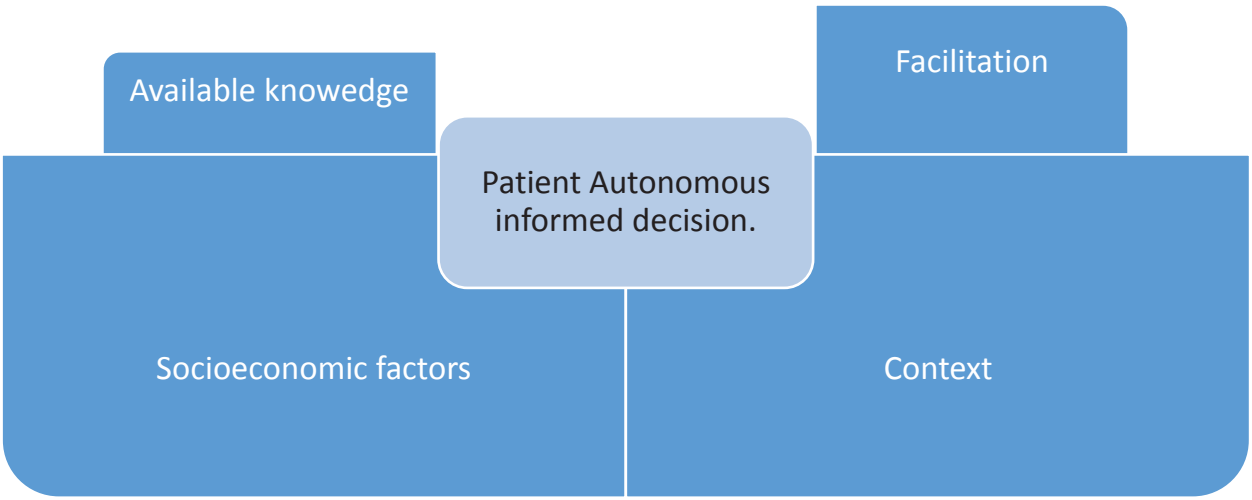

Figure 2. Changes in the balance of factors driving decisions

Chapter 5

The research approach

Introduction

This chapter provides the reasons why a qualitative approach was appropriate for this investigation and outlines the different methods of qualitative research that were considered. Justification for the choice of a qualitative descriptive approach is provided specifically in relation to the study design. In this chapter, I also declare my personal beliefs on the subject so that the reader can judge whether my preconceived notions have influenced the findings.

The development of the interview guide follows, referencing previous research in addition to the more recent debate in Australia about the ongoing subsidisation of BGTS. There is also an explanation of how study subjects were selected and invited to participate.

This chapter outlines how the data was gathered and analysed and how issues around ethical behaviour and trustworthiness of research were managed.

As I am interested in gaining insight into health care professional's perceptions of the value of self-monitoring of blood glucose in the Australian context, I employed a qualitative approach to this study. Qualitative research is concerned with the why and 'in what way' of decision-making rather than the what, where and when of an issue (Fossey et al. 2002). It relies on an exploration of perspectives, experiences, and meanings rather than on data that can be quantified (Carter & Little 2007).

Qualitative research aims to generate insight into the nature of the research question through the participant's eyes. In contrast to quantitative research, the relationship between the researcher and the participants becomes an integral component of the research itself (Milne & Oberle 2005).

The convictions that HCPs form regarding their practice is due to exposure to a multitude of influences. They are established through a variety of formal learning processes such as undergraduate training and post-graduate course work and informal processes such as personal experiences, discussions with peers and reading of related literature. These learning processes form the basis for practice based on "tacit" knowledge. Practice based on tacit knowledge is 'taken for granted' and is difficult to articulate or write down (Zeira & Rosen 2000).

Qualitative research typically involves a study of a smaller number of subjects using interviews and conversations to allow subjects the freedom to reflect on their experiences and explain in their words how they arrived at their conclusions. Further, as it involves the study of the subject in their natural setting, a qualitative researcher may use observation, field notes and photographs to enrich their understanding of the data and make sense of phenomena in the terms of the subject (Ritchie & Lewis 2003). Through a qualitative approach, it may be possible to understand how and why HCPs develop their convictions and make certain recommendations regarding SMBG.

Having determined that a qualitative research approach is appropriate for this study, it was then important to determine the appropriate qualitative method to utilise.

The qualitative description approach

There are a number of forms of qualitative research (Whittaker 2000): Phenomenology (Al-Busaidi 2008), Biographical study (Roberts 2002), Ethnography (Al-Busaidi 2008), Case study (Soy 2007) and Grounded theory (Strauss & Corbin 1994).

Other forms of qualitative research include Action research (Berg 2004), Narrative inquiry (Josselson 2006) and Feminist research (Hesse-Biber 2012).

As the study protocol under consideration involved interviewing a range of health care professionals I initially considered the grounded theory approach would suit the objectives of this study.

However, grounded theory research tends to focus on close investigation of a phenomenon by interviewing a limited number of subjects in great depth using a limited number of questions. The researcher attempts to develop theories from “the ground up” - in other words, to develop an explanation that emerges from the analysis of the data collected to explain certain human behaviours (Thomas & James 2006).

My intention was to interview a larger number of health care professionals from a broad range of health disciplines, using a structured question route with the capacity for elucidation and clarification. As a consequence, I chose a qualitative descriptive approach for this study.

Qualitative description is a general inductive approach commonly used in health and social science research and has particular utility in health services research. A qualitative descriptive approach typically involves the development of an interview guide, and the researcher uses this to provide a framework for discussion with the subjects of interest. The interview is

recorded, transcribed and the data is then analysed to determine themes and ultimately to arrive at a possible explanation for the behaviour under investigation (Thomas 2006).

A qualitative, descriptive approach employs an interview guide that is based on a series of open-ended questions in a larger and varied representative sample of the subjects of interest. The researcher applies less of an interpretive approach to explaining human behaviours and is less intimately involved in developing theories from the data (Neergaard et al. 2009).

As with grounded theory, the qualitative, descriptive approach provides a rich, description of experiences or events. However, a more literal and less interpretive analysis of the data allows for a description of the participants experience more or less in their own language (Neergaard et al. 2009).

A major benefit of the qualitative descriptive approach is that it allows for more significant or unanticipated themes to emerge from the raw data rather than potentially being obscured or remain unidentified when the researcher a employs more interpretive approaches such as Grounded Theory where themes are used to generate a theory or Phenomenology where emerging themes are used to convey in words how people derive meanings from certain experiences. (Thomas 2003).

Ontology has been identified as the form and nature of reality and what can be known from it (Guba & Lincoln 1994). The qualitative descriptive approach enabled me to gain insight into how health care professionals come to their current beliefs and attitudes about self-monitoring of blood glucose in their own words and demonstrate a clear link between my findings and the research objectives. The product of this research is an attempt at concisely capturing and summarising the data provided by the participants.

From an axiological point of view I hope that this research may help guide practice or policy particularly in the areas of government subsidy and HCP training. At a minimum I am motivated to challenge health care professionals to examine how it is that they draw conclusions about the value of health interventions.

From an epistemological stance there must be an acknowledgement that although the interpretation of the health care professional's perception of the value of SMBG for people with NITT2DM in this study may have been generated less from other more theoretical approaches there will always be an element of interpretation by the researcher (Kahlke 2014).

Personal beliefs and positioning

It is appropriate in qualitative research to position oneself in relation to the research. For the sake of transparency, it is important to declare my views on the subject to reveal my biases and to explain the steps I took to minimise their impact on the study.

My professional role as a diabetes educator has brought me into contact with many people with diabetes. It has been my observation that people with diabetes who own a blood glucose meter may derive benefits from its use. These benefits may include learning how to recognise hypoglycaemia, the satisfaction that they are actively participating in managing their condition and, to some degree, determining the effects of lifestyle and oral medication on blood glucose levels. However, I have also observed that other people with diabetes who have not received adequate instruction or discussion about the limitations inherent in the use of these devices may have an unsatisfactory or even stressful experience.

My career has included five years working at Diabetes Australia-NSW (now Diabetes New South Wales), the peak body representing people affected by all types of diabetes and those at risk. During this time, I was charged with coordinating a diabetes education program for pharmacists and pharmacy assistants. This experience gave me valuable insight into the commercial aspects of blood glucose monitoring. I have noted and discussed with pharmacists an apparent tension between their genuine desires to assist customers while simultaneously conducting a viable financial venture.

My experience as a member of the Australian Diabetes Educators Association (ADEA) Board of Directors included involvement with the ADEA Sponsorship Committee. This experience brought me into contact with many high-level executives and representatives from blood glucose meter companies. I was also a long-serving member of the Australian Diabetes Educator, Magazine Editorial Advisory Group (MEAG) where decisions regarding the amount of blood glucose meter advertisements and advertorials were considered.

Over 20 years working as a diabetes educator and observing the interactions of representatives of companies that sell blood glucose meters highlighted that blood glucose meter companies face a similar dilemma; in other words, supplying meters as part of a profit-making venture to people who may or may not gain substantial benefit from using them.

I, therefore, declare a level of scepticism about the claims that some blood glucose meter companies and health care organisations make regarding the benefit of blood glucose monitoring for ALL patients with diabetes. By acknowledging these preconceived views, I was

able to minimise the effects of any bias I brought to the analysis by reviewing the data for ideas and concepts that did not match my own (Malterud 2001). Importantly, throughout the research process, I was aware of my positioning, and this was openly discussed within the research team.

Development of the interview guide

Interview guide and synopsis

It has been said that the quality of qualitative research may rest on how well the researcher understands the subject (Gibbs et al. 2007). My immersion in the field of interest has given me a unique perspective and knowledge on the subject providing me a greater insight into issues relating to blood glucose monitoring.

In 2011, a study of Canadian health care professionals (Latter et al. 2011) was reported and included a number of similar aims to this proposed study. Following permission granted by Latter, I adapted her interview guide to suit the aims of the current study. Different from them, I was interested in understanding how HCPs form their views regarding the value of SMBG in people with NITT2DM, if and how they are educated in the purposeful use of self-monitoring of blood glucose, and what information they would like to receive and in what way. Also, I was keen to see if the participants had been aware of patients experiencing any positive or negative outcomes related to the practice of SMBG.

Further modifications to the study guide came about due to an analysis of submissions included in the Australian Health and Welfare Institute Utilisation Review of Blood Glucose Test Strips. In 2012, the Australian Department of Health Care and Ageing launched a review of the BGTS subsidies. The objective of this review was to evaluate the body of clinical evidence regarding diabetes interventions to ensure people with diabetes are using the most appropriate medicines and products (Dept Health and Ageing 2012).

As part of the review, the Department of Health and Ageing received 32 written public submissions. These submissions were provided by a variety of individuals, consumers and health professional and industry organisations. Further discussion about these submissions and detail about the analysis can be found in Appendix C.

The call for submissions for the review of blood glucose test strips (Pharmaceutical Benefits Scheme 2012a) included the following terms of reference:

1. Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes;
2. Determine the clinical outcomes and benefits of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with type 2 diabetes not treated with insulin;
3. Consider the clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring.

Understanding the drivers for blood glucose monitoring in NITT2DM is dependent on understanding a range of views of stakeholders.

I seized on the opportunity to analyse the written submissions in order to:

1. Explore the views of the various stakeholders
2. Determine themes emerging from the data (thematic analysis)

The aim of the thematic analysis was to identify issues raised in the submissions and use this information to help generate questions for use in the interview guide for this study.

A common theme that emerged from many of the submissions was the importance of using a structured approach to blood glucose monitoring if patients with NITT2DM are to benefit from the practice. From this theme, questions were formulated to ascertain if HCPs had received training in the use of this structured approach.

Consequently, the interview guide was modified to include the following questions:

1. Can you give me examples of any information you have recently accessed or have been exposed to that has indicated the value or lack of value regarding the use of structured SMBG in patients with non-insulin treated diabetes?
2. Can you tell me if that information you have accessed or received has been helpful in assisting your non-insulin treated patients perform structured SMBG in an effective manner?
3. Can you tell me if your professional training – undergraduate or postgraduate, contained specific information about how to teach people with diabetes to perform structured SMBG?

4. Can you tell me if there is any information or training you would like to receive that would be helpful in assisting your patients with diabetes perform SMBG in an effective manner?

I was also interested in exploring if, and to what extent, they were aware of any controversy regarding the use of SMBG in people with NITT2DM. Therefore a question was included to ascertain whether the HCPs were aware of the evidence in the scientific and grey literature that SMBG may not provide significant clinical improvements in glycaemic control. This may result in the HCP also questioning the value of the practice and influence their perceptions of the value of SMBG.

In total, the study guide that was developed centred around the same four broadly-based categories that were used in the Latter et al. (2011) study. These categories were:

1. Beliefs, recommendations and practices in relation to SMBG

2. How the HCP uses the results from blood glucose monitoring

3. Factors influencing the health care professional's recommendations regarding blood glucose monitoring

4. The sources of information HCPs access or are exposed to in relation to blood glucose monitoring

From these categories, an interview guide consisting of thirteen open-ended questions was developed to guide the interview and ensure a degree of consistency of discussion (Appendix B).

The use of open-ended questions allowed the participants to elaborate on their responses and provide as much rich and detailed information as they were willing to provide (Boyce & Neale 2006). The flexibility inherent in this approach allowed me to draw out further detail and ask the participant to expand on an issue using probing questions to invite further reflection (Boyce & Neale 2006).

The interview questions were designed to be as neutral as possible without appearing judgemental, and were to be asked one at a time and worded clearly (Turner 2010). The data that arose from the interview transcripts and field were repeatedly analysed. This sequential or interim analysis allowed for changes in the direction of the enquiry as a better understanding of the data emerged (Pope, Ziebland & Mays 2000).

The use of semi-structured interviews allowed for focused discussion of the topic (Fossey et al. 2002). HCPs had the opportunity to describe their experiences in depth and explain their reasons for their answers (Neergaard et al. 2009). HCPs were allowed, for example, to explore to what degree their views and decisions have been influenced by their undergraduate and postgraduate training, currently available guidelines or advertising.

A number of questions were the same or similar to the Latter et al. (2011) study, and I am confident that the findings from this study will add to our understanding of the similarities and differences between the views held by different HCPs regarding the value of self-monitoring from an international perspective.

To refine the interview guide, a pilot study was conducted with four participants. Recordings of pilot interviews and the transcripts were analysed to ensure the researcher allowed those interviewed the opportunity to provide their views. The interview guide was structured to be brief so as to capture a wide range of health care providers.

Selection of participants

Purposeful sampling of a variety of HCPs with direct relevant knowledge helps to gain insight into the subject (Neergaard et al. 2009). It is important to include enough participants to ensure that the views of those working in the different professions are adequately represented (Coyne 1997).

Qualitative sampling requires identification of the appropriate people who can participate in, and inform the study (Coyne 1997). My intensive and varied involvement in the field of research allowed me to identify those health care professionals who can provide insightful as well as diverse views (Gibbs et al. 2007).

There are a variety of HCPs potentially involved in the care of people with type 2 diabetes. These HCPs include general practitioners, diabetes educators, primary care nurses, dietitians, endocrinologists, podiatrists, optometrists/ophthalmologists, psychologists, and exercise physiologists (Diabetes Australia 2013). A sample of three to five persons from the following professions were invited to participate. There were no age or gender criteria for selection.

Pharmacists

Blood glucose meters are most often obtained through pharmacies with customers served by pharmacists or pharmacy assistants (Bwititi, Angel & Day 2008).

Pharmacists were invited to participate via targeted phone calls to pharmacies in the Northern Sydney Local Health District (NSLHD) area. Some pharmacists were invited to participate by their colleagues by way of a "snowball effect".

General practitioners, primary care nurses and endocrinologists are in a position to encourage the use of SMBG and to interpret the results to assist with decision making regarding medication and lifestyle practices. General practitioners and primary care nurses were invited to participate with the assistance of the North Shore Medicare Local. Endocrinologists who work in the Northern Sydney Local Health District were contacted by direct phone call.

Dietitians may also encourage the use of SMBG and interpret the results in their assessment and education of patients regarding food intake (Dietitians Association Australia 2006). Dietitians from the Northern Sydney Local Health District Diabetes Special Interest Group were invited to participate via email or phone call.

Diabetes Educators were invited to participate via a direct phone call to metropolitan diabetes centres. Diabetes educators from the Northern Sydney Local Health District were not included due to my close working relationship with many which may have influenced the answers provided in the interview process.

Participants who agreed to be interviewed were asked to sign a consent form prior to participation, and all interview transcripts were de-identified.

I determined not to interview representatives from the professions of podiatry, psychology, and optometry/ophthalmology or exercise physiologists as they would be less likely to influence a patient's decision to perform self-monitoring of blood glucose.

Pilot study

Ethical approval was obtained for the study as shown in Appendix A. Initially; four pilot interviews were conducted with HCPs to ensure the HCP understood the questions that were asked and that I had not influenced the responses of the interviewees. Those interviewed included a pharmacist, a general practitioner and two primary care nurses.

My principal Academic Supervisor (PD) conducted an interview with a pharmacist. I (GB) interviewed the remainder of these participants.

Rapport was readily established as both interviewer and interviewee were health professionals. The HCPs were keen to share their experiences and generously made time for

the interviews. Although I had met with the general practitioner and the primary care nurses, I had not worked directly with them. Each interview commenced with a brief overview of the aims of the study and reassurance that participation in the study was voluntary and that the interviewee could withdraw at any time without fear of penalty.

The interview process

The interview process was mindful of ethical issues and consideration of individual participants. Participants did not need to answer any question they did not wish to discuss and were free to clarify any questions or add additional information at any time.

It was explained to all interviewees that data would be de-identified and that their anonymity was assured. Permission was sought to audio-tape all interviews. Signed consent was then obtained from the interviewee.

This introduction provided an opportunity for the participant to ask any questions. Interview questions were asked as per the interview guide and were recorded using a data recorder. Following the interviews, the recorded interviews were subsequently transcribed by myself so that I could fully understand what emerged from the data. Transcription occurred as soon as possible after the interview to ensure that the written word was a close as possible to the spoken word. I listened to recordings twice to ensure the fidelity of the transcripts and to make any needed corrections.

Field notes were recorded describing the context in which the interview took place and any other relevant details. Questions that required clarification by the HCP were noted, as were questions that appeared to be repetitive or provided similar responses. Also, of note were questions asked by the interviewer that were not in the interview guide but prompted by the responses of the participant.

The limited interpretation used in the qualitative description approach demands neutrality on behalf of the researcher. Thus, it is vital that multiple researchers review the content of the recording and transcripts in the analytic process to identify if a breach of neutrality occurred.

A number of the transcripts were reviewed by my academic supervisors throughout the data collection process and analysis. This process ensured that I had conducted the interview in such a manner as to not bias the results by asking leading questions. The original study guide was reviewed and modified slightly to ensure the guide remained faithful to the project proposal and ethics approval.

The rigorous reading and rereading of the transcripts allowed some early data analysis. One early indication from the data was that pharmacists of all of the HCPs appeared to hold a more diverse set of views on SMBG than other health care professionals, prompting a decision to interview more pharmacists. This form of guided sampling is a strength of qualitative research and allows for an intensification of the understanding of the research problem (Gibbs et al. 2007).

The remainder of the interviews were conducted using the modified interview guide.

Sample and setting

In all, 25 semi-structured interviews were conducted, and all participants worked within the Central Sydney and Northern Sydney Local Health Districts. The interviews were conducted between June 2014 and January 2015. Interviews ranged between 12 minutes to 32 minutes.

Those interviewed included six pharmacists, five diabetes educators, three dietitians, four general practitioners (GPs), three primary care nurses and four endocrinologists. One pharmacist was a new graduate. The remaining were more senior pharmacists and all were employed in private pharmacies in metropolitan Sydney.

One of those interviewed, one was a general practitioner registrar. The remaining three GPs each had a minimum of 10 years practice and one with a career of over thirty years also had a role in teaching junior medical officers at a university.

One dietitian worked in a metropolitan hospital diabetes service the other two were working in private practice. All diabetes educators worked in hospital-based diabetes services and had a minimum of five years' experience in the role. Primary care nurses worked in a variety of small to medium sized general practices. All endocrinologists were working in private practice. Some had teaching roles at universities, and one was a visiting medical officer at the time of the interview at a large metropolitan hospital.

Where possible, interviews took place where participants felt most comfortable to allow the HCP to feel at ease when answering questions (Boyce & Neale 2006). The majority of the interviews occurred at the HCP's workplace on a face-to-face basis. Seven interviews were conducted by phone as was the HCP's preference. If preferable the participants were able to come to my office for the interview. Two interviews occurred in my office; one occurred in the interviewee's home and one in a spare room at a shopping centre.

The interview guide was modified slightly to clarify the question of a structured approach to SMBG. Sequential analysis of the data was inevitable as researchers cannot help to think about

what is being heard and seen. This interim analysis has the advantage of allowing for constant refinement of the interview questions and the pursuit of emerging avenues of inquiry (Pope, Ziebland & Mays 2000).

Analysis

All interviews were audio-taped, and recordings transcribed verbatim. One-third of the interviews were transcribed by myself and the remainder by a professional transcribing service. All transcripts were reviewed twice while listening to the recorded interview to ensure the fidelity of the transcription and to review the discussion and the manner in which it was conducted.

Field notes were compiled during the interviews depicting contextual and non-verbal data illustrating, among other things, the environment in which the interview took place. Drawing on these aspects of the interview helped to recall certain details and a greater depth of analysis (Creswell 2007; Green et al. 2007).

Open-ended questions result in data that is rich and time-consuming to explore fully and analyse. Consequently, a primary consideration was to allow sufficient time for the sifting through the vast amounts of data until I became familiar with the content. Through this process, I gained an understanding of the themes and events covered in the text (Thomas 2006).

The transcripts were read and re-read (Sandelowski 1995). Re-reading the transcripts allowed a detailed examination of what had been said so that ideas started to be generated (Green et al. 2007). Although the findings may have been influenced by own objectives or questions, the analysis focused directly on the raw data, not from my expectations (Thomas 2006).

The content of these transcripts then underwent content analysis. Words that appeared to capture key concepts were highlighted and coded to elicit common themes (Hsieh & Shannon 2005). These fundamental concepts were then placed into categories and subcategories to help identify similarities and differences between the different responses (Stemler 2001).

The more general categories were derived from the aims of the study with specific categories emerging from multiple readings of the raw data (Thomas 2006).

To give voice to those interviewed, it was necessary to incorporate multiple perspectives and quotes from participants. According to Gall, Gall, and Borg (Gall, Gall & Borg 2006), this

reduces researcher bias within the study, particularly when the study involves multiple participants. Many of these quotes are included in the reporting of the data.

As discussed in the previous chapter, the qualitative descriptive approach for the analysis of data condenses information into a brief, summary format; and links these to the specific research question. This enables the structuring of views, perspectives and experiences emerging from the data.

Assessing trustworthiness

The interpretive nature of qualitative research analysis is unavoidably influenced by the views of the researcher, potentially giving the participant the impression that their views have been misrepresented or taken out of context (Richards & Schwartz 2002).

Ultimately, the published results are a 'version' of the truth. The validity of the results is inevitably judged by the care with which the data has been analysed and how authentically the participant's points of view are presented. It is important that a clear account of the process of data collection and analysis be outlined (Pope, Ziebland & Mays 2000).

I will discuss how systems of classification evolved, and clearly define how the concepts and explanations were derived in the results chapter.

The quality of the trustworthiness of the data was determined in three ways:

1. Comparison to the Latter study: As a similar study has been conducted by Latter (Latter et al. 2011), I made comparisons with the categories developed in their study.
2. Inter-rater reliability: After undertaking an initial analysis and developing a set of categories, a second coder was asked to separately review the evaluation objectives and the raw text found in the transcripts.
3. Stakeholder checks: Analysis of the findings were made available to participants prior to being published upon their request. This opportunity allowed the participants to validate the information they have provided should they feel the need to do so.

A further strategy employed to help ensure that the research is reliable and to develop a more sophisticated understanding of the issue was to use different data gathering techniques (Fossey et al. 2002).

During the data collection phase, I collected additional data in the form of guidelines /resources used by health care professionals to guide/inform their practice. This information

along with interview transcripts and field notes was included in the analysis of data (Blumer 1969).

Ethical Issues

Confidentiality and consent

Consent to participate in the study was obtained from the participants prior to the interview. I clearly outlined the purpose of the study, briefly explained my background and my interest in the subject. I discussed the scope and types of questions that were to be asked, the methods that were to be used to de-identify participants, and how the results will be disseminated (Richards & Schwartz 2002).

Data were only made available to my supervisors who made up the study team and who have received training in ethics, confidentiality and consent (Fritz 2008).

Results were reported in a manner to maintain anonymity. All transcripts and field notes were recorded in such a way as to not contain personal identifiers and were stored in a locked cabinet in my office at Hornsby Hospital. Other methods to ensure confidentiality included keeping raw and processed data locked and password protected.

Participants were not coerced or offered any inducements to participate in the study. I explained that involvement in the study was voluntary and that it was possible to withdraw at any time.

To reduce the possibility of selection bias, only participants with whom I had not directly worked with were targeted and participated in the study. Ethical approval is shown in Appendix A.

Conclusions

A qualitative approach was identified as the most appropriate method to understand the perceptions of a wide range of Australian HCPs and also explore the complex interaction of social, political and economic factors. In this instance, the study subjects included those HCPs directly known to be directly involved in the delivery of diabetes care with specific experience related to the use of blood glucose monitoring.

Further, this approach allows for analysis and interpretation of the data to directly answer the research questions. The choice to use a number of similar questions and subjects to a previous study was deliberate as it provides an opportunity for an international comparison and a strengthening of the validity of the study results. However, the interview guide was modified

in response to issues raised by the Pharma lobby in the Australian Department of Health and Ageing (2012) review of the blood BGTS subsidies.

This chapter has presented the methodological considerations regarding the choice of a research method. A qualitative method was determined as appropriate to answer the primary research questions. The following chapter provides the findings of the study.

Chapter 6

Findings

Introduction

This chapter presents the findings of the research study and analysis including the research themes that have been generated.

Seven main themes are presented. Theme one: The perceived value of blood glucose monitoring in people with diabetes varies within and between health professional groups. Theme two: The information our patients receive about blood glucose monitoring is limited. Theme three: Blood glucose monitoring is not a benign activity and can have negative consequences. Theme four: The health care professionals most likely to use the results in a structured manner are diabetes educators and dietitians. Theme five: the capacity to provide specialised training to patients is limited. Theme six: Professional training does not address blood glucose monitoring. Theme seven: HCPs want impartial information about SMBG and would like to receive it in a convenient manner.

Theme one. The perceived value of blood glucose monitoring in people with diabetes varies within and between health professional groups.

In this section, I have organised the results in relation to research question one:

What perceptions do HCPs hold about the value of self-monitoring for people with type 2 diabetes with NITT2DM?

Overall there was a wide variety of views and perceptions expressed both from within the same professional group and between different professional groups. Some HCPs from within the same professional group would indicate that there was no point in SMBG as it did not change their practice while others expressed a view that SMBG provided benefits irrespective of the level of glycaemic control.

These benefits ranged from engaging the patient in the management of their condition to providing feedback about the food they were eating. However, several HCPS also reported witnessing patients being adversely affected by SMBG and would actively discourage the practice.

While the responses were varied, the HCPs considered a range of factors including respect for the autonomous decision of the patient to monitor blood glucose levels. Other factors that would influence their perceptions were the age and personality of the patient, if the patient was unwell, changes to their HbA1c and escalating medication requirements.

Interestingly those from the medical professions expressed quite different points of view; while most GPs questioned the value of SMBG in all people, the endocrinologists indicated that they would routinely recommend the practice. As a consequence of these different views, patients appear potentially exposed to conflicting information depending on whether they saw a GP or a diabetes specialist.

Pharmacists provided diverse views with some stating that they would recommend SMBG, and others stating that they would not, feeling that the regular visit to the doctor was adequate. At least one pharmacist seemed to contradict himself by saying that he would not recommend SMBG in this group, however also commenting that it would be a good habit because it helps them to identify the effects of food: “As a general rule, no. If they are motivated, I wouldn’t deter them it would be good habit forming tool because it would show them if they’d eaten poorly, then I would say maybe I should decrease that part of my meal and increase something else”.

A common theme begins to emerge at this point in relation to pharmacists wishing to foster a professional relationship with local doctors, with one pharmacist indicating that they would take direction from those with which they have dealings: “If their doctor has asked them then they should be doing that…..the doctor is trying to monitor them to see whether they need medication”.

Moreover, another said: “Patients are going to get the best treatment if they have a regular record of how their sugars are travelling. This allows the patient to track how their medication is working and assist the doctor make dose adjustments”.

Diabetes educators provided complex and also at times apparently contradictory responses, giving thought to a range of factors that would potentially influence their perceptions.

One educator indicated that they would not view SMBG as essential but rather a useful skill to have in order to understand postprandial rises in blood glucose levels. While another states: “I don’t generally. I give them the option, if they don’t want to, I say their GP could monitor it through HbA1c”.

One response was quite revealing and demonstrated how ambivalent diabetes educators are in relation to this practice: “I would have to dig deep to find a reason for it” on one hand, but then going on to say that they often use it as a “learning tool”.

Several sub-themes emerged from these questions. The choice of oral medication that could cause hypoglycaemia played an important role increasing the perceived value of SMBG for most HCPs. Another was that multiple medications would indicate a deterioration in glycaemic control and prompt them to support the practice. It was suggested that SMBG results might be used to help patients understand the rationale for escalating medical management including insulin.

Some HCPs expressed frustration regarding the proliferation of blood glucose meters and the marketing strategies of some meter companies.

There was also a recognition of the importance of education for the patient using blood glucose monitoring effectively. However, it was expected that a diabetes educator would provide this education.

From the range of responses, it could be inferred that if a patient has a satisfactory HbA1c result and they are not on medication that can cause hypoglycaemia, monitoring may be considered more a matter of choice. However, if the patient chose to monitor the decision should be supported by relevant education.

Sub-theme one: Blood glucose monitoring is not necessary

Overall these responses indicated that HCPs felt SMBG is not necessary for monitoring glycaemic control, which is more appropriately determined by the HbA1c assay.

Primary care nurses, as a rule, did not recommend SMBG and felt that an HbA1c assay was satisfactory for determining glycaemic control.

Dietitians also felt that SMBG was not critical and recognised that SMBG could prove to be problematic for some patients. There was an appreciation that sometimes people are simply not motivated to conduct SMBG and for some it is a cause of distress. One dietitian commented: “For many people they find it an annoyance, or it is something unpleasant that they have to put up with”. The issue of patients experiencing a level of distress was a recurring theme throughout the interview process and is covered in more detail in theme three.

Another commented: “You see people who are regularly testing and their blood sugars are all pretty much perfect, and they just keep testing and testing routinely. I would tell them you don’t really need to be doing it on an ongoing basis”.

Dietitians felt that some people may be able to use it as a way to obtain feedback on the effects of food: “If clients want feedback about the effect of certain foods on their blood sugars I certainly wouldn’t discourage it”. However, dietitians suggested that the recommendation for SMBG would be more likely to come from a diabetes educator or doctor.

One practising GP indicated that they felt the need for SMBG in this group is questionable as it “does not change what they do from day to day”. She differentiates between SMBG as a tool to help keep them on “the straight and narrow” and as a tool to change management: “I think in medicine we do way too many things that don’t have a lot of value. Like if something is not going to change what I do in any way then I think we need to be questioning whether we routinely recommend it”.

The GP Registrar substantially agrees with these sentiments: “These patients are at no particular risk of hypoglycaemia or determining the effects of medication”, suggesting that she would tend to rely on HbA1c and fasting BGLs. In fact, she commented further that “the introduction of oral medication was unlikely to change her opinion”.

Sub-theme two: SMBG is always recommended – especially when there is education

A recognition of the importance of education for the patient using blood glucose monitoring effectively emerged, and there was expectation expressed that diabetes educators would provide this education. Some HCPs expressed frustration with the proliferation of blood glucose meters and the marketing strategies of some meter companies.

The one group that were in favour of SMBG in this group were endocrinologists who would routinely recommend the practice, commenting that it could be educational: “I personally would, but the frequency and the timing would probably differ depending on various factors such as how good their insight is and what their existing control is like”. Another indicated that they felt patients may monitor more carefully early on after diagnosis but reduce the frequency of monitoring over time.

One endocrinologist stated that they (the patient) “kind of know they’ve got something to do, and that will help them feel in control as well in terms of managing their diabetes”. Another recommends that patients monitor for five to seven days prior to medical appointments so they can have some numbers to look at during the appointment.

Diabetes educators were also more likely to view SMBG is being valuable but indicated they believed it important to provide education for patients to use it effectively. As one educator commented, some patients monitor their BGLs without understanding why they are doing it: "If they're not going to do anything about it then, yes, obviously there's no point for them to do monitoring". Another diabetes educator felt that SMBG provides patients with information other than what the HbA1c provides and would not be persuaded at all by the patient's HbA1c level. He mentioned that he had seen research that demonstrates a "swinging pattern of BGLs may be just as bad as highs or lows on their own".

One GP did feel it was useful for patients to monitor BGLs routinely, indicating that those patients that chose to do so may still demonstrate periodic mild elevations in their BGLs. These elevations would be discussed at the appointment: "I use the results to talk about the things to look out for and as a motivational tool". The GP went on to say that whether a person chooses to perform SMBG or not depends on personality. He commented that some people like to do it to keep them "on target" and remind them: "I do have diabetes - I do need to watch what I'm doing I can't just go crazy and eat whatever I want and sit here and be a couch potato anymore kind of stuff".

Another GP indicated he would recommend SMBG to all patients even if they were on Metformin alone. The GP suggested that all of these patients would be expected to see a diabetes educator to learn how to monitor BGLs. This GP felt that patients on oral glucose lowering medication would invariably be monitoring, and he would discuss their findings during an appointment.

Although most pharmacists indicated they saw SMBG as valuable there was an insightful view on the responsibility of the pharmacist when providing blood glucose meters to patients: "I think people hand out monitors willy-nilly which is a strong irk of mine because they don't know what they are doing with it and 'what's the point of doing it?'" Once again, another indicated they would ascertain the view of the patient's doctor and "see what they were recommending at their end".

Glycaemic control also rated a mention with one dietitian suggesting a period of elevated blood glucose levels would prompt them to suggest an intensification of monitoring prior to an appointment with the doctor: "If the patient experienced a period of poor control I have said it might be worth monitoring intensively for three days and discussing it with their doctor". Another dietitian respondent felt that there may be some initial benefit to performing SMBG as patients learnt the effects of food and exercise.

Sub-theme three: The choice of oral medication(s) played an important role.

The majority of HCPs indicated that the use of oral medication that could result in hypoglycaemia would positively influence their perception of the value of SMBG. One diabetes educator believed that it was more important if the patient had a lower HbA1c as they were at an increased risk of hypoglycaemia. One pharmacist suggested that the choice of medication was not an important factor: “There is not one medication that is more important than another, it is taking the amount prescribed that is important”.

Some HCPs indicated that they felt SMBG is more important when patients are taking multiple diabetes medications as it indicates a deterioration in glycaemic control: “If they are on multiple medications for their diabetes that would prompt me to recommend it.”

Several diabetes educators expressed a view that if a patient was not on a medication that was likely to cause hypoglycaemia, they had satisfactory glycaemic control, and they were not interested in SMBG, they would not be too concerned. On the other hand, if the HbA1c rose above target it increased the likelihood that they would suggest SMBG as it was likely the patient would require an increase in medication.

There was a range of responses given by the endocrinologists, from encouraging SMBG if patients were using medication that can cause hypoglycaemia to all patients irrespective of their medication. Those that did saw it as a way of engaging the patient with their condition and helping them feel in control. Another endocrinologist indicated they would use it to help patients understand how much they need to eat to avoid hypoglycaemia.

Concerns about sulphonylureas causing hypoglycaemia in some patients had prompted one endocrinologist to be less inclined to prescribe such medications and hence there was a corresponding reduction in the need for SMBG. On the other hand, if they were considering commencing the patient on insulin they would use the information to help the patient understand the rationale behind the decision.

Dietitians felt it was not necessarily their role to recommend SMBG although again there was a feeling that a patient using sulphonylureas might benefit due to the risk of hypoglycaemia. For those patients using metformin alone dietitians were less likely to encourage the practice.

As the availability and uptake of oral diabetes medications that do not specifically cause hypoglycaemia increases, it appears that there is less perceived value of SMBG in this population.

Theme two. The information our patients receive about blood glucose monitoring is limited.

In this section, I have organised the results in relation to research question two: Why and how do Australian HCPs make recommendations for self-monitoring in patients with NITT2DM, and what are the ways they use the results?

In relation to SMBG in people with NITT2DM, it was felt by most groups that setting up the meter correctly so that accurate results could be obtained and subsequently downloaded was crucial. There was also an agreement between groups that patients should be advised about glycaemic targets and provided advice as to when to seek medical help.

There was mention of the need to provide patients with education about using SMBG in a constructive or structured way. However, there were few who indicated that they would provide any other information beyond giving patients blood glucose targets and suggestions about the times to monitor. One limiting factor to providing additional training that was mentioned was the lack of time they had available.

There was an observation that most people want to know what they can do to bring their readings down. There was an assumption that patients would be seen by a diabetes educator to teach them to utilise SMBG for this purpose. Diabetes educators essentially agreed with this.

Interestingly there was little discussion about advanced features of meters. One diabetes educator commented that the additional features that newer meters have is “much of a muchness” and questions “how many people download results anyway?”

The close relationship between pharmacists and doctors was emphasised with one pharmacist stating that they would ask their patients “what are you going to do with all the numbers you get? Are you writing it down are you taking it back to the doctor?”

Dietitians and diabetes educators are the two groups that appear to be more likely to provide education about using SMBG in an purposeful manner while recognising the difficulties inherent in the process: “Do they know what to do with the information its giving them? That’s the hard bit.”

Sub-theme one: Setting up the meter and ensuring patients could obtain an accurate result.

Pharmacists appeared to be primarily concerned with instructing people how to obtain a result. Only one indicated they would provide further instructions on how to obtain a reliable result such as the importance of having clean test strips and washing hands beforehand.

Pharmacists expressed a view that patients were not going to remember everything on the first visit and the most important thing was to ensure they were confident about how to use the device. As this quote from one pharmacist demonstrates: “When I am first giving someone a machine there’s so much for them to take in its hard to then launch into the science behind good numbers and bad numbers and good times of the day and bad times of the day and all that sort of thing”.

Endocrinologists also appeared mostly concerned with the process of obtaining an accurate result stating that it was important to ensure that the meter was correctly set up and patients were instructed how to use the device. Again there was an assumption that patients would receive instruction by a diabetes educator who would educate patients about SMBG.

Diabetes educators also focused on the importance of teaching people how to obtain an accurate result. There was an emphasis on the need to ensure that the meter had the correct date and time as educators indicated that they might download the results for their patients. “This leads to an important point in that if patients are not writing their results down, this simple error of incorrect date and time can make monitoring virtually pointless”.

Sub-theme two: Providing patients with target ranges and explaining when to seek help

Primary care nurses indicated that they felt it was important to instruct patients to keep a record of their blood glucose levels and have an understanding of blood glucose targets. They felt that patients should have an understanding of when to be concerned and seek an appointment with their health care professional.

Dietitians also described the need for patients to understand their glycaemic targets so they know when to ask for help: “The level at which to contact the doctor and at what level they should be treating hypoglycaemia.”

Pharmacists agreed: “Listen, if you’re consistently over seven for a month then I think this is a point where at that point you go and see your doctor. You have got to give them a guideline of what to do if they’re hitting results that need to be acted on”.

Another pharmacist invites his patients to contact him when their blood glucose levels are out of the target range: “I always write down a bit of a zone on what I want them to achieve and if they’re out of that zone consistently - not sporadically - then they give me a call”.

One endocrinologist felt it essential to provide patients with an indication about when to monitor blood glucose levels, e.g., fasting and two hours after a meal although tailoring the advice to the individual.

There was an emphasis on giving people blood glucose level targets by diabetes educators. One indicated that it was important to explain to patients when to seek help in response to their blood glucose levels: “There is no point giving somebody a machine and not giving them any ideas what they’re looking for”.

The GP Registrar agreed saying that the patient needs to know “what a goal blood sugar is and then if it is too high, how many high readings before they seek medical help”.

Sub-theme three: Providing patients with information regarding how they could use the information to modify behaviour and who is best to deliver the education

One primary care nurse described the limitations they experience explaining: “We don’t have a lot of time for one-on-one and you can start off talking to someone and very quickly get interrupted because you have five or six doctors feeding patients to you and phone calls and whatever. I think it’s wrong to start off with someone and then cut them off and not be able to give them your full attention and your time because it’s important that they understand it”.

One senior GP indicated that he felt the purpose of monitoring was to identify high and low readings, especially when using medication that can cause hypoglycaemia, and that monitoring “can help validate symptoms”. He went on to add that he expected this information would be provided during a (diabetes education) program, however he did indicate he would emphasise to his patients that “blood sugar levels will change depending on meals and doses and things like that”.

The GP registrar indicated that the real value of SMBG was to obtain a pattern of blood sugars across a number of weeks. That information would then be collated to see what modifications could be made to their diet or their medication.

One endocrinologist felt it was essential to instruct those at risk of hypoglycaemia to monitor after meals so they can understand how much carbohydrate to consume.

Sub-theme four: I provide information about how to integrate SMBG results into the diabetes care plan

Diabetes educators did feel it was part of their role to provide the additional information about SMBG. As one educator explained: “It’s the interpretation of the results that I think is the core thing, that gives a value to blood glucose monitoring”.

Further, there was the recommendation that patients should be provided with: “ A framework for looking at patterns. So are there any highs and lows, are there any patterns to those highs and lows and what action would you take about those highs and lows”. Hence giving patients information about the timing of monitoring is also important.

Dietitians looked at the issue slightly differently by focusing less on the mechanical aspects of monitoring, explaining that they would tell patients the type of information they are likely to obtain from monitoring. One dietitian referred to “structured testing” soon after diagnosis to see the effects of food. She also stated that it was not necessary to continue testing if blood glucose levels remain stable and on target or if the patient was not going to do anything with the readings.

Theme three. Blood glucose monitoring is not a benign activity and can have negative consequences.

The health care professionals interviewed described a range of positive and negative consequences of performing SMBG for these patients. The HCPs described far more negative experiences than positive patient experiences from the use of blood glucose meters.

The negative experiences ranged from the check simply being a painful procedure and an intrusion to more worrying experiences such as loss of self-esteem and anxiety. Other adverse experiences included a lack of familiarity with the technology or how to interpret results and that in some cases “no one bothered to look at the results anyway”.

Positive consequences mentioned included some patients experiencing a sense of control through SMBG and helping them feel that they were on track. One lady had credited SMBG with helping her achieve weight loss.

One pharmacist explained how their perception of SMBG may be distorted as they are more likely to see patients who have a positive experience and continue to purchase BGTS.

One diabetes educator summarised the situation as he saw it, commenting: "Whether a patient has a positive or negative experience may come down to the education they receive".

However, many HCPs indicated that at least some of their patients had experienced adverse outcomes from SMBG, which suggests that the decision to monitor should not be taken lightly. The recommendation for SMBG should involve an assessment to determine if the patient is a suitable candidate for SMBG. Ideally the patient should be subsequently reassessed after a set period to determine if they are adversely affected by the practice.

Sub-theme one: Negative experiences

Pain

There was a general acknowledgement by HCPs from different professional backgrounds that obtaining a blood sample is at least uncomfortable. As one GP commented, people can experience discomfort in the fingers. Further, there was this comment: "Obsessive patients have no problems with it at all". A dietitian also stated: "It is painful, although not too many people are traumatised by it".

Other health care professionals reported more severe trauma with one pharmacist describing a patient whose fingers were "black and blue and they couldn't get any blood out of them". Also, one diabetes educator commented: "Some people absolutely hate it and get sore fingers, also the thought of pricking their fingers is scary".

There was an acknowledgment that SMBG is an intrusion into people's lives. As one GP explained: "I do think it's an intrusion but it does depend on the personality of the patient and the education they have received to take their readings".

It is such a hassle!

One pharmacist commented that some his patients found it "such a hassle to fit it all in their life".

A diabetes educator explained that many people felt obliged to conduct SMBG and complain that it "takes over their life".

A dietitian commented that her patients saw it as interference in their daily routine and find structured testing as not always easy if they are busy and trying to remember two hours before to conduct their post-prandial levels.

The GP Registrar indicated that “in the wrong patient it might make it all too hard, and it is one more thing that they don’t think they can achieve”.

Some people appear to become “obsessive” about SMBG.

One primary care nurse likened it to blood pressure monitoring where people monitor obsessively. Although patients could not make their blood glucose levels go up and down, by obsessive monitoring they can “overly worry about the problem and make it worse”.

Another commented that those who become compulsive about their SMBG become negative and talk about “over-monitoring” and that it “really does not achieve much more than what they’re needing to be doing anyway”.

Indeed, some patients appear to become very concerned about their blood glucose levels with one diabetes educator indicating that it can result in a negative experience for them. One diabetes educator commented: “I have those who test every bloody five minutes just about because they want to make sure they are doing the right thing”, and another: “Some people really want to know everything that is going on and might ring you every second day telling you that their blood sugar went up to eight today”.

At least on dietitian questioned why some people monitor when they have already had perfect readings.

Other negative psychological issues

Many other HCPs described adverse psychological consequences of SMBG in their patients with one diabetes educator stating: “It brings the condition to life in a sense and that they’re forever faced with it”. The frustration that some patients experience was also described especially for those who do not know what to do with the results or had unrealistic expectations. As one diabetes educator commented: “They sometimes pull things out of context a little bit, so they have a sugar of 11 they freak out - Oh God my sugar is way too high”, and another: “Other people get stressed when they see a result that might be quite normal to us. Those sort of people I do suggest put it away”.

The negative experiences described can be quite significant. A diabetes educator described one such response: “I’ve got one guy in particular in mind who has very low self-esteem and would not monitor because whenever he saw high readings, which was regularly, it just added to his poor self-esteem. So he just stopped monitoring because it was just making him feel worse”.

Pharmacists describe a range of negative emotional responses including how some patients felt compelled to monitor BGLs, and were disheartened by their results. Other negative issues associated with SMBG is that the process is unfamiliar and "there is a fear of trying to be reliant on something". Another pharmacist felt that many people do not know how to get the information out of the meter which are now more technical. Also, it was felt that many patients with type 2 diabetes "are older people, and they don't understand the data".

The GP in practice stated that it can be an excellent tool but they "can be a nightmare and people worry about every fluctuation and every variable. They don't have a good appreciation of why it might be happening even when well educated. That it causes them more angst than it does give them any benefit".

No-one seems to listen!

One described what she felt was a common experience for her patients which resulted in her spending more time with patients and reviewing their SMBG results: "Then there are the people on the opposite side have got high readings in their teens and they are showing them to their doctor. They're showing them to everyone, and nobody is telling them what to do about it or how to manage it".

Sub-theme two: Positive Experiences

A sense of control

A smaller number of HCPs described positive experiences by their patients. As one pharmacist described: "For some patients it settled their mind I think to see a figure each day that kept it within control and definitely keep that in check". And: "yep I am looking after my diabetes". A dietitian commented that it "can help people feel that they are on track with their diabetes". One diabetes educator explained that some patients "do love the information to enable them to get better control".

Weight loss

One primary care nurse described a very positive experience for one patient who believed it helped her lose weight: "One patient comes to mind that SMBG appeared to help her embrace her diabetes. She started monitoring and was quite overweight. The dietitian gave her a diet to follow, and she could see how her levels were more stable. This person would most likely be worried without the meter".

Theme four. The health care professionals most likely to use the results in a structured manner are diabetes educators and dietitians

The majority of HCPs, except primary care nurses, indicated that they would review their patient's blood glucose records if they were made available. There was a general agreement that for this information to be useful it was important that it was conducted frequently enough to establish if there were discernible patterns in the blood glucose levels.

For most of the HCPs, lack of time appears to be a major limiting factor for reviewing blood glucose records as well as a perceived scope of practice. There was a tendency for patients to be referred on to either a diabetes educator or a dietitian if blood glucose levels were unstable.

Indeed, the health care professionals most likely to review the results included diabetes educators and dietitians who may use this information to suggest changes to medications or diet. If blood glucose levels were not used to influence management, they could be used to alert patients when to seek further assistance.

However, it was indicated that many patients who were monitoring were doing so without purpose or education and were considered to be "flying blind". Again, it was mentioned that they review the monitoring diaries because the patient has been monitoring diligently, and they want to share their results. However, for some, no one appears to be paying any attention to them.

Sub-theme one: Those Health Care Professionals who do not review patient results or use the information they provide

The primary care nurses indicated that they had limited opportunity to review blood glucose records or make recommendations based on the blood glucose levels. One primary care nurse appeared to lament this and felt that she would like more involvement in the education of patients on diet and exercise.

This limited opportunity to review SMBG results further limits the opportunity to do anything about the results: "Our patients come in once a year for a review and if I note they are making bad lifestyle choices then I will try to make a referral to a health care professional". One commented that most patients had not seen a diabetes educator, dietitian or an

endocrinologist but since their practice had employed a dietitian she had instigated a few more referrals.

One pharmacist indicated that they would not want to make a comment to the patient because they did not want to worry them unnecessarily.

Another pharmacist admitted that they did not review the reading but would like to, “because that’s been one big selling point of one of the monitors that you get a really good report for the doctor, but I haven’t seen the report yet”.

Sub-theme two: Those HCPs who do review blood glucose results and how they use the results

One senior GP explained that he regularly checks the patients’ BGLs held in the meter memories. He explained that he would tell patients not to worry about the occasional high reading, however if they had a pattern of high readings he would investigate why: “What happens more often is when a patient rings up to say they have a cold, and their readings have changed. That’s when we talk about doing the readings regularly. If there is a pattern of high readings and it doesn’t resolve over a day or two to come in”.

One GP in practice would also review the patient’s results if they brought them in but would discourage them from monitoring if they were becoming in his words “neurotic or worrying too much”. On the other hand, if the patient perceived a benefit then she would encourage them to continue.

The GP registrar indicated she would look at SMBG results in context with the HbA1c: “ I might seek the opinion of one of my supervisors”. However, she had not provided any advice to patients based on their BGLs apart from those using insulin.

Pharmacists indicated that although patients often came in when there was a problem with the meter most tend to review blood glucose levels. Occasionally they would provide reassurance: “Hey listen it's going down, that’s really great. Yeah sure it’s not six but come on your heading in the right direction. Let’s not give ourselves a kick in the teeth”.

Again, the close relationship with the patient’s doctors and pharmacists was highlighted. The pharmacists interviewed all indicated that they would make general comments about BGL results in relation to diet and exercise but would always refer the patient back to the doctor to discuss the need for a change in medication: “Well look I think at this point your results clearly

are on the trend upwards and I think you're probably going to need Diamicron, but you need to go and talk to your doctor about this and get your three monthly reading".

One pharmacist pointed out that they cannot prescribe, but will sometimes write a letter to the GP if they see a problem: "I think it's better for them to take the fresh data to the doctor and get them on the right medicine dosage."

Diabetes educators indicated that education regarding SMBG is a two-way street. Diabetes educators provide education regarding the practical use of SMBG for problem-solving and in turn patients who understand how to use the meter effectively can use this information to seek advice from the diabetes educator.

All diabetes educators indicated that if they suggested to a patient to perform SMBG they would subsequently review the results: "What's the point of asking a patient to do it if you don't look at the results or do anything constructive?" Another indicated SMBG provided an opportunity for patients to seek help: "If the education has been correct they will be coming in because their readings are above the target set by the team. If a trend of elevated readings continue I would encourage them to contact the diabetes centre".

Most diabetes educators saw SMBG as an opportunity for lifestyle advice or problem-solving: "The primary role of diabetes education is not as a case manager. It's enabling the patients to make informed decisions. I am addressing the BGLs as a tool to educate and help patients understand how they can manipulate their own blood glucose levels". Another indicated that they used the information to determine if there is a pattern at a certain time of day: "You can suggest they eat more, exercise around that time of day. You would try to learn the reason why blood glucose levels are high, e.g., forgetting their insulin injection or maybe an extra slice of cake".

One diabetes educator lamented that many patients do not appear to have been given the skills necessary to use the devices to provide benefits: "Invariably I think considering the amount of people that are doing blood glucose monitoring, I dare say many, many of those aren't actually having this education and they actually testing blind really, they don't know why they're testing, they don't know what the numbers mean when they get it".

Another diabetes educator indicated that they reviewed logbooks or interrogated the meter memory. Some reported that they used downloadable programs to view the results: "I do look at the readings, and I encourage people to use the software to download the reports as well. I tend to download the results. That's a great way of showing them the graphs and charts and

how they're doing. Look, you've got 80% in the green zone and 95% in the red zone fantastic. Now let's work on getting less in the red zone".

One educator noted that the HbA1c cannot always provide accurate results: "For renal patients most of them are anaemic, so you have to rely on blood glucose results which is more reliable than HbA1c".

Some diabetes educators would use the results to make adjustments to medication: "I think food is one of the most obvious things, so that I use monitoring to see what medications best match. So I use it for medication adjustment. Also, if they're having lows at a particular time after exercising, is there something we can do with their medication?" Other diabetes educators may provide advice to the prescribing doctor: "In relation to the advice it depends on how high the results are. If lifestyle is not enough, then yes, I recommend treatments, oral agents, insulin GLP 1". If they are consistently high you can just point out: "look your sugars are high, you need a change of treatment so we might say: we'll up your that or the other or add in whatever. Some endocrinologists are quite happy for me to help with those adjustments. So in that case I'm happy to do that once I've got it in writing".

If the diabetes educator does not have authority to adjust medication, they might use the results to provide recommendations to the patient's doctor: "If the readings are high, I might suggest they see the doctor and get an HbA1c done". Or another: "If the sugars are 15 plus I'll be on the phone to the doctor to say we need to do something and book the patient back to the GP". Some will make recommendations about specific changes regarding the medication: "As a nurse I do not have the immediate authority to adjust medication, but I will go through them and make the relevant recommendations to the prescribing health professional".

Endocrinologists explained that they tended to base control mainly on the HbA1c, but all do tend to look at the blood glucose records: "Monitoring will add further information. I think it does have a correlation with the HbA1c level". Although they might review the BGLs, they complain that they had limited time to do so: "Yes I do, but I look at the whole patient assessing for ischaemic heart disease eyes, etc. so I don't have much time to discuss diet but the very basics".

Another endocrinologist reported using the results to prompt a referral back to allied health care professionals: "I might get the dietitian involved. Some don't want to see a dietitian but some of them do, and it's usually a very positive experience". Another endocrinologist commented: "I refer to allied health for more in-depth sessions on education, for example,

carbohydrate counting which I often think needs more input beyond the scope of the amount of time I have allocated to a patient".

Endocrinologists rely on the HbA1c to understand when things have changed but will utilise the SMBG results to instruct the patients about lifestyle and medication choices: "I tell people if they've got an HbA1c of 8%, but I'm not sure where the problem is because they're not really monitoring".

One endocrinologist commented to make a rational recommendation about adjusting medication, they need to know what glucose levels are at different times of the day: "I can reinforce to the patient, look you're doing this in the right way and it either positively or negatively correlates with the HbA1c".

Another endocrinologist commented that she used the SMBG to address exercise, weight gain, weight loss and carbohydrate intake: "What I usually do is give people targets so that when we talk about things I might say, if your glucose levels are generally above seven before meals, I would like you to do this".

Other endocrinologists mentioned that they will ask patients to contact them if their BGLs are out of the agreed target range: "I will give those targets before and after meals. If levels are above the target they can always email me the results and then we can go from there". Or: "If someone is fairly elderly I would say if you're finding that it drops below five at any particular time of the day, then I need to decrease this and if you're not sure what's going on give me a call".

Sub-theme three: Limitations on SMBG recommendations

One endocrinologist indicated that if someone was on diet control they probably wouldn't be asking them to contact her except at their routine review: "I don't normally recommend two-hour postprandial levels because I just think it's more of an imposition for people to remember, especially if their HbA1c is good".

Dietitians all indicated that they would review their patient's BGLs although their motivation to do so may not be straight forward. Patients want to share their results. One dietitian commented: "They like to show them. They like someone to take an interest because often they are doing this recording. They try showing it to their GP; they try showing it to other health professionals, and nobody looks".

One dietitian did question whether patients needed to perform SMBG. However, when patients did show the dietitians BGL results, they used the information to provide feedback: “If there is a trend we could look at the diet, I can relate readings back to food such as quantities of carbohydrates”.

One dietitian advised patients to perform SMBG in a structured way for a short period in conjunction with a food diary: “ So that we can actually do something with that information rather than just look at a pile of numbers, then, we might make some modifications. Maybe spacing carbohydrate or switching to lower GI foods or putting some exercise in there or here”.

One dietitian did indicate why they might refer the patient back to the doctor: “If the fasting levels are high but prandial readings are not, then maybe, it’s not the meals. If there is a trend of elevated readings, I would encourage them to go back to the GP.”

Theme five. Access to literature or guidelines is limited, trusted sources of information are contradictory

This section relates to Research Question 3. What are the predominant factors that have influenced the views of health care professionals?

The primary factor that appears to influence the perceptions of HCPs regarding SMBG in patients with NITT2DM is personal experience. Interestingly, a common view expressed by the HCPs was that personal experience had led them to question the benefits of SMBG in all patients with NITT2DM – especially on an ongoing basis.

Few HCPs could indicate any specific information or literature that they had accessed. However, the responses they gave suggest the literature provides conflicting recommendations.

There appears to be a growing reliance on targeted email alerts and web-based news for HCPs to obtain information. Access to formal guidelines appears limited. The main formal guideline described was the RACGP handbook on diabetes management for GPs. Interestingly, the latest edition does not support the routine use of SMBG by people with diabetes with NITT2DM except those taking sulphonylureas.

Blood glucose meter company representatives were not highly rated by HCPs as a possible influence. A number of those HCPs who deal with company representatives appear sceptical, acknowledging that their primary role is to sell their product.

Another important influence was the opinions of peers. As one dietitian stated, if she was seeking more information she would**: "**ask some people who have more experience than me".

The potential role of the ADEA was mentioned with one diabetes educator stating that she would look for information in the Australian Diabetes Educators Magazine or attend diabetes educator update days.

Sub-theme one: Personal experience

Personal experience rates the most highly of all the influences reported by all of the HCPs interviewed. One primary care nurse commented that it was the lifestyle choices that some people make that may prompt them to recommend the practice.

As one dietitian stated: "I think I'm partly influenced by feedback from clients and their feelings about it and their experience of it and whether they've found it helpful or not".

However, this experience could result in either positive or negative points of view.

Negative viewpoints.

Diabetes educators rank personal experience as the most important factor that influenced their views with many indicating that for many patients SMBG was not valuable. They made reference to the number of patients who had become highly focused on small variations in their blood glucose results**:** "My thinking has changed over the years because you realise they can come in with a book and with numbers that are higher by 0.5 because they have eaten an extra slice of bread at one meal, or is that the meter."

Moreover, another: "When you come across people that obsess about their blood glucose monitoring when their blood sugars are fine then I discourage them from monitoring as often as they are if I can. With experience, you start noticing there's not much use for it in this kind of scenario". Moreover, another asks: "Is the person doing anything with the results? That's certainly a factor".

Another educator raised concerns about the cost of monitoring unnecessarily and the possible harm this was doing to his patients: "I think it's just experiences over time, just seeing patients. We have had patients on diet and exercise testing 10 – 12 per day. Cost is a concern but you also have to wonder from a psychological point of view, is this a good thing?"

Another mentioned that as their understanding of the risks associated with hypoglycaemia matured and new medications appeared on the market they were more or less compelled to recommend SMBG: "As time has gone on, I have also gained a better understanding of different therapies and who's truly at risk of low blood sugar."

Also one diabetes educator had noted, many people with NITT2DM had obtained a meter but had not received any specific training: "Certainly there is a large number of people I've come across who are testing but it is pretty meaningless to them and they don't like it and maybe it isn't justified. This has been reinforced by professional development things I've been too".

Endocrinologists also rate the personal experience as a likely influence: "I think just from clinical experience. If people have pretty good control and their numbers are pretty much the same every time, they tend to stop because they don't see any advantage".

Another endocrinologist commented: "If I don't think it would be beneficial for them to be monitoring, I don't encourage it because I look at so many other parameters. I think blood pressure and lipids are more important". On the other hand, if HbA1c is elevated: "I recommend it, otherwise you are going in with a single number to define glycaemic control over a three month period, but you don't know where in the day you need to make a change."

These views were supported by several pharmacists who agreed that many people who obtain a meter without receiving education are sometimes adversely impacted. This situation leads to frustration for the pharmacists as well. As one pharmacist described: "Oh I've got this blood glucose monitor, and you turn it on and the date and the time is not even right. it's a complete waste of time what they are doing. You ask them, okay, so what are your normal readings, and they got no idea. So they are monitoring, but they've got no idea what the levels are. It frustrates me."

This also led to one pharmacist expressing irritation at the blood glucose meter companies: "The unnecessary amount of blood glucose meters that are out really annoy me".

Positive viewpoints

However, some HCPs report a more positive view but note that this might be because they have seen people who are more likely to be motivated. As one dietitian explained: "In private practice you tend to see a fairly motivated group of individuals. A lot of people that I see actually want to be monitoring to get a better idea". And another: "I do find if it is doing structured testing in conjunction with a few diary and blood sugars it can give them a bit more

insight into what some foods can actually do to their blood sugars and its effects and benefits of exercise".

At least one pharmacist also indicated that personal experience can play an important role. "What I like about blood glucose monitoring is it gets the patient involved and interested in their own treatment, and the more someone knows about what's wrong with them, the better treatment they end up getting".

Sub-theme two: Literature and targeted email alerts.

While some the HCPs admitted to not having accessed any information in journals, those that had could recall few specific details. A typical example of this was a diabetes educator who commented: "I think there was something written in the ADEA journal a year or two ago. It is now so long ago that the details are just a blur".

While the specific journal articles may not have been recalled, the opinions amongst diabetes educators about the studies were critical. For example, one diabetes educator commented: "Things that don't support it would be more around the studies and the literature that comes out that tells you there's not much benefit in improving HbA1c. I think the problem with some of those studies is that it is about the action, not the process".

While one diabetes educator added: "There are lots of papers saying the benefit of home blood glucose monitoring". Another commented: "I was involved in a bit of a literature review and I know that the research tells us that in many instances there's not a lot of benefits in terms of HbA1c, but it's not just about that number".

At least one dietitian referred to reading literature on the issue: "Evidence as well. I can't say I've read any papers that monitoring for somebody on certain oral hypoglycaemic agents is not going to give them anything useful to use".

At least some HCPs appeared to have read articles discussing the need for a structured approach to SMBG, with one endocrinologist also mentioning being aware of information in journals: "I know there's a study that basically looked at if glucose monitoring is not changing what you do, not changing your management, frequent glucose monitoring increases patient anxiety without having a benefit".

Some of the literature mentioned by HCPs appears to put the role of SMBG in people with NITT2DM in a positive light. One dietitian also mentioned being aware of some information

discussing a structured approach in journal articles: “There’s been a bit published on structured testing, but I guess that’s how I tended to use it anyway”.

Endocrinologists also indicated that they had reviewed the literature to help form their opinions: “Probably I’d say the literature. I was driven to look at this because a lot of people don’t monitor, or they rarely monitor. The literature indicates if they do a limited period of monitoring before they come that can be helpful”. And another indicated: “I know there’s literature on postprandial rises and this can be important in determining some risks”.

Sub-theme three: Guidelines I turn too

Interestingly, the main reference to any form of guidelines referred to by the HCPs on this matter was the Royal Australian College of General Practice “General practice management of type 2 diabetes” which does not recommend routine SMBG for patients with NITT2DM. However, this was only cited as a reference by one primary care nurse, a pharmacist, an endocrinologist and the GP Registrar.

One pharmacist pointed to the lack of guidelines regarding blood glucose monitoring in patients with NITT2DM: “I think there is a distinct lack of guidelines and training apart from the book I got sent from the RACGP”.

The pharmacist also went on to say that he did not believe that many pharmacists would even look for guidelines: “I don’t think any other pharmacy within cooee would have the RACGP handbook and would base their recommendations on the Australian Medical Handbook, which is not that accurate. I would be surprised if many other pharmacists had any idea of what guidelines or procedures to follow with it would be. I’d be surprised”.

One other pharmacist commented that she had accessed the AMHS stating: “It’s more important to monitor blood glucose in people who are taking sulphonylureas and those on insulin”.

Some HCPs admitted that they rarely accessed guidelines, with one GP admitting to not having obtained any specific information recently other than: “Standard medical journals with a GP focus”. He went on to say how easy it is to access information from the internet and attitudes to medical management can change radically over a year. However, he also admits that: “being around for a long time makes you less inclined to adopt new things”.

Another GP felt that: “managing sugars is only part of a complex pattern and that it is important to monitor other health factors”. The GP hinted at research that has demonstrated

that: “by more rigorous management and aiming for better control, we know we can control the morbidities associated with cardiovascular disease, kidney disease and eye disease”.

The majority of endocrinologists could not recall obtaining specific information with a couple stating that they were not interested, citing time issues as a primary barrier to seeking that information. There was an expression by one to find out more information:” I’m very interested to hear what’s available. I haven’t trawled the literature for anything”.

One pharmacist admitted having never looked for guidelines: “In all honesty the main thing that I use is the manual within the box. I personally have not found a reference that is more detailed than that”.

Sub-theme four: Blood glucose meter company representatives

Only pharmacists and primary care nurses indicated that meter company representatives may have been influential in forming their views as they may receive instruction when they provided meters to pass on to patients.

Perhaps not surprisingly, pharmacists appear to have significant exposure to company representatives: “Well look these guys (reps) coming in here all the time, and they seem to have good intentions. They say things like - averages don’t show the highs and lows- and all this kind of stuff. I think that’s advertising to promote it obviously because that’s their financial viewpoint”.

Another pharmacist also indicated that most of the information she is exposed to comes from the meter company representatives: “I see the Abbott and Roche reps most often and they’re always selling me the positives if you like and training the girls on how to sell the meter”.

While the GP indicated he did see representatives: “they are mostly pharmaceutical reps or pathology reps, and I don’t think we have had any detailing around monitoring itself”.

One diabetes educator also mentioned that meter company representatives had a primary objective to promote their product as superior to their competitors: “You get reps telling you how much better their machine is versus their competitors. Sometimes they will show you journal articles to back their claims”.

Not all of the information provided by the companies was considered advertising. Several diabetes educators indicate that they use the “360-degree program” developed by Roche Diagnostics: “The assessment tool that the Roche people put out which has the before and afters. I use that sometimes in people who are fairly newly diagnosed to say - Let’s get a

snapshot of what affects you and to learn which meals seem to …..". And another, "The 360 program has shown me value in terms of how you can apply a systematic approach to monitoring rather than the random one".

Although these diabetes educators indicated that they utilised the 360 Program developed by Roche Diagnostics, they also commented that they do not see many patients who have NITT2DM. Amongst the other HCPs, there was no mention of the 360 Program. For most the primary resource appears to be the Diabetes Australia website.

The HCPs interviewed on this issue did not appear to be accessing much in the way of resources, although one Primary care nurse indicated that they did give out some educational material: "On the whole I usually recommend that people go onto the Diabetes Australia website".

The Pharmacists did not mention anything specifically about structured blood glucose monitoring although they would refer patients to the Diabetes Australia website or consider the material developed by the National Prescribing Service.

Sub-theme five: The importance of peers

A primary influence was the diabetes educators. As one HCP explained: "It would be more through talking to educators rather than dietitians".

One diabetes educator highlighted the important role that peers have in forming opinions: "You hear something along the grapevine somewhere and go - Yeah that works for me, I'll pick up on that".

Peer influence was also a factor in the responses by dietitians and the GP in practice: "Probably other colleagues and just feedback from them as well. I think it is probably talking to other people, other doctors when we discuss things, and I think it is not so much my observation of how people use blood glucose monitoring".

Endocrinologists also list peer influence and early training as their primary source of information in this area: **"**Initially it's from my colleagues and also from my past reading about the postprandial levels is more important for type 2 than the early morning glucose."

Theme six: Professional training does not address blood glucose monitoring

It is interesting that formal education plays a lesser influence on the way that HCPs develop their views. Few HCPs could recall any specific training regarding structured or purposeful monitoring of blood glucose levels in either the graduate or post-graduate studies. It is noteworthy that SMBG has been around in a similar form for decades however only one pharmacist mentioned it being covered in any specific way.

Even those who had undertaken a Diabetes Education and Management course accredited by the ADEA could recall little in the way of targeted education on this particular issue. Several diabetes educators hinted at these deficits with one specifically stating: "New staff members really don't know what to recommend to patients".

Only diabetes educators mentioned having used the Roche Diagnostic 360 program. This program has been promoted as a way of educating patients in the structured use of blood glucose meters. However, they made the comment that they see patients with NITT2DM less frequently than they used too.

Primary care nurses are generalist by nature and indicated that they are primarily exposed to information that they seek themselves, through the different courses they undertake and the people they are exposed too.

None could recall any undergraduate training on this issue. However, two had undertaken some post-graduate study, specifically self-directed training that they had sought themselves: "A lot of training we do as a postgraduate or if you like, within my role, is that you choose what you think will benefit you most so I don't think I've done much education on diabetes since I went into practice really."

One primary care nurse did recall discussing SMBG with a diabetes educator while completing an ADEA accredited Diabetes Education and Management course. It was exposure to a diabetes educator attached to a clinical placement that provided the training she received rather than an explicit component of the course.

Pharmacists reported that blood glucose monitoring had been discussed in both undergraduate and postgraduate training. However, only one recalled structured blood glucose monitoring being covered, and that was by a particular tutor: "I remember a tutor we had at Uni. She was a diabetes educator. She probably influenced my thinking the most. There

was one tute in particular that the person was getting strange numbers, but they were doing it at different times of the day and it was really important to do it at the right times of the day and to do it regularly and what you would then do with the numbers, not just writing them down and putting the book away, but using the information taking it to the doctor and talking about it".

One senior GP with many years of experience in general practice explained that although he could not describe any particular training, he had been to lots of talks on diabetes: "The thing with education its often focused education and it reflects either a product type if it's been sponsored by a pharmaceutical company or it tends to reflect the interests of the consultant specialist who is presenting the material".

The GP had a role in educating Junior Medical Officers and explained that there was no specific training on the issue: "Because diabetes is common, because it's one of the primary care areas or priority for the Commonwealth, there is a lot of education around diabetes. That's how we teach our undergraduate students these days. We get them to identify a patient with a clinical question, and we say go look at the evidence and critically evaluate the evidence".

The GP Registrar echoed this sentiment: "There's nothing that really stands out as information. I would not know what to tell them, how often to take their blood glucose or what to do about it, other than bring the results in and use them in collaboration with other results".

Another GP in practice indicated that she had trained a long time ago and that the recommendation to monitor BGLs remains relatively automatic behaviour: "because that was how I trained".

Pharmacists indicated that they did receive some training while at university, however, the information was brief and often restricted to how to use the meter and blood glucose targets: "We just get taught the appropriate ranges and if it's consistently outside those ranges we need to direct the patient back to see the doctor".

Another stated: "Not so much. We did a little bit of training at the University on the machines and how they worked. There are a lot of people now testing their sugars". Another: "Not specifically, no. Only in our education at University specifically on using the machine. In terms of using it effectively it was more really just a step-by-step process of how to use it at the right times of the day." Another: "There might have been a module on it, but it wasn't given a lot of time. I mean there's a lot of things to cover too, and not everyone works in a community pharmacy".

Only one pharmacist indicated that they had received any specific training that involved more than merely obtaining a reading: “There was one tute in particular. It was really about how important it is to do it at the right times of the day and to do it regularly and what you would then do with the numbers, not just writing them down and putting the book away but using the information, talking to the doctor and talking about it”.

One pharmacist who had undertaken the ADEA Diabetes Education and Management Course indicated that the issue had not been specifically covered: “I was thinking of these things when I was doing the course. I thought the course was hugely self-directed, which is fine”. He went on to discuss the role blood glucose meter company representatives in education: “I think the information you get about monitoring would have been from the companies themselves and it's obviously skewed, isn’t it?”

Diabetes educators also did not indicate that they recalled specific information in their training: “I would say no, nothing whatsoever. Not really in diet or tablets treated only. Most of that is focusing more on the people on insulin, particularly with the newer meters with the bolus calculators. But otherwise, in orals or diet treated, I don’t think there has been anything really outstanding that has come my way in recent times”.

One diabetes educator suggested that the ongoing professional development at their diabetes centre might potentially address this issue: “We have ongoing training for our centre so whatever the latest evidence, what’s the timing of the testing all that. We have inservices and go to workshops and conferences”.

A few diabetes educators cited blood glucose meter company generated material: “I would say that (360) assessment tool. Prior to that I was using something similar but that was actually formalised and done in a more structured way” and another: “I can recall this 360 program. There’s a lot of information I’ve read around things like the GI, so using the monitoring in terms of seeing what action food would have. You read stuff all the time, and you’ll see reference to it”.

The endocrinologists did not indicate that they had received any specific information regarding SMBG in people with NITT2DM: “No never and I don’t think they will either. Nothing in my formal training, which is interesting isn’t it?”

Another endocrinologist: “During my endocrine diabetic training, we haven’t actually been told exactly why or how often should our patients monitor blood glucose in different types of diabetes or different forms of treating it.” And another: “No. That sounds terrible, but I can’t

really remember anything from my training. It may have been mentioned, but it's not something that clearly stands out, specifically for this group of people, no".

The dietititans did not report anything distinct from their undergraduate training although two had undertaken an ADEA Diabetes Education and Management Course. From their recollections, they could not recall information about the practical use of SMBG being covered in the course: "I did do the diabetes educators course through Deakin University. Less on guidelines regarding appropriate monitoring and more on the technique of monitoring rather than how to use the tool, so it's most effective for that particular client". And another: "The Diabetes Educators course I did was much more on overall teaching and learning type education than the actual teaching of someone how to monitor type thing, the practical stuff but it was an awfully long time ago".

Theme seven: HCPs want impartial information about SMBG and would like to receive it in a convenient manner

Both online information and seminars were put forward as possible ways to provide the information with no one group appearing to favour one over the other. One diabetes educator suggested a variety of methods: "I think really the whole gamut because it is really a quite contentious issue".

Pharmacists were quite specific about who should provide this information: "I think proper evaluated impartial data provided through the Health Department, Therapeutic Goods Administration or the National Prescribing Service". Another stated: "I think Information provided by some reputable organisation like the National Prescribing Service or Diabetes Australia".

Several pharmacists suggested that they might also get some other benefit for doing courses such as accreditation points: "I would recommend articles in Australian Pharmacist, and then CPD questions are useful because you are testing your knowledge".

Sub-theme one: what information do HCPs want to receive?

Although one GP in practice could not think of any specific information, she did indicate the need to work closely with local diabetes education clinics and to make sure she supported their recommendations.

The GP Registrar indicated that she would like to have meetings with diabetes educators or endocrinologists or senior GPs. She mentioned online training modules or during the clinical placements.

Another GP was relatively unconcerned regarding the matter, however, and commented: "One of the issues for General Practice is contextualising it in the context of our patients who often have other co-morbidities" and indicated he would likely send patients on to a diabetes educator to receive this training.

Primary care nurses explained that they were generalists by nature: "I tend to update on those things that interest me. So I probably need to expand my knowledge". Another commented that they wanted only to be kept abreast of what the recommendations are and: "little tips I can pass on to my patients". In this regard, the issue of blood glucose monitoring was discussed: "I need more information on blood glucose monitoring – whether it is a good thing to be doing or something that is not so important".

Pharmacists were interested in some more practical issues: "Information on such things as an evaluation of currently available meters and who it best suits and who it least suits" and some information about what could: "help patients in the management of their diabetes".

Diabetes Educators suggested the following topics to be covered: "Information about preventative medicine through blood glucose monitoring". Another acknowledged the cost to the taxpayer: "I think there needs to be a big, big focus in terms of what do people actually need to test, what is the benefit of testing, because essentially we are recommending treatments that have an effect, definitely from a psychological basis but also on a cost basis as well. Someone has to pay for all the strips and with the growing burden of type 2 diabetes in Australia, how sustainable is this?"

Endocrinologists appeared to have mixed views on the subject with some believing that they needed more information while others felt it was the role of the diabetes educator to provide this information: "In my eyes, it's up to the educator to make sure they're using the meter correctly and make sure they are using a meter that suits them. Patients are not here to hear about how the glucometer works from me".

Other endocrinologists appeared to be much more interested professionally: "Yes, if there was information that could improve my practice I'd be most interested".

Dietitians were most interested to hear what GPs think about monitoring: “because that is where we get our referrals from”. It was also felt to be helpful putting blood glucose monitoring in context for dietitians.

There was a request for more guidelines by one dietitian: “I think it would be great to have a little bit more in terms of guidelines in that area”. And a pharmacist: “To have a guideline or education package that is really good and clear for patients as to what is the benefit of monitoring for those patients on hypoglycaemia reducing medications”.

Sub-theme two: How should that information be provided?

Some HCPs, including dietitians, pharmacists and primary care nurses, expressed an interest in the information being provided via online training. One endocrinologist went on to show an interest in online journal information: “The best source of information for me comes through journal watchers. It’s an email, it’s quite summarised, it’s fantastic”. Moreover, another: “I would like that delivered in probably something like a webinar would be really good or something that you could access online is probably the most useful thing”.

Dietitians were also in favour of online or webinar type training: “I find this preferable just in terms of being able to manage to fit in rather than going somewhere. They have a speaker and you can log into it like a teleconference, but you can also get them on CDs afterwards”. Another suggested a website like: “Changing Diabetes or Diabetes Educators Update” but for dietitians.

One diabetes educator also suggested a lecture format: “Probably a workshop and interactive sessions. We get a lot of emails, we are so busy we just don’t have time to look at them. I think forums where people get to talk, so some small forum work or chat work combined with presenting programs that gave you an approach to monitoring or a value to monitoring”. There was one suggestion of a formal teaching session regarding the Roche Diagnostics 360 Program.

One dietitian also felt that conference-like presentations were desirable: “I always like going to presentations and hearing someone speak about either their experiences or research.”

One endocrinologist commented: “If it’s from an evidence-based source, yes, I think a seminar would be useful to start off with because that information appears to get in more.”

Conclusions

This chapter has presented the results of this study through the eyes of a number of professional groups. The following chapter provides a discussion of the research findings.

Chapter 7

Discussion

Introduction

For some time, there has been a recognition that the monitoring of blood glucose in people with non-insulin treated diabetes, particularly in those who have not received any specific education about how to use the results in any meaningful way, does not result in sustained, significantly improved glycaemic control. (Aakre et al. 2012; Malanda et al. 2012; McGeoch & Moore 2007; Therapeutics Intitiative 2011).

Despite this, blood glucose monitoring is still widely recommended as an integral component of diabetes self-management in various clinical guidelines and the activity remains subsidised at substantial cost to the Australian taxpayer (National Diabetes Services Scheme 2015b; Prescription Benefit Scheme 2013).

This situation is becoming increasingly unsustainable. The findings of this research come at a critical time. It has recently been announced that the Federal Government will move to restrict the availability of BGT to people with NITT2DM from June 2016 (Choosing Wisely Australia 2015).

It important that this subsidisation be reviewed to ensure that the health dollar is spent where it will most likely provide the greatest benefit. This thesis has demonstrated that influencing the implementation of evidence-based practice is subject to a range of factors.

This thesis attempts to help fill a gap in our understanding of how Australian health care professionals directly engaged in the management of diabetes perceive the value of blood glucose monitoring in patients with diabetes not treated with insulin. Through their detailed accounts, they also shed light on how they form these perceptions and the sources of information that they access. It also discusses how factors such as community pharmacies and pharmaceutical companies can moderate decision making.

In this chapter, the research questions are considered in relation to the current literature, conceptual framework and the findings of this study.

What perceptions do HCPs hold about the value of self-monitoring for people with type 2 diabetes with NITT2DM?

This thesis has demonstrated that despite 50 years' experience of blood glucose monitoring, there remains significant variation regarding the perceived value of SMBG in people with diabetes with NITT2DM, both within health professions and between different HCP groups.

It is clear from all of the HCPs interviewed in this study that blood glucose monitoring is a very common practice. For some, it remains an important component of diabetes management, and they indicated they would routinely recommend the practice to their patients. For others, SMBG is considered optional, and they question the value of it as part of diabetes management. Some actively discourage it.

Those people who were most in favour were endocrinologists and some GPs who saw it as an opportunity for the patient to engage in their diabetes management. Diabetes educators and dietitians were more likely to have a positive view of SMBG if they had engaged with the patient and had provided patients with additional education. However, they were also the HCPs who were most concerned about the apparent distress that some patients had experienced in relation to SMBG.

This was particularly true of those patients who had obtained a blood glucose meter and subsequently referred to them for education. These diabetes educators and dietitians had to deal with any anxiety that the patient had experienced as they helped them to understand how to interpret the results.

The conflicting views held by many HCPs about the value of SMBG in people with NITT2DM has no doubt resulted in confusion for some patients as they are presented with conflicting recommendations as they interact across the health care system. Some Australians with NITT2DM will be urged to obtain a blood glucose meter while others will be actively discouraged. If they then proceed to get a meter, they will likely be given conflicting information about when and why to perform BGL checks.

A similar study conducted by Latter et al. (2011) found that overall Canadian HCPs were more likely to perceive value in SMBG for people with NITT2DM than their Australian counterparts. This study was conducted several years prior to the current study. Attitudes may have changed. However, the study did identify that Canadian HCPs' recommendations about the frequency and timing of blood glucose checks varied both within and among healthcare professional groups.

These two studies indicate that people with NITT2DM, both in Australia and Canada, are exposed to conflicting recommendations regarding SMBG depending upon which HCP they access within a profession, or from different professions. In this sense, both studies asked many of the same questions to a similar range of HCPs and the consistency between studies lends strength to the validity of the results and introduces a multi-national aspect to the study findings.

When multiple oral diabetes medications are used, this raises the perceived value of SMBG for many HCPs as it was felt it helped people understand why their medication was being escalated. There is also those who suggest that people with NITT2DM, who use medications that can cause hypoglycaemia may benefit from SMBG. However, there is an indication that those oral medications are now being prescribed less frequently as more alternative drugs reach the market.

Interestingly, both high and low HbA1c results could increase the perceived importance of SMBG in this group. However, the HbA1c result did not appear to be a major reason a HCP would recommend SMBG.

What was surprising was that blood glucose meter representatives rated lowly as a potential influence despite the fact some HCPs frequently saw them. This is reassuring in the context of collecting and appraising information on which to base clinical decisions.

Why and how do Australian health care professionals make recommendations for self-monitoring in patients with type 2 diabetes with NITT2DM, and what are the ways they use the results?

It is evident that many patients with NITT2DM who are being provided with blood glucose meters receive scant education on how to use them in a constructive or structured manner.

The ADEA recommend that: “Individualised educational interventions are considered important in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes” (Australian Diabetes Educators Association 2009 page 4). However, it is clear that many people do not receive this education and remain confused and disillusioned about the practice. This finding is consistent with findings from the literature search (Bwititi, Angel & Day 2008; Mathew et al. 2012; Peel, Douglas & Lawton 2007).

There was a consensus by the HCPs interviewed in this study that education is necessary for patients if they are to conduct SMBG effectively. However, there was also a view expressed by

many of the HCPs that their responsibility in relation to providing education to patients regarding SMBG was limited to setting up the meter and ensuring that the patient could obtain an accurate result.

This study suggests that it is mainly diabetes educators and to a lesser extent dietitians who are likely to be called up to provide this more intensive individualised education to patients. In fact, the diabetes educators in this study agreed that that was a part of their role. However, there was an acknowledgement that due to time constraints fewer people with NITT2DM are seen in community based diabetes education centres than in the past and are increasingly focusing their attention on patients with more complicated presentations.

The trend for diabetes education centres to see fewer patients with NITT2DM is likely linked to workforce issues. The ADEA recently released a report that indicated that there is a shortage of Credentialled Diabetes Educators in Australia. The current number of Credentialled Diabetes Educators are only capable of caring for only 57% of Australians with diabetes (Australian Diabetes Educators Association 2014). This situation is likely to become more difficult as the number of people with diabetes continues to grow (Australian Institute of Health and Welfare 2015; Herman & Zimmet 2012a).

The question then arises as to who currently provides this training? The majority of people obtain blood glucose meters from pharmacies (Bwititi, Angel & Day 2008). Increasingly, blood glucose meters are becoming available online where the chances of receiving any education on the matter are limited at best.

Pharmacists provided a varied range of responses about what education that they provide to patients on this issue. However, beyond instructing the patient how to obtain a result, most indicated that they may only go as far as to recommend targets or suggest the timing of blood glucose checks. Rather than instruct on lifestyle choices, they would refer patients on to their doctor if the patient had concerns about the results. They indicated that this was in part due to the need to respect their professional relationship.

Interestingly, some GPs in this study indicated that they do not see SMBG in patients with NITT2DM as being all that helpful. While most indicated that they would review the results if the patient brought them to the appointment, there was also a view that it would be unlikely to alter their management.

Dietitians in the study also indicated that they would review patients' SMBG records and make recommendations, but their motivations were not always straight forward. More than one

indicated the main reason was that the patient wanted someone to look at the results because no-one else seemed to take much interest. These results are consistent with other qualitative studies looking at the experience of patients with NITT2DM (Peel, Douglas & Lawton 2007).

The first principle of any medical intervention is “Primum non nocere” – or translated "first do no harm”. This law should apply to SMBG.

SMBG is not necessarily a benign practice for the patient. Many HCPs identified patients who have had negative experiences regarding the use of SMBG. These observations are not unique. A number of studies have identified that people with diabetes can experience feelings of failure, and guilt when blood glucose levels are above the target levels (Beverly et al. 2012; Franciosi et al. 2001; O'Kane 2008; Polonsky 1999; Rubin & Payrot 2001; Simon et al. 2008). Further, these feelings are exacerbated when education is lacking, or health care professionals show scant interest in the results they diligently collect (Peel, Douglas & Lawton 2007; Rubin & Payrot 2001). This study adds a depth of understanding to the difficulties HCPs experience in providing this information.

While it is not possible to conclude that SMBG causes depression or anxiety, it may be reasonable to suggest that SMBG is recommended with caution to those with an underlying anxiety or depressive condition. The study also suggests that we need to be alert to the pressures that our diabetes workforce are experiencing.

What are the factors that have contributed to these perceptions?

The limited and ad hoc training that Australian HCPs have received over the years has contributed to their variable perceptions about the value of SMBG in people with NITT2DM. Consequently, Australian health care professionals have formed their views based largely on personal experience or from discussions with peers. This has led to an apparent contradiction with several HCPs indicating that it is through experience that they come to question the value of this practice.

The HCPs in this study indicated that they use a patient-centred approach and will consider factors such as the age and dexterity of the patient when forming their views on how appropriate it is for a patient to perform SMBG. Further, they would respect a patient’s views and support their choice to perform SMBG if that was their decision.

Further, the limited time to review the available literature means that HCPs are relying more on targeted news emails rather than searching out specific information themselves.

What are the education and training sources healthcare professionals receive about self-blood glucose monitoring, and how do they identify and access trusted sources of information?

This study has demonstrated that Australian health care professionals receive inconsistent training in this area and trusted guidelines relating to the issue contain conflicting recommendations. For many Australian HCPs, the lack of time available to provide education on the purposeful use of SMBG in patients with NITT2DM results in patients receiving little more than blood glucose targets they must achieve. Some patients may receive a recommendation regarding the timing of the blood glucose tests. It is clear that many HCPs are not engaging their patients in the process in any substantial way, meaning that the patient is unlikely to obtain substantial benefit from SMBG and are less likely to continue.

The lack of consistency in the perceived value of blood glucose monitoring may in part be due to inconsistent quality and content of training. The interviewees indicated that training around structured or purposeful monitoring of blood glucose levels is ad hoc and not a routine part of the curriculum in undergraduate or postgraduate programs. Even those who had undertaken an ADEA Accredited Diabetes Education and Management course could recall little in the way of targeted education on this particular issue.

This erratic and unreliable training represents a further potential factor contributing to the confusion patients experience when seeking guidance. It is unclear what education Australian health care professionals are accessing in relation to SMBG.

There are several online training programs that are available:

- In 2011, the International Diabetes Federation released a series of diabetes education modules to be used for the development of programs to educate HCPs about diabetes management (Internatonal Diabetes Federation 2011).
- The Australian Diabetes Educators Association has developed an online training program for diabetes educators and other HCPs (Australian Diabetes Educators Association 2011).
- The Australian Practice Nurse Association (APNA) has developed online diabetes learning packages for primary care nurses (Australian Practice Nurse Association 2011).

However, none of the HCPs interviewed referred to these or other available programs.

An important source of information regarding the use of SMBG in those interviewed appears to be scientific literature, although those interviewed could not cite any particular reference and the information they recall reading is conflicting.

One of the problems that HCPs from all professions identified was a lack of time to read current literature. While several indicated that have read information on this subject, none could recall precisely what it was or when they accessed it. This observation is not intended as a criticism, but rather an acknowledgement that the numbers of people being diagnosed are increasing at a faster rate than the diabetes workforce is growing. For many, the primary opportunity for the reading of scientific literature is an email alert program, and learning is now very much self-directed. Another source of information identified was peers, particularly those perceived to have greater experience.

Most current clinical practice guidelines recommend that SMBG should be considered as part of diabetes management. However, it is also recommended that SMBG should only be utilised in patients with NITT2DM who have the knowledge, skills and willingness to incorporate SMBG and therapy adjustment into their diabetes care plan (Australian Diabetes Educators Association 2015; International Diabetes Federation 2009; National Institute for Clinical Excellence 2009).

Only a small number of people interviewed indicated that they would seek information from these guidelines, and there appeared little knowledge of what guidelines existed. The trusted sources of information that HCPs mentioned, contain conflicting recommendations regarding the use of SMBG in patients with NITT2DM (see Table 4). The formal guideline most often described was the RACGP handbook on diabetes management for GPs. Interestingly the 2014 edition does not support the routine use of SMBG by people with NITT2DM not using sulphonylureas (Royal Australian College of General Practitioners / Diabetes Australia 2014–2015).

Table 4. Trusted sources of information	
Source	Recommendation
Diabetes Australia (Diabetes Australia 2015a).	Regular blood glucose monitoring is necessary to see if the treatment being followed is adequately controlling blood glucose levels.
National Prescribing Service Medicinewise (National Prescribing Service 2015).	People with diabetes need to test their blood glucose regularly, by self-monitoring using the tests below at home and with blood tests ordered by their doctor.
General practice management of type 2 diabetes 2014–15 (Royal Australian College of General Practitioners / Diabetes Australia 2014–2015)	Routine SMBG in low-risk patients who are using oral glucose-lowering drugs (with the exception of sulphonylureas) is not recommended

In contrast the Diabetes Australia website and the NPS prescribing service both stress the importance of SMBG for patients with NITT2DM (Diabetes Australia 2015a; National Prescribing Service 2015). Given that these are the primary sources of information cited it would be unfair to be entirely critical of the opinions HCPs form.

The one particular patient resource referred to by HCPs was developed by a blood glucose meter company. Two diabetes educators interviewed indicated that they use the “360 Degree” program developed and evaluated by Roche Diagnostics (Hoffman 2013). The 360 Degree

program is a paper or computer-based program that allows patients to plot blood glucose levels against food intake and exercise over a three-day period.

Interpretation of findings according to the conceptual framework

The conceptual framework as shown in figure 1 has provided an important method to investigate the various components necessary for a patient to make autonomous and informed decisions regarding SMBG.

Pillar one: Facilitation

Firstly, this study has reinforced the finding of the literature review that the facilitator - in this case, the diabetes HCP - carries the burden of instructing the patient with NITT2DM in regards to SMBG.

This study has also confirmed that the role of the diabetes HCP in Australia is disadvantaged by training that is ad hoc and inconsistent. Further, the facilitator is time poor and overwhelmed by the numbers of people that they see with diabetes, limiting the opportunity for self-directed learning or undertaking additional courses.

The study has demonstrated that Australian HCPs have great empathy and a passion for the care of their patients. Diabetes educators and dietitians, in particular, have shown they have the capacity and experience to provide additional training and assessment for the patient with NITT2DM about SMBG. However, due to the relatively few numbers in the workforce compared to the task at hand, they are not as accessible to all people with NITT2DM as is necessary to support them in this form of diabetes self-care.

This finding is supported by a study of 43 people with diabetes in the Riverina region of NSW. In this study, it was found that 75% of people obtained a blood glucose meter from a pharmacy (Bwititi, Angel & Day 2008). In this study, it was found that 40% of respondents had taught themselves how to use the meter, and 38% reported being unsure about how to respond when their blood glucose levels were abnormal.

Pillar two: Available knowledge

In relation to Pillar 2 the evidence necessary for informed decision making, there is now studies that question the effectiveness of SMBG in people with NITT2DM (Allemann et al. 2009; Malanda et al. 2012). This information is more current than many of the guidelines that are available, and no doubt will play an important role in future decisions about the ongoing funding for BGTS.

Access to contemporary literature about SMBG in NITT2DM is limited with few HCPs recalling having obtained any recent training or information. So while information is available, it is not widely accessed and is in conflict with many of the current guidelines. The result is that information provided to patients is likely to be confusing or simply not available.

Patients with NITT2DM, who are unable to receive training from HCPs may access the same resources mentioned in this study, such as the Diabetes Australia or blood glucose meter company websites. These sites will inform them that SMBG is a "valuable management tool" and that it will "allow them to be in control of their diabetes" (Abbott Diabetes Care 2015; Accuchek 2012; Diabetes Australia 2015b).

Pillar three: Socioeconomic factors

From a socioeconomic point of view, SBMG remains highly affordable, and blood glucose test strips remain subsidised. When the new restrictions on subsidisation take effect, this may remove one of the incentives to obtain a blood glucose meter. However, for now, the messages that the patient with NITT2DM receives is confusing with consumer organisations and many HCPs recommending that they should perform SMBG and the government and RACGP suggesting otherwise.

Pillar four: Context Local contextual factors

The context in which people make informed, autonomous decisions is shifting with HCPs having access to guidelines that actively discourage the use of SMBG in people with NITT2DM. The recent changes announced by the Australian Federal Government to restrict the future subsidisation of BGTs may start to change the way that SMBG is seen in context. However, the value of SMBG for consumers with NITT2DM may remain confused for some time with some diabetes educators heavily criticising the proposed restrictions and RACGP guidelines (Worsely 2015a).

This study, when viewed in relation to the Conceptual Framework, indicates that many Australian HCPs from within and between health professions will have developed very different and at times conflicting perceptions about the value of SMBG for their patients with NITT2DM.

Limitations / Strengths

The primary limitation resulted from the nature of the research. It was necessary to interview representatives from a wide variety of different health care backgrounds. While this process adds to our understanding of the issues around SMBG from many different perspectives, it limited the number of HCPs from within those professions that were able to be interviewed.

The sampling frame and context driven issues limit the generalisability of the findings. For example, it is acknowledged that primary care nurses work in a wide variety of settings from general practice to schools and custodial settings, and those that took part in this study may not represent the full range of primary care nurses experience.

Further, as the HCPs interviewed were drawn from a localised area, it is unknown to what extent results would vary in different practice settings.

Despite these limitations, this study has several strengths. Firstly, it has captured the wide range of health professionals with a focused question route. Secondly, findings are positioned within a review of the published literature as well as a description of the social, political, historical and economic factors that have led to its widespread use of SMBG by people with NITT2DM. Thirdly these findings provide a review of contemporaneous issues in Australia influencing diabetes health related practices through the lens of self-monitoring of blood glucose.

Summary

This chapter has provided an analysis and discussion of the study findings applying a lens of the social, political and economic factors impacting on self-monitoring of blood glucose. In particular, a lens of critical social theory, challenging stereotypes and accepted norms provided an important framework for challenging a review of evidence-based practice and the importance of translational research.

Chapter 8

Conclusions and recommendations

Introduction

This thesis has built a case for considering HCPs' views of diabetes management within the complex milieu of social, political and economic factors impacting contemporary healthcare (Weaver et al. 2014). Investigating the role of evidence-based practice within this context is increasingly important and, in particular, using a critical framework.

Seven main themes emerged from the analysis: (1) The perceived value of blood glucose monitoring in people with diabetes varies within and between health professional groups; (2) The information our patients receive about blood glucose monitoring is limited; (3) Blood glucose monitoring is not a benign activity and can have negative or positive consequences; (4) The health care professionals most likely to use the results in a structured manner are diabetes educators and dietitians; (5) the capacity to provide specialised training to patients is limited; (6) Professional training does not address blood glucose monitoring; and (7) HCPs want impartial information about SMBG and would like to receive it in a convenient manner.

This thesis builds upon the work of many others who have investigated this established component of diabetes management and the barriers and facilitators to evidence-based practice (Allemann et al. 2009; Clar et al. 2010; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009). However, this is the only study of its kind to investigate the perceptions of a range of Australian health care providers and critically review how they formed their opinions regarding SMBG. This chapter summarises the study and suggests implications for policy, practice, education and research.

Policy

The escalating cost of diabetes to the health budget necessitates careful consideration of how the health dollar is spent. This thesis has demonstrated that a number of bodies, including industry and professional bodies, lobby to influence health care policy. With health expenditure expected to grow $324 billion AUD by 2054-2055, the Australian Government made a number of decisions to improve the sustainability of health funding (Hockey 2015). One of the proposed changes includes the restriction of BGTs to people with NITT2DM from July 2016. From that date, people with NITT2DM will be restricted to six a month supply from diagnosis via PBS prescription. Access can be extended if a diabetes medication is initiated or

changed. Further, prescribers will be given the discretion to extend this period if they believe that it is necessary to the patient due to illness or co-prescribed medication that adversely impacts glycaemic control.

People with insulin-treated diabetes and gestational diabetes mellitus will be able to continue to obtain BGTs without restriction, as they are now. It is unclear how this will impact access through the NDSS as there is no current mechanism for prescribing or limiting access. The move has been questioned by ADEA Chief Executive Office Dr Joanne Ramadge, who has pointed out that this appears to exclude diabetes educators from the decision-making process (Worsely 2015b).

The findings of this study support the view that there should be limited access to BGTs for people with NITT2DM. However, the suggested changes to access put forward by the Australian Federal Government and the NPS indicate that access to subsidised BGTS will involve a limitation of time. This restriction will not guarantee that people with diabetes will receive comprehensive training in the use or interpretation of SMBG.

This study argues that only people with NITT2DM, who have been assessed as likely to benefit from SMBG and have received education from an adequately trained, appropriately qualified and impartial HCP, should be eligible for access to subsidised BGTS. Under the new funding arrangements, the discretion to extend the timeframe for BGT prescription will rest with prescribers. That currently would include the GP or endocrinologist and a limited number of nurse practitioners.

I believe that this study argues for a different approach as the findings demonstrate that GPs and endocrinologists rely on diabetes educators and dietitians to assist patients to learn and utilise SMBG. Those most likely to qualify for this role would be an experienced diabetes educator or dietitian. An example would be a credentialled diabetes educator (CDE) or certified practising dietitian (CPD).

The introduction of a six-month period for access to BGTS does not change the fundamental findings of this study. In fact, it argues for a more purposeful approach to SMBG so that the patient and the taxpayer obtain maximum benefit. This study has highlighted that current guidelines regarding SMBG are inconsistent and should be reviewed. Moreover, this study emphasises that SMBG should be considered within a range of contextual factors to ensure care is person-centred and appropriate.

A new set of guidelines will be necessary when these changes are enacted to guide future practice. These guidelines should be developed in consultation with impartial organisations that could include, but should not be limited to, the PSA, NPS, ADEA, RACGP, DAA, ADS and DA. There should be no funding or sponsorship from any pharmaceutical device company for the development of these guidelines. Urgent funding instead should be made available through an NDSS National Development Program.

Practice

This study points to a limited opportunity for many people with diabetes to obtain the education necessary to support the purposeful use of blood glucose meters. This has implications for the education of health care professionals in the context of entry to practice education and continuing professional development. Further, it demonstrates that at least a certain percentage of people with NITT2DM have received conflicting advice in regards to SMBG.

Ultimately it is the HCP's responsibility to review information and training critically when forming their opinions regarding the value of a treatment option. The literature review identified the sparse evidence base for blood glucose monitoring as well as the complexity of diabetes self-management treatment strategies (Allemann et al. 2009; Australian Diabetes Educators Association 2009 page 4; Clar et al. 2010; Duke, Colagiuri & Colagiuri 2009; Malanda et al. 2012; Poolsup, Suksomboon & Rattanasookchit 2009).

Diabetes self-management education embraces an empowerment model and espouses a patient-centred care approach (Asimakopoulou & Scambler 2013; Funnell & Anderson 2004). Both models agree that the responsibility of the health professional is to assist patients make well-informed decisions and then respect the health choices they make. It is, therefore, central to this approach that people with such a chronic disease are provided with sufficient information to understand fully the benefits and costs of any health strategies.

To provide a blood glucose meter to a person with only a description of potential benefits might not be seen as providing an opportunity for a truly informed choice. A fully informed decision must also include an acknowledgement that there also costs, inconvenience and limitations embedded within the practice. Ultimately the patient is at a disadvantage if they have not received this balanced view. They will make a decision based on a fraction of the information available. Moreover, an emphasis on technology to control an individual's

condition may serve to minimise the importance of non-pharmacological recommendations, such as diet and physical activity that are important in the control and management of diabetes. Undertaking a tailored and targeted assessment of the individual's capacity for self-care, health literacy and perception of risk is important in care planning.

There is an ethical imperative to the patient. As this study has demonstrated, blood glucose monitoring is not a benign activity (Beverly et al. 2012; Fisher et al. 2011; Franciosi et al. 2001; O'Kane 2008; Rubin & Payrot 2001; Schwedes, Siebolds & Mertes 2002; Simon et al. 2008). Whether a person benefits from the practice or is physically or emotionally harmed, depends on the quality of education they receive and their engagement with HCPs.

It is important to consider not only the direct cost of the subsidisation of the BGTS but also the cost of providing adequate diabetes education regarding SMBG to patients. These costs must be considered against the likely benefit to the patient and the taxpayer who is shouldering much of the burden of the cost of BGTS.

Our diabetes workforce is becoming overwhelmed with the numbers of people being diagnosed with this chronic condition. Also, the complexity of the cases they are dealing with is limiting opportunities to review important clinical guidelines and undertaking additional self-directed study.

HCPs in this study indicated a desire for training programs and guidelines regarding SMBG that reflect the evidence, are developed by independent and impartial organisations and are consistent among health care professions so that they can improve the consistency of recommendations to their patients. While online programs do exist, they were not mentioned by those HCPs interviewed suggesting that such programs need to be better advertised, and there should be incentives for undertaking them.

This study has important implications for both patient education and the training of HCPs. Undergraduate and postgraduate programs for HCPs should include a module regarding the appropriate use of blood glucose meters within diabetes management. This module should be consistent across all health care professions and referenced back to the previously mentioned guidelines.

These training modules should be widely advertised and available as online training programs. Completion of these training modules should attract professional development points.

Issues for further research

Much research has been conducted on how effective SMBG is in improving glycaemic control in people with NITT2DM. However, this study highlights a broader area of concern. That is the matter of patient autonomy and informed decision making (Asimakopoulou & Scambler 2013; Funnell & Anderson 2004; Holmström & Röing 2010). It also has implications for translational research and how HCPs obtain and synthesise information and accordingly make decisions.

If our role as HCPs is to inform our patients of their rights and responsibilities in relation to their diabetes management fully, this study begs the question of how other choices are presented to our patients.

Are HCPs explaining the benefits as well as the potential negative consequences of the choices to their patients? Patient-centred care is not a process of giving patients the opportunity to make decisions about how they will comply with our demands.

Patient-centred care implies a much greater responsibility for the HCP. It requires a more thorough explanation of disease and an exploration of the feelings, beliefs and expectations of the patient (Bauman, Fardy & Harris 2003). Patients want to be understood in the context of their world and consideration given to their emotional needs and life issues. Further, they want to find common ground with the HCP and be actively involved in decisions regarding their management (Stewart 2001). The HCP has the responsibility to provide patients with the best possible information in a balanced and unbiased manner so they can make informed decisions. We then must respect those choices and help them to achieve their goals (Asimakopoulou & Scambler 2013).

As health care professionals, we must have the courage to hold up our practice for scrutiny and be held accountable. In addition, we must be open to taking on board and acting on criticism by others (Bulman & Schultz 2013). This scrutiny emphasises the importance of reflective practice and life-long learning. In addition, we should be self-critical and consider the basis upon which we form our views. There are other areas in diabetes management that must be viewed under the microscope such as dietary and exercise recommendations, the choice of diabetes medications and equipment such as disposable versus reusable insulin pens. There is always a benefit and a cost to the patient.

In the specific area of diabetes education, other outcomes in addition to glycaemic control must be considered. It has been identified that the goal of diabetes self-management is patient knowledge, self-determination, self-efficacy and the ability to make appropriate decisions

(Eigenmann & Colagiuri 2007). Further research regarding how health care professionals form their views on treatment options for their patients with diabetes in addition to outcomes is a logical and necessary next step.

Summary

Although the sampling frame prohibits wide generalisability, this thesis has demonstrated in a sample that the perceptions of Australian HCPs regarding the value of SMBG in people with NITT2DM are varied and largely based on inconsistent information, training, the influence of marketing and other key stakeholder groups. In the context of the available literature, it is unlikely this is an isolated example. The consequences of inconsistent decisions not based on evidence have implications for the health care system, provider and patients.

Globally, diabetes is a growing problem and requires each individual to adapt to a range of recommendations. SMBG is recommended as an intervention that can contribute to improved glycaemic control for people with non-insulin NITT2DM. However, there is now substantial evidence of the limitations of this approach.

Inconsistent recommendations to patients can contribute to adverse health care outcomes and rising health care costs. These findings provide an empirical basis to inform educational and policy interventions to help ensure that training and recommendations regarding blood glucose monitoring are standardised and evidence-based.

Clinical care does not occur in isolation but is also moderated by a number of social, political and economic factors. Understanding these factors and the role of key stakeholder groups is critically important in understanding clinical practice patterns.

This study has provided both a historical and contemporaneous description of diabetes care and in particular, identified the evidence and issues of the application of SMBG recommendations. It has also identified that clinical decisions do not occur in isolation but are mediated by a range of factors including prior experience, social and professional networks and are also influenced by lobbying and political factors. Information generated from this thesis has cast the spotlight on practice patterns and identified key areas for future attention to improving diabetes care.

Appendix A

Ethics approval

NSW GOVERNMENT Health
Northern Sydney
Local Health District

27 November 2012

Mr G Barker
Diabetes Education Service
Hornsby Ku-ring-gai Hospital
Hornsby
NSW 2077

Dear Mr Barker,

1212-455M: *A qualitative study of Australian health care professionalsâ€™ understanding of self-monitoring of blood glucose in people with non-insulin treateddiabetes. Mr G Barker,*

Thank you for providing additional information as requested at the meeting on **27 November 2012** by the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC). Following a review of the application, the HREC Executive have determined that the proposal meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). The HREC Executive is pleased to advise that your study has now granted scientific and ethical approval.

It is noted that the approval covers the following NSW Health sites:

- Hornsby Ku-ring-gai Hospital

The documentation included in the approval is as follows:

- Application Form for Ethical and Scientific Review of Low and Negligible Risk Research – AU/6/A79F010
- Research Proposal, undated
- Participant Information Sheet and Consent Form, version 1, dated 1/10/2012

It is noted that the study has been assessed by the HREC for *ethical* and *scientific review* ONLY and that clearance on the Site Specific aspects of the trial (local sign-off's, legal documentation etc) MUST be obtained from the above listed sites prior to commencement of research. Each site has different requirements; NSW Area Health Service sites require submission and approval of a Site Specific Assessment (SSA), which can be completed at: www.ethicsform.org/au. Please contact the local site for advice on what will be required.

At this time, we also remind you that, in order to comply with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia*, and in line with NSLHD HREC policy, the Chief Investigator is responsible to ensure that:

1. *The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.*
2. *The HREC is notified of all Serious Adverse Events (SAEs) or Serious Unexpected Suspected Adverse Reactions (SUSARs) in accordance with the Serious Adverse Event Reporting Guidelines. Please refer to the Research Office website.*
3. *Proposed amendments to the research protocol or conduct of the research that may affect the ethical acceptability of the project are submitted to the HREC on an amendment form (including any relevant attachments). For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each of the sites so that they can notify their Research Governance Officer.*
4. *Proposed changes to the personnel involved in the study are submitted to the HREC on a Change in Personnel Form (accompanied by the investigator's CV where applicable).*

AURED NEAF REF: ***LNR/12/HAWKE/436***
NSLHD REF NO: 1212-455M,

Research Office
Building, Level 13
Royal North Shore Hospital
St Leonards NSW 2065
Tel (02) 9926 4580 Fax (02) 9926 6179

Health
Northern Sydney
Local Health District

5. *The HREC must be provided with an annual progress report for the study by the 31st October each year. For multi-centre studies the Chief Investigator should submit to the Lead HREC on behalf of all sites.*
6. *The HREC must also be provided with a final report upon completion of the study. For multi-centre studies the Chief Investigator should notify the Lead HREC and the investigators at each site should notify the relevant Research Governance Officer.*
7. *The HREC must be notified, giving reasons if the project is discontinued at a site before the expected date of completion.*

Please refer to the NSLHD Research Office website to access forms such as the amendment form, Annual/Final Report Form, Change in Personnel Form and Serious Adverse Event Guidelines and Forms;

Internet:
http://www.northernsydneyresearch.com.au

HREC approval is valid for five (5) years from the date of the approval letter. **Your approval will therefore expire on the 27 November 2017. Your first progress report is due on the 31st October 2013.**

Yours sincerely,

Professor Stewart Dunn/ Dr Liz Newton
Co Chairperson
NSLHD HREC

AURED NEAF REF: ***LNR/12/HAWKE/436***
NSLHD REF NO: 1212-455M.

Research Office
Kolling Building, Level 13
Royal North Shore Hospital
St Leonards NSW 2065
Tel (02) 9926 4460 Fax (02) 9926 8173

Appendix B

Interview guide

APPENDIX A: INTERVIEW GUIDE

Category Question

Beliefs, recommendations and practices

- Let's start by considering clients/patients who are attempting to control their diabetes with diet alone. Do you recommend that those clients/patients perform SMBG?

- Next, let's consider clients/patients who are also taking oral agents. Do you recommend that those clients/patients SMBG? –

- Thinking specifically again of all clients/patients with type 2 diabetes not taking insulin and having HbA1c ≤7.0%, do you think that SMBG is useful in these circumstances?

- What are the more important or less important elements to include in any information provided to people with diabetes regarding SMBG?

- Can you give me any examples of your non-insulin treated patient's experiences, positive and/or negative, regarding their use SMBG including physical or psychological?

Use of results

- Do you review your clients'/patients' SMBG records?

- If yes: How do you use this information?

- What do you advise clients/patients to do regarding abnormal results?

Factors influencing recommendations

- Can you tell me what do you feel are the predominant factors that influence you to recommend or not recommend to people with non-insulin treated diabetes perform SMBG?

Sources of information

- Can you give me examples of any information you have recently accessed or have been exposed to that has indicated the value or lack of value regarding the use of SMBG in patients with non-insulin treated diabetes?

- Can you tell me if that information you have accessed or received has been helpful in assisting your non-insulin treated patients perform SMBG in an effective manner?
- Can you tell me how if your professional training – undergraduate or postgraduate, contained specific information about how to teach people with diabetes how to perform SMBG?
- Can you tell me if there is information or training that you would like to receive that would helpful in assisting your patients with diabetes perform SMBG in an efficient manner.

Appendix C

Using publically accessible data to answer views and perceptions

PBAC – Post Market Review of Pharmaceutical Benefits Scheme Products Used in the Management of Diabetes on Stage One: Blood Glucose Test Strips

Aim/Method

Understanding the drivers for blood glucose monitoring in NITT2DM is dependent on understanding a range of views of stakeholders.

In 2012, the Australian Department of Health Care and Ageing launched a review of the blood glucose meter subsidies (Pharmaceutical Benefits Scheme 2012a, 2012b). The objective of this review was to evaluate the body of clinical evidence regarding diabetes interventions to ensure people with diabetes are using the most appropriate medicines and products.

In particular, the review focused on the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) and the clinical outcomes and benefits of SMBG for people with type 2 diabetes not treated with insulin.

A report was prepared by the Veterans Medicines Advice and Therapeutic Education Services, University of South Australia generated from the review detailing the number of BGTS supplied to patients in Australia.

The purpose of this project was to:

1. Examine the content of the various stakeholder submissions.
2. Determine themes emerging from the data (thematic analysis).
3. Identify issues raised in the submissions and use this information to help generate questions for use in a qualitative study.

Understanding a range of views and agendas

The call for submissions for the review of BGTS included the following terms of reference:

- Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes;
- Determine the clinical outcomes and benefits (e.g. HbA1C) of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with type 2 diabetes not treated with insulin;
- Consider the clinical criteria for eligibility for subsidised access to BGTS under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring.

In addressing the above issues, the respondents raised a number of points. The submissions were read, and comments listed. These comments were then grouped into themes.

Themes were then used to generate possible questions to be included in the Interview Guide for the Primary Qualitative Study.

Theme 1. Self-determined treatment/monitoring

Points raised

- Respecting the individual's right to choose management options and to receive optimal care in their social and health context mandates that SMBG is available to all, but not mandatory for all.
- Many people already practise it (SMBG) and removing this might be seen as removing a fundamental right by some people.
- It is important that, as with many diabetes self-care activities, it is the choice of the individual to engage in SMBG.

Potential questions in relation to self-determined treatment

1. Do you give patients the option of performing SMBG or not performing SMBG?

2. What are the more important or less important elements to include in any information provided to people with diabetes regarding SMBG?

Theme 2. Negative consequences of not subsidising SMBG

Points raised

- Possibly delaying detection of deteriorating glycaemic control
- Potential delay in treatment escalation
- Removal of subsidy suggests that t2DM is not important.

Potential questions in relation to adverse consequences

1. Do you regularly review your clients'/patients' SMBG records?
2. If yes: How do you use this information?
3. What do you advise clients/patients to do regarding abnormal results?
4. Do you feel that people with NITT2DM who perform SMBG take their diabetes more or less seriously than those who do not perform SMBG?

Theme 3. Limitations of HbA1c

Points raised

- HbA1c does not reflect day-to-day fluctuations – cannot detect hypos.
- Patients less able to access HbA1c data or patients may present without results or outdated results.
- Two individuals may have the same HbA1c, but markedly different diurnal glycaemic patterns.
- HbA1c measurements can provide misleading information based on the influence of analytical, genetic, physiological or pathological factors.
- There are costs associated with visits to a GP to order an HbA1c assay and for the pathology service.
- The taxpayer bears the cost of an HbA1c assay in the way of a Medicare rebate for HbA1c.

Potential questions in relation to limitations of HbA1c

1. Do you routinely have access to HbA1c results?

2. If yes: how do you use this information?

3. Can you describe any limitations of the HbA1c assay as a determinant of glycaemic control?

4. What are the more important or less important elements to include in any information provided to people with diabetes regarding HbA1c?

Theme 4. Limitations of existing research

- Only a small number of studies have evaluated a structured approach to SMBG.
- In many studies the intervention (SMBG) groups achieved a reduction in HbA1c of 0.25% compared to the non-SMBG groups. A between-group difference in HbA1c of 0.5% is required to be considered clinically significant.
- Setting a relevance threshold of 0.5% reduction in HbA1 appears to be "somewhat arbitrary", especially in diagnostics.
- In many studies, blood glucose monitoring is viewed as an intervention rather than a tool to determine the effects of an intervention
- There is a reliance on older studies
- Some studies including people with good glycaemic control – *Is it reasonable to expect clinically significant improvements when baseline HbA1c was close to optimal?*
- Studies have either used random monitoring or have failed to guide study participants on how to use the SMBG data for patient management
- Apparent improvements in HbA1c following SMBG merely reflect a normalisation of levels in response to treatment by medication or lifestyle modification following a worsening of glycaemic control prior to the start of SMBG.
- Some patients may have experienced the 'Hawthorne effect' -- where participants' outcomes improve as a result of being part of an experiment or study.
- Widespread education of healthcare professionals is needed to assist them to interpret the available evidence relating to SMBG.

Potential questions in relation to limitations of research

1. Can you tell me about any information that has been brought to your attention regarding the controversy in relation to the value of SMBG in this population in the literature?
2. Can you tell me how you respond to the following statement: There is no value in SMBG in this population?
3. Can you give me examples of any information you have recently accessed or have been exposed to that has indicated the value or lack of value regarding the use of SMBG in patients with non-insulin treated diabetes?
4. Can you tell me if that information you have accessed or received has been helpful in assisting your non-insulin treated patients perform SMBG in an effective manner?

Theme 5. Benefits of SMBG

Points raised:

- Provides feedback when medical practitioners modify medications.
- Can help to identify hypoglycaemia in those with higher risk than those patients using sulphonylurea agents, with renal impairment or chronic kidney disease, and the elderly.
- Helps identify hypoglycaemia in people using sulfonylureas working in high-risk occupations.
- Helps to understand and optimise glycaemic control prior to conception and during pregnancy.
- Helps to establish a baseline BGL pattern prior to initiation of insulin (and thereafter).
- Understanding of actual blood glucose levels assists compliance in relation to exercise and diet.
- SMBG helps facilitate initial diabetes self-management education
- SMBG helps to monitor changes in blood glucose levels during intercurrent illness.
- Early identification of deterioration in glycaemic control.

- Some patients report enjoying performing SMBG and derive some sense of well-being from the practice.

- Opportunities for education and regular follow-up with the GP possibly through the current PBS script provisions.

Potential questions related to benefits:

1. Thinking specifically again of all clients/patients with type 2 diabetes not taking insulin and having HbA1c ≤7.0%, 53mmol/mol, do you think that SMBG is useful in these circumstances?

2. Let's start by considering clients/patients who are attempting to control their diabetes with diet alone. Do you recommend that those clients/patients perform SMBG?

3. Next, let's consider clients/patients who are also taking oral agents. Do you recommend that those clients/patients SMBG?

4. Can you tell me what do you feel are the predominant factors that influence you to recommend or not recommend to people with non-insulin treated diabetes perform SMBG?

5. Can you give me any examples of your non-insulin treated patients' experiences, positive and/or negative, regarding their use SMBG including physical or psychological?

Theme 6. Using a structured approach to SMBG

Points raised:

SMBG should be used only when patients and/or their clinicians "*have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plan in order to attain agreed treatment goals*".

- Individuals should be given clear, consistent signals from the various health professionals whom they consult regarding the need for SMBG relative to their personal situation and clinical outcomes and how they should interpret readings.

- Structured assessment of self-monitoring skills, the quality and use made of the results obtained, and of the equipment used, should be made annually.
- When providing meters, education in their use and interpretation of the results should be given. Review of technique, data analysis and meter function should be a part of the Annual Review
- Collaborative (patient and healthcare professional) use of structured SMBG data leads to earlier, more frequent, and more useful treatment modification recommendations for poorly controlled, non-insulin treated type 2 people with diabetes.
- In the STeP study, people with diabetes in the structured testing group showed significant reductions in average, pre-prandial, postprandial and bedtime blood glucose levels at 12 months.
- NITT2DM patients need to be proficient in a number of self-care skills supported by SMBG, including diet and exercise choices, medication adjustment, timing of medication administration, and understanding when and why they are at most risk of hyper- and hypoglycaemia.
- Structured SMBG (e.g., a seven-point blood glucose profile was taken on three consecutive days one week before the GP visit, four times per year) is relatively inexpensive and naturally rationalises the use of blood glucose testing strips.

A structured approach requires that there be agreement between the patient and the HCP regarding:

- the clinical question to be addressed;
- the establishment of blood glucose targets;
- recommended frequency and timing of SMBG;
- training of health professional in the interpretation of SMBG data;
- training of the person with diabetes in the use of the blood glucose meter and analysis of SMBG results;
- appropriate feedback of SMBG data to the person with diabetes;

- a plan for how to intervene to improve the blood glucose levels, e.g., to change diet/activity level or medications; and
- action, i.e., a change in diet/activity level or medications, and reflection on the effectiveness of changes made.

Potential questions related to structured approach:

1 Can you give me examples of any information you have recently accessed or have been exposed to that has indicated the value or lack of value regarding the use of structured SMBG in patients with non-insulin treated diabetes?

2 Can you tell me if that information you have accessed or received has been helpful in assisting your non-insulin treated patients perform structured SMBG in an effective manner?

3 Can you tell me how if your professional training, undergraduate or postgraduate, contained specific information about how to teach people with diabetes how to perform structured SMBG?

4 Can you tell me if there is information or training that you would like to receive that would helpful in assisting your patients with diabetes perform SMBG in an effective manner?

5 How much time do you devote to training people in using a structured approach?

6 In your view, is teaching a structured approach to SMBG achievable for all patients?

7 Effective and structured SMBG for all people with diabetes would need to be supported by better access to support and education of relevant health professionals, including diabetes educators. How could this education be supported?

8 Evidence-based, structured education and support for people with NITT2DM who do not use insulin is also needed. Whom do you feel could deliver this?

9 Is the effort into training people to do structured SMBG in people with near normal HbA1c's justifiable and sustainable?

10 This indicates that it is the visits to the GP which are critical and did not demonstrate that structured use of SMBG affects lifestyle.

Theme 7. Financial considerations

- No evidence that restricting subsidies would save money
- People on average use less than one strip per day and so there are no significant savings to be had by removing the subsidies

Potential questions related to financial considerations

1. Is cost a consideration for your patients regarding SMBG?
2. Do you feel that the financial investment of the NDSS in subsidising BGTS for people with NITT2DM is value for money?

Theme 8. Psychological well-being

Points raised:

- Studies do not indicate that SMBG has an impact on quality of life
- Some studies have found that SMBG causes distress or impairs quality of life.

Potential Questions related to psychological wellbeing

1. Can you give me any examples of your non-insulin treated patient's experiences, positive and/or negative, regarding their use SMBG including physical or psychological?

Theme 9. Negative aspects of SMBG

Points raised

- Regular use of SMBG should not be considered part of routine care where diabetes is well controlled by nutrition therapy or oral medications alone.
- The rate which patients perform SMBG declines over the first 12 months.

Potential Questions related to negative aspects of SMBG

1. How much extra time will this will require from HCPs and how will this be facilitated?
2. Do you discuss the potential positive and negative consequences of SMBG with your patients?

3. Should healthcare providers assess and consider individuals' psychological needs when assisting newly-diagnosed patients to commence SMBG?

4. Are patients given realistic expectations about what SMBG can do for a patient?

5. Did you receive education or training to teach patients how to perform SMBG?

Other issues

Emotive Language

"Structured SMBG provides crucial information that allows clinicians to identify and address specific patterns of hyperglycaemia and hypoglycaemia when they are evident…."

Emotive words such as "Crucial" are frequently used. In one submission, it appears six times; as is the word "essential". It is hard not to believe that this may be overstating the positive effect of structured SMBG based on the limited studies to date.

Contradictions

There were a number of contradictions noted in the submissions

RDA: Criticism of studies measuring small changes in HbA1c. This criticism is in contradiction with the recommendation of ongoing monitoring in all people where it is argued that even small improvements in HbA1c are important.

RDA: "People with NITT2DM use on average less than one blood glucose strip per day confirming that the current systems in place by the health care professionals regarding utilisation are indeed effective in minimising overutilisation and wastage". This argument is in contrast to the claims that HCPs are inadequately resourced to instruct patients in using a structured approach.

The suggestion of using the meter for a short while after diagnosis so people can understand glucose response in relation to changes in diet or exercise habits contradicts the claim that ongoing monitoring is necessary due to the progressive nature of type 2 diabetes to facilitate timely intervention

Theme 10. Criteria for access

- Regular use of SMBG should not be considered part of routine care where diabetes is well controlled by nutrition therapy or oral medications alone.

- Access to glucose strips is necessary when patients are on diabetes medications that have a high risk of hypoglycaemia (sulfonylureas and insulin).
- A reduction in the reliance on treatments that can cause hypoglycaemia may reduce the cost of SMBG.
- Physicians should determine suitability.
- There is reasonable evidence for placing a cap on access to approximately 400 strips per year.
- For patients to receive initial and ongoing training regarding structured SMBG they will need better access to HCPs.

Potential questions related to access

1. Considering clients/patients who are attempting to control their diabetes with diet alone. Do you recommend that those clients/patients perform SMBG?
2. Consider clients/patients who are also taking oral agents. Do you recommend that those clients/patients SMBG?

Negative aspects either not mentioned or acknowledged

- The act of performing SMBG continues to require a drop of blood and, therefore, remains somewhat painful.
- While aspects of monitoring are free or subsidised, there remains some costs associated with SMBG.
- SMBG results remain similar to HbA1c results and contribute to some confusion.
- Increasingly people obtain meters online or over the counter with little or no training.
- There are not enough diabetes educators to train everyone to conduct SMBG in a structured manner.
- SMGB continues to be time-consuming to perform despite the speed of getting the result as it involves a process and often finding a private area.

- Alternatively, performing SMBG in a non-private area discloses to the world you have diabetes.
- SMBG requires that people carry the equipment with them.
- People with diabetes may experience anxiety or even a sense of failure when results fall outside the desired range.
- Is a reminder to the person that they have diabetes.
- Can be associated with feelings of guilt.
- Some people reduce food intake in order try and improve BGLs.
- Some people falsify results to impress their HCP.
- SMBG provides spot checks only – not a continuous tracing thereby limited by the amount of data collected.
- Results taken at random times can be misleading as the readings may be taken at a time of a peak or trough in BGLs.
- SMBG can have a degree of inaccuracy and are dependent upon factors including proper operation.
- Do not necessarily directly correlate with formal BGTS or other meters they may compare with causing concern and confusion.
- Meters were originally developed for confirming the diagnosis of hypoglycaemia or the diagnosing of diabetes and are not designed for purpose for which they are used.
- Additional training of health professionals would be required to teach people how to monitor BGLs in a structured manner.
- Additional training of patients by health professionals would be time-consuming and cost-prohibitive.
- Need for ongoing review by HCPs as outlined by IDF would be unsustainable given the size of the current workforce.

- Time consuming to train patients when many patients present with more complicated problems.
- Some people find that their friends, relatives and HCPs get angry if they do not monitor.
- Some HCPs and families see SMBG as a demonstration of “compliance” and self-care/management.

Discussion

Publically accessible data, both quantitative and qualitative, provides a useful resource for researchers. It can provide a lucrative data source to contextualise a diverse perspective of views and opinions. Such data can be highly relevant to investigating issues that are mediated by a range of patient, provider and health care system perspectives.

The use of the publically accessible submissions in relation to the subsidisation of BGTS provided access to a range of opinions enabling analysis of a range of key stakeholder views.

Not surprisingly, the submissions were overwhelmingly in favour of the ongoing subsidisation of BGTS. Selection bias needs to be considered. Organisations with a financial interest in the subsidy of BGTS submitted 19 of the 32 submissions.

An invitation such as this was unlikely to attract submissions that were raising objections to the ongoing subsidisations of SMBG.

The analysis of the submissions and the themes that were generated provided useful questions to be considered for inclusion in the primary qualitative study guide.

Appendix D Literature search

Does SBGM improve glycaemic control?

In more recent years, there has been debate as to whether owning and using a blood glucose meter equates to clinically significant improvements glycaemic control, particularly for those with NITT2DM.

To help determine whether SBGM is associated with an impact on glycaemic control or quality of life a significant number of RCT and observational studies have been conducted. The results of these studies have been variable and often contradictory.

As the number of published individual studies has increased, there have been various meta-analyses of the literature.

A review of these meta-analyses was conducted to determine if there was a consistency in the findings.

Search Strategy

PubMed	Results
1. Type 2 Diabetes	115354
2. Blood Glucose Self-Monitoring / or blood glucose monitoring:	12580
3. Meta-analysis or meta-analysis:	88553
4. 1 + 2 + 3 =	48 results

Date: March 2015

Medline database of the National Library of Medicine (1974 to present) and EMBASE (1974 to present).

Medline (Ovid)	Results
5. Type 2 diabetes	92925
6. Blood glucose self-monitoring / or blood glucose monitoring	3760
7. Meta-analysis or meta – analysis results	74236
8. 1 + 2 + 3	25

A total of 73 results were obtained from both searches.

Discarded = 60 results. Duplicates on not directly related to the question.

When searching both Medline and PubMed 13 meta-analysis articles were found that directly related to the question. (Allemann et al. 2009; CADTH 2009; Coster et al. 2000; Farmer et al. 2012; Holmes & Griffiths 2002; Malanda et al. 2012; McIntosh et al. 2010; Poolsup, Suksomboon & Rattanasookchit 2009; Sarol et al. 2005; Shekelle et al. 2007; St John et al. 2010; Towfigh et al. 2008; Welschen et al. 2005) The article by Holmes was excluded because it only listed results from the studies analysed and did not pool results.

The conclusions from the meta-analyses are very similar and suggest that the use of SBGM is associated with a statistically significant but clinically modest improvement in glycaemic control in people with non-insulin treated type 2 diabetes, particularly where the HbA1c values < 8.0%.

Further the range of results reported varied with some participants experiencing negligible effects or even an actual worsening of glycaemic control (see Table 1.)

Author	Year	Pooled HbA1c %	95% Confidence Interval
Coster	2000	-0.25	-0.61 to -0.10
Sarol	2005	- 0.39	- 0.54 to -0.23
Welschen	2005	- 0.39	- 0.56 to -0.21
Jansen	2006	- 0.40	- 0.70 to -0.07
Shekelle	2008 (6 months)	- 0.21	- 0.38 to +0.04
Shekelle	2008 (12 months)	- 0.15	- 0.36 to +0.06
Towfigh	2008 (6 months)	- 0.21	- 0.38 to - 0.04
Towfigh	2008 (12 months)	- 0.16	- 0.38 to - 0.05
Allemann	1009	- 0.31	- 0.44 to - 0.17
CADTH	2009	- 0.25	- 0.36 to - 0.15
Poolsup	2009	- 0.24	- 0.34 to - 0.14
St John	2010	- 0.22	- 0.34 to - 0.11
McIntosh	2010	-0.25	-0.36 to -0.15
Farmer	2012 (6 months)	- 0.25	-0.39 to -1.6.
Malanda	2012 (6 months)	-0.30	-0.4 to -0.1
Malanda	2012 (12-month follow-up	-0.10	-0.3 to 0.04
Average of the		- 0.255	

pooled result			

Table 1.

These findings are similar to an analysis of systematic reviews (Clar et al. 2010).

In this analysis of systematic reviews, it was found that SMBG was associated with a reduction in HbA1c of - 0.255% when compared to no SMBG.

Appendix E Literature search

SMBG and the association with anxiety and depression

Some literature indicates that the use of blood glucose meters may be associated with higher levels of anxiety and depressive symptoms (Clar et al. 2010; O'Kane 2008; Rubin & Payrot 2001).

Medline database of the National Library of Medicine (1974 to present) and EMBASE (1974 to present).

PubMed	Results
Blood glucose monitoring	12580
Type 2 Diabetes Mellitus	115354
Anxiety	163149
Depression	323807
1+2+3+4	17

Ovid Medline	Results
Blood glucose monitoring	3760
Type 2 Diabetes Mellitus	92925
Anxiety	100456
Depression	166022
1+2+3+4	9

A total of 26 results were obtained from both searches.

19 results were discarded as not specifically related or were duplicates and another result by Barnard (Barnard, Young & Waugh 2010) was not considered as it was a published survey of members of Diabetes UK who were confirmed users of blood glucose meters.

Two results obtained from both searches contained articles by Clar (a metanalysis) and O'Kane.

Scrutiny of bibliographies resulted in the retrieval of a total of 7 publications (Franciosi et al. 2001; O'Kane 2008; Peel, Douglas & Lawton 2007; Polonsky 2011; Polonsky et al. 2011; Rubin & Payrot 2001; Schwedes, Siebolds & Mertes 2002; Simon et al. 2008). See Table 2.

Author	Year	Depression/ Anxiety	Comment
Franciosi	2001	Yes	2,855 people with type 2 diabetes in Italy completed a questionnaire regarding SMBG habits. Those who reported conducting SMBG scored higher in regards to levels of distress, worries, and depressive symptoms.
Rubin	2001	Yes	A discussion paper is exploring the psychological issues and treatment for people with diabetes. Relates patient experiences of frustration with high or unpredictable results and the inconvenience of monitoring itself.
Schwedes	2002	No	Six-month study with 12-month follow-up. SMBG used in conjunction with food diary and additional training. Hba1c at baseline 8.47%. Well-being improved in SMBG group. However, SMBG was noted as a significant problem by people in the intervention group.
Peel	2007	Yes	A qualitative study of SMBG use. SMBG decreased over time. Participants perceived a lack of interest in results by health care professionals. Some participants felt guilty when readings from SMBG were above target.

			Some participants find readings difficult to interpret. Many participants do not act on results of SMBG.
Esmon	2008	Yes	RCT 184 participants randomised to SMBG or no SMBG over 12 months. SMBG group experienced 6% increase in depression scale. Trend towards greater anxiety scores
Simon	2008	Yes	453 pts. Allocated to standard care, enhanced follow-up and/or intensive education and monitoring. The more intensive group experienced increased anxiety and depression compared to controls at 12 months.
Polonsky	2011	No	*Structured SMBG program involving training of both participants and health care professionals. At 12 months, both SMBG and standard treatment groups improved well-being scores, although the SMBG group had a statistically significantly, but clinically marginal higher score on WHO-5.

Table 2.

*It is noteworthy that a greater percentage of participants in the intervention group were not included in the analysis due to dropping out or not adhering to the study protocol than those in the standard care group. Consequently, 71% of usual care participants compared to 51% of people in the intervention group were included in the final analysis. This suggests a degree of selection bias in relation to this result.

Appendix F Literature search:

Qualitative studies relating to type 2 diabetes and SMBG

Search strategy

PubMed Search	Results
Blood glucose monitoring	12583
Type 2 Diabetes Mellitus	115406
Qualitative Research	96013
1+2+3	43

Ovid Medline	Results
Blood glucose monitoring	5277
Type 2 Diabetes Mellitus	114848
Qualitative	22172
1+2+3	12

Scrutiny of bibliographies resulted in the retrieval of a total of 55 publications.

50 were discarded as they did not specifically relate to the topic or were duplicates (Bond & Hewitt-Taylor 2014; Farmer et al. 2009; Mathew et al. 2012; Peel, Douglas & Lawton 2007; Peel et al. 2004).

Author	Year	Comment
Peel	2004	Qualitative repeat-interview study of 40 patients with recently diagnosed diabetes from Scotland. The study found that although SMBG can alert people to the impact of lifestyle choices, poor understanding of the results can result in feelings of anxiety and guilt.
Peel	2007	Longitudinal Qualitative study of patients perceptions over time.

		SMBG decreased over time. HCPs appeared more concerned with the HbA1c results. Some saw the readings as determining if they had been good or bad and chastised themselves when BGLs were off target. The main reasons for continuing SMBG was reassurance and habit. The study identified that people do not always receive education about SMBG from their health professionals.
Farmer	2009	Primarily a study designed to determine the impact of SMBG on HbA1c results a secondary outcome measure was a quality of life scores. The study concluded that although some people found SMBG to be of benefit, many were not clear about how results related to lifestyle.
Matthew	2012	35 patients in from a Canadian Diabetes Education Centre took part in focus groups. The aim of the research was to help determine gender differences in various diabetes self-management practices. Both men and women described worry, fear and frustration in relation to blood glucose monitoring.
Bond	2014	An examination of online discussion groups. To determine how self-testing of blood glucose contributes to self-management strategies. This group were self- motivated and utilised SMBG results to guide food choices, etc., particularly in the early period after diagnosis. Where people perceived a lack of support from health care professionals, it was seen as unhelpful and demotivating.

Table 3

These suggest that from an international perspective although some people with NITT2DM found blood glucose monitoring to be beneficial and reassuring, there remained, however, a lack of clarity for many about how to relate the results to lifestyle.

At worst, patients with NITT2DM described a lack of understanding about SMBG leading to worry and fear and a view that the meters were determining if they had been “good” about their diabetes management. If health care professionals are perceived to provide inadequate support, this was a demotivating experience.

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