

**THE SOUTH AFRICAN COMMUNITY PHARMACIST AND TYPE 2 DIABETES
MELLITUS: A PHARMACEUTICAL CARE INTERVENTION**

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ABSTRACT

Type 2 diabetes mellitus is a chronic disease of pandemic magnitude, increasingly contributing to the disease burden of countries in the developing world, largely because of the effects of unhealthy lifestyles fuelled by unbridled urbanisation. In certain settings, patients with diabetes are more likely to have a healthcare encounter with a pharmacist than with any other healthcare provider. The overall aim of the study was to investigate the potential of South African community pharmacists to positively influence patient adherence and metabolic control in Type 2 diabetes. The designated primary endpoint was glycated haemoglobin, with the intermediate health outcomes of blood lipids, serum creatinine, blood pressure and body mass index serving as secondary endpoints.

Community pharmacists and their associated Type 2 diabetes patients were recruited from areas throughout South Africa using the communication media of various non-statutory pharmacy organisations. Although 156 pharmacists initially indicated interest in participating in the study, only 28 pharmacists and 153 patients were enrolled prior to baseline data collection. Of these, 16 pharmacists and 57 patients participated in the study for the full twelve months.

Baseline clinical and psychosocial data were collected, after which pharmacists and their patients were randomised, nine pharmacists and 34 patients to the intervention group and 8 pharmacists and 27 patients to the control group. The sample size calculation revealed that each group required the participation of a minimum of 35 patients. Control pharmacists were requested to offer standard pharmaceutical care, while the intervention pharmacists were provided with a scope of practice diabetes care plan to

guide the diabetes care they were to provide. Data were again collected 12-months post-baseline.

At baseline, proportionally more intervention patients (82.4%) than control patients (59.3%) were using only oral anti-diabetes agents (i.e. not in combination with insulin), while insulin usage, either alone or in combination with oral agents was conversely greater in the control group (40.7%) than in the intervention group (17.6%) (Chi-squared test, $p=0.013$). Approximately half of the patients (53.8% control and 47.1% intervention) reported having their HbA_{1c} levels measured in terms of accepted guidelines. There was no significant difference in HbA_{1c} between the groups at the end of the study (Independent t-test, $p=0.514$). In the control group, the mean HbA_{1c} increased from $7.3\pm 1.2\%$ to $7.6\pm 1.5\%$, while for the intervention patients the variable remained almost constant ($8.2\pm 2.0\%$ at baseline and $8.2\pm 1.8\%$ at post-baseline). Similarly, there were no significant differences between the groups with regard to any of the designated secondary clinical endpoints. Adherence to medication and self-management recommendations was similarly good for both groups. There were no significant differences between the two groups for any of the other psychosocial variables measured.

In conclusion, intervention pharmacists were not able to significantly influence glycaemic control or therapeutic adherence compared to the control pharmacists.

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List of abbreviations

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ACE	Angiotensin-Converting Enzyme Inhibitor
ADA	American Diabetes Association
AIDS	Acquired Immune Deficiency Syndrome
ARB	Angiotensin Receptor Antagonist
ASHP	American Society of Health-System Pharmacists
BMI	Body Mass Index
BMQ	Beliefs about Medicines Questionnaire
BP	Blood Pressure
CARDS	Collaborative Atorvastatin Diabetes Study
CE	Continuing Education
CCM	Chronic Care Model
CPD	Continuing Professional Development
CPS	Cognitive Pharmaceutical Services
DAWN	Diabetes Attitudes Wishes and Needs Study
DCCT	Diabetes Control and Complications Trial
DCP	Diabetes Care Plan
DES-SF	Diabetes Empowerment Scale-Short Form
Discovery	Discovery Health Medical Aid
DM2	Type 2 Diabetes Mellitus
ECG	Electrocardiogram
ECHO	Economic, Clinical and Humanistic Outcomes
GFR	Glomerular Filtration Rate
HbA _{1c}	Glycated Haemoglobin
HDL-C	High Density Lipoprotein-Cholesterol
HIV	Human Immunodeficiency Virus
HOT	Hypertension Optimal Treatment Study
IDF	International Diabetes Federation
LDL-C	Low Density Lipoprotein-Cholesterol
MARS	Medication Adherence Report Scale
MDI	Major Depression Inventory
MDRTC	Michigan Diabetes Research and Training Center
MEMS	Medication Event Monitoring System

NCD	Necessity-Concerns Differential
NICE	National Institute for Health and Clinical Excellence
RCT	Randomized Controlled Trial
SEMDSA	Society for Endocrinology Metabolism and Diabetes of South Africa
SMBG	Self-Monitored Blood Glucose
UKMRC	United Kingdom Medical Research Council
UKPDS	United Kingdom Prospective Diabetes Study
USA	United States of America
WHO	World Health Organisation

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CHAPTER 1 INTRODUCTION

1.1 Rationale and motivation for the study

This study investigated the potential of South African community pharmacists to influence patient adherence to long-term therapies and self-care recommendations, and to improve metabolic control in Type 2 diabetes mellitus (DM2).

Prior to the introduction of the managed care principle of pharmacy benefit management in South Africa during the 1990s, almost all chronically ill patients who were medically insured had unfettered access to what the local health insurance industry termed 'chronic medicine benefits'. Patients were able to access medicines prescribed for their chronic conditions without having to make co-payments or without having their chronic illness benefit prescribed or limited by any medicine formulary. Despite the apparent largesse of the health insurers in providing open access to chronic medication, anecdotal evidence revealed that many chronically ill patients were not having their prescriptions refilled at the expected 30 day intervals, while others simply ceased to refill their prescriptions altogether.

There was consensus amongst members of the Faculty of Pharmacy at Rhodes University, that a critical lack of knowledge existed on the subject of patient adherence to long-term therapies in a South African pharmacy practice context and that research to address the contribution of pharmacists to this subject was relevant in contributing to establishing an evidence base for South African community pharmacy practice.

The World Health Organization (WHO) published a report in 2003 entitled, *Adherence to long-term therapies: evidence for action*¹ in which the economic, clinical and humanistic cost of poor levels of therapeutic adherence – the term 'compliance' having by now been rejected by many authorities in favour of the less condescending term of 'adherence' – are discussed and possible solutions considered.

The report set the scene by defining adherence, describing the magnitude of the problem and considering the implications of poor adherence in terms of health policy and management. The report then dealt with improving adherence from the perspective of lessons learnt, i.e. factors affecting adherence and the discussion of interventions in terms of five dimensions of adherence, namely socio-economic, therapy-related, patient-related, condition-related and healthcare system factors. The report then went on to consider adherence in terms of specifically identified disease entities. Special mention was made of the behavioural mechanisms explaining adherence.

The following “take home messages” which were included in the report, highlighted the magnitude and consequences of the problem, the benefit of finding solutions and the potential of pharmacists to play key roles in improving scope of practice aspects of therapeutic adherence.

- *“Poor adherence to the treatment of chronic diseases is a worldwide problem of striking magnitude”.*
- *“Adherence to long-term therapy for chronic illnesses in developed countries averages 50%. In developing countries, the rates are even lower”.*
- *“The consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs”.*
- *“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment”.*
- *“There is no single intervention strategy, or package of strategies that has been shown to be effective across all patients, conditions and settings, Consequently, interventions that target adherence must be tailored to the particular illness-related demands experienced by the patient.”*
- *“Pharmacists are well positioned to play a primary role in improving adherence to long-term therapy because they are the most accessible health care professionals and because they have extensive training in pharmaceuticals”.*

It was decided to focus the study on the disease entity of DM2 as it received special mention in the WHO adherence report.¹ DM2 is a disease of pandemic proportions increasingly making its presence felt in the developing world where, it is predicted, most of the world’s diabetes burden will in future be borne.^{1,2} Furthermore, it is a disease where pharmacotherapy and lifestyle modification play major roles in the treatment and management of the condition,^{3,4} and where health promoting interventions in both these

therapeutic areas are accommodated within the pharmacist's defined scope of practice.⁴⁻¹¹

Most, if not all, DM2 patients make use of long-term pharmacotherapy to manage their disease. The prescription refill dynamic provides for frequent personal and informed contact between the patient and the pharmacist and thus positions the community pharmacist for roles in diabetes care beyond the traditional medicine-dispensing role.⁸⁻¹¹ Encounters of this nature present pharmacists with ideal opportunities to provide pharmaceutical care across a range of chronic diseases.¹²⁻¹⁵

Pharmacists in South Africa, in concert with their colleagues elsewhere, have for some time expressed a desire to play expanded roles in the delivery of primary health care.^{16,17} While a number of studies have reported on the positive effect of pharmacist co-ordinated interventions in promoting patient adherence to therapy and/or influencing patient health outcomes in DM2,^{5,8-10,12,18-22} the position in South Africa is less certain due to a paucity of published local practice based research.¹⁷ A Pubmed search using the search term, 'pharmaceutical care or cognitive pharmaceutical services AND Type 2 diabetes AND South Africa', produced no results. Discussions with the South African Pharmacy Council and the Pharmacy training institutions at both the University of the North West in Potchefstroom and the Nelson Mandela Metropolitan University in Port Elizabeth confirmed the absence of published literature relating to diabetes care in pharmacy practice in South Africa. A further motivating factor, therefore, is the desire to contribute to the body of knowledge in an important, if neglected, area of pharmacy practice and to be able to share such knowledge with colleagues in the profession, other interested parties and the students who are charged with taking the profession into the future.

1.2 Research problem and questions

The research problem is subject to the influence of a number of factors including: the nature of the disease, the influence of therapeutic adherence on health outcomes, accepted models of care in DM2, international evidence relating to pharmacist interventions designed to promote adherence in DM2 and, most importantly, the capacity

of South African community pharmacists to deliver diabetes care given the dynamics of pharmacy practice in the country.

In formulating the research problem the following questions were considered:

- Why did the WHO single out DM2 for special attention in the adherence report?
- What are the key components of care in DM2?
- What evidence exists to support roles for pharmacists in patient care in DM2?
- Is there a need for the study and is it likely to be of value in informing practice, education and further research?

The study hypothesis that South African community pharmacists are able to apply scope of practice diabetes care interventions capable of improving patient adherence and intermediate health outcomes in DM2 was informed by five main constructs: national and international guidelines for the treatment and management of DM2, the chronic care model, aspects of health behaviour theory, pharmacy practice-based evidence derived from the literature, and South African legislation mandating the practice of pharmaceutical care.

1.3 Structure of the thesis

The earlier chapters that provide the theoretical basis for the study include a review of the literature and a health care consumer survey designed to inform aspects of this research. The chapters following the consumer survey are concerned with the study methodology, the results, a discussion of the results, and the conclusions and recommendations. In addition to the annexures, lists of abbreviations, tables, figures and references are provided.

Chapters 2, 3, 4 and 5 are devoted to a literature review appropriate to the scope of practice of a community pharmacist.⁶ Chapter 2 reviews the growing contribution of DM2 to the world's total disease burden.² Clinical aspects of the disease are explored in the context of international guidelines.⁴

Chapter 3 describes key aspects of community pharmacy practice with a focus on extended roles for pharmacists in providing disease management, pharmaceutical care

and other cognitive pharmaceutical services.²³ An overview of relevant aspects of the health care system of South Africa is provided and pharmacy in South Africa, with an emphasis on community pharmacy practice, is discussed. Pharmacist-directed interventions provided internationally in DM2 and other chronic diseases are contrasted with the situation in South Africa. The state of practice-based research in South Africa is briefly examined. Aspects of patient care, including disease state management and the evolving paradigm of patient-centred care are discussed in this chapter.^{24,25}

Behavioural change theories, models and interventions,²⁶ patient self-management behaviours,²⁷ and a review of the literature relating to patient adherence are discussed in Chapter 4

As the main study is a randomised controlled trial, the design of such trials as well as trials involving complex interventions are discussed in Chapter 5.^{28,29} The conceptual framework of the study is described in this chapter.

The study hypothesis is founded, in part, on certain assumptions pertaining to the interaction and relationship existing between the patient and the pharmacist. These assumptions are associated with patient access to pharmacists and issues relating to the provision of cognitive pharmaceutical services. International literature has described key aspects of the professional relationship between the patient and pharmacist,³⁰⁻³⁴ but the South African situation regarding the patient-pharmacist relationship is less clear. As a result a sample of randomly selected insured health care consumers was surveyed in order to test selected assumptions related to this relationship,¹⁷ and this study is described in Chapter 6.

The study design presented in Chapter 7 is a randomised controlled trial of a diabetes-related pharmaceutical care intervention,^{28,35} with the methodology informed by the literature and previous studies^{9,12,15,19,36-38} and adapted for use in the South African health care setting of community pharmacy. In Chapter 8, the results relating to the primary and secondary endpoints of glycated haemoglobin, other intermediate clinical outcomes and aspects of therapeutic adherence are presented.

The results are discussed in Chapter 9 in terms of the study hypothesis and are contextualized within the literature. The limitations of the study are addressed in this chapter.

An alternate design for the intervention, some opportunities for community pharmacy practice and recommendations for future practice-based research are discussed in Chapter 10.

Chapter 11 discusses certain key conclusions arising from the study.

CHAPTER 2

TYPE 2 DIABETES MELLITUS

2.1. Introduction

In a report entitled *Preventing Chronic Diseases: a vital investment*, the World Health Organization (WHO) states that more than 60% of all deaths worldwide in 2005 were attributable to chronic diseases, with 80% of these occurring in low and middle income countries.³⁹ Cardiovascular disease, with 17 million deaths in 2005, is by far the largest contributor to global disease-related mortality.^{39,40} Diabetes is a major risk factor for cardiovascular disease, which accounts for between 50% and 80% of diabetes-related deaths.⁴⁴ Once considered to be a disease of minor importance it is now viewed as one of the major threats to human health.⁴² The cost of the diabetes pandemic in humanistic terms is enormous. Diabetes was estimated to directly affect 171 million people worldwide in 2000 and to account for at least 3.2 million deaths, or six deaths every minute.⁴¹ Diabetes is the seventh leading cause of death in the USA, where it is also the leading cause of lower-limb amputation, end-stage renal disease and blindness in people aged between 18 and 65 years.^{1,43}

The psychosocial impact of diabetes on the community and family providing socio-emotional and tangible support to diabetics is considerable.⁴⁴ Absenteeism from places of employment results in extra work-related burdens for colleagues. The microvascular and macrovascular complications of diabetes, resulting in blindness, stroke, renal failure, amputation, cardiovascular disease, diabetes distress and depression, hospitalization and premature death, have an enormous emotional and psychological impact on family and friends.^{41,45,46}

2.2 The epidemiology of type 2 diabetes mellitus

Industrialisation has given rise to the rapid urbanisation of many previously rural communities. More recently globalisation has provided additional impetus to the epidemiological transition with the result that traditional lifestyle and dietary practices have increasingly disappeared and been replaced by less healthy, more sedentary

lifestyles and diets.⁴⁷⁻⁴⁹ The net result is the increasing level of obesity which is evident world-wide, especially in developing countries.^{48,49}

DM2 is a chronic disease and a cardiometabolic risk factor of increasing importance in the context of global disease burden.^{1,42-44} More women than men have DM2, which accounts for between 85% and 95% of all diabetes in the developed world, with even higher percentages in some developing countries.^{47,48} Current data reveal that DM2 is more prevalent in the developed than the developing world but that the latter will bear most of the brunt of the burgeoning pandemic.⁴⁷ In 1985 an estimated 30 million people suffered from diabetes.⁴⁸ The IDF predicts that by 2025 some 380 million people will have diabetes, with approximately 70% of these living in low and middle income countries.^{1,48}

In developed countries the age group over 65 reflects the highest prevalence for the disease whereas in the developing world greater prevalence occurs in the age group 45-64 years.⁵⁰ The pancreatic β -cell dysfunction which is characteristic of DM2 is at the same time a natural consequence of aging and thus contributes to the increased prevalence of the disease in older persons.^{51,52}

The genetic propensity for diabetes tends to manifest when people are exposed to a so-called Western lifestyle.^{53,54} Type 1 diabetes is the most prevalent form of diabetes in children, but as the prevalence of diabetes in children and adolescents is expected to increase within the next 10 to 20 years, so too is DM2 expected to replace type 1 diabetes at the apex of the non-adult diabetes pyramid.⁴⁹

Diabetes prevalence in South Africa in 2000 was estimated to be 3.4% and predicted to increase to 3.9% by 2025.⁴⁸ Stratification by age-group reveals that 5.5% of South Africans over the age of 30 have diabetes. Prevalence increases with age in all race groups with the incidence peaking at age 60-69 for South African Indians (30%) and urban Blacks (10.8%), and age 70-79 for people of mixed race (26.9%) and for Whites (10.8%). Non-urban Blacks in age groups over 60 (5.4%) had the lowest prevalence.⁵⁵ Females have a greater prevalence for DM2 in all adult age groups except between age 30-44 years.

2.3 Definition, diagnosis, pathophysiology and clinical characteristics of DM2

Type 2 diabetes is a well documented disease characterised by hyperglycaemia and is often associated with microvascular, macrovascular and neuropathic complications.^{4,56} The American Diabetes Association (ADA) defined diabetes mellitus as “...a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both”.⁵⁹ The WHO and IDF diagnostic criteria for DM2 are either a fasting plasma glucose of ≥ 7.0 mmol/l or a 2-hour postload plasma glucose of ≥ 11.1 mmol/l during an oral glucose tolerance test.⁵⁷ The ADA modified their diagnostic criteria in 2003 to include “...symptoms of diabetes plus casual plasma glucose concentration ≥ 200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss”.⁵⁹

It is insulin deficiency that determines the primary development of hyperglycaemia in DM2.^{56,58,59} The hyperglycaemia that characterises diabetes mellitus results from a lack of endogenous insulin which can either be absolute as is the case with Type 1 diabetes or relative as in DM2.⁵⁶ In the case of DM2, the pathophysiology includes a combination of insulin-related mechanisms including pancreatic β -cell failure and peripheral insulin resistance. The pancreatic β -cell dysfunction results in decreased insulin secretion, decreased peripheral glucose uptake, elevated hepatic glucose production and increased lipolysis.^{56,59} The hyperinsulinaemia common in the early stages of DM2 is due to increased pancreatic β -cell activity in an effort to overcome the developing insulin insensitivity. As the disease progresses the insulin levels decrease as pancreatic β -cell activity decreases.^{58,59} Pancreatic β -cell function naturally decreases at a rate of approximately 1% per year over time. In DM2, this loss may increase to approximately 7% per year.⁵⁹

DM2 is a heterogeneous metabolic disease influenced by both genetic and clinical risk factors. The genetic component of DM2 is complex and not well understood, with a number of genes possibly associated with the disease.^{56,59} Evidence of a genetic influence is provided by the increased prevalence of the disease in certain ethnic groups and in the children of diabetic parents.⁶⁰ Both pancreatic β -cell failure and insulin resistance appear to be heritable components of DM2, and although most people with

DM2 will have both some degree of insulin deficiency and be insulin resistant, not all of those presenting as insulin resistant will have DM2.⁵⁶ This is particularly the case with obese insulin resistant persons who are not necessarily glucose intolerant.⁵⁶

The lifestyle and clinical risk factors associated with the development of DM2 include the following:⁶⁰

- *Increasing age.* The greatest prevalence occurs in people over the age of 45 years in developing countries and in those over 65 years in developed countries.⁵⁰
- *Obesity and waist circumference.* There is a direct correlation between DM2 and body mass index (BMI) in excess of 30 kg/m², and a waist circumference in excess of 102 cm for men and 88 cm for women.^{62,63}
- *Ethnicity.* The 'thrifty genotype' theory has been postulated to explain the propensity for DM2 in certain urbanised ethnic populations.⁶⁶
- *Low birth weight.* This is a risk factor that appears to have its origins in pancreatic dysfunction occurring as a result of foetal malnutrition.⁶⁶
- *Family history of diabetes.* The prevalence of DM2 increases fourfold with one diabetic parent and almost eightfold if both parents have the disease.⁶⁶
- *Impaired glucose tolerance, impaired fasting glucose and gestational diabetes.* These are dysfunctional metabolic states that precede DM2.^{67,68} Gestational diabetes predicts the later development of DM2 in women.^{69,70}
- *Diet.* Poor nutrition is a modifiable risk factor in DM2.⁷¹ Diets that are associated with a high demand for insulin may play a role in compromising pancreatic β -cell function over time. Diet is also a well-known contributing factor in obesity which is in turn associated with increased insulin resistance.⁷²⁻⁷⁴
- *Sedentary lifestyle.* This modifiable risk factor increases the risk of DM2 by between 20% and 40%, independent of BMI.^{48,61} Exercise may improve insulin resistance even in the absence of any accompanying weight loss.^{61,67}
- *Hypertension.* Studies have noted hypertension and/or the use of antihypertensive agents to be a risk factor in DM2.^{75,76}
- *Dyslipidaemia.* Hypertriglyceridaemia and low levels of High Density Lipoprotein-Cholesterol (HDL-C) are considered to be predictors of DM2.⁷⁷

In addition, polycystic ovary disease,⁵⁶ tobacco smoking and abstinence from alcohol are considered to be possible risk factors in the development of DM2.⁶¹ There is evidence to

suggest that a moderate consumption of alcohol is associated with a reduction of approximately 30% in the risk of developing DM2.^{78,79} There is a correlation between the onset of hyperglycaemia and DM2, and the use of antipsychotic medications such as chlorpromazine, olanzapine and clozapine,⁸⁰ as well as with the use of corticosteroids,⁸¹ and the presence of other diseases that interfere with actions of insulin such as Cushing's syndrome, acromegaly and pheochromocytoma.⁵⁶ Of particular relevance in South Africa is the reported association between the use of combination antiretroviral therapy and the increased risk of the development of diabetes.⁸³

It is estimated that DM2 occurs some four to seven years before presenting clinically in patients.⁸⁴ Patients often present asymptotically with the hyperglycaemia being discovered incidentally during the course of laboratory screening associated with non diabetes-related medical interventions. On interview, patients are most likely to describe, in varying degrees, any of the following symptoms known to be associated with DM2; nocturia, polyuria, fatigue, polydipsia, visual disturbance (i.e. blurred vision), weight loss, infections, pruritis, paraesthesia and erectile dysfunction.^{45,59,84}

2.4 Microvascular and macrovascular complications of DM2

The main health objective in DM2 is the prevention or amelioration of the complications of hyperglycaemia and the cluster of co-morbidities associated with the disease. DM2 is associated with progressive long-term microvascular and macrovascular complications,⁸⁵⁻⁸⁷ The landmark Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) both demonstrated the value of intensive glycaemic control in moderating the risk of microvascular complications.^{85,86} Epidemiological evidence points to an association between HbA_{1c} and cardiovascular disease even within the normal range of HbA_{1c}, and thus targeting levels lower than 6.5% would seem desirable.⁴ A recent study has, however, reported that attempting to reduce HbA_{1c} below 6% in patients with cardiovascular disease or with additional cardiovascular risk factors is associated with increased mortality.⁸⁸ The consequences of the findings of the study are important given that approximately 70% of DM2 patients present with hypertension, an important cardiovascular co-morbidity.⁸⁹

There is an association between sustained hyperglycaemia over time and the development of microvascular complications of retinopathy, nephropathy and neuropathy.^{85,86,90,91} The UKPDS demonstrated that intensive glycaemic control reduced progression to retinopathy by between 20% and 30%.⁸⁷ Glycaemic control should be exercised gradually in the presence of existing retinopathy as too rapid a reduction may exacerbate the condition.⁹¹ The blood pressure control arm of UKPDS revealed a further 13% reduction in microvascular complications for every 10 mm Hg decrease in systolic blood pressure.⁹³

Macrovascular disease, in particular coronary heart disease, cerebrovascular disease and peripheral vascular disease, in which the underlying pathology is atherosclerosis, is the most common cause of diabetes-related morbidity and mortality.⁹⁴ Prospective epidemiological studies have confirmed the association between hyperglycaemia and the risk of major vascular events.⁹⁵ Coronary heart disease occurs more frequently and at an earlier age in diabetics than in the general population.⁹⁴ Diabetic men have a twofold and women a fourfold risk of a coronary event, in part due to the frequent association of diabetes with other cardiometabolic risk factors.⁹² In men with diabetes, sudden death occurs 50% more often than in men without the disease. In women with diabetes the differential increases 300%.⁹⁴

Intensive glycaemic control in the UKPDS demonstrated significant risk reduction for microvascular complications and for myocardial infarct in DM2 but not for the combined cardiovascular outcome.^{87,96} More recent studies have not been able to demonstrate that intensive glycaemic control leads to a reduction in major cardiovascular events in patients with established cardiovascular disease or with additional cardiovascular risk factors.^{88,95} There may well be a negative correlation between intensive glycaemic control in high risk patients with DM2. A recent study, the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study, was discontinued after 3.5 years of follow up due to higher mortality in the intensive therapy arm than in the group receiving conventional therapy.⁸⁸ Research has, however, demonstrated the benefit of reducing the modifiable risk factors for cardiovascular disease in DM2.^{94,97-100}

2.5 Commonly associated co-morbidities of DM2

The clustering of the cardiometabolic risk factors of hypertension, dyslipidaemia, obesity and diabetes is commonly referred to as the metabolic syndrome. Metabolic syndrome occurs in approximately 86% of patients with DM2, and the prevalence of cardiovascular disease increases substantially in patients with this syndrome.¹⁰¹

2.5.1 Hypertension

In addition to being a possible risk factor for DM2, hypertension is a commonly associated co-morbidity factor that presents in up to 70% of patients with DM2.^{45,61,64,89} Hypertension is a continuous risk factor for both macrovascular and microvascular complications including cardiovascular disease, stroke, peripheral vascular disease, retinopathy, nephropathy, and possibly neuropathy in people with diabetes.^{64,93,102,103}

In a randomised controlled trial, UKPDS demonstrated the value of tight blood pressure control. In comparing a group assigned to achieve a blood pressure of less than 150/85 mm Hg with a group where the target was a blood pressure of less than 180/105 mm Hg, the intensive group had 32% fewer diabetes-related deaths, 44% fewer strokes and 37% fewer microvascular endpoints.¹⁰⁴

For hypertensive diabetics, the Southern African Hypertension Society's hypertension management algorithm recommends including agents from the Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Antagonist (ARB) classes, usually in combination with a diuretic (Annexure 3.1). The SEMDSA guideline for the treatment and management of DM2 suggests low dose diuretics (hydrochlorothiazide or indapamide) as first line agents, especially in Black hypertensive diabetics. Both the IDF and SEMDSA favour therapy based on ACE inhibitors especially in the presence of albuminuria and for patients over the age of 55 who present with other cardiovascular risk factors.^{4,105} The National Institute for Health and Clinical Excellence (NICE) guideline suggests adding a diuretic or calcium-channel blocker as first line therapy for patients of black African origin.¹⁰⁶ Patients with a history of myocardial infarction or angina are suitable candidates for the use of β -adrenergic blockers although care must be exercised in their use (as with thiazide diuretics) as these agents may affect metabolic

control.⁴ Most patients will require more than one agent, and the UKPDS demonstrated that three or more agents were often required to effect blood pressure control.¹⁰⁴

2.5.2 Dyslipidaemia

The dyslipidaemia of DM2 is typically associated with low HDL-C, slightly elevated or near normal Low Density Lipoprotein-Cholesterol (LDL-C) and raised triglycerides.¹⁰⁷ This dyslipidaemia, i.e. triglycerides greater than 1.7 mmol/l and HDL-C less than 1 mmol/l for males and 1.3 mmol/l for females, occurs well before the onset of dysglycaemia and is considered to be one of the diagnostic criteria of the metabolic syndrome.⁷² In addition to being an independent risk factor for both microvascular and macrovascular disease, blood lipid abnormalities of dyslipidaemia may be implicated in the development of DM2.^{61,77}

The IDF's Global Guideline for Type 2 diabetes makes the following comment with regard to informing blood lipid therapy: *"The evidence that people with Type 2 diabetes have an abnormal, atherogenic, lipid profile (high triglycerides, low HDL cholesterol, small dense LDL cholesterol) is generally accepted, and leads all the major guidelines which have addressed the area to recommend assessment of a full serum lipid profile as a guide to therapy"*.⁴ In terms of recommended treatment regimens for dyslipidaemia, lifestyle interventions in the form of modified diet and increased physical exercise are considered first line therapy.^{4,105} Therapeutic lifestyle modification includes a reduction in intake of saturated fats and dietary cholesterol, an increased intake of dietary fibre, increased physical exercise and a reduction in body mass.¹⁰⁸ The SEMDSA guidelines recommend the introduction of a statin in incremental doses if dietary intervention does not result in a LDL-C level below 3 mmol/l.¹⁰⁵ Statins are considered to be the pharmacotherapeutic option of choice in diabetic dyslipidaemia.^{4,105,99,100,109}

Recent large randomized controlled trials have demonstrated the substantial benefit of statin therapy in patients with DM2.^{99,100} The Heart Protection Study found that 40 mg of simvastatin taken daily will translate into approximately one third fewer myocardial infarctions, strokes and coronary revascularisations.⁹⁹ The Collaborative Atorvastatin Diabetes Study (CARDS) reported similarly and found that for DM2 patients, an atorvastatin regimen of 10 mg daily could be expected to yield a 36% reduction in acute

coronary heart disease events, a 31% reduction in coronary revascularisation and a 48% reduction in the incidence of stroke.¹⁰⁰

2.5.3 Obesity

Globalisation and urbanisation have led increasingly to the over-consumption of diets high in refined carbohydrates, saturated fats, trans-fats and sugars.^{39,42,47} The management of obesity is complex and involves a range of long-term strategies that start with population-based environmental support for improved access to healthy food and facilities that promote physical activity.^{39,47} Body mass control in DM2 is often a frustrating and unrewarding exercise for both patient and healthcare provider as fluctuations in body mass are common and sustained weight loss rare.¹¹⁰⁻¹¹³ The problem is compounded by the tendency for weight gain resulting from the effects of a number of the more effective DM2 treatment modalities (sulphonylurea and insulin).¹¹¹

Obesity is a major DM2 risk factor and the increased prevalence of obesity is contributing to the world-wide diabetes pandemic.^{1,47,49,50,114} Obesity is generally more prevalent in older people than in the young although childhood obesity is wide spread in some countries.⁴⁹ A person with a BMI in excess of 25 kg/m² is considered to be overweight and with a BMI greater than 30 kg/m² to be obese.⁴⁹

Women with a BMI in the range 25-26.9 kg/m² were five times more likely to self-report DM2 than women whose BMI was less than 22 kg/m². Men with waist-hip ratios greater than 0.99 or waist circumferences of more than 101 cm were significantly more likely to self-report DM2.¹¹⁵ For women increased risk is indicated where the waist-hip ratio exceeds 0.75 and the waist circumference exceeds 76 cm.¹¹⁵ The Diabetes Cardiovascular Risk-Evaluation: Targets and Essential Data for Commitment of Treatment (DETECT) study found that there was little difference in the anthropometric parameters of waist-hip, waist circumference or BMI, in their ability to predict prevalent cardiovascular risk.¹¹⁶ The South African Demographic and Health Survey found that about a third of men and over 50% of the women were either overweight or obese and that central adiposity occurred more often in women than in men by a ratio of four to one.¹¹⁷

Physical exercise along with nutrition is a key aspect in the non-surgical treatment of obesity.¹¹⁸ Lack of exercise is associated with the development of DM2 even after adjusting for BMI.¹¹⁹ Conversely, increased physical activity is associated with the prevention of and improved health outcomes in DM2.^{118,120} The Finnish Diabetes Prevention Study demonstrated a 58% reduction in the risk of DM2 with a lifestyle intervention that included diet and exercise, and which resulted in weight loss and improved biochemical markers.¹²¹ Despite the well documented benefits of physical exercise, many DM2 patients do not exercise at all or exercise less than the recommended 30 minutes per day.¹¹⁸

Restrictive dietary programmes are often associated with a preoccupation with food, depression and, paradoxically, overeating and other inappropriate eating behaviours.^{111,112} There is almost no evidence that significant and sustained weight loss is possible and in the long-term most patients return to their baseline weight.¹¹¹

2.6 Treatment guidelines for DM2

In the United Kingdom the National Institute for Health and Clinical Excellence developed NICE guideline 66 Type 2 diabetes: the management of type 2 diabetes.¹⁰⁶ The American Diabetes Association published the Standards for Medical Care in Diabetes.¹²² South Africa, under the auspices of the Society for Endocrinology, Metabolism and Diabetes of South Africa, has the Revised SEMDSA Guidelines for diagnosis and management of type 2 diabetes mellitus for primary healthcare.¹⁰⁵ The SEMDSA recommendations for glycaemic control and lipid and blood pressure goals are included in Table 2.1.

The IDF, recognising the complexity of diabetes care, the enormous and comprehensive amount of existing evidence-based data, the paucity of cost-effective resources available to implement best-practice diabetes care and the diversity of standards of clinical practice throughout the world, developed an internationally accepted guideline for DM2 entitled Global Guideline for Type 2 Diabetes, which was published in 2005 and which was used to inform aspects of this study.⁴

In addition to national and international guidelines, DM2 treatment in the South African private insured healthcare sector is informed by an algorithm developed by the Council for Medical schemes, a statutory body that regulates the insured healthcare sector.¹²³ The algorithm (Annexure 3.2) is particularly focused on guiding pharmacotherapy for glycaemic control in DM2 and does not address therapeutic options for any of the commonly associated co-morbidities.

Table 2.1. SEMDSA recommendations for glycaemic control and lipid and blood pressure goals			
Recommendations for glycaemic control ^a			
Biochemical Index	Optimal	Acceptable	Additional Action Suggested ^b
Capillary blood glucose values ^c			
Fasting (mmol/l)	4 – 6	6 – 8	> 8
2-hour post-prandial (mmol/l)	4 – 8	8 – 10	>10
Glycated haemoglobin (%)	< 7	7 – 8	>8
Anthropometric measurements			
BMI (kg/m ²)	<25		>27 ^d
Male Waist circumference (cm)	<94		>102
Female Waist circumference (cm)	<82		>88
^a These values are for non-pregnant adults ^b “Additional action suggested” depends on individual patient circumstances. Such actions may include enhanced diabetes self-management education, co-management with a diabetes team, referral to an endocrinologist/diabetologist, change in pharmacotherapy, initiation or increased self-monitoring of blood glucose or more frequent contact with the patient. HbA _{1c} is referenced to a non-diabetic range of 4.0 – 6.0%. Note that action should ideally be instituted before these levels are reached. ^c Preferably assessed over several visits. ^d In the presence of diabetes mellitus this level is 27 and not 30.			
Lipid and blood pressure goals (For non-pregnant adults)			
Blood pressure (mm Hg)		Lipids (mmol/l)	
Systolic <130		Total-cholesterol < 5.0	
Diastolic < 80		LDL-cholesterol ≤ 3.0 ^e	
		HDL-cholesterol < 1.2	
		Triglycerides < 1.5	
If persistent dipstick proteinuria (macroalbuminuria)			
Systolic <120		^e American National Cholesterol Education Program (NCEP) III recommends a level of <2.6 mmol/l especially in the presence of existing vascular disease (stroke, peripheral vascular disease, and ischaemic heart disease).	
Diastolic < 70			
Reproduced with the permission of SEMDSA ¹⁰⁵			

2.7 Clinical variables and indicators: DM2 and associated co-morbidities

The monitoring of blood glucose and other biochemical and clinical markers associated with diabetes and common co-morbidities form part of evidence-based diabetes care.⁴ The SEMDSA guidelines include recommended key tests and examinations (Table 2.2).¹⁰⁵

Table 2.2 SEMDSA guideline: key tests and examinations	
Key tests and examinations ^a	
Test / Examination	Frequency
Glycated hemoglobin	<ul style="list-style-type: none"> • Quarterly if treatment changes or if not meeting goals • At least twice a year if stable
Dilated eye exam	Once a year
Comprehensive foot exam	At least once a year (more often in high-risk foot conditions)
Lipid profile	Once a year (less frequently if normal)
Serum creatinine	Once a year
Microalbumin	Once a year (if no persistent dipstick proteinuria - macroalbuminuria)
Blood pressure	At each regular diabetes consultation
BMI & waist circumference	Initially and weigh at each regular diabetes consultation
ECG	Once a year (if possible)
^a All tests and examinations to be done at the initial diabetes consultation	
Reproduced with the permission of SEMDSA ¹⁰⁵	

2.7.1 Glycated haemoglobin and self-monitored blood glucose

The key variable in DM2 is glycaemia which is measured as blood or plasma glucose and HbA_{1c}, the latter being the standard by which long-term glycaemic control is determined.^{4,56,105} The IDF guideline suggests an HbA_{1c} value of less than 6.5%, while

SEMDSA recommends an HbA_{1c} of less than 7%.^{4,105} The SEMDSA guideline suggests an HbA_{1c} every three months for patients with poor glycaemic control and a bi-annual HbA_{1c} for patients with good glycaemic control.

The other glycaemia-related indicator that is important in diabetes care is the capillary plasma or blood glucose value, although there is some debate as to the value of self-monitored blood glucose (SMBG) in non-insulin dependant DM2.¹²⁴ SMBG has proven invaluable in Type 1 diabetes and in insulin-dependant DM2 as it serves to increase patient awareness of the level of very recent glycaemic control, provides a basis for clinical decisions (to inform any adjustments to therapy which is especially important where insulin is being used) and to alert patients to potential hypo- or hyperglycaemia.^{124,125}

SMBG data provides patients with a reliable method of assessing their level of diabetes control as it provides real-time feedback on the results of their medication therapy, diet and exercise. SMBG targets included in the SEMDSA guideline are fasting blood glucose of 4 to 6 mmol/l and 2-hour post-prandial blood glucose of 4 to 8 mmol/l.¹⁰⁵ The IDF's equivalent target levels are fasting values of less than 6.0 mmol/l and 1–2 hour post-prandial values of less than 8.0 mmol/l.⁴

2.7.2 Dilated eye examination

Diabetic retinopathy, which is asymptomatic in the early stages of the condition, is the most common microvascular complication of DM2 and is a major cause of impaired vision, especially in adults aged 20–74 years.^{4,122,126} An initial screening by a competent healthcare professional followed by annual re-examination is recommended.^{4,105,122} Patient awareness of diabetes-related eye problems, in turn, helps to foster awareness about the need to optimise both glycaemic and blood pressure control.⁶⁴

2.7.3 Comprehensive foot examination

Diabetic neuropathy is the most common form of neuropathy in the developed world.⁹⁰ It presents most often as a symmetrical distal peripheral sensory motor neuropathy, and approximately 50% of diabetics will eventually develop some degree of neuropathy.¹²⁷

All diabetics should receive an annual foot examination and high-risk individuals (those who have had diabetes for ten years or more, or have experienced foot ulceration, amputation, poor glycaemic control, cardiovascular disease, retinopathy or nephropathy) should be assessed more frequently.¹²² Patient self-management education should include self-assessment techniques as well as preventative measures to promote foot care.¹²²

2.7.4 Blood lipid profile

SEMDSA, IDF and ADA guideline values for the individual components of the lipid profile vary slightly within narrow parameters (Table 2.3).^{4,105,122} The SEMDSA guideline suggests an annual lipid profile except for those patients who do not meet guideline or who are at increased risk of vascular disease.¹⁰⁵ The IDF suggests more frequent reassessment at routine clinical encounters in order to attain blood lipid targets.⁴

Table 2.3 ADA, IDF and SEMDSA blood lipid targets in non-high risk patients with DM2			
Variable	Blood lipid targets (mmol/l)		
	ADA	IDF	SEMDSA
Total-cholesterol	-	-	< 5.0
HDL-cholesterol	> 1.1	> 1.0	> 1.2
LDL-cholesterol	< 2.6	< 2.5	≤ 3.00
Triglycerides	< 1.7	< 2.3	< 1.5

While point-of-care cholesterol testing has increased in recent years, the utility of these tests is generally limited to screening for serum total cholesterol. Currently a full lipogram remains largely within the province of the medical laboratory as there is, as yet, insufficient evidence to support the use of point-of-care monitors for this purpose.¹²⁸

2.7.5 Serum creatinine

The early detection of microalbuminuria is an essential element in the process of preventing the development of progressive diabetic nephropathy. Diabetes guidelines suggest an annual test for renal function.^{4,105,122} A simple and inexpensive test is provided by the proteinuria dipstick method, although this test is subject to false-positive and false-negative results.¹²² The estimated glomerular filtration rate (eGFR) is a reliable index of kidney function and it may be calculated by means of the Modification of Diet in Renal Disease predictive equation, which factors in the patient variables of age, sex, ethnicity and serum creatinine. The equation is available free online.¹²⁹

2.7.6 Blood pressure

Both the IDF and SEMDSA (Table 2.1) recommend a target blood pressure of 130/80 mm Hg for DM2 patients whose diabetes is uncomplicated by nephropathy.^{4,105} The target is reduced to 120/70 mm Hg in the presence of macroalbuminuria.¹²⁶ Guidelines generally recommend measuring blood pressure at every diabetes consultation.^{4,105,106,122}

2.7.7 Body mass index

While waist circumference and waist-hip ratio are accepted measures of central adiposity, the standard anthropometric measure for obesity and overweight remains the BMI, which is calculated by dividing body mass in kilograms by the square of height in metres (kg/m^2). A person with a BMI of 25 to 29.9 kg/m^2 is considered to be overweight and anyone with a BMI in excess of 29.9 kg/m^2 is considered obese.^{49,115} The SEMDSA guideline recommends that patients be weighed at every diabetes consultation.¹⁰⁵

CHAPTER 3

COMMUNITY PHARMACY PRACTICE AND PATIENT CARE

3.1 Introduction

Pharmacy practice has evolved significantly since prescriptions were first written, thought to be around 2700BC, although medicines were probably used before this with their genesis “...lost in the remoteness of history”.¹³⁰ Healthcare systems throughout the world continue to evolve as society attempts to respond to the ever increasing need for quality cost-effective healthcare.¹³¹ The growing burden of disease, especially chronic disease, which is fuelled by the effects of increasing globalisation, urbanisation, unhealthy lifestyle practices and ageing populations, demands a response from society to the challenge of having to care for increasing numbers of chronically ill people.^{42,47,132,133}

3.2 Scope of practice of a pharmacist

Most countries provide a combination of private and public healthcare and this dichotomy influences the practice of pharmacy, especially with regard to the range of services provided, and to the reimbursement of pharmacists.¹³⁴ The advent of state sponsored social health systems (public sector) and health insurance (private sector) led to third-party payers, rather than the patients themselves, reimbursing pharmacists for the supply of medicines.

World-wide, community pharmacists tend to be private practitioners who derive income from the sale of pharmaceuticals, other products and, to a lesser extent, from the provision of clinical and other services. In addition, some countries such as the United States of America and the United Kingdom have deepened pharmacy's reach into the clinical domain with the recent introduction of pharmacist prescribing.^{135,136}

Blenkinsopp et al,¹³³ in a systematic review of the effectiveness of community pharmacy interventions, draws attention to an important feature of community pharmacy practice, namely that for most urban populations, and some rural communities, relatively easy access to trained healthcare providers is made possible, firstly due to the physical

location of most community pharmacies, and secondly because the consumer-pharmacist encounter is not usually subject to prior appointment. The easy access that individuals have to pharmacy practice has been described as community pharmacy's most significant characteristic, as pharmacists often are the first point of contact for individuals seeking health-related information or advice.¹³⁷

The practice of pharmacy has evolved from being essentially product orientated to becoming more patient focused. This evolutionary process, spurred on by the advent of clinical pharmacy, gave rise in the early 1990s to the professional practice of pharmaceutical care, which has expanded the role of the pharmacist and redefined the value of pharmacy practice.²³

3.3 Pharmaceutical care

The acceptance of pharmaceutical care by the profession has heralded a new focus for pharmacy practice.^{138,139} Cipolle et al,¹⁴⁰ defined the philosophy of pharmaceutical care as “...(1) *the recognition of a social need, (2) the patient-centered approach, (3) caring as a modus operandi, and (4) specific responsibilities to identify, resolve and prevent drug therapy problems*”.

Patient-centredness is a central aspect in the pharmaceutical care process as it informs the development and maintenance of therapeutic relationships essential in addressing patient medication-related needs.^{141,142}

Pharmacists are able to contribute to disease risk reduction especially in populations such as the elderly, smokers, obese individuals and those with diseases such as hypertension, cardiovascular disease and obesity.¹⁴³⁻¹⁴⁵ Identifying individuals from pharmacy records, assessing risk indicators, providing health-related education and educational materials, counselling on the appropriate use of medication, discussing and agreeing on self-management options, on-going monitoring, and referral for further investigation are scope of practice pharmacy services that fall within the ambit of disease prevention and management.^{24,36,133}

Professional pharmacy-based services are variously referred to as pharmaceutical care services, cognitive pharmaceutical services, cognitive services, patient clinical care services or medication therapy management services.¹⁴⁶⁻¹⁴⁹ The term ‘cognitive pharmaceutical services’ (CPS), which identifies the activities associated with the practice of pharmaceutical care, is used in this manuscript for the purpose of standardisation.¹⁵⁰

Pharmacists, while recognising both the desirability and value of pharmaceutical care, believe that barriers exist preventing the widespread implementation of CPS, especially at community pharmacy level.^{12,133,151} The main barriers to the provision of these services appear to be financial and economic such as pharmacist reimbursement, human resources and time constraints.¹⁵² At the opposite end of the care continuum, the paucity of robust research that unequivocally demonstrates the economic, clinical and humanistic value of pharmaceutical care across a range of disease entities continues to be an obstacle to the broad-based acceptance of the practice by the stakeholders and funders of healthcare.^{12,152-154}

Collaboration with patients and other healthcare providers is an essential element of pharmaceutical care and evidence-based disease management,^{24,155-158} with the benefit to patients of inter-professional collaboration noted.^{5,155,159} The most common impediments to collaboration between medical practitioners and pharmacists include ill-defined or unspecified areas of responsibility, lack of trust, or simply failure to initiate the collaboration process.¹⁶⁰⁻¹⁶² These problems are barriers to the delivery of pharmaceutical care and contribute to this high ideal of pharmacy practice remaining largely “...*aspirational in many parts of the world*”.¹⁶³

Anderson et al,¹⁶⁴ in a systematic review of healthcare consumer perceptions and experience of services provided by community pharmacists, concluded that consumers tended to view pharmacists as ‘drug experts’ and not as a readily available source of health-related advice and information. Nevertheless, those consumers who did access and make use of pharmacy-based health initiatives expressed satisfaction with their experiences. The reviewers conclude that if community pharmacy is to extend its reach in healthcare, consumer awareness of the pharmacist as a potential source of valuable health-related advice must be enhanced.

3.3.1 Cognitive pharmacy services and diabetes

Patient orientated CPS, which covers a wide range of activities designed to optimise the use of medication and improve health outcomes,^{158,165,166} creates opportunities for the pharmacist to:^{158,167,168}

- Record salient patient demographic data and a brief medical history.
- Develop or enhance relationships with both patients and providers.
- Develop an understanding of patient health beliefs and a level of knowledge about their conditions.
- Discuss patient therapeutic goals and concordantly develop pharmaceutical care plans to support these goals.
- Comprehensively assess the appropriateness of all medicine being used.
- Assess the patient's medicine-taking behaviour.
- Address medication and other scope of practice-related problems and, where possible, agree on remedial action.
- Provide tailored medication-related counselling, and health-related education and information.
- Reinforce patient self-efficacy and self-management behaviours.
- Monitor patient response to pharmacotherapy and self-management recommendations.
- Evaluate the care process and outcomes, consult with other healthcare professionals and, if necessary, refer for escalated care.

These services should be aligned with the principles of the continuous patient care process described by Cipolle et al¹⁶⁹ (Figure 3.1). In addition, advice-giving should be kept to a minimum,¹⁷⁰ with the pharmacist-patient discourse preferably informed by evidence-based counselling methods such as that of brief Motivational Interviewing.¹⁷¹ All elements of care should be recorded in a manner that allows for assessment of the pharmaceutical care provided and for easy and appropriate access by other healthcare providers.^{158,167,172}

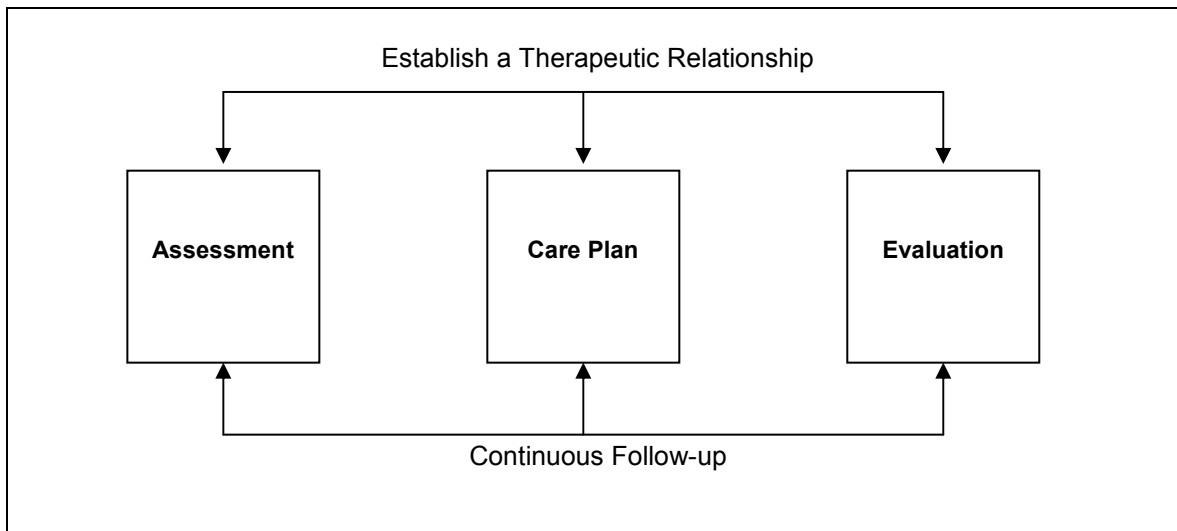


Figure 3 .1 The patient-care process¹⁶⁹

The importance and ongoing nature of pharmacotherapy in DM2 facilitates relatively frequent encounters between patients and their community pharmacists,¹¹ whom patients generally trust and value^{17,25} and who have demonstrated the ability to provide diabetes care services.^{8,9,38,173} The main elements of diabetes care provided by pharmacists include the scheduling of appointments,¹⁷³ medication counselling,^{18,174} setting diabetes-related goals,¹⁷⁵ providing self-management education and support,^{174,176,177} health-related information,¹⁷⁵ patient reminders,³⁸ monitoring key diabetes variables,^{9,173} and collaborating with and referring to other healthcare providers.^{19,178}

In studies investigating the effect of pharmacist interventions in diabetes management, patient adherence to therapy and the effect of the interventions on glycaemic control, expressed as HbA_{1c}, are most often reported in the literature, and psychosocial and economic outcomes are reported less frequently.^{9,10,38,173,176,179} Table 3.1 includes examples of diabetes-related CPS studies.

Table 3.1 Cognitive pharmaceutical services in diabetes

Author	Intervention	Outcome measure
Garret et al ¹⁷⁶	Scheduled appointments, collaborative coaching and reinforcement of self-management, medication review, goal setting, monitoring, evaluation and referral.	Adherence, economic, clinical and quality of life measures.
Cranor et al ^{9,19,178}	Diabetes education, goal setting, self-monitored blood glucose (SMBG) training and review, reinforcement of medication adherence, foot examination, monitoring of indicators.	HbA _{1c} , self-management adherence.
Coast-Senior et al ¹⁷⁹	Scheduled consultations, assessment, diabetes education, monitoring of indicators, adjustment of therapy, SMBG review, medication review, collaboration with medical practitioners, telephonic follow-up.	HbA _{1c} , fasting blood glucose, and random blood glucose.
Berringer et al ¹⁰	Collaboration with medical practitioners, monitoring of indicators, review of diabetes-related data, quality of care assessment.	Fasting blood glucose, adherence, frequency of SMBG.
Lindenmeyer et al ³⁸	Self-management education, patient reminders, adjustment of therapy, review of SMBG data, referral.	Adherence, fasting blood glucose, random blood glucose, quality of life measures, persistence, economic outcomes.
Fera et al ¹⁷³	Collaborative patient-centred programme (medical practitioner, patient, employer, pharmacist) that included scheduled consultations, clinical assessments, goal setting, adjustments to therapy, referral.	Biochemical and clinical markers, influenza vaccination, foot and eye examination, self-management goals for nutrition and exercise and body mass, diabetes-related knowledge and satisfaction with care.

3.3.2 Barriers to cognitive pharmaceutical services

Pharmacists may have difficulty providing CPS in practice due to structural and process constraints that mitigate against the successful provision of such services.^{12,180} Barriers to the provision of CPS may be broadly classified as attitudinal barriers i.e. resistance on the part of patients, funders, pharmacists and other healthcare providers; environmental or structural barriers i.e. healthcare systems that do not support the practice of pharmaceutical care, infrastructural limitations, and economic barriers, especially those relating to the reimbursement of pharmacists.^{151,152,181} Other barriers include the lack of sustainable business models supporting the provision of CPS, inadequate maintenance and quality assurance of pharmaceutical care programs, a lack of access to clinical data, and a shortage of skilled and motivated pharmacists.¹⁴⁷

Although many CPS studies have reported positive clinical outcomes, minimal robust data on cost-effective and humanistic outcomes exists,¹⁸²⁻¹⁸⁴ and this further compounds the matter of pharmacist reimbursement.^{152,185} There is also a paucity of data on patient willingness to pay which is a surrogate marker for value in pharmaceutical care.^{152,185} While some progress in addressing barriers to CPS is evident in a number of countries, pharmacist reimbursement remains a significant challenge for the profession and, in many instances, pharmacists continue to provide these services free of charge.^{17,147,152}

3.4 Community pharmacy practice research

The need for the practice of pharmacy to be informed by the evidence of applied practice-based research is a view shared by a range of healthcare stakeholders including pharmacists in practice and in academia, organised pharmacy and the WHO.^{6,181,184,186,187}

Evidence of positive economic, clinical and humanistic outcomes is the “hard” currency of value in healthcare.^{184,186} However, there appears to be little rigorous research investigating the effectiveness of CPS provided by community pharmacy.¹³³ Beney et al,¹⁸³ in reviewing studies relating to expanded roles for pharmacists in community pharmacies, found so few studies that satisfied the initial review criteria that they

broadened their scope to include other outpatient settings. The reviewers, in concert with other researchers, had difficulty in interpreting their findings because of the heterogeneity of the interventions and a lack of clarity about their nature. Problems relating to the methodological quality of CPS studies have been reported, and doubts expressed concerning the generalisability of some studies.^{183,184,188}

Benrimoj,¹⁸⁹ in discussing the matter of pharmacy practice research, noted the need for a “...*symbiotic relationship between practitioners and academic researchers*”. Pharmacists in practice who undertake research without adequate academic oversight may suggest practical solutions to problems, but the work may not stand the test of scientific rigour. Academic researchers, on the other hand, working isolated from the realities of day-to-day pharmacy practice may, in turn, produce well designed studies but their application in practice may be of limited value. It has been suggested that in order to stimulate interest in practice research, joint practice-based research symposia may be held to bridge the research gap between practicing and academic pharmacists.¹⁸⁹

Barriers to practice-based research include inadequate funding, lack of national research agenda, and pharmacist disinterest.¹⁴ Armour et al¹⁸¹ reported that pharmacist unwillingness to participate in research was informed mainly by attitude i.e. a lack of confidence in their ability to participate effectively, and a negative perception of the value of research. Insufficient communication regarding the objectives, requirements and benefits of research and a lack of resources including infrastructure, time, money and staff were also noted as significant factors. Some positive factors included the stated realisation that practice research was essential if community pharmacy was to advance its cause in healthcare. Pharmacist participation in research was often fuelled by personal interest in research topics, and a sense of professional satisfaction.¹⁸¹

There appears to be a lack of published research relating to community pharmacy practice in South Africa despite research being a defined good pharmacy practice standard and a pharmacist scope of practice function.⁶ As universities are the primary drivers of practice research, funding is largely dependant on grants. Sponsorship by organised pharmacy, the pharmaceutical industry, private foundations, or organs of the state, rarely occurs in most countries.^{14,147} In keeping with the situation in many countries, South African pharmacy practice research is limited by inadequate funding,

the lack of a national research agenda and an absence of a research culture amongst practising pharmacists.

3.5 Patient care

3.5.1 The evolution of patient care

Acute models of care that rely on expert healthcare providers interacting with naive patients have proved inadequate in addressing the complex needs of the chronically ill.^{1,190,191} In general, acute ambulatory models of care are designed to provide patients with ready access to healthcare in systems that are focused on those conditions requiring consultations of short duration and where, following diagnosis and brief didactic advice, treatments for the alleviation of symptoms are most often prescribed. Such treatments may require further laboratory or other investigation and often involve the use of medication.^{155,190} Chronically ill patients are unlikely to have their needs met in such a healthcare environment.¹⁹¹ The management of their conditions should be primarily focused on preventing the development or exacerbation of disease-related complications.¹⁵⁵

3.5.2 Disease management

The term 'disease management' was first coined in the USA in the early 1990's and was advocated in response to the spiralling healthcare costs resulting from the epidemiological shift from acute to chronic disease.^{192,193} It was initially used without specific definition to describe informal activities that included aspects of evidence-based medicine and the use of multidisciplinary teams to deliver care.^{194,195} Disease management is focused on a systematic approach to the long-term management of chronic disease,¹⁹⁶ and has been defined as "*A systematic, population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes*".¹⁹⁷

Disease management has matured and although the early promise of substantial cost savings has generally not materialised, with few studies able to prove this early objective, it has been (and continues to be) associated with the healthcare

process.^{174,192,198,199} However, the varied and interacting components of disease management make assessing the effectiveness of individual elements difficult. In a review of disease management programmes designed to improve clinical and economic outcomes in 11 chronic conditions, Ofman et al¹⁹² found that few studies were able to demonstrate significant cost reduction. Weingarten et al,²⁰⁰ in a meta-analysis of English language articles on disease management published between 1987 and 2001, revealed that patient education was the most studied intervention, with programmes using education, reminders or financial incentives the most successful in improving disease control.

In a systematic review of controlled trials of interventions designed to improve the management of diabetes in primary care outpatient and community settings, Renders et al¹⁸⁸ reported that in all settings the studies were multifaceted, and that complex interventions were required in order to demonstrate improvements in the care process. Interventions aimed at improving provider adherence to clinical guidelines, with regular and structured patient review, improved the care process. The addition of patient education and/or enhancement of the nurse's role led to both improved process of care and patient outcomes.

The IDF guideline for the management of DM2 notes that evidence-based and cost effective diabetes care should be made available to all people with the disease. The guideline suggests a range of care delivery elements to be incorporated into diabetes care plans.⁴ Close consideration of the IDF recommendations reveals the collaborative nature of the care delivery being suggested, which underpins the relatively new paradigm of patient-centred care that recognises the pivotal role of the empowered and expert patient in diabetes care.^{201,202}

3.5.3 Patient-centred care

Patient centredness is a foundational element of collaborative care and the practice of patient self-management.²⁰²⁻²⁰⁶ While the provision of healthcare has always been underpinned by a desire to provide for the patient's welfare, the practice of medicine has historically focused on provider-centred models of care. In these models patient participation is largely limited to compliance with provider instructions, with provider-

patient relationships often being paternalistic.²⁰⁷ Patient-centred care has been defined as “...healthcare that is closely congruent with and responsive to patients’ wants, needs, and preferences”.²⁰⁷

Wagner,¹⁵⁵ in developing the Chronic Care Model (Figure 3.2) described an ‘ideal world’ scenario for chronic care as one in which an informed and motivated patient’s interaction with an adequately resourced healthcare system would include planned and collaborative consultations with prepared and proactive members of the patient’s multidisciplinary team. The collaborative interaction between the patient and healthcare team allows for systematic assessments to be made in terms of accepted treatment protocols, decision support and support for appropriate patient self-management initiatives.

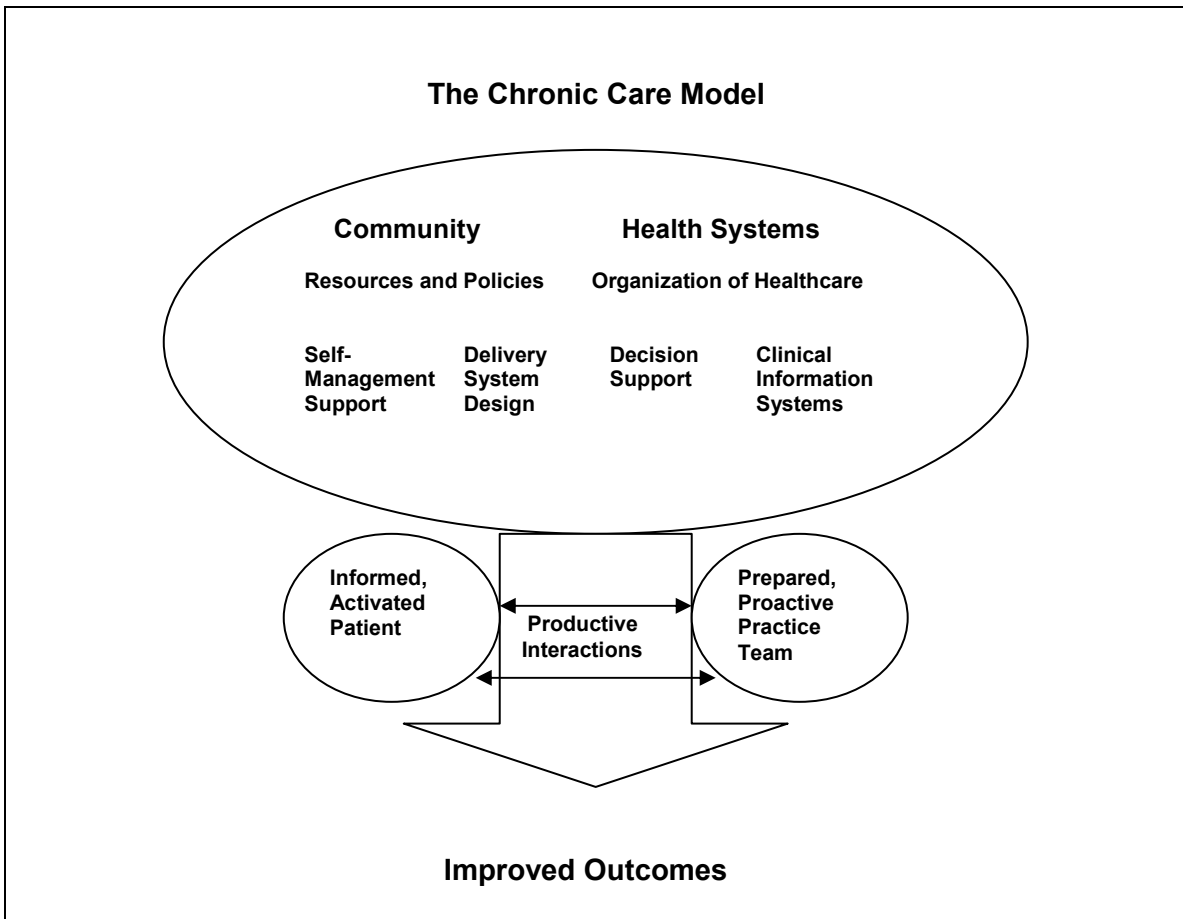


Figure 3.2 The Chronic Care Model¹⁵⁵

In addition the model proposes the monitoring of key indicators and recording of all patient data in readily accessible information systems with regular follow-up by the healthcare providers.

A number of studies have reported on the application of individual elements of the Chronic Care Model.^{143,157,191,208,209} Tsai et al,¹⁹¹ in a meta-analysis of interventions designed to improve care in chronic disease, including diabetes, firstly investigated the extent to which outcomes were improved when one or more of the elements of the model were implemented, and secondly evaluated the relative effectiveness of elements of the model. Four elements of the model i.e. delivery system design, support of self-management, decision support and clinical information systems were found to be associated with both improved care processes and outcomes. Interventions relating to delivery system design and self-management support occurred more frequently than interventions relating to the other elements of the model. At a clinical outcome level, interventions that incorporated one or more elements were associated with improved surrogate outcomes.

Patient-centred care has been described as having five main domains:²⁰¹

- *Exploring* – the patient's experience, feelings, ideas and problems related to the disease and illness.
- *Understanding* – the whole person in the context of personal and social (family) needs and realities of life.
- *Collaborating* – finding common ground about treatment goals, priorities, interventions, problems and role assignments.
- *Promoting* – monitoring and implementing health enhancement practices (to ensure risk reduction).
- *Enhancing* – healthcare provider and patient relationships and care delivery.

Patient-centred care philosophy encourages and facilitates patient involvement in healthcare decision-making with the result that the emphasis shifts from compliance with instructions to acceptance of the right of patients to make decisions, and of the obligation of the provider to support the patient empowering process.²⁰⁷

The individualized care that characterises patient-centred care in chronic illness has been described as a stepped process in which collaboration between patient and

provider results in the setting of agreed goals, the developing of a care plan, training and support to facilitate self-management, monitoring, and the modification of care as is necessary.^{202,210} Supported self-management, monitoring and active follow-up, guided by evidence-based protocols, are the main interventions required to prevent the development and exacerbation of disease-related complications.²¹¹

Barriers to patient-centred care in chronic illness include the over-emphasis on diagnosis and treatment. Healthcare providers, because they are often faced with the competing demands of time and attention, tend to neglect preventative aspects and services.²¹¹ Furthermore, disparities in healthcare provision continue to exist with socioeconomic status, ethnicity and race being significant barriers to patient-centred care in chronic disease.^{157,212,213}

The advent of managed care has introduced commercial considerations to the practice of medicine and as a result the relationship between the insured patient and the healthcare provider may be subject to economic rather than clinical considerations.²¹⁴. Managed care may constitute an impediment to patient-centred care.^{207,215} In South Africa managed care is generally perceived in a negative light as the managed care organisations may withhold or limit diagnostic procedures and treatment modalities in an effort to control utilisation.²¹⁶⁻²¹⁸ In addition, some believe that managed care in South Africa has in recent times contributed to healthcare provider emigration thereby negatively impacting on the health system's capacity to deliver patient-centred care.²¹⁸

CHAPTER 4

BEHAVIOURAL CHANGE AND PATIENT SELF-MANAGEMENT

4.1 Introduction

A significant proportion of the global disease burden is associated with aberrant health behaviours, especially those related to lifestyle.¹³² Health behaviours may be influenced by a broad spectrum of factors such as learning, social norms, reinforcement and modelling, genetics, emotional factors including anxiety, stress and fear, the severity of symptoms, personal beliefs and the beliefs of significant others such as a spouse or partner and healthcare providers.²¹⁹

The increased recognition of the relevance of health behaviours in determining health outcomes has fostered the development of biopsychosocial approaches to the treatment and management of illness.^{220,221} In chronic disease management, models of care such as the patient-centred Chronic Care Model are providing the impetus for growing acceptance of the biopsychosocial paradigm.²²²

The newly diagnosed diabetic is faced with the physical and psychosocial impact of having a serious chronic disease. The patient will have to manage the disease on a day-to-day basis, and this includes lifestyle modification and adherence to a range of self-management recommendations,^{223,224} all of which involves significant health-related behavioural change.^{225,226} The lifestyle behaviours include physical activity, diet, smoking and alcohol use as well as those behaviours associated with clinical practice guidelines, i.e. keeping appointments, having tests done and being examined, self-monitoring (e.g. body mass, blood glucose), and using medication appropriately.^{105,227}

Incorporating behavioural and psychosocial screening into routine care enhances the quality of the healthcare encounter as the process allows for the identification, and possible resolution of specific problems. If the provider is competent to deal with the problem and has the agreement of the patient, then appropriate remedial interventions may be identified and implemented. Should the provider or patient feel that the provider is not qualified to engage any further with the problem, or if the patient requests further

investigation by another provider, then screening serves the care process by providing an informed basis for such referral.^{122,221}

4.2 Adult education theory

Adults often interpret new health-related experiences and information based on their beliefs and their past experiences or those of others, especially significant others¹⁹⁹ and use this amalgam of belief and experience to facilitate learning experiences both for themselves and for others.²²⁸

In discussing diabetes education in their book, *The Art of Empowerment: stories and strategies for diabetes educators*, Anderson and Funnell²²⁹ state that while many thousands of lectures have been delivered by diabetes educators in an effort to teach patients about diabetes and how to care for themselves ('what to do'), this didactic approach has failed to consider that patients and providers view diabetes from very different perspectives. Providers are mostly educated and trained to view diabetes as a disease – as a subject (i.e. 'theoretical diabetes'), whereas patients are generally not interested in diabetes as a subject – they are interested in *their own* diabetes (i.e. 'real diabetes'). The teaching and learning approaches that appear best suited to educating adult patients are egalitarian, respectful and empathetic. They are furthermore based on theories that incorporate problem-solving, and that recognise the patient's past experience and their expertise in attempting to resolve their own real-life challenges.²²⁹

Anderson and Funnell,²²⁹ suggest a stage-based model that reduces the process of adopting (learning) a new behaviour to the following four stages: (i) experience – which is defined as the total sum of an individual's perceptions, (ii) reflection – the element that melds past experience, aspirations and anticipated actions, (iii) insight – flowing from reflection, which allows for the bridging of past and current experience and informs the realisation of new models, objectives opportunities and relationships, (iv) change – in knowledge, perceptions, attitudes and behaviour. The process of learning (change) is cyclical and continuous with new learning giving rise to new experiences which encourages more reflection and greater insight.

The Kolb model of experiential learning has been extensively used to provide a theoretical framework for adult education, informal education (e.g. patient education) and life-long learning such as that to be found in programmes designed to deliver continued education and continuous professional development.²³⁰ The Kolb model is comprised of four elements: concrete experiences, reflective observation, abstract conceptualisation and active experimentation, all underpinned by two preference dimensions of learning, namely a perception dimension and a processing dimension. Individuals will exhibit preferences along these continuums.

Both the stage-based model suggested by Anderson and Funnell²²⁹ and the Kolb model²³⁰ may be used to underpin the two main lifelong formal educational approaches to maintaining the professional competency of pharmacists and to meeting new and developing standards of practice.²³¹ The traditional method employed by professional associations and bodies is the continuing education (CE) option, which is designed to provide for the broad-based educational needs of pharmacists.²³² The other and more recent approach is termed continuous professional development (CPD), which is focused on the professional development of the individual pharmacist.²³¹

The main difference between CE and CPD appears to lie in the method of assessment. CE relies on the quantitative evaluation of the pharmacist, whereas CPD, which may be more time consuming and resource demanding than CE, is based on a connecting circle of reflection, planning, action and evaluation. Both CE and CPD may make use of a range of methods of instruction including lectures, workshops, meetings, printed material and Internet-based resources. However, research shows that pharmacists are far more likely to obtain CE from printed materials than from any other source.²³²

4.3 Health-related behavioural change: models and theories

A variety of theories and models have been used to explain and influence health-related behaviours in primary care.²³³ The most common appear to be: Social Cognitive Theory, Self-regulation, Learning Theories, the Health Belief Model, Self-efficacy Theory, Theory of Reasoned Action, Theory of Planned Behaviour, and the Stages of Change Model.²³³⁻²³⁷

Bandura,²³⁸ who first developed Social Cognitive Theory, postulated that behaviour is determined by an individual's sense of expectancy that a behaviour may be dangerous e.g. that smoking may cause lung cancer (situation outcome expectancy), that the individual is capable of a behaviour that will mitigate such harm e.g. stop smoking (outcome expectancy) and that the individual is capable of effecting remedial behaviour e.g. able to stop smoking (self-efficacy expectancy). In addition to expectancy, Bandura suggested that incentives and social cognitions were other determinants of behaviour. Incentives in the context of behaviour relate to consequences e.g. smoking cessation may lead to less anxiety about developing lung cancer. Social cognitions are central to these models as they include "*...measures of the individual's representations of their social world. Accordingly social cognition models attempt to place the individual within the context both of other people and the broader social world*".²³⁹

The self-regulatory model proposed by Leventhal²⁴⁰ assumes that people who are ill or who have the symptoms of an illness view such a state of affairs as a problem and will approach the illness or symptoms in much the same way as they approach other problems. Problem solving thus lies at the heart of self-regulatory theory with motivation being provided by an innate desire to return to a perceived state of normality.²⁴⁰ Problem solving is said to occur in three stages. Firstly there is interpretation through symptom perception (e.g. pain) and/or social messages (e.g. diagnosis by medical practitioner). A combination of symptom perception and social messages informs the development of illness cognitions within the dimensions of identity, cause, consequences, time-line, management or cure. These cognitive elements assign meaning to the problem and allow the patient to develop coping strategies which define the second stage of the self-regulatory model. Two main strategies of coping have been defined as approach coping which involves positive action (e.g. taking medication, changing unhealthy behaviour) and avoidance coping (e.g. being in denial). The third or appraisal stage of the model involves the evaluation of the coping strategy by the individual and a decision on whether to continue with the chosen strategy or to adopt another in an attempt to return to a state of perceived normality.²⁴¹

Learning theories stress that the complex pattern of behaviour, which is associated with behavioural change, may be learned incrementally. These theories suggest that complex pattern behaviour (e.g. walking for one hour every day) is learnt gradually by reducing

the behaviour to manageable proportions or components (e.g. starting with 10 minutes and then slowly increasing the time spent walking). Component behaviours that are part of the ultimate goal (walking for an hour every day) require reinforcement and must first be established if the goal is to be obtained.²³⁶ Competing past behaviour (e.g. watching TV instead of walking) is often a complicating factor when attempting to introduce new behaviours. Thus, in addition to reinforcement, rewards and incentives may play important roles in establishing and sustaining behaviour, although extrinsic reinforcement has not proved reliable in sustaining behavioural change over the long term.²³⁶

The Health Belief Model, which was first proposed by Rosenstock²³³ and developed by others, has been used to predict patient behaviour in both acute and chronic diseases.^{233,242,243} Behaviour is premised on a set of core beliefs: susceptibility to disease, the severity of the disease, the cost of a modifying behaviour, the benefit of such behaviour, and action indicators which may be internal (e.g. symptoms) or external (e.g. advice of a significant other).²³³ The original model was subsequently modified to include self-efficacy which is an expression of confidence by the individual in his/her ability to accomplish set objectives (e.g. change behaviour). It is a prerequisite for successful behavioural change and reflects a combination of the experience of earned past success and learned competency.^{242,244} In addition to being a key element of the Health Belief Model, self-efficacy informs a number of theories including the Theory of Reasoned Action and the Theory of Planned Behaviour.^{236,239}

The Theory of Planned Behaviour is informed by the suggestion that many behaviours may be predicted by the individual's intentions with regard to performing such behaviours.²³⁹ Behavioural intentions result from the following beliefs:²³⁹

- ❖ Attitude – which is derived from the positive and negative evaluation of a behaviour together with beliefs about the outcome (expected value).
- ❖ Subjective norms – perception of what important others may think and the motivation to comply with this pressure.
- ❖ Perceived behavioural control (or self-efficacy beliefs) – perception of being able to effect the behaviour by overcoming barriers.

Other influences which may affect intentions such as demographic, personality and environmental factors, are assumed to do so via their influence on the primary determinants of attitude, subjective norms and perceived control. The Theory of Planned Behaviour allows that the relative importance of the three primary determinants in influencing behavioural intentions may vary within an individual or in populations.²⁴⁵

A number of theories and models have been used to specifically describe and evaluate pharmacist practice-related behaviours, the most common of which appear to be the Theory of Planned Behaviour²⁴⁶⁻²⁴⁸ and the Stages of Change Model.²⁴⁹ Others include the Health Belief Model²⁴⁶ role theory,²⁵⁰ organisational theory,²⁵¹ self-efficacy theory,²⁵² and the Pharmacists' Implementation of the Pharmaceutical Care model.²⁵³ The latter model was developed in an effort to provide a theoretical framework for pharmaceutical care and it identifies the following key behavioural factors relevant to the design and implementation of pharmaceutical care interventions: attitude, perceived behavioural control, social norm, intention, psychological appraisal processes and recent behaviour.

4.3.1 Stages of Change Model or Transtheoretical Model

The Stages of Change Model or Transtheoretical Model (TTM) is the most commonly used stage-based model and includes concepts from the Health Belief Model, the Locus of Control model and elements of Cognitive Behavioural Therapy.²⁵⁴ The framework of the TTM has been used to describe a range of health behaviours including those associated with smoking and alcohol cessation, physical exercise and diet.²⁵⁴ The model has proved popular as it appears to offer some explanation as to why group-based interventions are often ineffective. It supports the notion that interventions tailored for an individual are more likely to be effective than a 'one-size-fits-all' approach, as the model is premised on an individual being at a specific stage along the change continuum at any given time.²⁵⁵ It is suggested that an individual changes behaviour by a gradual process and that the barriers individuals face will differ given the particular stage that the individual finds him/herself in.²⁵⁶ The model has also been used to inform the development of other behavioural interventionist strategies and methods such as Motivational Interviewing (Section 5.4.2).^{235,257}

The TTM involves five distinct identifiable stages:²³⁴

- ❖ Precontemplation – not intending to change for at least the next six months
- ❖ Contemplation – intending to change within the next one to six months
- ❖ Preparation – intending to change within the immediate future (within the month)
- ❖ Action – engaged in a new behaviour for less than six months
- ❖ Maintenance – sustained behavioural change for more than six months.

Termination, which is the ultimate goal for persons who have changed aberrant behaviour, is only possible if regression is unlikely (e.g. having been an ex-smoker for many years).²³⁴

Precontemplation, contemplation and preparation are described as motivational stages, while action and maintenance are orientated towards achievement. The model intends that individuals proceed sequentially from one stage to the next, but this does not always happen and they may relapse to an earlier stage before advancing once again.²³⁴ In addition to the five stages, the model suggests that there are 10 processes of change (activities) which individuals utilize in an effort to overcome any barriers to change that they may encounter in a particular stage. The most widely used of these processes is termed consciousness-raising, i.e. raising one's level of awareness by increasing the amount of information available either about one's self or the problem one faces. The model further proposes that readiness to change is a key aspect in effectively moving from one stage to another.²³⁴

While the TTM has been used to inform self-management behavioural change in a number of chronic conditions including diabetes,^{235,257-260} recent systematic reviews of interventions based on the model have reported some problems associated with the stage-based studies.^{255,256,261} These included methodological difficulties such as lack of validation of the instruments and a lack of explanation of the interventions used. The problems associated with the model may be founded in the complex nature of stage-based interventions, which require development and evaluation on more than one level.²⁶² The reviewers concluded that there is often insufficient evidence to suggest that these interventions were likely to be any more effective than non-stage-based interventions, and sounded a word of caution with regard to the elevated status that the model appears to enjoy.

Despite concluding that applying the model to complex behaviours may be problematic, Brug et al,²⁶³ state that the interventions have shown promise in some instances and that, contrary to other apparently negative findings relating to the effectiveness of the model, such evidence may be interpreted differently. In their book entitled, *Health Behavior Change; a guide for practitioners*, Rollnick et al,¹⁷⁰ comment on the danger of equating the TTM to a single method of intervention when no such method exists. They remind readers that it is a *transtheoretical* model and that those who apply the model in practice will invariably do so using a variety of interventions.

4.3.2 Motivational Interviewing

Miller et al,²⁶⁴ in developing the counselling style of Motivational Interviewing, drew on the TTM in an attempt to cross the divide between theory and practice, in particular with regard to the assessment of motivation in terms of the change concepts of readiness, importance and confidence.

Motivational Interviewing has been described as a counselling style where “...it is the practitioner’s task to expect and recognise ambivalence, and to be directive in helping the patient examine and resolve the ambivalence”.²⁶⁵ The method was initially developed as a patient-centred counselling tool for use in patients with addictions, but it has subsequently been adapted for use in other healthcare settings, including in caring for individuals with chronic diseases.^{235, 244, 265-268}

Motivational Interviewing has been suggested for use in pharmacy^{171,266} and it is the counselling method suggested in the conceptual framework of the diabetes care plan discussed in Chapter 5 (Section 5.4.2). The pharmacist, in applying its principles, assumes the role of a behavioural change agent by assisting patients to recognise and resolve ambivalence or resistance to change.^{171,269,270} This approach is very different from the traditional view of pharmacist counselling which is essentially based on advice giving.^{6,271} Research reveals that only 5-10% of patients modify health-related behaviour as a result of advice-giving interventions.²⁶⁴ Furthermore, few patients request advice, and many patients do not want to be given prescriptive advice especially if the healthcare provider only emphasises the benefits of change. Unsolicited advice-giving may also be viewed as confrontational by the patient and so increase ambivalence or

resistance to change.²³⁵ Overcoming resistance to change or resolving ambivalence requires motivation to change, which is strongly influenced by the patient's sense of importance and confidence in effecting behavioural change.²³⁵

Motivational Interviewing is founded on the core sequential process elements of elicitation, provision and elicitation, and for each of the core elements five counselling principles apply.^{264,265} Elicitation in the first instance involves encouraging the patient to identify disease or condition-related needs, and any barriers preventing the needs from being met. The use of open-ended questions assists the pharmacist to identify any patient resistance to change or ambivalence.²⁶⁵

Ambivalence and resistance to change result from a cost-benefit analysis that is fundamental to therapeutic decision making. Patients weigh up the need to change a particular health-related behaviour (perceived benefit) versus concerns they may have about any possible negative effect that might result from such a change (perceived cost).²⁷² The 'provision' element of the Motivational Interviewing process allows the pharmacist to provide information in a manner that is directional (i.e. the pharmacist has a goal in mind in engaging with the patient), but without being dictatorial, argumentative or confrontational as any of these approaches may result in a defensive patient arguing against change.²³⁵

Elicitation in the second instance recognises the patient's ambivalence and continues the directive open-ended questioning approach by restating the problem together with any decision that the patient may have reached. As a result of providing patients with appropriate information and answering their questions it is possible that other concerns may be elicited. An important aspect of Motivational Interviewing in providing information is seeking patient permission before offering unsolicited advice. This underscores the collaborative and supportive nature of the pharmacist-patient discourse in Motivational Interviewing.²⁷⁰ Five principles or skills underpin this "elicit, provide, elicit" process. These principles are: rolling with resistance, expressing empathy, avoiding arguments, developing discrepancy, and supporting self efficacy.²⁶⁵

Rolling with resistance.

Patients who appear ambivalent or who resist change are not confronted directly. Instead resistance or ambivalence is used to facilitate the development of dissonance.^{265,270} Dissonance so created plays a complementary role in motivating patients to change behaviour. Rolling with resistance encourages the development of dissonance whereas the alternative i.e. confrontation often results in the patient assuming a defensive position. Pharmacists are able to utilise dissonance to directionally foster behavioural change. Rolling with resistance furthermore signals pharmacist acceptance of the patient's right to ultimately determine and be responsible for their own healthcare.²⁷³

Expressing empathy

Expressing empathy tangibly demonstrates the pharmacist's acceptance, in a non-judgemental manner, of the patient's reality of living with chronic disease.^{171,235} Identifying and developing an understanding of the patient's apparent resistance to change or ambivalence through a process that includes reflective listening and empathetic responses promotes the development of trusting relationships between patients and pharmacists and improves the effectiveness of the counselling intervention.^{171,228}

Avoiding arguments

Arguments between pharmacists and patients may lead to patients becoming defensive and to resistance to change becoming entrenched.²⁶⁵ While Motivational Interviewing is non-confrontational it is nevertheless directive as it encourages patients to confront their disease-related problems, including any aberrant behaviour, and to find solutions without confrontation or argument.^{265,270}

Developing discrepancy

Creating dissonance results from the misalignment of the patient's health-related behaviour and a desired health outcome. Motivational Interviewing encourages patients to weigh up their current health status in terms of their diabetes-related goals. If dissonance results, then patients are more likely to be motivated to change behaviour than if there is little or no dissonance.^{259,270}

Supporting self-efficacy

Patients are not only required to accept that a particular intervention may improve their health-related quality of life, but must also be confident they are capable of implementing it.²³⁵ In supporting patient self-efficacy, the pharmacist tangibly demonstrates support for the fundamental role of self-management.^{265,274} Practical ways in which the pharmacist can assist the patient to develop self-efficacy include providing relevant and unambiguous information, expressing sincere interest in the patient's welfare, encouraging persistence and adherence in a non-judgemental manner in times of relapse, praising and rewarding success and ensuring regular patient follow-up.^{171,274}

The process of Motivational Interviewing is not a linear one, as in practice patient behaviour and the patient-pharmacist discourse are subject to a number of competing and interacting factors.^{131,171,228} Motivational Interviewing while not a universal panacea for resolving poor patient health-related behaviour,²⁶⁶ is able to direct patient decisions towards appropriate behavioural change.^{171,264}

4.3.3 The 5 A's Behavioural Change Model

The 5 A's model (assess, advise, agree, assist and arrange) has been suggested as a unifying framework to inform the development and implementation of behavioural change educational interventions designed to support the improvement of chronic disease self-management in primary healthcare settings.^{275,276} The model, included as Figure 4.1, identifies five change concepts (Assess, Advise, Agree, Assist and Arrange) and makes suggestions for the collaborative interaction between the patient and the provider (the nexus of the Chronic Care Model).

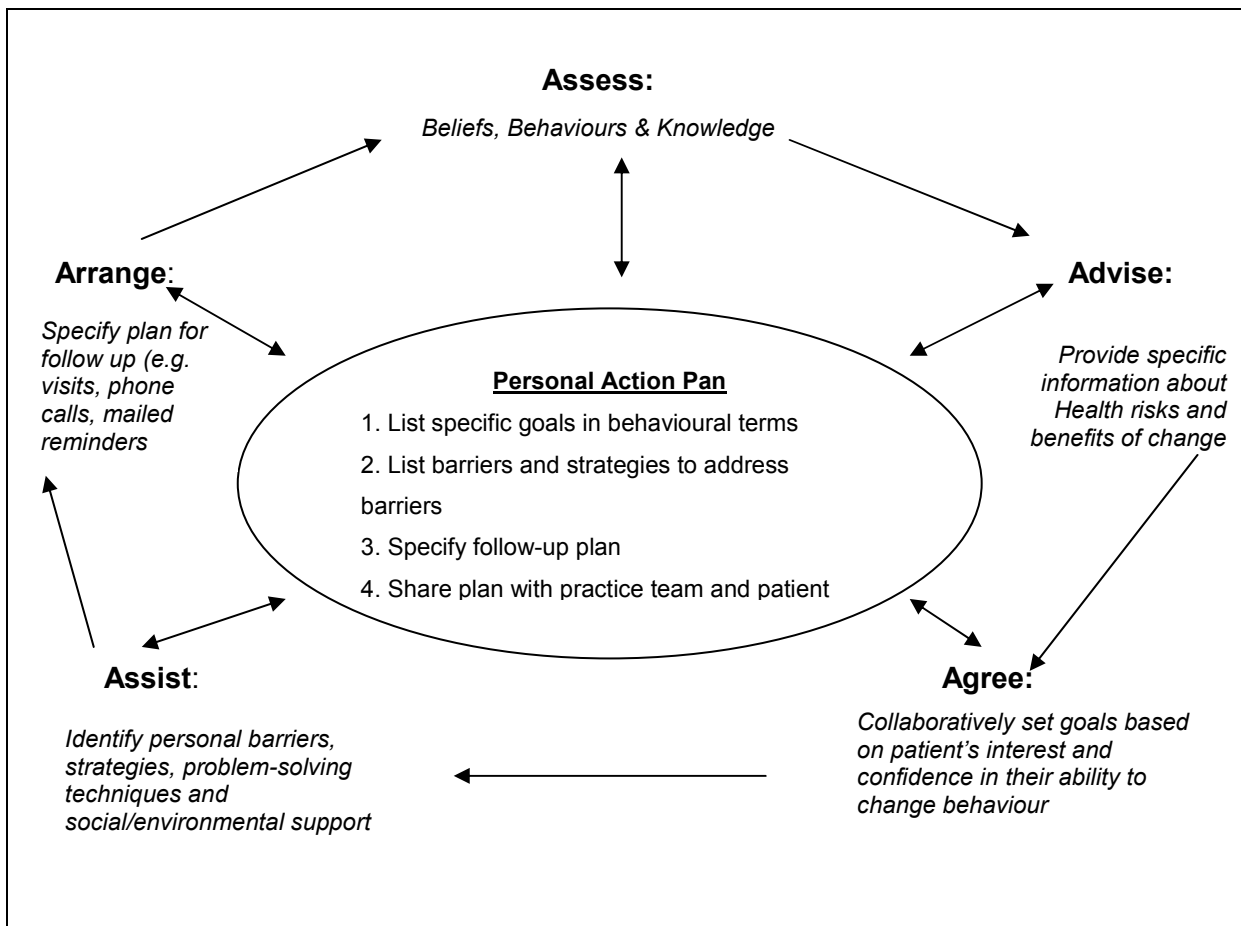


Figure 4.1. The 5 A's Behavioural Change Model for Adapted for Self-Management Support²⁷⁵

4.4 Effecting behavioural change

The task of the healthcare provider, in attempting to influence patient behaviours in the course of day-to-day clinical practice, is made difficult by a lack of time (work overload), lack of training and skills, the absence of an integrated screening and intervention approach applicable to multiple risk behaviours, as well as the mitigating influence of the provider's own behaviours and socio-ecological perspectives.^{237,276}

Rollnick et al,²⁷⁷ in discussing the training of healthcare professionals as facilitators of behavioural change in patients, note that there is very little that may be applied to health behavioural change in patients that does not apply to practitioners. The authors go on to state that the training of providers involved in promoting patient health behavioural

change *“is sometimes viewed as an inconvenient by-product of a more worthy endeavour: getting the patients to change”*.²⁷⁷ They caution against the oversimplification of the process of skills acquisition by providers who are charged with working with patients to effect behavioural change. A common but mistaken notion is that all that is needed is a workshop or two for the provider to be sufficiently skilled to influence behavioural change. Just as patients are unlikely to change behaviour overnight, neither are healthcare professionals. A balanced approach to training that is based on structured skills acquisition within the provider’s real-world practice environment appears to offer the most promise.

In a Cochrane systematic review of the effects of continuing education meetings and workshops on professional practice and health outcomes, the reviewers noted educational meetings and the dissemination of printed educational materials were the two most common forms of continuing education for healthcare providers.²⁷⁸ Reviewers found that there was a great deal of variation in the complexity of targeted behaviours and that stand-alone interactive workshops produced mixed results whereas a combination of workshop and didactic lectures produced significant results. There were no statistically positive results for studies based only on didactic presentations.

A systematic review of provider behavioural change noted that there are no “magic bullets” for changing provider behaviour, and while some interventions had some effect in certain circumstances, none were effective in all situations. Furthermore, multifaceted rather than single interventions were more likely to be successful.²⁷⁹ Interventions identified in the review, and which may be relevant to pharmacy practice, include continuing education, the provision of practice guidelines and printed educational material, reminders and computerized decision support. Guideline effectiveness increased when active educational methods were used, and if consideration were given to local conditions and supported with patient specific reminders.²⁷⁹ Others have found good evidence that training to improve cultural competence resulted in improved knowledge, attitudes and skills of providers, as well as in patient satisfaction.²⁸⁰

4.4.1 Provider-patient communication

Allied to both provider and patient behavioural change is the key aspect of provider – patient communication.²⁸¹ Communication between the provider and patient that is respectful, compassionate and empathetic is a key aspect of patient-centred care, and has been shown to have a positive effect on patient health outcomes.²⁸¹ No matter how well constructed an intervention, it is inconceivable that pharmacists would be able to influence patient health behaviour or outcomes in the event of poor communication.²⁸² Pharmacist-patient communication is commonly referred to as patient counselling, although the term patient education has also been used.^{228,283}

In a review of studies relating to patient counselling by pharmacists, Shah et al,²⁸³ noted that almost half of the studies reviewed (19 out of 39) conceptualised this form of counselling as solely providing patients with basic information (e.g. the name of the medication, the dosage and adverse effects). A total 16 studies included aspects of the interpersonal behaviour of pharmacists in addition to the information provision element. These interpersonal aspects include the time taken in engaging patients, willingness to offer assistance, demonstrations of empathy, and pharmacist accessibility. The reviewers noted that very little attention had been paid to studying patient communication behaviour and the processes involved in the exchange of information between the dyad.

van Dam et al,²⁸⁴ in a systematic review of randomised controlled trials designed to examine the effect of provider – patient interaction and provider consulting style on the process of care and patient outcomes in diabetes, tentatively concluded that focusing on improving collaborative care held more promise from both a process and outcomes perspective than did attempts to change provider behaviour. An important advantage of a primary care provider, such as a community pharmacist, in facilitating behavioural change in patients who are chronically ill, lies in the often good relationship between the two and the potential for frequent contact (and thus for multiple “teachable moments”²⁶) as a result of the prescription refill dynamic.¹⁷ Added to this is the increasing acceptance of collaborative and empowering patient-centred approaches to chronic disease self-management.^{285,286}

4.4.2 Effectiveness of behavioural interventions

Effecting behavioural change is often difficult as behaviour is dictated by a multitude of personal, societal and environmental influences in effect at the level of the individual, between the individual and others, and at the level of broader society.²³⁷ The difficulties associated with behavioural change are exacerbated by the clustering of risk behaviours within individuals, e.g. smokers who may be overweight and lead a sedentary lifestyle.²⁷⁶

A review of evidence relating to multiple risk factor interventions in primary care noted that the complexity and difficulty of promoting behavioural change in primary care settings is demonstrated by the modest and often inconclusive results of health promotion programmes and services aimed at increasing physical activity, improving diet, smoking cessation and modifying alcohol consumption.²⁷⁶ Such modest or inconclusive results are often in contrast to the successful behavioural modification outcomes achieved in specialised clinical settings.^{120,121} The challenge for primary care providers, such as community pharmacists, is to translate the research conducted in these specialised settings into day-to-day patient care in their own practice settings.

A Canadian study which used the constructs of community pharmacist beliefs, self-efficacy, behavioural control and evaluations to develop a causal model to predict pharmacist behaviour in providing pharmaceutical care, found that pharmacists were generally positive about pharmaceutical care. Pharmacists rated their beliefs about the benefits of pharmaceutical care outcomes highly but assigned a much lower rating to behavioural control, which indicated that they were not confident about turning strategy into action.²⁴⁶ In terms of self-efficacy, they were moderately confident, which when considered with the relatively high rating for beliefs in the benefits of pharmaceutical care, corresponded with the findings of an earlier study which considered an intervention to change patterns of community pharmacy practice.²⁵³ The latter study found that pharmacists often did not provide pharmaceutical care despite have high intention to do so. The authors suggest that this discrepancy may be due to low social norm with regard to medical practitioners, low behavioural control, low self-efficacy and low affect.

The Canadian authors suggest that applying a stage-based interpretation to their findings reveals that many of the pharmacists were either in a precontemplative or

contemplative stage because of their perceived difficulty of converting intention into action.²⁴⁶ They suggested that in order to foster changes in practice, pharmacist perceptions of behavioural control need to be addressed, as this variable may impact directly on beliefs, self-efficacy and evaluation. Programmes that include enabling enhancements to the practice environment of pharmacists together with positive perceptions of behavioural control may lead to improved self-efficacy and evaluations, and consequently to improved pharmaceutical care.^{246,253}

4.4.3 Behavioural change intervention strategies

The following intervention strategies have been associated with positive outcomes in studies aimed at modifying behaviours:²⁷⁶

- ❖ Assessment and tailoring to address patient needs^{19,287}
- ❖ Self-monitoring, goal setting and problem solving^{173,288}
- ❖ Empowering patient education²⁸⁸
- ❖ Combination of pharmacotherapeutic and behavioural interventions^{289,290}
- ❖ Internal (patient and provider) and external (community) support^{25,291}
- ❖ Multiple modalities^{188,290}
- ❖ Regular follow-up contacts^{287,292}
- ❖ Use of multidisciplinary teams^{18,293}
- ❖ Targeted elements of a health system^{25,291}

Goldstein et al,²⁶ in their review of behavioural interventions in primary care note that most individuals are at risk for multiple behavioural risk factors. This is especially so in chronic conditions such as DM2 where, in addition to hyperglycaemia, patients may be hypertensive, obese, dyslipidaemic, depressed, smoke, lead a sedentary lifestyle and suffer from any number of complications often associated with diabetes.²²⁷ The multi-component nature of behavioural interventions has led to their classification as *complex interventions*,²⁹⁴ requiring an approach that is different from that more appropriate for a single (component) intervention.²⁹⁵ Both CONSORT²⁹⁶ and the Medical Research Council of the United Kingdom²⁹⁴ have published guidelines for consideration in the development and evaluation of complex interventions. Complex interventions are further discussed in more detail in Section 5.3.

4.5 Patient self-management in chronic disease

The main drivers of desired patient health outcomes in chronic disease management are pharmacotherapy, lifestyle modification and the monitoring of clinical indicators,⁴ all of which involve self-managed health-related behaviours.^{143,297} Resistance to modifying behaviour is a major barrier to effective self-management in chronic disease.^{171, 235,265}

Self-management is often the defining component in the overall care continuum for most chronic illnesses. For example, it provides for approximately 95% of the care diabetics receive.^{67,226,298-300} An important role for providers is to support the chronically ill patient's efforts to acquire the necessary information and skills to be able to effectively care for themselves.³⁰¹⁻³⁰³ The nature of DM2 dictates that the patient should not be a passive recipient of diabetes care but should be empowered to be actively involved in all aspects of their care, including identifying diabetes-related needs, setting goals, discussing and agreeing on strategy, implementing interventions and monitoring outcomes.^{275,299,304,305}

The empowerment approach to both behavioural change and self-management education in diabetes care has resulted in a shift from provider-centred care to more patient-centred models that acknowledge the primacy of patients in providing care, i.e. recognition of the reality that most patients are ultimately responsible for their care choices and the consequences of these choices.^{222,306-308} Patient empowerment does not occur simply by inviting patients to participate in their care, nor does it result if providers discount the patient's experience of living with the disease or if they fail to provide the resources needed to foster problem solving, informed decision making and self-efficacy.^{301,309} Self-efficacy, which has been defined as the "...*confidence to carry out a behaviour necessary to reach a desired goal*",³⁰¹ is an outcome of patient empowerment and the central component of self-management.^{310,311} Furthermore, self-efficacy is the result of a transformational process, developing as patients become increasingly successful in identifying and resolving diabetes-related problems.^{301,303}

There seems to be a lack of consensus about what constitutes a successful chronic disease self-management programme, which elements should be universally applied regardless of the disease, or which elements are disease specific.¹⁷⁷ While the mechanism by which self-management education effects improves patient outcomes

remains unclear,³¹² there appears to be substantial support for self-management education aimed at promoting the key process outcome of patient adherence to the behavioural and clinical aspects of evidence-based care.^{52,306,313}

The features of evidence-based diabetes self-management education include the application of appropriate theories of behavioural change, concordant goal setting, a combination of individualized didactic and practical instruction, simplification of treatment regimens, provider support, follow up and patient feed back, and participation by family and significant others.^{224,314}

Traditional diabetes patient education is based on providing information about diet, exercise and medicines as well as technical skills such as those associated with SMBG. Diabetes self-management education complements traditional patient education by providing training in problem solving and coping skills.^{224,301} Self-management education that is focused on empowering patients to develop their self-management skills appears to be more effective in improving clinical outcomes than education that is simply based on information transfer.^{224,301}

The findings of the DCCT and UKPDS support the need for self-management as many of the activities associated with improved disease control and the prevention or arresting of complications are undertaken directly by the patient.^{92,315-317} Diabetes self-management education provides for an evidence-based approach to disease-related risk reduction.³⁰¹ In the USA it has been reported that only 52% of diabetics received self-management education and yet between 50% and 80% of patients lack sufficient diabetes-related capacity to be able to effectively manage their disease.³¹⁶ Adherence to self-management recommendations is substantially lower among patients who have not received diabetes self-management education and these patients are four times as likely to develop complications.³¹⁶

There appear to be three main barriers to the provision of diabetes self-management education: a paucity of trained and culturally competent personnel; the continued socialization of patients to dependant relationships with providers where acute models of care are in effect rather than collaborative patient-centred chronic care models; and

lastly the reluctance of the funders of healthcare to reimburse educators for providing self-management education.³⁰¹

4.5.1 Compliance, concordance and adherence

The medical narrative dating back to the time of Hippocrates reveals that the medical establishment has long been concerned about patients not “...*following doctors orders*”.³¹⁸ Patients with tuberculosis in the early 1900’s who did not follow medical practitioner instructions were often chastised and even described in the literature as “...*ignorant and vicious consumptives*”.³¹⁸ It was, however, only with an improved understanding of the aetiology and pathophysiology of diseases such as tuberculosis that the compliance aspect of evidenced-based disease management became therapeutically meaningful.³¹⁸ The terms compliance and non-compliance began to appear in the literature in the 1960s. Sackett and Haynes,³¹⁹ who pioneered much of the early research, stimulated the discourse about therapeutic compliance with their books in the 1970s.

Developments in health psychology have given rise to a number of theoretical models used to describe aspects of adherence.^{272,320} Horne and Weinman²⁷² state that “*Social cognition models and the self-regulatory theory share the common assumption that individuals develop beliefs that influence the interpretation of information and experiences and which guide behaviour*”. Social cognition models such as the theory of planned behaviour have been used to explain medication adherence variability, for example, in hypertension, diabetes and kidney disease.²⁷² These models are used to predict behaviour and/or behavioural intentions as well as examine the reasons why individuals fail to sustain behaviours.²³⁹

The psychology of adherence suggests that adherence behaviour is strongly influenced by the patient’s belief about the illness and the result of weighing up the perceived costs and benefits of a particular therapy (e.g. taking medication, stop smoking) versus any concerns about taking the action (e.g. adverse effect of the medication or weight gain).^{233,272,321-323}

4.5.2. Compliance

Compliance has been defined in terms of three process elements: matching the patient's actual consumption of medication with that of the prescribed regimen; matching the patient's medicine taking or lifestyle behaviour with the advice provided by the healthcare professional; and the actual doses of medication not taken, or taken incorrectly.³²⁴ An alternative outcomes-based definition of compliance is less concerned with the number of doses taken than with the outcome of the regimen.³²⁴

Haynes et al³¹⁹ defined compliance as “...the extent to which a person's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice”. However, as compliance appears to be associated with patient blame i.e. a non-compliant patient is seen as being incompetent, deviant or recalcitrant in following provider instructions,³²⁵ the term has been superceded in the recent literature by the term adherence,³²¹ which has been formally adopted by the WHO.¹ However, there are those who hold that the concepts of compliance and adherence are not appropriate in chronic disease care as the focus of healthcare providers should be constrained to collaborating with and empowering patients to optimise self-management.^{301,327}

4.5.3 Concordance

The term concordance has more recently appeared in the literature, particularly that emanating from the United Kingdom.³²⁷⁻³²⁹ Concordance is not a synonym for either adherence or compliance but is an evolving concept that refers to the consensual agreement reached between a patient and a healthcare provider, and reflects the patient's considered choice.^{324,328-330}

Concordance, in a pharmacotherapeutic context, has been defined by the Medicines Partnership Group as “...agreement between the patient and the healthcare professional, reached after negotiation that respects the beliefs and wishes of the patient in determining whether, when and how their medicine is taken, and (in which) the primacy of the patient's decision (is recognised)”.³³¹ Promoting concordance requires flexibility and skill on the part on the provider in order to elicit the approach favoured by the patient.^{324,331,332} The term is, however, not without problems. In the USA for example, concordance has been

defined as “...a similarity, or shared identity, between physician and patient based on a demographic attribute such as race, sex, or age”.³³³

Concordance may possibly be a condition precedent for improving adherence but this does not mean that where concordance exists adherence is guaranteed. For example, a patient and a provider may agree on the need for the patient to use medication, however, the patient may simply forget or find the regimen too complex.^{327,328}

There is a paucity of literature relating to the effect of concordance on patient outcomes, and little evidence exists with regard to key aspects such as the information needs of patients and providers, which interventions improve communication between patients and providers, and whether or not enhanced communication necessarily translates into improved outcomes.^{328,334} The complex and interdependent (or sometimes conflicting) nature of the various elements of concordance make it a difficult subject to research. Added to this is the need for substantial change to values and practice dynamics if concordance is to become an entrenched healthcare model.^{334,335}

4.5.4 Adherence

The advent of patient-centred care has encouraged the abandonment of language that speaks of ‘recalcitrant’ or ‘deviant’ behaviour for those patients who, for whatever reason, choose not to follow healthcare provider advice. Terminology that excludes pejorative terms such as non-compliance is increasingly being used to accommodate the reality that the chronically ill make the important day-to-day decisions about their care and are thus responsible for, and in control of, the care process.^{273,326}

The WHO defined adherence as “...the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider”.¹ A previous definition included the phrase “the extent to which the patient follows medical instructions”. However, the WHO adherence meeting in June 2001 held that the term “medical” did not allow for the inclusion of non-medical interventions, crucial in chronic disease care. Similarly, “instructions” inferred that collaboration only extended to the patient being a submissive recipient of expert provider treatment and care.¹

4.5.4.1 Importance of adherence

Adherence to therapy is an important chronic disease self-management behaviour.¹ However, no more than 50% in high-income countries, and even less in medium and low income countries adhere to long-term therapy conscientiously.¹ Inadequate therapeutic adherence is associated with economic, clinical and humanistic outcomes as it increases the financial cost of healthcare, diverts scarce healthcare resources and results in poor patient quality of life.^{1,336} The WHO endorsed the profound view expressed by Haynes et al³³⁰ that *“Increasing the effectiveness of adherence interventions may have a far greater impact of the health of the population than any improvement in specific medical treatments”*.¹ Krumholz et al³³⁷ underscored the relevance of adherence in a disease management context by describing medication adherence as a patient-centred measure that should be included in the clinical outcomes domain of a disease management taxonomy. Importantly, there should always be sound clinical reasons for attempting to increase adherence rates, and there should be patient-provider concordance, as such interventions are always associated with ethical considerations.³³⁰ For example, in certain instances intentional non-adherence may well be in the patient’s interest and the pharmacist may have an ethical obligation to support such a decision.

Most adherence-related research has been focused on pharmacotherapy, especially with regard to the causes of non-adherence and the strategies and interventions to improve adherence.^{188,324,330} In addition to emphasising medication persistence and adherence in diabetes care, the importance of adherence to non-pharmacological self-management recommendations such as nutrition, exercise and self-monitoring is increasingly receiving due consideration.^{225,338,339}

4.5.4.2 Factors influencing adherence

Non-adherence may be intentional or unintentional. Intentional non-adherence, which occurs when the patient decides against following advice or instructions, is informed by both health beliefs and motivation.^{272,324,340} Unintentional non-adherence is influenced by cognitive, physical and socioeconomic constraints and is thus a function of skill, ability and capacity.^{321,341-343} A number of psychosocial factors including economic status,

patient-provider communication, emotional stability and a supportive social environment affect adherence,^{224,344,345} whereas demographic characteristics appear to have less leverage on adherence.³²⁴ Of all the psychosocial correlates associated with adherence, patient health beliefs may have the strongest influence.^{272,321,344,345}

In the WHO report on adherence in diabetes, five core and interacting health-related factors influencing patient adherence to therapy were identified: socioeconomic factors where cost of care is most often cited; health system factors with patient-provider relationship being key; disease-related factors with duration of disease and co-morbid depression having most influence; therapy-related factors mainly expressed as complexity of treatment; and patient-related factors where lack of self-efficacy and poor self-management capacity are most important.¹

Other adherence influencing factors that have been identified include forgetfulness, health beliefs especially beliefs about medicines and denial about health status, adverse effects of medication, medication effectiveness, lack of concordance, poor healthcare provider communication, alcohol abuse, lack of social support, linguistic and cultural differences between patient and provider, absence of diabetes education, low levels of diabetes-related knowledge, and anxiety.^{175,318,324,346-349} Neither the disease itself nor the clinical settings are necessarily indicators of adherence.

In DM2, monotherapy, diabetes education and diabetes related knowledge are associated with adherence and outcomes.^{4,106,318} Diabetes education is, however, not always associated with improved adherence or disease-risk reduction, possibly because of the confounding effect of focusing diabetes educational efforts on patients with poor glycaemic control.^{318,324} While improved understanding of medication use may improve adherence, acquiring diabetes-related knowledge may exacerbate concerns about the adverse effects of medication or about the possibility of a negative prognosis.³⁴⁹

Adherence is a 'moving target'. As patient circumstances are subject to change so too are the variables influencing patient adherence. The dynamic and multifaceted nature of adherence contributes to the difficulties associated with the behaviour that is often encountered in practice.³⁴⁹ A review of adherence-related studies noted that of almost

200 provider-patient encounter variables studied none were found to consistently predict adherence.³²⁴

4.5.4.3 Adherence interventions

Adherence to therapy facilitates the bridging of the process of care with the outcome of the intervention.^{350,351} Patient adherence to therapy is a complex health-related behaviour.^{1,175,330} Haynes et al³¹⁹ listed the three fundamental criteria that should be satisfied when designing and implementing adherence promoting interventions: a correct diagnosis of the disease is required; the intervention in question must do more good than harm, and lastly the patient must be informed and willingly participate in the process. The design of adherence-promoting interventions should incorporate the enhancement of patient understanding, recall motivation and self-management skills.³²⁴

Interventions designed to improve adherence in chronic disease may be classified according to the following five broad themes: technical, educational, behavioural, affective and multimodal.³⁴⁶

Technical interventions

Technical interventions generally relate to the medication regimen and include patient reminder services (computerized alerts), simplifying medication regimens (tailoring therapy and fixed-dose combinations), unit-dose packaging, and dosing schedules.^{324,344,352-354}

Educational interventions

These interventions are primarily aimed at informing the patient's knowledge base with regard to key aspects of the disease including principles of self-management education, offering individualised disease-related training (e.g. use of monitoring devices) and providing health-related information.^{38,188,355,356}

Behavioural interventions

Interventions for behavioural change include those concerned with diet, exercise, body mass, smoking cessation, alcohol consumption, medicine taking, making and keeping appointments and monitoring clinical indicators.^{9,338,357-361}

Affective interventions

These interventions are psychosocial in nature and include individual counselling sessions, social support, telephonic follow-up, empowering patient-provider relationships, facilitating self-motivation, reinforcement and reward programmes.^{225,266,308,330,360,362-366}

Multimodal interventions

Multimodal or multifaceted interventions are those that combine elements from the other four major categories e.g. a counselling session for both spouse and patient on meal planning, exercise, self-monitoring of blood glucose and education on the correct use of insulin.^{324,330,346,360,367-369}

Interventions to improve adherence to medication are generally complex, labour intensive and their effectiveness inconsistent in many instances.^{324,330,353,354} Even the most effective interventions do not produce large improvements in adherence or health outcomes.^{324,330}

The interventions that appeared most effective include prescription-refill reminders simplifying regimens and unit-dose packaging and these should be first-line strategies.^{324,352-354,370} While integrated educational interventions are effective, the provision of educational material or advice as stand-alone interventions appear to have little or no effect on adherence.^{38,352,371,372}

Reasons why interventions often appear ineffective include inadequacies in the development-evaluation-implementation process, e.g. lack of a coherent underpinning theory, lack of evidence supporting the likelihood of a successful cost-effective intervention (ideally substantiated by systematic reviews), inappropriate design, lack of clarity regarding interventions, impractical interventions, lack of adequate feasibility studies (pilot studies) and lack of process evaluation.²⁹⁴

Other methodological problems commonly identified in systematic reviews include the recruitment of only those patients willing to participate in the research rather than the wider population (i.e. patients may already have high baseline adherence levels), small

numbers of participants and per-protocol rather than intention to treat analysis. Issues such as non-blinding of researchers and payment of researchers raise questions about generalisability of results in practice. Uncertainty as to whether an effect was due to the intervention in question or due to the effect of simply being experimentally measured (Hawthorne effect) constitutes a potential problem as does an absence of any assessment of the individual components of a complex intervention. Control patients are often referred to as having received usual or standard care without such care being fully described. Furthermore, there are very often problems associated with measuring adherence, with a frequent reliance on imprecise self-reported adherence data as well as a lack of clarity on acceptable adherence cutoff points.^{153,324,330,348,32,368}

Provider-related factors that may negatively impact on the effectiveness of adherence interventions include the poor quality of provider-patient interactions,^{324,373} and the provider's failure to negotiate priorities with patients, follow clinical practice guidelines,³²⁴ tailor interventions to meet individual patient needs,³⁷⁴ monitor and reinforce adherence at each visit and follow up with patients regarding missed appointments or prescription refills. Providers should implement medication regimens that are simple and cost-effective and that avoid multiple medications and dosages, complicated or unclear instructions and use medication that is effective, inexpensive, and free of unwanted side effects.³⁶⁹

In a review claimed by van Wijk et al¹⁵³ to be the first systematic review of the effectiveness of adherence promoting interventions by community pharmacists, the authors noted the paucity of published studies and consequently that it was not possible to identify an overall strategy that may result in improved adherence to medication prescribed for chronic conditions.

Patient-related factors that may contribute to lack of effectiveness of adherence interventions include health-related beliefs,^{324,374} forgetfulness,^{369,375} past experience of illness and the role of medication,³²⁴ the complexity and the behavioural demands of multifaceted treatment regimes (which may include taking and/or using a number of medications at various times during the day and night),³⁶⁹ adverse effects of medication,³⁶⁸ following eating plans, exercise or smoking cessation programmes, self-monitoring blood pressure and or blood glucose levels,³⁶⁹ and attending appointments

and having biochemical and other tests done.^{294,324} Further potential confounders include psychological (e.g. depression),³²⁴ socio-economic (e.g. lack of social support, poverty and other financial constraints and transport related factors)³⁷⁵ and health-system factors (limited healthcare resources including medicines, personnel and infrastructure). In addition, patients may wish to make their own decisions regarding care, or simply decide independently to disengage from care (intentional non-adherence).^{229,324} Negative reinforcement such as threatening or coercing patients may produce results opposite to that intended.²²⁹

4.5.4.4 Measuring adherence

One of the most problematic aspects of adherence research concerns the measurement of adherence.^{330,353,376} Vermeire et al³²⁴ refer to the lack of a 'gold standard' in measuring adherence, largely due to variations in definition and because of the heterogeneity and complexity of the interventions.

Methods that have been used to assess medication adherence include the direct measurement of medication or metabolite levels in blood, urine and saliva.^{324,377,378} Biological markers or tracers have been used but their utility is limited as they tend to mirror recent and not sustained patient behaviour.^{346,377} Direct observation is another direct measurement method but its application is largely limited in practice to research settings, single dose therapy or for use with hospitalised patients.^{324,346} While direct measures provide the most accurate assessment of medication adherence, the methods may be considered invasive, expensive, labour intensive and not applicable for all medication or practice settings.^{324,346,377}

Biochemical and clinical indicators (HbA_{1c}, LDL-C, blood pressure) have been used as surrogate markers for adherence but because of possible confounding influences such as the patient's health status, the appropriateness of prescribed medication, sub-optimal dosing, and possible adverse medication effects, they may be less reliable than other more direct measures.^{346,348}

Indirect methods of measuring adherence have greater practical utility than the direct methods and, despite shortcomings, are the most often reported methods in the

literature.³⁶⁶ These methods include the process measures of tablet or pill count, patient interviews, pharmacy claims data, prescription refill data, patient self-report, provider report (including therapeutic response assessment) and micro-processor enabled medication event monitoring system (MEMS).^{324,366,376,377,379} MEMS may have little practical application in practice as the technology remains relatively expensive. Tablet or pill counts as well as any surreptitious assessment of adherence raises ethical questions as such measures involve invasion of patient privacy and, where applied, should require patient consent.³⁷⁷

Pharmacy prescription refill data has been used in studies as an adherence measure and is generally well accepted.^{330,376,380} Patient self-report is a convenient and easily applied adherence measure, but has been associated with the overestimation of adherence.^{346,376,377,381,382} Patient self-report has been found to correlate with MEMS as a general measure of non-adherence i.e. less than perfect adherence.³⁸³ Patient interview, conducted with open-ended questioning and reflective listening in a non-threatening and non-judgemental manner, is an applicable method of assessing adherence,^{377,381} and when combined with patient self-report and pharmacy prescription refill data, may offer the best opportunity of measuring patient adherence to medication therapy in practice settings.^{346,376} Adherence to self-management recommendations including diet, exercise and blood glucose monitoring have been measured by means of validated instruments developed in collaboration with patients and providers.³⁸⁴⁻³⁸⁶

The lack of standardisation of key aspects of adherence to medication and self-management recommendations continues to confound the measurement process. Furthermore, none of the direct or indirect methods of measuring adherence have been able to demonstrate unequivocally that any health-promoting behaviour is being adhered to, or that medication has actually been used by the patient. Consequently the search continues for the 'holy grail' to measure patient adherence to therapy.^{346,348}

4.5.4.5 Improving adherence in diabetes

The literature relating to adherence in diabetes is fairly modest, and has been largely informed by related studies in other chronic diseases, especially hypertension and cardiovascular disease.³⁵⁰ Interventions to improve adherence traditionally focused on

didactic diabetes education and emphasised patient knowledge. More recently behavioural and psychosocial interventions in the realm of diabetes self-management have been applied and investigated.^{1,357,387} The benefits of self-management adherence in diabetes include improvements in patient comprehension, self-care behaviour, the alleviation of symptoms and ultimately in glycaemic control and reduction of the risk of diabetes-related complications.^{1,347,388,389}

Lifestyle interventions in DM2, particularly those related to behaviour changes in diet, exercise and pharmacotherapy, are associated with improved glycaemic control and health outcomes,^{1,4} although patients often have difficulty sustaining these behaviours.³⁵¹ Individualized or tailored and multimodal diabetes self-management education programmes appear to best serve the patient's desired outcomes.^{36,350,390-392}

A number of diabetes-related interventions have been investigated including prescription refill reminders, verifying patient recall, understanding treatment regimens, clarification and reinforcement of the benefits of treatment, setting diabetes-related goals, simplification of regimens, unit-dose packing, regular self-monitoring of blood glucose, electronic monitoring, telephonic and email follow-up, mobile phone short message services, lifestyle coaching, home visits, psychosocial interventions such as improved problem solving skills, emotional support (including family/friends, referral for psychological counselling, and the use of generic medicines to ease financial burdens).^{38,347,350,363,393-396} However, the adherence literature reveals inconsistent findings, and even when effects are reported these are often small and short-lived, being associated with the length of time the intervention is applied.^{350,395} The heterogeneity of studies, including the key aspect of measuring adherence, render assessment and comparison of interventions problematic.^{1,330} Glasgow et al³²⁶ noted the methodological shortcomings of some studies relating to adherence in diabetes, including matters relating to conceptualization when adherence is viewed as a "...single unitary construct" rather than as a complex collection of multifaceted behaviours. These authors, in concert with others such as Anderson et al,²⁷³ furthermore question the appropriateness of the concept of adherence, given the nature of diabetes and the primacy of self-management in providing comprehensive diabetes care.

Many of the interventions designed to improve adherence are interdependent, e.g. patient education and counselling are likely to be more effective if a member of the family or significant other is supportive of the intervention.³⁹⁷ Similarly, self-management in chronic disease is more likely to occur if patients understand the implications of self-care and are motivated.³⁷⁰ Importantly, adherence is not constant and varies from time to time as the interacting processes involved vary in response to any of a range of influencing factors.³⁴⁹

4.5.5 Assessment of beliefs, behaviours and knowledge for DM2 self-management

The behavioural, psychological and social status of diabetics can impact considerably on their ability to self-manage their disease.^{143,319,397} The diabetes care encounter between patient and healthcare provider creates opportunities for the provider to appropriately assess or screen patients for aspects of their psychosocial status and health-related behaviours^{122,275,357,} and pharmacists are well positioned to measure certain key psychosocial variables using validated scales.^{355,399-401} There is a comprehensive array of screening tools available that may be used in behavioural and psychosocial screening in primary healthcare settings.

Behavioural and psychosocial screening in DM2 includes, but is not limited to, the patient issues of health beliefs, attitudes about the disease, expectations relating to diabetes care provided by healthcare professionals, satisfaction with care, planning diabetes care, self-management practices and behaviours, including adherence, knowledge and understanding of key aspects of the condition, empowerment, self-efficacy, coping skills, problem solving, social support and depression.^{4,122,221,357,402}

The 5 A's Behavioural Change Model²⁷⁵ (Section 4.3.3) includes a provision for the periodic assessment of patient health-related beliefs, behaviours and knowledge, which allows for informed discussion about clinical status and most challenging barriers to self-management (identified by patient and directed by provider), including readiness, importance and confidence. Surveys allow for personalized assessment and feedback on aspects of and factors affecting self-management such as patient medication-related beliefs, satisfaction with care, empowerment, adherence, disease-related knowledge, and the monitoring of risk indicators.

4.5.5.1 Assessment of health-related beliefs

Adherence to prescribed pharmacotherapy is strongly influenced by the patient's perception of the necessity of taking medicines versus any concern the patient may have about possible adverse effects associated with using the medication.^{272,321,384} Researchers have used a variety of instruments to measure patient medication-related beliefs, with the most popular in recent times appearing to be the Beliefs about Medicines Questionnaire (BMQ), which consists of two parts.³⁸⁴ The first section considers patient beliefs in terms of the key adherence-related domains of necessity and concerns about the medication prescribed for the patient. The second part of the questionnaire refers to patient perceptions in general about the harm that medicines may cause and the possible overuse of medicines by medical practitioners.³⁸⁴ The BMQ may identify aspects of the patient's medication belief construct requiring clarification or remedial intervention.^{174,340}

Patient satisfaction, together with understanding aspects of the disease and recall ability plays a pivotal role in the adherence dynamic.⁴⁰³ Patient satisfaction correlates positively with therapeutic persistence and adherence and to intermediate health outcomes in chronic disease management.^{9,359,404,405} It is also a measure of healthcare provider competency.⁴⁰⁵ Various scales have been developed to measure patient satisfaction including the Patient Satisfaction Scale, which has three subscales: technical, information and patient support,⁴⁰⁶ and the 17-item Satisfaction with Information about Medicines Scale, which is designed to assess the extent to which patients feel satisfied with the level of information they receive when medication is prescribed.⁴⁰⁷ Patient satisfaction, in terms of specific medication experiences (e.g. perceived effectiveness, adverse effects, convenience), has been investigated by the Treatment Satisfaction Questionnaire for Medication.⁴⁰⁸

A study that investigated the provision of CPS in diabetes included a 12-item instrument that considered satisfaction in terms of the quality of information provided, the perceived competence of the pharmacist and an overall rating of care.⁴⁰⁹ The Diabetes satisfaction

Scale is a three part sub-scale of the Diabetes History scale designed by the Michigan Diabetes Research and Training Center (MDRTC).⁴¹⁰ The first section relates to satisfaction with the current level of diabetes care being received; the second section identifies the patient's main provider of diabetes care, and the third section considers satisfaction during the previous 12 months with the information transfer process (from provider to patient) and the patient's opinion about the degree of collaboration between the providers.

Diabetes self-efficacy is positively associated with health outcomes.³⁹⁸ Self-efficacy may be fostered by patients focusing on their success in problematic areas of diabetes self-management. Identifying and re-enforcing self-management successes may set in motion additional positive behavioural changes leading to further self-management success.^{357,411} Instruments used to measure patient self-efficacy in diabetes include the Confidence in Diabetes Self-care Scale, a 20-item self-report of the patient's perceived ability to perform diabetes self-management tasks,⁴¹² and the Diabetes Empowerment Scale-Short Form (DES-SF) was developed by the MDRTC from a comprehensive 37-item questionnaire designed to assess patient diabetes-related psychosocial self-efficacy.⁴¹³ The latter instrument examines patient self-efficacy in eight domains which include recognising the need for change, developing a diabetes care plan, identifying and overcoming barriers, being solution focused, positively developing coping skills, identifying and requesting support, becoming self-motivated and making appropriate self-management decisions.⁴¹³

4.5.5.2 Assessment of health-related behaviours

The significant behavioural and lifestyle changes demanded of diabetes patients places the patient and the patient's social support structure (relatives or friends) at the centre of the collaborative treatment continuum.^{174,414,415} As self-management adherence is strongly associated with diabetes-related attitude,⁴¹⁶ an improved understanding of this behaviour may assist in the design and implementation of diabetes self-management plans.^{416,417} Tools that have been used to assess diabetes self management include the Summary of Diabetes Self-Care Activities self-report which, because of the multidimensional nature of diabetes self-management, assesses each component separately rather than by combining scores across components.⁴¹⁸ Other self-report

scales such as the Diabetes Regimen Adherence Questionnaire have, however, combined scores in different areas in order to produce a total adherence score.⁴¹⁸ The Self-management Adherence Scale, a 4 part sub-scale of the Attitudes Towards Diabetes Scale, is a section of the MDRTC's Diabetes Care Profile.³⁸⁵ Patients are requested to self-report adherence in four areas of diabetes self-management: glycaemic control, body mass, other self-care activities i.e. diet, exercise and medicine use, and emotions or feelings i.e. fear, worry or anger.

The value of patient self-reported adherence is well documented, despite being associated with an overestimation of adherence.^{1,286,376,419,420} The literature concerning medication adherence is voluminous,^{38,330,344,353} and a number of instruments have been developed to assess this important variable. Among the instruments that appear to be more commonly used are the Morisky Medication Adherence Scale consisting of four items, each requiring either a yes or no answer,⁴²¹ and the Medication Adherence Report Scale (MARS).⁴²² The latter instrument is a 5-item scale used to examine self-reported medication use in five medicine adherence domains: forgetfulness, dose alteration, discontinuing therapy, intermittent use of medication and dosage reduction.

Depression, with an estimated prevalence of 15%–20%, is a relatively common co-morbidity in diabetes compared with prevalence in the general population of between 2% and 9%.⁴²³ This condition results in increased patient self-report of diabetes symptoms, poorer physical functioning and a decrease in adherence to pharmacotherapy and to the lifestyle imperatives of diet, exercise and other self-management behaviours.⁴²³⁻⁴²⁵ A number of self-report instruments have been used to screen for depression including the Centers for Epidemiologic Studies-Depression (CES-D) Scale,⁴²⁵ the Beck Depression Inventory,⁴²⁶ and the Zung Self-Rating Depression Scale.⁴²⁷ The Major Depression Inventory (MDI) is a diagnostic and rating scale for depression developed by the Psychiatric Research Unit of the WHO's Collaborating Center for Mental Health.⁴²⁸ The MDI has proved reliable in indicating depression symptomatology and is a useful screening tool for onward referral for patients requiring further investigation.^{428,429} As a depression rating scale, the MDI consists of 10 items with total scores ranging from 0 to 50. Mild depression is said to be associated with a total score of 20 to 24, moderate depression with a score of 25 to 29 and major depression with a score >30.

4.5.5.3 Assessment of diabetes-related knowledge

Improved patient understanding of diabetes can lead to improved glycaemic control and can impact positively on other intermediate health outcomes.^{398,430} The Mutual Understanding Scale includes the investigation of patient understanding of aspects of the consultation process (e.g. self-management education).⁴³¹ The capacity of patients to understand and use health information in order to make informed and appropriate health-related decisions has been investigated using newly developed scales for measuring health literacy in terms of the functional, communicative and critical aspects of diabetes self-care.⁴³²

Glycaemic control is associated with diabetes knowledge across different age groups and levels of literacy.^{182,433,434} Instruments used to assess patient knowledge of diabetes include the Diabetes Knowledge Scales,⁴³⁵ the Spoken Knowledge in Low Literacy in Diabetes Scale,⁴³³ and the Brief Diabetes Knowledge Test,⁴³⁶ which was designed by the MDRTC as a 23-item diabetes knowledge questionnaire. The first part of the MDRTC instrument consists of a 14-item general diabetes knowledge test which includes four questions about diet, six that are glycaemia related and four relating to knowledge about aspects of the more common complications of diabetes. The second part is a 9-item insulin-specific test.⁴³⁶

The Understanding Self-management Practices Scale, a 10-item sub-scale of the Diabetes Care Profile, is derived from the MDRTC's Understanding Management Practice.³⁸⁵ Patients are asked if they had received diabetes education, and if so then to rate their understanding of the following cardinal aspects of diabetes self-management: diet and glycaemic control, management of body mass, physical exercise, medication use, adherence to pharmacotherapy, foot care, diabetes-related complications, eye care, SMBG, and alcohol consumption.

The IDF guideline recommends that patients using insulin structure SMBG in line with their insulin therapy.⁴ For those patients using oral agents only, the IDF is less

prescriptive about SMBG but recommends that it should be ongoing and used to assess glycaemic control, especially for potential hypoglycaemia, in instances where modification to lifestyle and medication therapy occur, and in times of concurrent illness.⁴ The ADA suggest SMBG of three or more times daily for patients on multiple injections of insulin.

Scales that have been used to measure aspects of SMBG include a Visual Analogue Scale which was used to measure SMBG frequency in intensive insulin therapy in children and adolescents.⁴³⁷ A large Italian study of patients with DM2 investigated SMBG frequency by means of a questionnaire that included a six-point scale and a further question in another section of the questionnaire about the number of times SMBG had been performed in the past 14 days. The answers to the two questions were found to correlate strongly, thus confirming the reliability of data collected in this manner.⁴³⁸ The Blood Sugar Adherence Monitoring Questionnaire, which is informed by the MDRTC Diabetes Care Profile,³⁸⁵ asks patients if they self-monitor blood glucose levels and, if so, how often (days per week and times per day), and if they keep a record of their readings.

CHAPTER 5

RANDOMISED CONTROLLED TRIALS AND CONCEPTUAL FRAMEWORK

5.1 Introduction

A critical element of the research process relates to selecting an appropriate design for the study. A number of different study designs have been used to evaluate the services provided by pharmacists including randomised controlled trials (RCTs), quasi-experimental designs, pre-post studies, cohort studies and descriptive studies.⁴³⁹

Quasi-experimental designs, although weaker than RCTs, are used when randomisation is problematic. Non-random allocation is effected by a process of 'matching' in order to maximise group equivalence. Examples of the use of this design in pharmacy practice research include the Asheville Project, a well documented study of the long-term clinical and economic outcomes of a community pharmacy diabetes care program,¹⁹ which also assessed the factors affecting participation in and the benefits of a pharmaceutical care programme designed for patients with chronic conditions.⁴⁴⁰

Pre-post or before-and-after designs rely on the comparison of baseline and post-intervention data. While this design has been successfully used in a number of pharmacy studies,^{183,441} the lack of a control group may confound the results and thus be a limiting factor.⁴⁴²

Cohort studies follow patients longitudinally. A number of important diabetes-related studies have employed this design, including the UKPDS.⁸⁵ Other examples include a year-long observational study where pharmacists working in three university-based primary care clinics provided diabetes education and management services to a cohort of 191 patients with diabetes,⁴⁴³ and a study of a community pharmacy-based smoking cessation programme.⁴⁴⁴ A problem with this design, in the absence of a control group, is that it may not be possible to attribute an outcome to a particular antecedent intervention rather than to other variables.⁴⁴⁵

Descriptive studies are often used in pharmacy practice research and most studies that investigate patient counselling by pharmacists are descriptive.⁴⁴⁵⁻⁴⁴⁷ The survey of patient opinions about pharmacists discussed in Chapter 6 is a descriptive study.

5.2 Randomised controlled trials

A randomised controlled trial (RCT) has been defined as “a trial in which subjects are randomly assigned to one of two groups: one (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control) receiving an alternative (conventional) treatment.”⁴⁴⁸ The results of a RCT, which are derived from the comparative analysis of the two groups, are used to assess the effectiveness of the intervention.

The RCT is considered to be a ‘gold standard’, i.e. “provide the best evidence on the efficacy of health care interventions.”³⁵ A well designed healthcare-related RCT has the following features:⁴⁴⁸

- ❖ It should have a sufficient number of participants to allow for a high probability of detecting differences between treatments, should such differences exist.
- ❖ The participant sample should be apposite to the hypotheses being tested in order to ensure generalisability of the findings.
- ❖ Randomisation to control and intervention groups should be concealed in order to prevent selection bias.
- ❖ The researcher and participants should be blinded to group allocation so as to ensure that groups are treated equally in all respects save for the intervention to be applied.
- ❖ The researcher should be blinded to the allocation of the intervention and participants analysed within the group to which they were allocated irrespective of whether or not they experienced the intended intervention (i.e. subject to intention to treat analysis).
- ❖ Analysis should be focused on the research question that led to the trial (i.e. aligned with the a priori hypotheses). There should be no attempt to ‘trawl’ for significant differences.

- ❖ Given the potential for methodological flaws, it is important that every effort should be made to consult with an experienced researcher well versed in the design of RCTs early on in the process.

Furthermore, it is suggested that the Consolidated Standards of Reporting Trials (CONSORT) guidelines be referred to throughout the process.^{35,448}

RCTs, despite enjoying 'gold standard' status, are not without problems in evaluating healthcare services, and for this reason their use has, on occasion, been questioned⁴⁴⁹ for example, where there may be contextual issues in that the research setting may not necessarily reflect the real-world conditions in which patients and providers interact. Cultural and linguistic differences between the researcher and participants are potentially confounding issues, with the result that the sample may not be representative of the population at large and the results not generalizable. Furthermore, variabilities in the skill and expertise of providers involved in applying the interventions may have an influence on study outcomes.⁴⁵⁰ Selective participation by subjects, whether this occurs overtly or inadvertently, may jeopardise the generalisability of the findings.^{449,451,452} Willing participants may be more likely to adhere to a study protocol and thus provide a more complete set of data than would be the case in the wider population.⁴⁵¹

Blinding researchers and participants to allocation to either control or intervention is a major difficulty in RCTs, and shielding patients from the knowledge that they are receiving an intervention is often difficult. Patient awareness that they are participants in a study may give rise to the placebo effect.⁴⁵³ Other potential errors associated with a RCT include bias and chance. Selection bias, which occurs as a result of a systematic difference between the groups, and observer bias, which results when there are systematic differences between the groups in the way information is collected, are the main forms of bias encountered. Chance is a random error more likely to be a problem with small sample sizes.⁴⁴⁸

The CONSORT statement was originally developed for parallel group RCTs in which the unit of randomisation was the individual.³⁵ However, in some settings it is preferable to randomise organisationally-based units rather than individuals. These organisational units are referred to as 'clusters', and randomised trials involving these clusters are referred to as cluster RCTs.⁴⁵⁴ In the event that contamination of the control group is a

possibility (leading to biased estimates of effect size) then a cluster randomised design may be preferable. Cluster RCTs are more complex to design and are subject to more complex analysis and require larger numbers of participants in order to achieve a similar statistical power to that of individual RCTs.^{454,455}

A number of systematic reviews of pharmacist interventions in outpatient settings have included RCTs and in a number of instances there is good evidence of the value of interventions in both disease prevention and disease management.^{12,133,183,456-458} However, reviewers often reported methodological and other limitations. Beney et al,¹⁸³ in a Cochrane review that included RCTs, concluded that the interventions were often poorly defined, lacked patient outcomes data and cost-effectiveness data and had questionable generalisability. Roughead et al¹² noted that open allocation of participants to the groups and assessment of outcomes by investigators who were aware of the allocation, were common methodological limitations. The reviewers suggested that studies would be improved if pharmacists were not made aware of allocation, or alternatively if the pharmacy was designated as the unit of allocation and if independent reviewers were used to monitor outcomes.

Blenkinsopp et al¹³³ and Wubben et al⁴⁵⁸ noted that there were relatively few RCTs of interventions that were community pharmacy-based, with findings limited by design flaws, including high levels of selection bias. In a review of pharmacist interventions in diabetes management, Machado et al⁴⁵⁶ found that while a number of outcomes sensitive to pharmacist interventions were identified, too few studies were available for quantitative summary. A common thread running through the abovementioned reviews was the propensity for design flaws, the low numbers of community pharmacy-based RCTs and the recommendation for more rigorous research.

5.3 Complex interventions

The CONSORT statement was published as a guideline in an effort to improve the reporting of RCTs, most of which evaluated a single intervention (e.g. the effects of a medicine).²⁹⁶ However, there has been increased recognition of the need to submit non-pharmacological interventions to rigorous review. CONSORT in its original form was found to be inadequate in addressing these trials as they are often complex in design.²⁹⁶

Complex interventions are defined as being comprised of “*interventions that contain several interacting components*”.²⁹⁴ Examples include health promotion interventions aimed at individual patients or groups of individuals, strategies designed to promote the implementation of treatment guidelines, and those interventions aimed at effecting patient or healthcare provider behavioural change.²⁹⁵

Complex interventions are, by their very nature, difficult to develop, describe, standardise, administer and reproduce on a consistent basis, which makes the evaluation of these trials difficult.^{295,296} Further confounding influences which add to the complexity include contextual issues (i.e. local conditions), variations in provider expertise, available resources and time to devote to administering a trial, all of which may impact on the treatment effect of a given intervention.²⁹⁶

The United Kingdom Medical Research Council (UKMRC), in recognising the complexity of many interventions aimed at improving healthcare, published a revised guideline for the development and evaluation of RCTs for complex interventions entitled “*Developing and evaluating complex interventions: new guidance*”.²⁹⁴ Developing, piloting, evaluating, reporting and implementing complex interventions involves a number of stages and is likely to be time-consuming because of the non-linear nature of the process. Each stage is important and undue neglect of any stage may lead to trials of poor quality i.e. weak interventions that are difficult to evaluate and are less likely to be considered for implementation or implemented in practice.

The overall process of developing and evaluating a complex intervention has been summarised by the UKMRC as discussed below²⁹⁴

5.3.1 Developing an intervention

The development stage includes reviewing current evidence (preferably from systematic reviews), identifying or developing underpinning theory and modelling. Identifying or developing a theoretical understanding of the process of change is likely to require the collaboration of experts. Modelling a complex intervention, for example by conducting a pre-trial economic evaluation prior to undertaking a full-scale evaluation, is likely to benefit both the design and evaluation of the intervention as problems may be identified

in the early stages and remedied. It may even become apparent that the anticipated full-scale evaluation is unwarranted.

In developing a complex intervention, consideration should be given to:

- ❖ the relationship between what needs to be done, what outcome is expected and how such an outcome is likely to lead to change
- ❖ ensuring that sound theory and existing evidence underpins the proposed intervention, and that the intervention is likely to be cost-effective and both implementable and replicable.

Lack of effect may be due to implementation problems rather than to the apparent ineffectiveness of an intervention, and a comprehensive appraisal of the implementation process is required to pre-empt problems at this stage. Increased variability may necessitate larger sample sizes and, in some circumstances, it may be advisable to consider the use of cluster RCTs rather than RCTs randomised at the level of the individual. The study protocol may need to accommodate local conditions and be adapted accordingly. The key questions relating to complex interventions include consideration of (i) how the intervention works i.e. the key success factors and the mechanism of exerting effect, and (ii) the likelihood of the intervention working in everyday practice.

5.3.2 Piloting and feasibility

Key aspects of this stage include testing procedures, estimating the ability to recruit and retain participants and determining sample size. It is suggested that a pilot study (or a series of studies in order to progressively refine the process) be undertaken in order to ensure the overall feasibility of the study given the assumptions made with regard to effect sizes, recruitment, retention and other key variables are likely to impact on the main study.

5.3.3 Evaluating the intervention

Randomisation should wherever possible be considered in experimental designs as it is the most robust method of preventing selection bias. Should an individually randomised

parallel group design not be feasible, then consideration may be given to using either a randomised cluster trial (population level intervention), a stepped wedge design (the whole population receives the intervention but with randomisation occurring during phased implementation of the intervention), preference trials (treatment allocation based on patient preference), randomised consent trials (randomisation of subjects prior to obtaining consent) or N-of-1 trials (randomised trial in single or individual subjects).

An essential aspect of the evaluation process relates to the choice of outcomes, which should be based on a sound understanding of the theoretical underpinning of the intervention. A single primary outcome together with a small number of secondary outcomes may be the most uncomplicated manner in which to statistically view the data. However, this may not allow for the most effective assessment of an intervention, especially where the effects of the intervention may be observed in a number of areas. Measures adopted (e.g. self-report, biochemical, provider-report, etc.) should be appropriate for the design of the evaluation.

An overall assessment of the effectiveness of the intervention and developing an understanding of the process of behavioural change forms the basis of the evaluation stage. In pursuance of the Economic Clinical Humanistic Outcomes approach to interventions,¹⁹ it is suggested that an economic evaluation of the intervention be included as a cost-benefit analysis is likely to be a major factor in deciding on the possible widespread implementation of an intervention. Where possible, process evaluation should be included as this allows for the monitoring of the delivery of the intervention as well as the overall conduct of the evaluation. Process evaluation also may offer some explanation with regard to any discrepancies that may arise between the anticipated and observed outcomes, as well as provide some understanding relating to the local context and insight into the overall implementation process.

5.3.4 Reporting of the study

The report should be presented in an accepted format (e.g. for a RCT, as set out in the CONSORT statement²⁹⁶) and with as much detail to allow for careful evaluation and possible replication studies or broad-based implementation. Wherever possible, the

results should be discussed in the context of existing research, preferably systematic reviews.

5.3.5 Implementation

Despite the allocation of substantial resources to interventions designed to advance the cause of healthcare, translating research into practice remains a challenge as is demonstrated by the numerous examples of evidence-based research that are only partially adopted in practice, if at all.⁴⁵⁹ The key issues for the implementation stage include ensuring that the results are made available in a readily accessible format and that they are explicit and detailed enough to be able to present persuasive argument to policy and decision-makers. Post-implementation surveillance should include ongoing (long-term) practice-based process evaluation and the continued monitoring of outcomes. The UKMRC note that *“while some aspects of good practice are clear, methods for developing, evaluating and implementing complex interventions are still being developed, and on many important issues there is no consensus yet on what is best practice.”*²⁹⁴

As previously mentioned, the CONSORT group recognised the inadequacy of the original statement to fully address complex interventions such as non-pharmacological interventions involving behavioural change. This limitation was subsequently addressed in an extended version of the CONSORT statement, which now includes a comprehensive checklist for reporting non-pharmacological RCTs.²⁹⁶ This checklist is a useful tool in the hands of a researcher contemplating a RCT of a complex intervention, especially when read in conjunction with the abovementioned UKMRC guideline on complex interventions.²⁹⁴

5.4 Conceptual framework: a diabetes care plan

In developing a disease management taxonomy, Krumholz et al³³⁷ noted that pharmacists are well positioned to deliver disease management interventions. Therapeutic guidelines and treatment protocols for most chronic diseases include long-term pharmacotherapy. The almost universal use of medication as an important tool in the management of chronic diseases facilitates relatively frequent encounters and interaction between patients and pharmacists.^{1,11} It is the potential for providing care

inherent in these encounters, especially in supporting patient self-management initiatives, together with the pharmacist's expertise as a medication specialist, that lends substance to the claim that pharmacists are well positioned to contribute to disease risk reduction and consequently positively influence patient outcomes in DM2.^{1,9,36,175,460,461}

The hypothesis and the conceptual framework of the intervention for this study has largely been underpinned by the practice of pharmaceutical care, and the demonstrated value of those CPS that are patient orientated.^{9,19,33,147,175,462} The process of providing care to individuals with DM2 is complex and long-term, requiring the collaboration of multidisciplinary healthcare providers in support of patient self-management.^{4,346,415,419,432} Given the primacy of self-management in diabetes care,^{314,389} it follows that CPS should be designed to support patients in their self-management endeavours. Furthermore, given the professional role of the pharmacist, it is reasonable that matters relating to the use of medication by patients should be the focus of such services.

The CPS that informed the conceptual framework in this study were collated into a diabetes-related pharmaceutical care plan,⁵ referred to as a diabetes care plan (DCP) in this manuscript. The DCP, which is comprehensively described in Chapter 7, provides the intervention framework for the study. The plan was developed and informed by the practice of pharmaceutical care, diabetes-related CPS identified from the literature and by my own experience as a community pharmacist, and was refined after consultations with a number of health professionals from diverse disciplines. The DCP served to bridge the divide between theoretical evidence from literature and the CPS provided during the intervention phase of the study in an attempt to translate various aspects of research into practice.³⁰⁶

The development and evaluation of the DCP is schematically represented in Figure 5.1. The core elements of the DCP framework include (i) the existing evidence regarding pharmacist-directed diabetes care interventions (Section 3.3.1), (ii) the theories and models underpinning changes in patterns of practice by pharmacists (Section 4.3), (iii) the training and education of pharmacists to enable them to effectively develop and evaluate interventions (Section 4.2), and (iv) the development of appropriate clinical and patient education and counselling interventions, which are discussed below in Section 5.4.1 and Section 5.4.2. The aim of the DCP is to facilitate improved patient health

outcomes by supporting patient self-management both in terms of optimising adherence to prescribed pharmacotherapy and agreed non-pharmacologic self-care recommendations (Section 2.6 and Section 4.5).

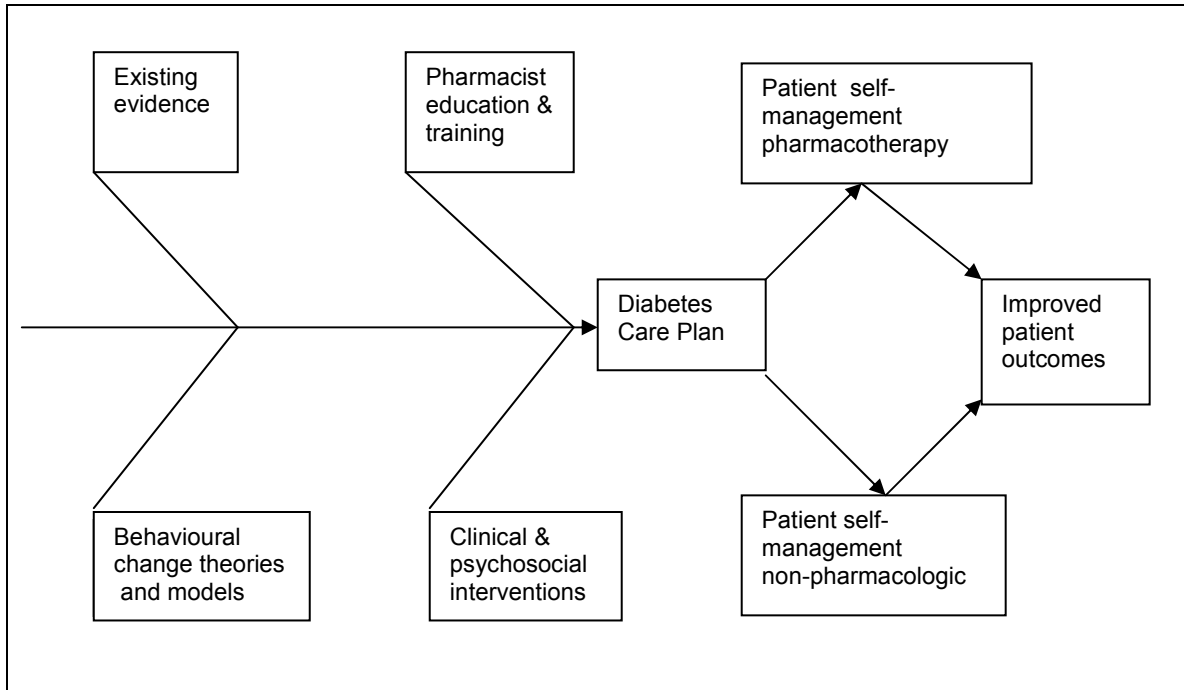


Figure 5.1 The conceptual framework of a diabetes care plan intervention

No single model appears to exist that fits the DCP, and therefore a framework was developed by integrating the following guidelines, models and methods:

- ❖ “Good Pharmacy Practice Standards” from the South African Pharmacy Council.⁶ These standards or rules define good pharmacy practice in South Africa.
- ❖ “Revised guidelines for the diagnosis and management of type 2 diabetes mellitus for primary healthcare in 2002”, from the Society for Endocrinology Metabolism and Diabetes of South Africa(SEMDSA).¹⁰⁵ This guideline informed aspects of the clinical intervention.
- ❖ “Global Guidelines for Type 2 Diabetes 2005”, from the International Diabetes Federation (IDF).⁴
- ❖ “ASHP Guidelines on Pharmacist-conducted Patient Education and Counseling”, from the American Society of Health-System Pharmacists. These guidelines offer a practical approach to the medication review process.¹⁷²

- ❖ The “Chronic Care Model”, which conceptualises and positions collaborative patient-centred care and empowered patient self-management (Figure 3.2).¹⁵⁵
- ❖ The “5 A’s Behavioural Change Model”, which has been adapted for self-management support in chronic disease.²⁷⁵
- ❖ The method of “Motivational Interviewing”, an evidence-based brief counselling method appropriate for the healthcare setting of community pharmacy.^{171,264}

The DCP, which links the key clinical and psychosocial aspects of disease risk reduction in DM2 with the practice of pharmaceutical care provided by community pharmacists, was comprised of two interdependent elements, a clinical intervention and a patient education and counselling intervention. While they are described as separate elements for the purposes of this study, in practice the boundaries between the two are blurred with each mutually influencing the other.

5.4.1 Clinical intervention

Pharmacists have demonstrated their ability to monitor clinical indicators and other variables such as adherence to pharmacotherapy, body mass index and satisfaction with pharmacy services, and to use the ensuing data to influence patient adherence to therapies and to effect improvements in health outcomes.^{9,38,173} The key elements of the clinical intervention included medication review,^{158,172} diabetes-related needs and goals analysis,⁴ and monitoring, evaluation and review of clinical and other variables.¹²⁶

The ASHP guidelines on pharmacist-conducted patient education and counseling informed the medication review process.¹⁷² Medication review is a fundamental element of the practice of pharmaceutical care.^{158,172,463,464} The objective of this key aspect of the clinical intervention was to identify and address any existing or potential medication problems.^{6,17,462}

The SEMDSA and IDF DM2 guidelines served to inform and benchmark patient diabetes-related goals.^{4,105} Many other organizations provide excellent patient resources and materials,⁴⁶⁵ and pharmacists are able to support self-management by facilitating access to these materials and resources, as well as by appropriately referring patients to other healthcare providers.^{36,158,466,467}

The monitoring intervention, which involves the collection, interpretation and discussion of the data, need not be time consuming.^{92,173,355} The prescription refill encounter presents the pharmacist with an ideal opportunity to monitor key clinical indicators and to optimise therapy and self-management regimens,^{10,468} Telephonic follow-up of patients between pharmacy visits has been shown to be a cost-effective monitoring and adherence- promoting intervention.^{358,469} Further remedial action may include patient referral.^{36,178,470}

5.4.2 Patient education and counselling intervention

The theoretical framework on which the principal aspects of the patient education and counselling intervention is based is informed by the Motivational Interviewing method²⁶⁴ (Section 4.3.2) which has been adapted for use in community pharmacy.^{171,269,270} Patient education and patient counselling are terms that have been used interchangeably to define a category of pharmacist activity and collectively they are the CPS most often described in the pharmacy literature.⁴⁷¹ For the purposes of this study these are discussed as two separate but interdependent activities.

Patient education is viewed primarily as a collaborative interaction between pharmacist and patient in order to address deficiencies in diabetes-related knowledge, rather than a one-way didactic intervention.^{182,472} Enhanced patient knowledge of DM2 and an understanding of the significance of clinical indicators may contribute to improved diabetes self-management.^{32,36,466}

Patient counselling is intended to encourage and facilitate the empowerment of patients to make informed decisions about medication use and other self-management behaviours.^{225,357,466} It is associated with fostering good relationships between patients and pharmacists,³² with informing the process of eliciting patient needs and goals,^{20,473,474} and with facilitating the identification of barriers to diabetes self-management.^{338,347,461} In counselling patients, pharmacists should be culturally sensitive, take cognisance of patient health beliefs,^{272,341,473} and encourage family support.^{397,475}

5.4.3 Research question, hypotheses, aims and objectives

This study is important given that community pharmacists are a key resource in the South African healthcare continuum, and given that South African pharmacists have begun to extend their healthcare reach and provide pharmaceutical care to the chronically ill.^{137,4476}

The rationale for the study and the development of the research problem and main hypothesis are discussed in Section 1.1 and Section 1.2 respectively. In formulating the research question, “Are South African community pharmacists able to positively influence patient adherence and surrogate health outcomes in DM2?”, the following three related hypotheses were considered:

- ❖ The relationship between the patient and pharmacist is such that pharmacists who have received appropriate diabetes-related continuing education are well positioned to provide diabetes-related CPS.
- ❖ Patients with DM2 who have been exposed to pharmacist-delivered individualised diabetes-related interventions are more likely to adhere to their therapies and self-management recommendations than patients who only experience usual or standard care.
- ❖ Improved patient health outcomes in DM2 may be reflected as improvements to the surrogate health outcomes such as glycated haemoglobin (primary endpoint) and other clinical indicators (secondary endpoints).

The abovementioned hypotheses are examined by means of a consumer survey described in Chapter 6, and a randomised controlled trial of a diabetes care intervention described in Chapter 7 and discussed in Chapter 9.

The aims and objectives of the consumer survey and the diabetes care study are as follows:

Aim of the consumer survey

To establish if foundational support exists within the insured patient – community pharmacist dyad for the provision of CPS.

Objectives of the consumer survey

These are described in more detail in Section 6.2. The objectives are concerned with key aspects of the professional relationship existing between the patient and the pharmacist, i.e. the provision of medication counselling and disease-related information and other CPS (i.e. monitoring of disease indicators), patient satisfaction with pharmacist advice, pharmacist reimbursement for CPS and the relative accessibility of pharmacists.

Aim of the diabetes care study

To conduct an empirical evaluation of pharmacist influence on surrogate health outcomes in DM2, as well as patient adherence to therapy and other self-management recommendations, by means of a randomised controlled trial.

Objectives of the diabetes care study

- ❖ To train pharmacists, using a distance education module, to deliver advanced diabetes care services.
- ❖ To assess the influence of community pharmacists on surrogate health outcomes including glycated haemoglobin, blood lipids, serum creatinine, blood pressure and body mass index.
- ❖ To assess the influence of community pharmacists on diabetes self-management including adherence to pharmacotherapy and self-care recommendations and monitoring practices.
- ❖ To assess the influence of community pharmacists on patient medication-related beliefs, diabetes-related knowledge, patient empowerment and satisfaction with diabetes care.
- ❖ To compare baseline versus post-baseline data of patients at goal for certain variables in terms of the national guideline for DM2, published by the Society for Endocrinology, Metabolism and Diabetes of South Africa.

CHAPTER 6

THE DISCOVERY HEALTH SURVEY: PATIENT OPINIONS AND PERCEPTIONS OF PHARMACY

6.1 Introduction

Internationally, pharmacists practice pharmaceutical care and provide CPS.^{12,20,147,149,456} However, a search of the literature using the terms, “pharmaceutical care OR cognitive pharmaceutical services AND Africa” revealed very few studies describing or investigating the practice of pharmaceutical care in African healthcare settings and there was a total absence of any research relating to the value placed by consumers on these services in South African community pharmacy practice. It is obvious, therefore, that further research is urgently required if the profession is to assess, plan, implement and evaluate its pharmaceutical care offerings in an evidence-based manner. Ad-hoc attempts to implement pharmaceutical care without informed preparation and valid assessment does both the patient and the profession a disservice.

Pharmacist co-ordinated interventions designed to promote patient adherence to long-term therapies and self-care recommendations in DM2 are a function of pharmaceutical care.⁴⁷⁷ Inherent in the practice of pharmaceutical care are the CPS associated with the use of medication by patients and the provision of appropriate health-related empowering information and support by pharmacists.^{24,360,478-480} The effective provision of CPS is dependant on concordant and satisfying relationships existing between patients and empathetic pharmacists.^{9,365,481,482}

There are a number of factors influencing the patient-pharmacist relationship which, in turn, impact on the pharmacist’s ability to influence therapeutic adherence. Importantly, these include easy access to competent and trusted pharmacists.^{133,137,164} Pharmacists, on the other hand, while recognising the need for and value of pharmaceutical care, are faced with a number of barriers that prevent the widespread implementation of the practice at community pharmacy level.^{12,133,151,476,483,484} Pharmacist reimbursement for CPS remains a major barrier. Perceived value and satisfaction with services on the part of patients are key determinants of the demand for the provision of those CPS.^{9,12,152,153}

The survey was therefore designed to investigate if an evidence-based foundation existed within the South African community pharmacy practice dynamic to support the provision of cognitive pharmaceutical services, given that the profession in South Africa largely relies on off-shore evidence and anecdotal information with regard to key aspects of the practice of pharmaceutical care.¹⁷

6.2 Aim and objectives

The aim of the study was to determine if support for aspects of pharmaceutical care exists within the dynamic of South African community pharmacy practice. The objectives were to investigate patient opinion regarding the provision of prescription medication, the provision of and satisfaction with cognitive pharmaceutical services (including medication counselling, disease-related information and clinical services such as the monitoring of health-related variables), patient willingness to pay for the provision of such services, and pharmacist accessibility.

6.3 Methodology

6.3.1 Study setting

Discovery Health (Discovery) is one of South Africa's largest health insurers, currently providing healthcare benefits ('medical aid') to a membership base in excess of two million people (hereafter referred to as 'patients'). This insurer was approached in preference to other South African health insurers as it has a large pool of potentially available patients, a good relationship exists between senior executives of the company and the researcher and Rhodes University, and a Discovery executive had previously indicated interest in the project when it was first mooted and promised assistance in facilitating company support.

6.3.2 Survey instrument

The conceptual framework underpinning the survey was developed from personal experience of 25 years of community pharmacy practice. This ontology was augmented epistemologically by the health belief model (previously discussed in Chapter 4 Section

4.3), the pharmaceutical care model,²³ and relevant aspects of the primary provider theory,⁴⁸⁵ a paradigm for patient-centred satisfaction which is based on the following: *“only patients judge quality, a network of satisfaction constructs where all measures are patient-centered, patients have a priori hierarchy of expectations, primary providers have the greatest utility to patients and satisfaction is set in motion at the nexus of provider power and patient expectations.”*⁴⁸⁵ In addition, a framework for understanding the utilisation of pharmacy services proposed by Hassell et al,⁴⁸⁶ which draws on a number of models in order to explain help-seeking and health services utilisation, was considered. These models, which include the health belief and socio-behavioural models,⁴⁸⁶ incorporate factors more in keeping with community orientated primary care such as patient clinical and socio-economic factors, perceptions of the professional role of the pharmacist, the efficacy of self-care, lay referral (i.e. by family or friends), the siting of pharmacies, as well as organisational factors (e.g. pharmacist access), financial and other resource factors.

The draft questions, informed by both personal experience in community pharmacy practice and the abovementioned constructs, were developed and refined after consultation with colleagues in the Faculty of Pharmacy at Rhodes University. The design, operationalisation and management of the webform version of the instrument were undertaken by the Webmaster at the university.

The questionnaire was tested for validity and reliability by a process that included a review of all questions by two experienced pharmacists, professional pharmacy colleagues at the university, and by piloting the questionnaire in a sample of 20 randomly selected medically insured employees of the university.^{449,485} This process included ensuring that the questionnaire was able to collect the information required to meet the survey objectives, that the questions were unambiguous, easily answered and that they reflected the theoretical constructs underpinning the survey.

The pilot study was conducted in July 2004. Twenty Rhodes University employees were randomly selected by name from the university's internal telephone directory. All university employees listed in the directory with a surname beginning either with the letter A or B, and who were either members or the dependants of members of a registered medical aid scheme, other than any employee of the Faculty of Pharmacy,

were eligible to participate in the pilot. The researcher identified and telephoned prospective respondents by selecting every third surname. Four potential respondents declined to participate in the pilot.

The following statement was used to introduce the researcher and explain the survey during the pre-test:

“Good day. My name is Peter Hill and I am a post-grad student in the faculty of pharmacy. As part of my research I need survey medical aid members with regard to aspects of their relationship with community pharmacists. If you are a member of a medical aid, are you willing to give me a few minutes of your time to answer a few questions for a pilot survey?”

Data were electronically captured using a beta version of the electronic form. The pilot confirmed that the survey was easily administered, that the length of the survey and number of questions was acceptable, and that generally the questions were unambiguous and easily answered. Only one question out of a total of 39 required changes: question 2.4.1, was amended to include a “more than once a month” option. There was also a technical design problem that required attention. The pilot revealed that once the form was uploaded to the host server by selecting the ‘submit’ button, it was necessary to exit and then re-enter the website before a new form appeared on the computer monitor. These problems were attended to by the Webmaster and the webform was declared ready for use in the Discovery survey.

6.3.3 Study population

All Discovery patients residing within the borders of South Africa were eligible to participate in the survey. Discovery provided the researcher with access to two trained call-centre operators, working in their outbound call-centre, between the hours of 08:00 and 17:00 for 10 working days in September 2004.

A data analyst at Discovery was briefed by the researcher and she was instructed to identify a convenience sample of patients from which a random sample would be identified. Discovery advised that it would not be possible to include their entire active claims database in effecting a sample size calculation. A pragmatic approach was

therefore adopted and the first 3000 patients who submitted medical aid claims during a defined six month period in 2004 were identified. From this sample, a total of 1000 patients were randomly selected for interview using an online random number generator.⁴⁵⁹ The decision to randomly select 1000 patients was based on a pre-survey estimation of the maximum number of patients that two call-centre operators would be able to telephonically survey during the 10 working days allocated to the researcher by Discovery. The call-centre operators and researcher were blinded to the selection of the initial sample of 3000 and to the subsequent randomisation of the final sample of 1000 patients.

6.3.4 The survey

The study protocol was approved by the Rhodes University Ethical Standards Committee prior to the commencement of the survey.

The call centre operators were briefed by the researcher and provided with a written script to ensure a degree of uniformity in their approach to patients. The operators were given two days to perfect telephone etiquette and to familiarise themselves with the survey questions and the capturing of patient data by telephoning and surveying members not included in the initial sample of 3000.

At the end of the two day trial period, the list of the 1000 randomly selected patients was equally divided between the two operators. Patients were telephoned and advised that the survey would take the form of a telephonic questionnaire and that the research would assist in informing the design and implementation of future patient-centred pharmacy services. Furthermore, they were advised that their participation was voluntary, that their personal details would not be captured and that all information provided would be treated as confidential. Responses were electronically recorded on the webform by the operators and each completed questionnaire was automatically saved to the university web-server. The operators experienced intermittent Internet connectivity problems during the 10-day survey period, with the result that a number of completed questionnaires were duplicated. A total of 703 responses were recorded during the 10 day period and of these, 75 responses were identified as duplicates and

deleted by the Webmaster, giving a total of 628 valid responses which were included in the final data set.

Each operator kept a log of the number of telephone calls made each day, the number of positive responses, the number of patients that declined participation and a record of the reasons why they declined participation. A total of 59 patients (8.6%) refused to participate in the survey. Insufficient time available to answer questions was the main reason given for non-participation. Examination of the logs revealed very little difference in performance between the two operators, who administered 318 and 310 questionnaires respectively.

6.3.5 Data analysis

Data were analysed using Statistica software (Stasoft Inc). Pearson's chi-squared test of independence was used to test for gender, age and ethnic group effects shown in Table 6.1, for pharmacist-related categorical variables in Table 6.2 and in examining the association between patient demographic and pharmacist-related variables in Table 6.4. The level of significance in all instances was set at 5%.

6.4 Results

As Table 6.1 reflects, there were significantly more female (63.9%) than male (36.1%) patients (Chi-squared test, $p < 0.0001$) and significantly more White patients (64.6%) than Black patients (22.9%), patients of Asian descent (7.3%) and Mixed-race patients (5.1%) (Chi-squared test, $p < 0.0001$). There were significantly fewer patients in the age groups less than 30 years old (12.1%) and over 65 years old (13.7%), than for those aged 30-45 years old (37.4%), and 46-65 years old (36.8%) (Chi-squared test, $p < 0.0001$).

Table 6.1 Patient demographics

Variable	N (%)	p value
		Chi-squared test
Gender		
Male	227 (36.1)	
Female	401 (63.9)	
		p < 0.0001
Ethnic group		
Asian	46 (7.3)	
Black	144 (23.0)	
Mixed-race	32 (5.1)	
White	406 (64.6)	
		p < 0.0001
Age		
<30 years old	76 (12.1)	
30-45 years old	235 (37.4)	
46-65 years old	231 (36.8)	
>65 years old	86 (13.7)	
		p < 0.0001

Approximately 80% of patients (N=507) received prescription medicines (Table 6.2), with a significant majority having received them from pharmacists only (60.2%). Just over a quarter (25.8%) received medicines from doctors only and the balance of 14.0% reported that they received prescription medicines from both pharmacists and doctors (Chi-squared test, $p < 0.0001$). Those patients who had their medicines dispensed by pharmacists were significantly less likely to be counselled on the use of the medicine and to be provided with information on their diseases or conditions (78.5%), than were those patients who made use of the services of dispensing medical practitioners (98.5%) (Chi-squared test, $p < 0.0001$).

While less than half of the patients (46.2%) consulted pharmacists for advice on health related matters, there was a significant difference between those that rated the advice as good (87.9%) and those that considered it to be adequate (12.1%) with none rating the advice provided as poor (Chi-squared test, $p < 0.0001$).

Table 6.2 Patient-provider variables

Variable	"Yes" N (%)	p-value Chi-squared test
Received prescription medicines (N=507)		
from a pharmacy only	305 (60.2)	
from a dispensing medical practitioner only	131 (25.8)	
from both pharmacy and dispensing medical practitioner	71 (14.0)	p <0.0001
Received counselling and information from healthcare provider		
when medicine received from a pharmacist (N=376)	295 (78.5)	
when medicine received from a medical practitioner (N=202)	199 (98.5)	p <0.0001
Consulted pharmacist for advice on health related matters (N=290)		
rated advice as "Good"	255 (87.9)	
rated advice as "Adequate"	35 (12.1)	
rated advice as "Poor"	0 (0)	p <0.0001
Willing to pay for cognitive services (N=625)		
yes	290 (46.4)	
no	335 (53.6)	p = 0.078
Rating of relationship with pharmacist (N=602)		
good	412 (68.4)	
adequate	88 (14.6)	
poor / no relationship	102 (17.0)	p <0.0001
Healthcare provider access (N=627)		
pharmacist most accessible	229 (36.5)	
medical practitioner most accessible	389 (62.0)	
nurse practitioner most accessible	9 (1.5)	p <0.0001

The term "professional services" was defined before patients were asked, "Do you think that pharmacists should be paid for providing professional services?" There was no significant difference (Chi-squared test, p=0.078) between those patients who believed that pharmacists should be paid (46.4%) and those who said that they should not (53.6%).

In considering the quality of the relationship between the patient and the pharmacist, a significantly higher percentage of patients considered their relationships with their pharmacists to be good (68.4%), as opposed to adequate (14.6%) or poor/no relationship at all (16.9%) (Chi-squared test, $p < 0.0001$).

In an attempt to standardise the definition of “healthcare provider access” used in the context of the survey, the operators defined accessibility as “conveniently situated, readily available to talk to, gives free advice or advice that you would be willing to pay for”. Table 6.2 shows that a significantly higher percentage of patients (62.0%) rated medical practitioners as being more readily accessible than pharmacists (36.5%) (Chi-squared test, $p < 0.0001$).

Table 6.3 shows that approximately 40% of patients said that their pharmacy either had an in-house clinic (39.1%) and/or employed the services of a nurse (38.4%). In terms of accessing monitoring services, approximately 10% of patients had had their blood pressure (10.6%) and cholesterol (10.5%) monitored in a pharmacy. Fewer patients had their blood glucose (4.3%) and body mass (2.6%) measured by pharmacy staff and 5.3% said that they availed themselves of a pharmacy-based vaccination service.

Table 6.3 Pharmacy-provided clinical services	
Variable	“Yes” N (%)
Pharmacies providing clinical services (N=578)	
pharmacy has an in-house clinic	226 (39.1)
pharmacy employs a nurse	222 (38.4)
Used monitoring and vaccination services	
blood pressure (N=611)	65 (10.6)
cholesterol (N=610)	64 (10.5)
blood glucose (N=607)	26 (4.3)
body mass (N=605)	16 (2.6)
vaccination (N=606)	32 (5.3)

Table 6.4 shows the association of demographic data with selected pharmacist-related variables. Significant differences are reported for gender and race for the patients who said that they received prescription medicines, with proportionately more females (83.3%) than males (76.2%) having received prescription medicines ($p=0.033$), and more Whites (89.9%) than Asians (82.6%), people of Mixed-Race (78.1%) and Blacks (54.9%) ($p<0.0001$).

Table 6.4 Association of demographic and pharmacist-related variables					
Variable	Received prescription medicines	Received counselling and information from pharmacist	Willing to pay for cognitive services	Relationship with pharmacist rated as 'good'	Provider access: pharmacist most accessible
	N (%)	N (%)	N (%)	N (%)	N (%)
Gender					
Male	173 (76.2)	97 (78.2)	110 (48.7)	148 (69.8)	69 (30.4)
Female	334 (83.3)	198 (78.6)	180 (45.1)	264 (67.7)	160 (39.9)
p value ^a	0.033	0.568	0.391	0.692	0.054
Ethnicity					
Asian	38 (82.6)	24 (82.8)	26 (56.5)	36 (81.8)	22 (47.8)
Black	79 (54.9)	42 (76.4)	56 (39.2)	54 (42.5)	46 (31.9)
Mixed-race	25 (78.1)	10 (55.6)	13 (40.6)	16 (53.3)	8 (25.0)
White	365 (89.9)	219 (80.0)	195 (48.3)	306 (76.3)	153 (37.7)
p value ^a	< 0.0001	0.084	0.116	< 0.0001	0.002
Age					
<30	43 (56.6)	25 (75.8)	30 (39.5)	31 (41.9)	35 (46.1)
30-45	173 (73.6)	102 (72.9)	102 (44.0)	131 (60.1)	105 (44.7)
46-65	211 (91.3)	126 (83.4)	118 (51.1)	181 (80.1)	76 (32.9)
>65	80 (93.0)	42 (80.8)	40 (46.5)	69 (82.1)	13 (15.1)
p value ^a	< 0.0001	0.125	0.256	< 0.0001	< 0.0001
^a Chi-squared test					

There was a significant difference in prescription medicine utilisation between the oldest and youngest groups. Amongst the patients in the over 65 year-old group, 93.0% reported that they received prescription medicines, whereas only 56.6% of the under 30 year-old group had received prescription medicines (Chi-squared test, $p<0.0001$).

Males (78.2%) and females (78.6%) were equally likely to receive counselling and information from pharmacists (Chi-squared test, $p=0.568$). There was no significant difference ($p=0.084$) in the provision of counselling and information to the different ethnic groups with approximately 80% of patients reporting that they received these services. Those most likely to receive counselling and information were in the age groups 46-65 years (83.4%) and over 65 years of age (80.8%)(Chi-squared test, $p=0.125$).

There was no significant difference between male and female responses in supporting pharmacist compensation (48.7% and 45.1%, respectively) (Chi-squared test, $p=0.391$). Although patients of Asian descent (56.5%) were more likely to support pharmacist reimbursement and Blacks least likely, (39.2%) the difference between ethnic groups was not found to be significant (Chi-squared test, $p=0.116$). Similarly, there was no significant difference between the age groups for this variable (Chi-squared test, $p=0.256$).

In investigating the association of pharmacist reimbursement with the patient's relationship with the pharmacist (not reflected in a table), it was noted that of the 290 patients who supported pharmacist reimbursement, a significant percentage (78.3%) categorised their relationship with their pharmacist as good, whereas significantly fewer who stated that pharmacists should not be compensated (54.9%), described their relationship with their pharmacist as good (Chi-squared test, $p<0.0001$).

Both females (67.7%) and males (69.8%) were equally likely to view their relationships with pharmacists as good (Chi-squared test, $p=0.692$). Asian patients (81.8%) and Whites (76.3%) were significantly more likely to consider their pharmacist relationships as good than were the other ethnic groups (Chi-squared test, $p<0.0001$). A significantly lower proportion of Black patients (57.5%, $n=73$) said that their relationships were either average, poor, or that they did not have relationships with pharmacists (Chi-squared test, $p<0.0001$).

There was a significant association between age and the perceived quality of patient-pharmacist relationship, with a majority (82.1%) of those over 65 years of age reporting a

good relationship with their pharmacist. This was followed by 80.1% in the age group 46-65 years-old, after which the approval rating dropped significantly to 60.1% in the group between 30 and 45 years of age, with a further drop to 41.9% for patients under the age of 30 (Chi-squared test, $p < 0.0001$).

Table 6.4 shows that although more females than males (39.9% vs 30.4%) were likely to consider pharmacists to be the most accessible healthcare provider, the difference was not significant (Chi-squared test, $p = 0.054$). Asians (47.8%) were significantly more likely to consider pharmacists more accessible than were Whites (37.7%), Blacks (31.9%) and people of Mixed-Race (25.0%) (Chi-squared test, $p = 0.002$). There was a significant difference across age groups for those participants who viewed pharmacists as being most accessible. The older age groups were less likely to consider pharmacists to be the most accessible healthcare provider than were the two younger age groups Chi-squared test, ($p < 0.0001$).

The association of patient-pharmacist relationship with healthcare provider accessibility (not shown in a table) was found to be a significant one, in that 41.1% ($n = 169$) of the participants who rated their relationships as good said that pharmacists were the most accessible healthcare providers, whereas only 21.9% ($n = 21$) of those who reported 'no relationship' with pharmacists held similar views (Chi-squared test, $p < 0.0001$).

6.5 Discussion

The General Household Survey for 2004, published by Statistics South Africa,⁴⁸⁸ revealed that less than 15% of the population had health insurance at the time of the Discovery patient survey, therefore comparing survey data with these national demographic data serves little purpose. A comparison of the study data with the national insured data revealed that the study population was not demographically representative. For example, national insured data revealed that 49% of this population was under the age of 30 years old, compared with 12% in the study. Similarly, 44% of the total insured population were White compared with 65% in the study. The differences between the national insured and study demographics may be due to the market segmentation strategy adopted by Discovery in marketing their product offering i.e. targeting specific groups of people thought to limit Discovery's exposure to insured benefit (financial) risk.

The importance of pharmacotherapy in the therapeutic continuum is evidenced by the data that reveals that more than 80% of patients surveyed used prescription medicines. This high proportion supports the notion of community pharmacists being opportunistically positioned to engage with patients on lifestyle and other health-related matters.⁴⁹⁰ Changes within healthcare systems, especially changes driven by increased patient access and patient demand for services and information, as well as increased costs, have caused pharmacists in various practice settings to investigate and develop health promotional aspects of pharmaceutical care that may be unrelated to the dispensing of medication.⁴⁹⁰ Research from around the world indicates that pharmacists are engaged in a variety of health promotion practices,^{12,147,173,491} and that patients value the contributions that pharmacists make in this regard.^{9,12}

In South Africa, medical practitioners may dispense medicines to their patients provided they have been licensed to do so.⁴⁹² The licensing process involves a competency-based examination conducted under the auspices of the National Department of Health. Currently the number of registered self-dispensing medical practitioners exceeds the number of registered community pharmacists by a ratio exceeding two to one (personal communication J Bothma, Pharmaceutical Society of South Africa). Despite this ratio, almost two thirds of all prescription medicines provided to the patients surveyed were dispensed by pharmacists.

Organised pharmacy in South Africa, as represented by the South African Pharmacy Council and the Pharmaceutical Society of South Africa, has long argued that pharmacist-only dispensing provides essential oversight with regard to the use of prescription medicines and that there should be a clear functional separation between the prescribing and dispensing of medicines. Their position has been that pharmacists provide patients with a superior level of CPS than do doctors who dispense medication.⁴⁹³ The survey, however, suggests that patients may not support this perception, and this should be of concern to the profession in South Africa.⁶

The results suggest that while more than three quarters of Discovery Health patients were counselled on the use of medicines and provided with disease-related information, this was not happening at a level commensurate with the pharmacy profession's position

on pharmaceutical care.^{6,23} It is unacceptable that at least two out of every 10 patients leave the country's pharmacies armed with powerful pharmacotherapeutic agents but without having been adequately counselled on their use. This finding, when considered in conjunction with the unfavourable finding on healthcare provider accessibility, demands of pharmacists further research and remedy.

There is growing per capita workload for pharmacists, who consequently have less and less time available to spend on patient-centred CPS. This unsatisfactory situation is largely due to the cumulative effects of community pharmacy consolidation, mainly as a result of the closure of small independent pharmacies and the advent of large corporately owned pharmacies, increased administration brought about by the advent of managed care, a national shortage of pharmacists (fuelled by the continuing emigration of pharmacists⁴⁹⁴), as well as improved access to insured healthcare by individuals from previously disadvantaged communities.

A sizeable percentage of patients (≈40%) stated that the pharmacies they frequented offered certain clinical services. Although advances in technology relating to point-of-care biochemical testing are increasingly bringing investigative interventions within the ambit of community pharmacy practice, the relatively small percentage of patients (7%) who were screened or monitored for certain chronic disease-related clinical indicators indicates that the value of such services are not yet fully recognised.^{19,23,173,470}

A systematic review by Anderson et al,¹⁶⁴ published in 2004, concluded that consumers did not generally view pharmacists as a health advice resource. An earlier 1998 study by the same author noted that fewer than 20% of consumers consulted pharmacists for advice, although those who made use of community pharmacy services were well satisfied with these services.⁴⁹¹ The Discovery survey found similarly in terms of patient satisfaction with almost 90% expressing satisfaction with the quality of pharmacist advice provided. However, a greater percentage (46%) of the Discovery patients indicated that they consulted pharmacists on health-related matters that was the case with the Anderson study.⁴⁹¹ Encouragingly, the survey reveals that patients who consulted pharmacists were overwhelmingly pleased with the quality of the advice provided, and that almost half were willing to pay for CPS. This indicates substantial potential to improve pharmacy's position as a healthcare advice/information resource.

A claim of community pharmacy world-wide is that pharmacist accessibility is facilitated mainly because of the physical location of most community pharmacies and because the consumer-pharmacist encounter is not usually subject to prior appointment.^{133,137} The survey data did not support this claim, and this is a disturbing finding for the profession as patients wishing to consult doctors in a private healthcare setting in South Africa must both make appointments and pay for consultations. Patients generally do not have to make appointments nor do they have to pay pharmacists for advice and yet almost two thirds considered pharmacists to be less accessible than doctors.

This surprising finding may offer some explanation as to why more consumers do not consult pharmacists about health-related matters. Patients may have been socialised by past pharmacy practice experiences to seeing the pharmacist simply as a dispenser of medicines.¹⁴ It is also possible that other variables, such as privacy, confidentiality and uninterrupted consultation, may have a mediating effect on perception and definition of healthcare provider access.⁴⁹⁵⁻⁴⁹⁷ As a number of authors have commented on the relative ease with which patients are able to access pharmacists,^{146,252,498} it is possible that this question may have been misinterpreted despite having the term explained during the interview.

For much of the world, the twin effects of increased life expectancy and decreasing fertility rates have given rise to an increasingly “greying” population.⁴⁹⁹ The elderly are the fastest growing segment of the population in a number of developing countries, and world-wide the number of people over the age of 60 is set to double between 2000 and 2025.⁴⁹⁹ Given the importance of attending to the complex health needs of this sector of the population, it is disturbing that the survey found that patients over the age of 65 were less inclined to consult pharmacists than were the rest of the survey population. As one would expect, the level of medicine utilisation reported by patients over 65 years of age reflected an association between the increasing prevalence of chronic disease and advancing age.⁵⁰⁰ In a multi-centre study involving elderly patients in seven European countries, the authors noted that very few studies have, to date, examined the impact of pharmaceutical care on the elderly as a group.⁵⁰¹

More than two thirds of patients viewed their relationships with their pharmacists as good. This, in turn, suggests that almost a third of patients felt that their relationships with pharmacists were problematic to some degree, and this finding must be of some concern given the association between the quality of the relationship and the patients' willingness to collaborate with healthcare providers.³⁰ Those patients reporting a good relationship were far more willing to pay pharmacists for CPS than those who reported negatively.

Black patients and those of Mixed-Race generally did not rate their relationships with pharmacists as good. In part, this may be due to the demographics of community pharmacists who are mostly White, the cultural and linguistic differences between patients and pharmacists, and the accessibility of the majority of community pharmacies which tend to be situated in urban shopping centres or within residential areas that, prior to 1994, were almost exclusively reserved for the White population. It is important, both economically and professionally, that pharmacists improve relationships with these apparently disenfranchised sections of the South African population. Furthermore, it is incumbent upon pharmacists to ensure that they are able to offer CPS that are educationally, linguistically and culturally aligned with the needs of individuals from these communities, not only because of their demographic weight but because of the increasing prevalence of chronic conditions such as cardiovascular disease, hypertension, obesity and diabetes in these populations.⁴¹

The administration of the survey via telephonic interview was found to be a convenient and practical method of surveying patients. The major advantages of this method, when compared to postal self-completed questionnaires, were convenience, the high strike rate, the opportunity for immediate clarification of any patient query and real-time efficient data capture. The structured nature of the questionnaire facilitated operator adherence to a standard protocol in administering the questionnaire. The level of comprehensibility of questions may be greater with telephonic surveys than with self-completed postal surveys as patients are able to seek clarification.⁴⁴⁹

6.6 Limitations

The absence of similar practice-based research in South Africa prevented the benchmarking of the questionnaire for local conditions. The survey was conducted at a time when community pharmacy in South Africa was on the receiving end of unfavourable media coverage relating to the proposed changes to the pricing of pharmaceuticals and to the structure of the dispensing fee, and this effect on public perception may have introduced a level of bias.

The determinants of patient attitudes and beliefs which underpin the survey constructs are complex.⁴⁴⁹ Both the conceptual framework and the design of the survey would have benefited from a more rigorous review of other studies. Validated instruments exist which measure constructs similar to those conceptualised for this survey,⁵⁰²⁻⁵⁰⁴ and these could have been adapted for this study rather than designing an entirely original survey instrument.

The procedure used to generate the sample frame involved two stages – a convenience sample of patients who submitted health insurance claims within a given period, followed by the random selection of patients from within the convenience sample. Given that it would not have been practical to have selected a survey sample that would have been fully representative of the national insured database, an improved sampling frame would have included a list of all members who submitted claims rather than only the first 3000. Other enhancements to the sampling frame that could have been considered include: the use of multistage sampling with potential respondents stratified geographically (according to postal code), ethnically and by gender in order to ensure greater representativity before final randomisation.³⁵

The survey may have benefited from the inclusion of the Nominal Group Technique prior to embarking on the pilot study, i.e. by involving an expert group of pharmacists in order to establish the explicit criteria to be addressed as well as to fine-tune the actual questions to be posed in operationalising the survey.⁵⁰⁵ In addition to defining criteria in the absence of local studies, the Nominal Group Technique, notwithstanding its own set of limitations, would have generated face, content and a level of consensual validity.⁵⁰⁵

As interviews were not conducted by the researcher but by trained operators, the potential for operator error and their ability to clarify queries may have impacted on the validity and reliability of the questionnaire. The survey relied on self-reported retrospective quantitative data collected via telephonic interview which may have subjected the answers to recall bias, which has been identified as a limitation in other studies.⁵⁰⁶ However, the potential for recall bias is smaller in the case of cross sectional descriptive studies than in cross sectional analytical studies.⁵⁰⁷

Other possible limitations associated with the real-time interview method include lack of time to reflect on the questions, operator interviewer bias, and limitations with regard to the level of complexity of questions, i.e. they were constrained to being simple in structure. There may have been an element of selective attention on the part of the patients, i.e. individuals tend to select and pay attention only to certain variables in a given situation.⁵⁰⁷

6.7 Conclusion

Patient opinion clearly indicated that pharmacists provide certain cognitive pharmaceutical services including medication counselling, disease-related information and health-related advice. Furthermore, these services are valued by patients who generally have good relationships with pharmacists, with a significant number of patients being willing to pay pharmacists for such services. The survey therefore demonstrated that support exists within the practice dynamic of South African community pharmacy to reasonably allow for the implementation of a pharmacist-based diabetes care plan intervention as envisaged in the empirical study described in Chapter 7.

The survey helped to identify aspects of community pharmacy practice that may benefit from further research. It is recommended that organised pharmacy consider undertaking formal market research relating to the provision of CPS with a view to developing an evidence-based strategy aimed at the effective marketing of the profession.⁵⁰⁸ Research within groups and communities classified demographically and by disease state would assist the profession in identifying and facilitate the targeting of CPS. The pharmacist as an accessible community-based healthcare information and counselling resource requires further investigation given the South African Pharmacy Council's statutory

requirement with regard to Good Pharmacy Practice, as well as the professional imperative of providing pharmaceutical care.^{6,23}

Research investigating the range and utility of the clinical services on offer in South African community pharmacy is suggested, especially as services such as biochemical monitoring play a key role in informing both the initiation and adjustment of therapies. Such research should include investigation into the skill and accessibility of pharmacists (and auxiliary staff) responsible for providing these services.

There is a paucity of local data describing the medicine-related knowledge, beliefs, attitudes and pharmacy related needs of consumers from previously disadvantaged communities, those with chronic diseases and those who may be classified as elderly. Community pharmacy could benefit from the availability of such information as these groups represent potentially important target markets. Well structured patient satisfaction surveys are useful tools in the hands of pharmacists wishing to assess practice performance and to plan remedial action.

If CPS are to be meaningfully provided by South African community pharmacists then, in concert with colleagues elsewhere in the world, pharmacists will have to be compensated for these services. Funders of the pharmacy benefit, including patients, are more likely to be willing to pay if they perceive value in the services. This, in turn, means that the apparent deficiencies in the elements of CPS identified by the survey and any barriers to pharmacist access will need to be addressed. Strategies should be developed that will encourage pharmacists to professionally market CPS. Appropriate marketing campaigns should increase healthcare consumer awareness.

CHAPTER 7

RESEARCH DESIGN AND METHODOLOGY

7.1 Introduction

This study was informed by a WHO report on adherence to long-term therapy.¹ The influence of the report on the rationale for the study is discussed in more detail in Section 1.1. The report notes that therapeutic adherence in DM2 is sub-optimal and constitutes a world-wide problem and also states that community pharmacists are well positioned to positively influence patient adherence in a number of chronic diseases including DM2.¹ The study hypothesis has largely been informed by the literature relating to aspects of the management of the disease by pharmacists, given the scope of practice of South African community pharmacists.^{6,173}

7.2 Aim and objectives

The aim of the study was to investigate the influence of South African community pharmacist intervention on certain intermediate health outcomes and therapeutic adherence in DM2. The objectives underpinning this aim are noted in Section 5.5.

7.3 Study setting and design

Unemployment, poverty, low levels of education, poor public health practices, an under-resourced public health sector, together with the ravages of infectious diseases (especially HIV/AIDS and tuberculosis), and the emerging pandemic of diabetes and obesity, renders a large proportion of the South African population vulnerable to a substantial burden of disease.^{132,509}

South Africa, with an ethnically diverse population of approximately 47 million people, has a healthcare system unequally divided between public and private health sectors.⁵¹⁰ The public health sector is state funded and services the healthcare needs of approximately 85% of the population.^{509,510} The private sector, which caters for about 15% of the population, is mostly funded by a combination of self funding and a form of

medical insurance, colloquially referred to as “medical aid”.⁵¹¹ Private healthcare expenditure, which accounted for 60% of South Africa’s total healthcare funding in 2005, reflects the inequality existing within healthcare.⁵¹² The disparity in healthcare financial resource allocation between the public and insured private sector has encouraged a number of government initiatives aimed at limiting private healthcare spending.

The cost of pharmacy-only medicines, or scheduled medicines as they are known in South Africa, accounted for a significant portion of the private healthcare budget in 2004.⁵¹¹ Accordingly, legislation aimed at controlling the price of medicines was promulgated in 2005, which reduced and fixed the mark-up of scheduled medicines and introduced price control on medicines via a legislated transparent medicine pricing system, referred to as the Single Exit Price for scheduled medicines.⁵¹³ The Single Exit Price model applies to all scheduled medicines. Community pharmacists have seen medicine margins eroded and revenue reduced as a result of the single exit pricing of medicines, and are thus being forced by economic necessity to identify additional revenue streams, including the delivery of services for which they may be able to levy fees.^{17,514}

There were approximately 11100 pharmacists and 2700 community pharmacies in 2007, with approximately 40% of the pharmacists employed in community pharmacy. (Moselakgomo M. Personal communication, Registration Officer, South African Pharmacy Council, May 2007). Community pharmacy focuses almost exclusively on providing pharmaceutical services to the private healthcare sector,^{137,515} and there are a number of community pharmacy practice models in existence, with independent pharmacist ownership dominating. Prior to 2003, community pharmacies in South Africa could only be owned by registered pharmacists, but ownership regulations changed in May 2003 when legislation was enacted that allowed for non-pharmacist ownership. There are also corporately owned private sector hospitals and clinics with pharmacies, as well as six courier pharmacies, similar in operation to the mail-order pharmacies found in the USA.⁵⁰⁹ The prescription medicine market in the private healthcare sector is further fragmented by the existence of more than 8000 registered medical practitioners licensed to dispense medicines.^{17,493,516}

Although community pharmacists have for many years had an expanded role in South African healthcare, there exists very little evidence, other than anecdotal evidence, relating to the provision and value of these services.^{17,137} The consumer survey reported in Chapter 6 was conducted in order to inform the researcher's understanding of the insured healthcare consumer's perspective regarding the CPS provided by South African community pharmacists.¹⁷ The survey revealed that in most instances pharmacists counselled patients on the use of medication and provided health-related information, that relationships with pharmacists were good and valued, and that almost half of respondents believed that pharmacists should be reimbursed for providing CPS.¹⁷

Notwithstanding the limitations of the survey, and a possible negative finding regarding pharmacist access, the results of survey demonstrated that South African community pharmacists are positioned to deliver chronic disease-related CPS. There appeared to be, therefore, sufficient foundational support to warrant an investigation of the study hypothesis, namely that South African community pharmacists are positioned to influence adherence to long-term therapy and key intermediate health outcomes in DM2.

The study was conducted in 17 community pharmacies in five of South Africa's nine provinces. A randomized controlled trial (RCT) informed by the CONSORT statement was adopted as the study design.³⁵ Post-baseline randomization to either control or intervention occurred at pharmacy level in order to prevent contamination of the groups. Ethical approval for the study was obtained from the Rhodes University Ethical Standards Committee.

7.4 Study population

7.4.1 Estimation of the sample sizes in the control and intervention groups

Pharmacist participation was canvassed as broadly as was possible using the communication media of pharmacy organisations, mainly the PSSA (Annexure 6.1), as this is a method commonly used to solicit pharmacist participation in practice for continuing professional development or education programmes. A gross response rate of approximately 4.6% (156/3400) was initially achieved.

The sample size calculation for patients was based on determining the minimum number of patients required to be able to detect a 0.5% difference in HbA_{1c} with 95% confidence. If the sample size calculation was based on detecting a 1% difference in HbA_{1c} between the two groups with a standard deviation of 1%, then a fixed sample size of 20 patients per group would yield a power of 88.5%⁵¹⁷

7.4.2 Pharmacist participants

All community pharmacists working in community pharmacies within the borders of South Africa were eligible to participate in the study. No other eligibility criteria, such as access to computerised records or provision of private counselling areas, were applied as all registered pharmacists are permitted by law to provide CPS from registered pharmacies. Pharmacist recruitment and participation was effected via the communication media of community pharmacist organisations who collectively represent approximately 75% of all South African community pharmacies.

There were two randomizations using a web-based random number generator noted in Section 7.4.3 below. The first involved patients only and was applied in order to inform the patient selection process. The second randomization occurred post-baseline four months later when pharmacists and their associated patients were randomized to either a control or intervention group. The key elements of the randomizations, namely sequence generation at recruitment and post-baseline group allocation, were concealed from the participants.

Prior to post-baseline randomization the pharmacists were stratified within three key employment/location domains, corporately owned and urban location (six pharmacies), independently owned and urban location (four pharmacies) and independently owned and rural location (seven pharmacies). Pharmacists were randomized to control or intervention separately in each of the domains and the results collated. Stratified randomization resulted in reasonably well-matched control and intervention groups in terms of the pharmacy location and ownership variables. The control group consisted of 8 pharmacists and 27 patients and the intervention group of 9 pharmacists and 34 patients.

The control pharmacists were telephonically contacted by the researcher and requested not to provide any form of additional diabetes care to their DM2 patients other than the 'standard' or 'usual' pharmaceutical care that they were accustomed to providing prior to the initiation of the study. Typically usual care would counselling patients on the use of their medicines. However, given that practice environments vary from pharmacy to pharmacy, and given that it was essential to try and prevent observation bias, no attempt was made to further describe usual care. The intervention pharmacists were provided with a diabetes care plan (DCP) intervention framework (see Section 7.5) to guide the 'enhanced' pharmaceutical care that they were requested to provide.

7.4.3 Patient participants

The inclusion criteria for patients are noted in Table 7.1. Patients were not excluded from the study on the basis of co-morbidity, health-risk rating, history of non-adherence to therapy, cognitive ability, race, age, or gender.

Pharmacists identified, listed and numbered all their DM2 patients and provided the researcher with the number of patients on file. In order to minimise selection bias a web-based random number generator (<http://www.randomizer.org/form.htm>)⁴⁸⁷ was used to determine the selection sequence for potential patient participants. A patient selection sequence was then forwarded to each pharmacist with the request to recruit up to a maximum of 10 patients. Patients complying with the inclusion criteria were approached by their pharmacists and asked if they would be interested in participating in a research project that would examine aspects of diabetes care being provided by South African community pharmacists. Pharmacists provided these patients with a brief overview of the study, together with copies of a patient study information and informed consent letter (Annexure 6.3).

Table 7.1 Inclusion criteria for patients

- Minimum 18 years of age.
- Diagnosed with DM2 at least 6 months prior to recruitment.
- Receiving a minimum of one prescribed anti-diabetic agent regularly from a participating pharmacy.
- Able to read and understand English.
- Willing to provide informed consent.

Patients who signed letters of consent subsequently received correspondence from the researcher reiterating the importance of completing the questionnaires and having the biochemical and clinical tests done, and thanking them for their participation. Patients were then contacted by their respective pharmacists and requested to meet in the pharmacy to discuss the contents of the patient study pack.

Throughout the duration of the study, pharmacists were encouraged to emulate 'real world' standards of day-to-day community pharmacy practice as closely as possible and to avoid any activities and interventions which could be construed as being limited to 'research practice'. In support of this objective, and in an effort to minimise participation bias, neither the pharmacists nor the patients were offered any form of compensation for their participation.

7.5 The Diabetes Care Plan (DCP) intervention

Practice conditions vary from pharmacy to pharmacy, and both pharmacists and patients, as individuals, are unlikely to approach adherence or any aspect of diabetes care in a structured uniform manner.⁵¹⁸ It was not the intention, therefore, to prescribe precise stage-specific diabetes care interventions, but rather to encourage pharmacists to tailor component interventions to suit individual patient needs within the reality of the pharmacist's day-to-day practice environment.^{480,519} It was for this reason that, in correspondence addressed to intervention pharmacists, the DCP intervention framework was referred to in the following terms: *"The intervention document, IDF guidelines and any other published article or paper that I send you are resource materials and provide a framework for individualized diabetes care plans that I trust you will develop with each of your patients. But,*

and this is important, it's up to you to decide on how you go about working with and assisting your patients" (Annexure 6.4).

As mentioned in the conceptual framework,(Section 5.4) two key aspects of the DCP intervention were the clinical and patient education and counselling interventions. A major component of the clinical intervention was the monitoring of clinical indicators and other variables. Intervention pharmacists were provided with a suggested monitoring schedule, which was informed by the SEMDSA and IDF guidelines.^{4,105} The schedule plus explanatory notes, which are shown in Annexure 6.5, linked the forms, questionnaires, validated scales and other instruments provided in the manual with consultations, monitoring and review activities in the following domains: diabetes history and medication review, diabetes knowledge and self-management, key clinical indicators, provider referral, and behavioural indicators. Although the clinical and patient education and counselling interventions are described separately, in practice the two are integrated by the 5 A's model for behavioural change,²⁷⁵ which is described in Section 4.3.3 as a unifying framework to inform the development and implementation of behavioural change educational interventions designed to support the improvement of chronic disease self-management in primary healthcare settings.

At the beginning of the recruitment process the researcher canvassed pharmacist opinion with regard to their willingness to attend after-hours training. Pharmacist reluctance to make such time available, together with the widespread geographical distribution of relatively few willing participants, meant that face-to-face training would not be a viable option. Intervention pharmacists were trained to provide the DCP using a self-study distance-learning method based largely on written material, which is a common format for South African CE programmes aimed at pharmacists. Intervention pharmacists were also encouraged to access web-based resources and to contact the researcher if further assistance was required. The resource material, in the form of a written DCP manual which is more fully described in Annexure 6.5, was designed to encourage collaboration between pharmacists and patients in the development and application of individualized DCP interventions. The manual, which was forwarded to pharmacists in December 2006, consisted of the following sections, (i) an executive summary, (ii) an overview of the DCP intervention, (iii) patient education and counselling

intervention (iv) clinical intervention, (v) scales and questionnaires and (vi) additional resource materials for the pharmacists.

The executive summary briefly described the clinical and patient education key elements of the DCP in terms of assessing patient needs, goals and problems, collaboratively planning strategies to address needs, goals and problems, implementing agreed interventions, monitoring key variables and reviewing the results forthcoming from the monitoring process.

The overview suggested roles for both patients and pharmacists before further outlining the clinical and patient education and counselling interventions. With regard to the role of the patient, it was stressed that patients should not be seen as passive recipients of diabetes care but that a collaborative patient-centred approach should be taken in support of self-management initiatives. The pharmacist's role was defined in terms of collaboratively providing evidence-based enabling diabetes care.

The detailed sections dealing with the patient education and counselling intervention and the clinical intervention followed the DCP overview. The patient education and counselling section briefly discussed the Chronic Care Model, patient self-management and patient behaviour in terms of readiness to change, before dealing with the counselling method of Motivational Interviewing, which was discussed in some detail as it formed the crux of this intervention. The clinical intervention was discussed in terms of the monitoring by pharmacists of key diabetes-related variables (set out in a suggested monitoring schedule on page 21 of Annexure 6.5).

7.5.1 Materials

The resource materials provided to support the patient education and counselling intervention are included in Table 7.2

Table 7.2 Resource material for patient education & counselling intervention	
Aspect	Source
Motivational Interviewing	Motivational interviewing helps patients confront change. ¹⁷¹ Assessing and interviewing patients for meaningful behavioral change. Part 1. ²⁶⁹ Assessing and interviewing patients for meaningful behavioral change. Part 2. ²⁷⁰ Motivational interviewing in health settings: a review. ²⁶⁵
Communication	Persuasive communication. Part 1 ⁴⁹⁷ Persuasive communication. Part 2 ⁵²⁰
Change	Change is a multistep process. ⁵²¹ Helping patients face change. ⁵²²

The diabetes-related resource materials, primarily DM2 guidelines, provided in support of the clinical intervention are shown in Table 7.3. Pharmacists were furthermore reminded to refer to “Good Pharmacy Practice in South Africa”, published by the South African Pharmacy Council, with regard to the statutory requirements for the provision of pharmaceutical care.⁶ The procedures relating to the use of these resource materials are further discussed in Annexure 6.5 and Section 7.5.2.

Table 7.3 Resource material in support of the clinical intervention	
Aspect	Source
Guideline and medicine review	A Desktop Guide to Type 2 Diabetes Mellitus. ⁵²³ Revised Guidelines for the diagnosis and management of type 2 diabetes mellitus for primary health care in 2002. ¹⁰⁵ Algorithm for Diabetes Mellitus Type 2, from the South African Council for Medical Schemes. ¹²³ Guidelines on Pharmacist-Conducted Patient Education and Counseling 2001 from the ASHP. ¹⁷²
Diabetes education	Education: IDF global guidelines for type 2 diabetes. ⁴
Self-management adherence	Improving adherence to diabetes self-management recommendations. ³⁵⁰

The forms, scales and questionnaires that pharmacists and patients were requested to complete at baseline and post-baseline are shown in Table 7.4, and further discussed in Annexure 6.5 and Section 7.5.2.

Table 7.4 Forms, questionnaires and scales to be completed by patients and pharmacists			
Form/ Scale/ Questionnaire	Aspect	Baseline (B) Post-baseline (PB)	Completed by Patient or Pharmacist
Patient Profile	Brief diabetes-related medical history	B	Patient
Beliefs about Medicines Questionnaire	Health-related beliefs	B & PB	Patient
Diabetes Satisfaction Scale	Health-related beliefs	PB	Patient
Diabetes Empowerment Scale	Health-related beliefs	PB	Patient
Self-management Adherence Scale	Health-related behaviours	B & PB	Patient
Medication Adherence Report Scale	Health-related behaviours	PB	Patient
Major Depression Inventory	Health-related behaviours	PB	Patient
Brief Diabetes Knowledge Test	Diabetes-related knowledge	PB	Patient
Understanding Self-management Practices Scale	Diabetes-related knowledge	PB	Patient
Self-monitored Blood Glucose	Diabetes-related knowledge	PB	Patient
Clinical data form	Biochemical and clinical variables	B & PB	Pharmacist
Prescribed Medication and Refill Questionnaire	Prescription refill data	PB	Pharmacist
Adjustments to oral anti-diabetic therapy	Prescription refill data	PB	Pharmacist

7.5.2 Procedures for implementing the Diabetes Care Plan (DCP)

Procedures relating to the DCP intervention, including suggestions on the process to be followed, were included in the DCP manual (Annexure 6.5) as well as in covering correspondence (Annexure 6.4). Pharmacists were requested to reflect on their practice situations and to take cognisance of the individual patient's language, cultural and ethnic preferences and psychosocial and socioeconomic status when designing, implementing and monitoring interventions. The core elements of the DCP intervention framework are presented in Table 7.5.

Table 7.5 Core elements of the DCP intervention framework
<ul style="list-style-type: none">▪ Assess patient diabetes-related problems, needs and goals in behavioural terms.▪ Discuss and agree strategies and interventions required to address needs and goals.▪ Specify follow-up plan and implement agreed interventions.▪ Share plan with practice team.▪ Monitor key clinical variables.▪ Regularly review and appropriately modify the DCP.

It was suggested that pharmacists discuss and agree on an individualized monitoring schedule with each patient. Given the time constraints generally faced by pharmacists in practice, it was suggested that pharmacists risk-rate patients in order to determine monitoring frequencies,^{525,526} i.e. increased risk for morbidity may require more frequent and comprehensive monitoring. It was also suggested that pharmacists structure fixed-time appointments for the initial study consultation and for subsequent consultations, with provision made for more frequent consultations that may be required for those patients who may be considered to be at high-risk for complications.

Pharmacists were requested to pay particular attention to identifying and addressing possible medication-related problems. In particular, it was suggested that pharmacists refer to the ASHP patient education and counselling guidelines when conducting

medication reviews.¹⁷² Pharmacists were advised to refer to the indicators recorded at baseline and the SEMDSA and IDF guidelines in order to guide goal setting and inform interventions. Pharmacists were encouraged to use opportunities created during patient-pharmacist encounters, especially those associated with the medication refill process, to facilitate the care process. It was further suggested that pharmacists maintain regular contact with their patients and that they use electronic and telecommunication technologies to follow-up with patients.

The psychosocial patient education and counselling intervention and the biomedical clinical intervention are mutually supporting elements of the DCP. In counselling patients, pharmacists were encouraged to use the non-judgemental method of brief Motivational Interviewing to explore patient health beliefs, attitudes and concerns in order to identify barriers to diabetes care and concordantly agree on suitable remedial action.

Patient education, in the context of the study, referred to the appropriate communication of DM2-related knowledge from the pharmacist to the patient in order to foster foundational support for diabetes self-management. Pharmacists were requested to ensure that their patients were appropriately grounded in key facets of diabetes self-management education as summarised in Table 7.6.

Table 7.6 Key features of diabetes self-management education

- Basic pathophysiology of DM2.
- Complications and co-morbidities commonly associated with the disease.
- Key tests and examinations recommended by SEMDSA.
- Recommendations for glycaemic control including the relevance of SMBG and HbA_{1c} monitoring.
- The role of anthropometric measures.
- The importance of blood pressure, blood lipid, and renal function values.
- Treatment options including diet, exercise and pharmacotherapy.
- Accessing psychosocial support.

The intervention group of 8 pharmacists was requested to implement the DCP intervention during the period December 2006 to May 2007. During June and July 2007, 12-month post-baseline clinical indicators and other variables were measured for both intervention and control patients.

7.6. Collection of baseline data

Each patient received a study pack from their pharmacist containing the following baseline forms and questionnaires (Annexure 6.2 and Table 7.4):

To be completed by the patient

- A patient profile form for recording demographic and diabetes-related data.
- Three baseline questionnaires
 - Beliefs about Medicines Questionnaire³⁸⁴
 - Diabetes Satisfaction Scale⁴¹⁰
 - Self-management Adherence Scale³⁸⁵

To be completed by the pharmacist

- A baseline clinical data form for the pharmacist to record biochemical and clinical indicators (proteinuria, blood pressure, waist-hip ratio, and body mass index).
- Pathology request forms to be used by the pharmacist to request biochemical tests (glycated haemoglobin, lipogram and serum creatinine).
- A medical practitioner study information letter to be signed by the pharmacist and forwarded to the patient's medical practitioner.

All instruments were previously validated and were used in this study with the permission of the authors. The scales were applied at baseline to benchmark adherence-related indicators in the areas of: medication-related health beliefs, planning and monitoring, satisfaction with care received, and self-reported adherence to self-management recommendations.

During April/May 2006 participants were requested to complete patient profile forms and provide data relating to the variables listed in Table 7.7

Table 7.7 Summary of patient profile data collected at baseline

- Demographic data.
- Duration and family history of DM2.
- Providers of medical care and frequency of consultations.
- Diabetes education and lifestyle issues of diet, exercise, social support, alcohol and tobacco use.
- Co-morbidities, medication used for DM2 and other co-morbidities.
- The monitoring of clinical indicators as specified in the SEMDSA guidelines.

The following clinical indicators were recorded at baseline:

- HbA_{1c}
- Total cholesterol
- HDL-cholesterol
- LDL-cholesterol
- Triglycerides
- Serum creatinine
- Proteinuria (urine dipstick)
- Systolic blood pressure
- Diastolic blood pressure
- BMI
- Waist – Hip ratio

In order to standardise the biochemical tests and to facilitate the reporting of results, HbA_{1c}, blood lipids and serum creatinine tests requested by pharmacists were performed in medical laboratories affiliated to the Ampath group. The balance of the clinical variables including proteinuria, blood pressure, BMI and waist-hip ratio were measured in the participating pharmacies either by pharmacists themselves, or under the supervision of pharmacists. Ampath emailed the biochemical test results directly to the researcher who, in turn, made these data available to the pharmacists. Pharmacists faxed the balance of the recorded clinical data to the researcher. Patients were

responsible for the costs of the biochemical tests performed by Ampath and settled these accounts directly or via their health insurers. In keeping with standard community pharmacy practice in South Africa, pharmacists did not levy fees for the in-pharmacy tests and measurements.

7.7 Collection of post-baseline data

In March 2007, pharmacists were provided with post-baseline clinical data forms and Ampath laboratory forms and asked to conduct a 12-month evaluation of their patients during April/May 2007 (covering letter Annexure 6.7 and Table 7.4)

12-month patient data to be provided by pharmacists

- HbA_{1c}
- Total cholesterol
- HDL-cholesterol
- LDL-cholesterol
- Triglycerides
- Serum creatinine
- Proteinuria (urine dipstick)
- Systolic blood pressure
- Diastolic blood pressure
- BMI
- Waist – Hip ratio

The use of clinical practice guidelines such as those published by SEMDSA serve not only to guide provider and patient behaviour, but provide an evidence-based standard for diabetes-related biochemical and other clinical indicators. Baseline patient profile data were analysed to determine patient adherence to the guideline recommendations with regard to attending examinations and having tests done. A comparative analysis of baseline and 12-month data including key biochemical and clinical indicator values was conducted.

Pharmacists were provided with the following questionnaires (described in Section 4.5.5) for their patients to complete under a covering letter (Annexure 6.8 and Table 7.4).

12-month patient data to be provided by patients

- Beliefs about Medicines Questionnaire³⁸⁴
- Diabetes Satisfaction Scale⁴¹⁰
- Self-management Adherence Scale³⁸⁵
- Diabetes Empowerment Scale Short Form⁴¹³
- Medication Adherence Report Scale⁴²²
- Major Depression Inventory⁴²⁸
- Self-monitoring Blood Glucose Scale³⁸⁵
- Brief Diabetes Knowledge Test⁴³⁶
- Understanding Self-care Practices Scale³⁸⁵

Pharmacists were also requested to complete two questionnaires (Table 7.4). The first was a Prescribed Medication and Refill Questionnaire (Annexure 6.9) that identified oral medication used by patients for hyperglycaemia, dyslipidaemia and hypertension, as well as the number of prescription refills obtained during the 6-month study period (December 2006 to May 2007). In addition, 12-month data was recorded relating to any adjustments made to the prescribed oral anti-diabetic therapy, as specified in Table 7.8

Table 7.8 Post-baseline adjustments to oral anti-diabetic therapy
<ul style="list-style-type: none">▪ Increase in dosage.▪ Alternative agent or agents prescribed.▪ Addition of an agent or agents to the existing regimen.▪ Insulin added to the regimen or substituted for any of the oral agents.

Pharmacists recorded patient clinical and prescription medication data and ensured that patients completed the questionnaires used in the study. Other than patient data provided by the pathology laboratories, all forms, clinical data and questionnaires were forwarded to the researcher by the pharmacists. The researcher captured the data directly from the forms, laboratory reports and questionnaires. Data capture errors were identified and corrected by verifying all entries prior to the data being submitted for statistical analysis.

Pharmacists were requested to return all post-baseline clinical data forms, patient and pharmacist questionnaires to the researcher during June/July 2007. As was the case with the collection of baseline data, numerous follow-up attempts were required before the data collection process could be completed.

7.8 Data analysis methods

Data analysis was premised on pharmacist influence on patient adherence to long-term therapy being evaluated by means of a RCT in which the differences in the primary endpoint of HbA_{1c} and the secondary endpoints (e.g. blood lipids, blood pressure and body mass index) for intervention and control patients served as surrogate outcomes.

Independent t-test analyses involved direct comparisons of group means between the control sample and intervention sample at both baseline and post-baseline intervals separately, on all biochemical and other clinical variables, as well as in health-related beliefs and behaviours and diabetes-related variables. Dependent t-test analyses were conducted on the data from the control sample and intervention sample between baseline and post-baseline intervals to investigate differences in biochemical and other clinical variables. Chi-squared tests were used to test for significant differences between the control and intervention groups in the frequency distributions of patient demographic and diabetes-related variables.

To guard against Type I error, Bonferroni adjustment to the level of significance was applied to the biochemical and other clinical variables test comparisons according to the number of participant characteristics investigated, including control or intervention group, gender, marital status, monitoring body mass, receiving diabetes education, consulting general practitioners or specialists, smoking, following a diabetes eating plan, exercising regularly, consuming alcohol (two or less units per day), and receiving social support (i.e. k=11 participant characteristics). Accordingly the alpha adjustment for the test comparisons, allowing for the Bonferroni adjustment to ensure that the overall level of significance does not exceed $\alpha = 0.05$, is $\alpha/k = \alpha/11 = 0.05/11 = 0.0045$.⁵²⁷ All tests were performed using Statistica[®] (Statsoft Inc.).⁵²⁸

CHAPTER 8

RESULTS

8.1 Introduction

The results of the DM2-related pharmaceutical care study described in Chapter 7 are presented in this chapter. As the questionnaires and forms used in the study were completed by patients or pharmacists without the assistance of the researcher, certain fields were occasionally left blank, and for this reason participant numbers may not be consistent within certain results tables presented in this chapter.

8.2 Pharmacist participants

The flow diagram (Figure 8.1) shows the pharmacist and patient participant flow through the study. The process of recruiting pharmacists to the study was both time-consuming (requiring a great deal of coaxing and follow-up) and disappointing, as evidenced by the fact that only 16 community pharmacists out of a potential pool in excess of 3000 were prepared to participate for the full 12 month period.

By the end of the initial phase of the recruitment process in September 2005, a total of 156 pharmacists had responded to the 'request for participation' correspondence (Annexure 6.1) and indicated in-principle interest in participating in the study. Seventeen pharmacists subsequently withdrew their offers of participation citing time and human resource constraints as the main reasons for their withdrawal. During October and November 2005, 139 pharmacists were requested to interrogate their prescription databases and identify, list and consecutively number all DM2 patients who met the study inclusion criteria. Sixty two pharmacists identified 4055 patients that they deemed eligible for study participation by the end of November 2005.

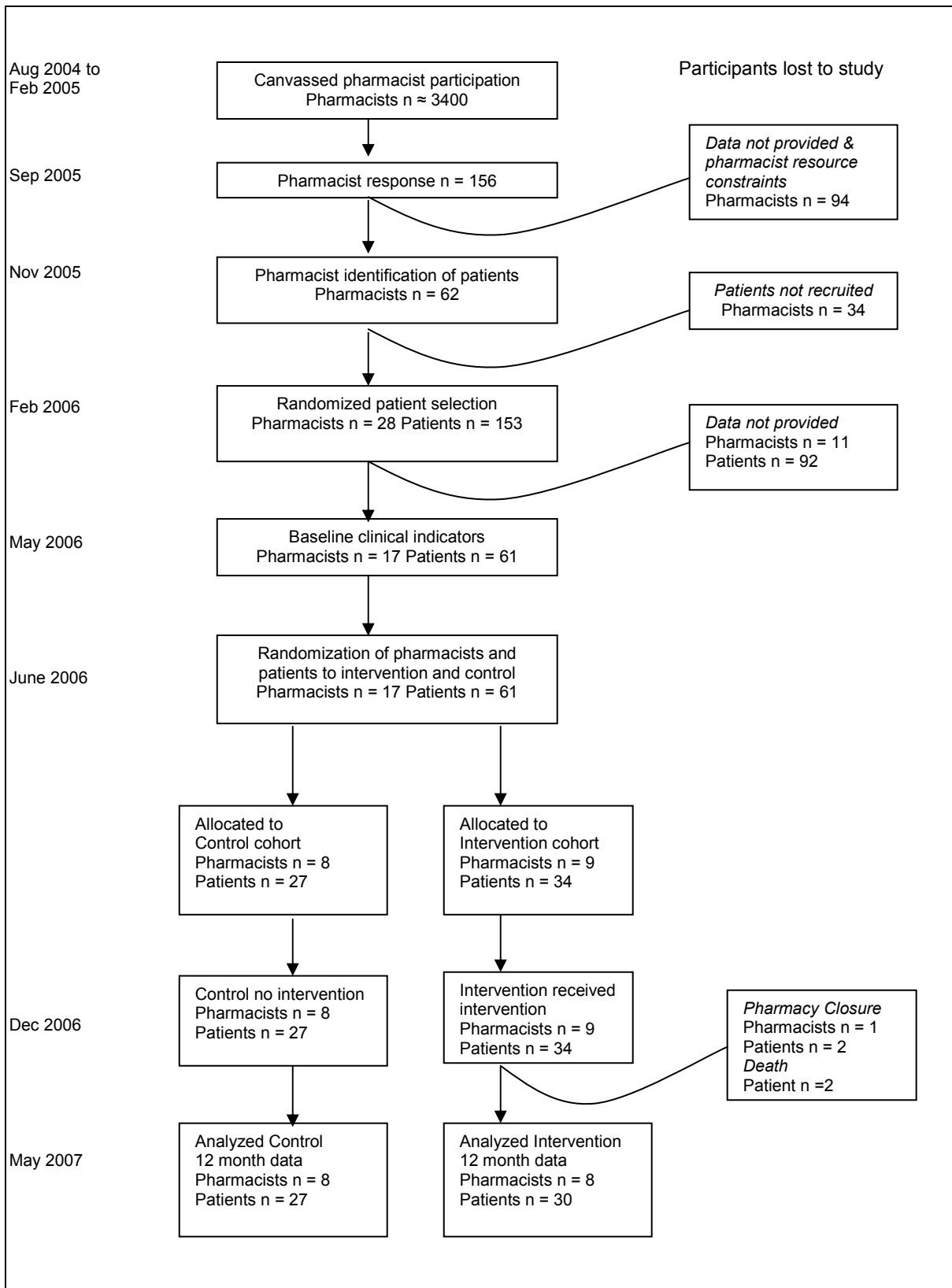


Figure 8.1 Study design: participant flow

Twenty eight pharmacists recruited 153 patients by the due date in February 2006. Sixty one patients associated with 17 pharmacists remained in the study by the baseline due date of 31 May 2006.

At a provincial level, five pharmacists each from Gauteng and the Eastern Cape, one from KwaZulu-Natal, three from the Western Cape and two from Mpumalanga were recruited to the study. There were no participants from the Northern Cape, Limpopo, Free State or the North West Province. One of the Mpumalanga pharmacies closed after baseline collection of data and the pharmacist and associated patients were consequently lost to the study.

8.3 Patient demographics

A total of 61 DM2 patients participated in the study and of these 27 were randomly assigned to the control group and 34 to the intervention group. Four patients were lost to the study, two as the result of the closure of a pharmacy and two due to death.

Table 8.1 reveals that there were no significant differences between the control and intervention groups at baseline for any of the demographic characteristics other than for language (Chi-squared test, $p < 0.001$), where in the control group English (74.1%) was more prevalent, whereas Afrikaans (76.5%) was the dominant language in the intervention group. Ethnically, the majority of the participants were white (85.2%). There were more male than female patients in both control (59.3%) and intervention (73.5%) groups, and the mean age was 59.8 ± 11.8 years for the control group and 57.1 ± 10.7 years for the intervention cohort (independent t-test, $p = 0.349$). Almost 90% of patients were married or living with partners, and equal numbers of patients completed secondary and tertiary education.

Table 8.1 Patient demographics: baseline N(%)			
Characteristic	Control N (%)	Intervention N (%)	p-value
Gender			0.238 ^c
Male	16 (59.3)	25 (73.5)	
Female	11 (40.7)	9 (26.5)	
Age in years –(mean ±SD)	59.81±11.8	57.09±10.7	0.349 ^d
Ethnicity			0.179 ^c
Black	0 (0.0)	1 (2.9)	
White	25 (92.6)	27 (79.4)	
Mixed race	1 (3.7)	6 (17.7)	
Asian	1 (3.7)	0 (0.0)	
Marital status			0.978 ^c
Married ^a	23 (88.5)	30 (88.2)	
Single ^b	3 (11.5)	4 (11.8)	
Education – highest level completed			0.383 ^c
Secondary	11 (42.3)	18 (54.6)	
Tertiary	15 (57.7)	14 (42.4)	
No schooling	0 (0.0)	1 (3.0)	
Home language			< 0.001 ^c
isiXhosa	0 (0.0)	1 (2.9)	
Afrikaans	7 (25.9)	26 (76.5)	
English	20 (74.1)	6 (17.7)	
Sesotho	0 (0.0)	1 (2.9)	
^a Married = living with a partner, ^b Single = living alone			
^c Chi-square test, ^d Independent t-test			

8.4 Baseline data

8.4.1 Type 2 diabetes-related variables

Table 8.2 reveals that there were no significant differences between the groups for any of the self-reported diabetes-related variables. The length of time following first diagnosis of DM2 was 9.5±8.7 years for the control group and 5.6±4.9 years for the intervention group (independent t-test, p=0.057). Just over 50% of patients reported that they had received diabetes self-management education, approximately 70% stated that they had consulted dietitians and followed diabetes eating plans, and a similar percentage (69%) reported having a family history of diabetes.

Data not in a table reveals that while there was a difference in HbA_{1c} between those with a family history of the disease (8.0 ± 1.9), those without such a history (7.5 ± 1.8) and those who were uncertain (7.2 ± 0.9), the difference was not significant (independent t-test, $p=0.521$).

Table 8.2 shows that the most prevalent of the self-management elements were social support and exercise-related advice. However, although over 80% of patients received advice on exercise, just over 50% exercised regularly and between a quarter and a third of patients (22.2% intervention and 35.3% control) did not follow meal plans designed to optimise glycaemic control.

A higher percentage of control patients (70.4%) consulted general practitioners about their DM2 than patients in the intervention group (55.9%), and proportionately more intervention patients consulted specialists (32.4% vs 22.2%). Six patients (two control and four intervention) were uncertain if their practitioners were specialists or general practitioners. Intervention patients consulted general practitioners and specialist physicians more often (3.7 ± 5.0 times per year) than patients in the control group (2.7 ± 1.3 times a year) but again this difference was not significant (independent t-test, $p=0.356$).

Table 8.2 shows that in addition to DM2, patients reported an average of almost two co-morbidities, with hypertension the most common condition (59.3% of control and 58.8% of intervention patients, Chi-squared test, $p=0.973$). Over a third of patients reported being dyslipidaemic, approximately one in five said they had heart disease and just over 10% said that they had been diagnosed with depression. Although the self-reported depression prevalence in the control group (7.4%) was lower than that in the intervention group (14.7%), the difference was not significant (Chi-squared test, $p=0.402$) possibly due to the small sample sizes.

Table 8.2 Frequency distribution of diabetes-related variables: baseline N (%)			
Patient characteristic	Control	Intervention	
Years since diagnosis (mean ± SD)	9.5±8.7	5.6±4.9	0.057 ^a
Number of annual doctor consultations (mean ± SD)	2.7±1.3	3.7±5.0	0.356 ^a
Medical practitioner consulted for diabetes			0.639 ^b
General Practitioner	19 (70.4)	19 (55.9)	
Specialist	6 (22.2)	11 (32.4)	
Not sure	2 (7.4)	4 (11.7)	
With family history of diabetes	19 (70.4)	23 (67.6)	0.968 ^b
Received diabetes education	14 (53.8)	21 (61.8)	0.538 ^b
Consulted a dietician	20 (74.1)	22 (66.7)	0.533 ^b
Follow a diabetes friendly meal plan	21 (84.0)	22 (66.7)	0.135 ^b
Advised by a healthcare professional to exercise	22 (81.5)	27 (81.8)	0.973 ^b
Exercise regularly 3 – 5 times a week	14 (53.8)	19 (55.9)	0.875 ^b
Receive social support from family and or friends	21 (80.8)	29 (85.3)	0.641 ^b
Smoke tobacco	5 (18.5)	8 (24.2)	0.592 ^b
Consume alcohol ≤ 2 units per day	13 (48.1)	16 (47.1)	0.933 ^b
Co-morbidities and complications			
Heart disease	6 (22.2)	7 (20.6)	0.877 ^b
Stroke	1 (3.7)	1 (2.9)	0.868 ^b
Hypertension	16 (59.3)	20 (58.8)	0.973 ^b
Dyslipidaemia	10 (37.0)	11 (32.4)	0.702 ^b
Depression	2 (7.4)	5 (14.7)	0.402 ^b
Nephropathy	1 (3.8)	0 (0.0)	0.249 ^b
Neuropathy	6 (22.2)	8 (23.5)	0.904 ^b
Retinopathy	11 (42.3)	12 (35.3)	0.580 ^b
^a Independent t-test, ^b Chi-squared test			

Retinopathy was the most commonly reported complication with almost 40% of patients stating that they had vision acuity problems which they ascribed to DM2. Only one patient reported having kidney disease, and approximately 20% indicated that they suffered from some form of neuropathy. About 50% of participants reported consuming two units or less of alcohol per day, and approximately 20% said that they smoked tobacco.

8.4.2 Prescribed medication

While all of the patients used prescribed medication as an aid to effecting glycaemic control, there was a significant difference between the groups at baseline with regard to the route of administration of the anti-diabetic agents (Chi-squared test, $p=0.013$). Table 8.3 shows that 59.3% of control patients and 82.4% of the intervention patients used oral agents exclusively, while insulin as monotherapy was used by six patients (22.2%) in the control group only. Data not shown in a table reveals that the mean HbA_{1c} for patients only using oral anti-diabetic therapy (7.7 ± 1.9) was lower than for those patients on insulin alone (8.3 ± 1.1) or those who used a combination of insulin and oral agents (8.3 ± 1.5 , independent t-test, $p=0.503$).

There was no significant difference between the groups for any of the other classes of agents prescribed and used to treat heart disease (Chi-squared test, $p=0.910$), hypertension (Chi-squared test, $p=0.702$), or dyslipidaemia (Chi-squared test, $p=0.341$). Patient self-reported use of anti-hypertensive medication (63.0% control and 67.6% intervention) approximated the incidence of hypertension reported in Table 8.2.

Table 8.3 Pharmacotherapy for DM2 and co-morbidities: baseline N (%)			
Variable	Control N=27	Intervention N=34	p-value Chi-squared test
Medication used for Type 2 diabetes:			0.013
Oral only	16 (59.3)	28 (82.4)	
Insulin only	6 (22.2)	0 (0.0)	
Oral and insulin	5 (18.5)	6 (17.6)	
Medication used for:			
Heart disease	5 (20.0)	7 (21.2)	0.910
Hypertension	17 (63.0)	23 (67.6)	0.702
Dyslipidaemia	11 (40.7)	10 (30.3)	0.341
Depression	1 (4.0)	3 (9.0)	0.449
Complementary medicines used for diabetes	2 (7.4)	2 (5.9)	0.643

Table 8.3 reveals that approximately one third of all patients said that they used medication to treat dyslipidaemia (Chi-squared test, $p=0.341$). The prevalence of antidepressant medication therapy was lower (6.6%) than the self-reported incidence (11.5%) of depression. Four patients (6.6%) reported using complementary medicines as part of their diabetes regimen. Metformin was the most widely prescribed oral anti-diabetic agent, accounting for 54.6% of all oral agents, followed by gliclazide (29.9%), glybenclamide (10.4%), glimepiride (2.6%), glipizide (1.3%) and pioglitazone (1.2%).

ACE inhibitors, either alone or in combination with diuretics, accounted for 37% of the 28 different agents prescribed for hypertension, followed by calcium channel blockers (21%), β -adrenergic blockers (20%), angiotensin receptor antagonists (15%) and diuretics (7%). Prescription refill data provided by pharmacists revealed that approximately 84% of the prescribed hypolipidaemic agents were statins, 13% were fibrates, and one patient used cholestyramine. Only one patient used both a statin and a fibrate.

8.4.3 Patient self-reported adherence to SEMDSA guideline

There were no significant differences between the groups in terms of self-reported adherence to the SEMDSA guideline parameters presented in Table 8.4, with neither

group fully adherent to any of the recommendations. Adherence percentages ranged from 11.1% (regular waist and hip measurement in the control group) to 85.3% (blood pressure measured at every consultation for the intervention patients).

Approximately 50% of all patients had an HbA_{1c} measured every six months, 33% were not tested and 17% were unsure if they had been tested for this key variable. There was no significant difference between groups with regard to the number of patients who had their HbA_{1c} measured bi-annually (Chi-squared test, p=0.643). Similarly, there were no significant differences in HbA_{1c} (independent t-test p=0.326) for those patients who tested every 6 months (8.0±1.6), those who did not have the test every six months (7.7±2.0), and those who said that they were not sure if their levels were ever measured (7.7±1.9)(data not included in a table).

Table 8.4 Patient self-reported adherence to SEMDSA ^a guideline: baseline N (%)			
Test/examination	Control N=27	Intervention N=34	p-value Chi-squared test
HbA _{1c} tested every 6 months	14 (53.8)	16 (47.1)	0.643
Self monitor blood glucose regularly	19 (73.1)	27 (79.4)	0.565
Annual lipogram	18 (66.7)	23 (67.6)	0.969
Blood pressure measured at every diabetes consultation	22 (81.5)	29 (85.3)	0.942
Annual kidney function test	12 (44.4)	11 (32.4)	0.223
Body mass measured at each diabetes consultation	12 (44.4)	17 (50.0)	0.768
Waist and hip measured regularly	3 (11.1)	6 (17.6)	0.551
Annual foot examination	13 (48.1)	12 (35.3)	0.252
Annual dilated eye examination	16 (59.3)	23 (67.6)	0.498
Annual ECG	11 (40.7)	13 (38.2)	0.897

^aSEMDSA : Society for Endocrinology, Metabolism and Diabetes of South Africa

Approximately 75% of all patients said that they self-monitored their blood glucose levels, and of these 50% monitored once a day, 39% once a week with the remaining 11% testing once a month. Data not shown in a table reveals that daily monitoring was associated with a lower HbA_{1c} than was weekly or monthly monitoring (7.8±1.7, 8.0±2.2, and 8.2±1.4 respectively), while those patients who never self-monitored blood glucose had a mean HbA_{1c} of 7.6±1.7. However, there were no significant differences in HbA_{1c} associated with frequency of self-monitoring (independent t-test, p=0.865).

Approximately one in six patients (16.4%) did not have their blood pressure measured at each diabetes consultation, although patients were more likely to have this test than to have any of the other tests recommended by SEMDSA. Fewer than 50% of all patients were weighed at each diabetes consultation and only about 15% reported having their waist and hip circumference measured. Approximately 60% of all patients did not have an annual foot examination or electrocardiogram. Just over two thirds said they had an annual lipogram. Adherence to the guideline tests and examinations exceeded 50% in only five out of the 10 tests/examinations recommended by SEMDSA.

8.4.4 Association of patient characteristics with primary and secondary clinical endpoints

The means and standard deviations of the primary and secondary endpoints associated with certain patient characteristics measured at baseline are shown in Table 8.5 and represent total data from all patients in the study (control and intervention).

Patients who said that they had received diabetes education had a higher average HbA_{1c} than those who had not received diabetes education (8.3±2.0vs 7.2±1.3, independent t-test, p=0.026)¹ and those patients who exercised regularly had a lower average HbA_{1c} than those who did not (7.3±1.6 vs 8.4±1.9, independent t-test, p=0.022)¹. Following a diabetes eating plan (independent t-test, p=0.314), and receiving social support (independent t-test, p=0.347) were associated with a lower HbA_{1c} but the differences were not significant.

Table 8.5 Association of participant characteristics with clinical variables: baseline									
Variable	HbA _{1c} ^a	Total ^b Cholesterol	HDL-C ^b	LDL-C ^b	Triglycerides ^b	Systolic ^b BP	Diastolic ^b BP	BMI ^b	
	N	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	
Gender									
Male	41	7.8±1.9	4.7±1.1	1.0±0.3	2.7±0.9	2.3±1.5	142±17	83±12	30.7±5.0
Female	20	7.8±1.7	5.7±1.2	1.3±0.4	3.9±1.0	1.9±1.0	142±18	77±12	32.7±6.9
Independent t-test	p	0.899	0.001 ¹	0.002 ¹	0.0001 ¹	0.259	0.955	0.082	0.262
Diabetes education									
Yes	35	8.3±2.0	5.2±1.3	1.1±0.3	3.2±1.2	2.2±1.5	143±17	82±13	31.9±5.9
No	25	7.2±1.3	4.8±1.1	1.1±0.4	3.0±1.0	2.2±1.2	140±18	81±12	30.9±5.4
Independent t-test	p	0.026 ¹	0.227	0.638	0.596	0.880	0.510	0.823	0.494
Follow a diabetes diet plan									
Yes	43	7.6±1.7	5.0±1.3	1.1±0.4	3.2±1.2	2.0±1.0	142±17	81±12	31.5±5.7
No	15	8.1±1.9	5.1±1.2	1.0±0.4	2.8±1.0	2.8±2.1	139±19	82±13	30.8±6.3
Independent t-test	p	0.314	0.838	0.297	0.316	0.029 ¹	0.631	0.781	0.723
Exercise regularly									
Yes	33	7.3±1.6	4.9±1.1	1.2±0.4	3.1±1.0	1.9±1.5	142±17	82±13	30.6±5.9
No	27	8.4±1.9	5.1±1.4	1.0±0.3	3.1±1.2	2.6±1.1	141±18	80±11	32.1±5.4
Independent t-test	p	0.022 ¹	0.460	0.056	0.947	0.075	0.920	0.387	0.337
Social support									
Yes	50	7.8±1.7	4.9±1.2	1.1±0.4	3.1±1.1	2.2±1.4	142±17	82±13	31.5±5.4
No	10	8.4±1.9	5.4±1.1	1.1±0.3	3.2±1.1	2.4±1.1	137±15	79±8	31.6±6.9
Independent t-test	p	0.347	0.222	0.975	0.730	0.577	0.377	0.413	0.947

a = primary endpoint, b = secondary endpoint
¹Significant (p < 0.0083, Bonferroni adjustment)

There were no significant differences in HbA_{1c} for gender or for any of the other patient variables not shown in a table including age, duration of diabetes, marital status, monitoring body mass, consulting general practitioners or specialists, smoking, consuming alcohol.

Neuropathy (independent t-test, p=0.312) and problems related to eyesight (independent t-test, p=0.294) were associated with higher HbA_{1c} but these differences were not

¹Significant (p < 0.0083, Bonferroni adjustment)

significant. There was a small and non-significant difference in HbA_{1c} between those patients who self-monitored blood glucose and those who did not (independent t-test, p=0.863).

Comparison of blood lipid data (Table 8.5) revealed that female participants had higher total cholesterol (5.7 ± 1.2 vs 4.7 ± 1.1 , independent t-test, $p=0.001$)¹, HDL-C (1.3 ± 0.4 vs 1.0 ± 0.3 , independent t-test, $p=0.002$)¹ and LDL-C (3.9 ± 1.0 vs 2.7 ± 0.9 , independent t-test, $p=0.0001$)¹ levels than did male patients. However, mean triglyceride levels were higher in males (2.3 ± 1.5) than in females (1.9 ± 1.0 , independent t-test, $p=0.259$). Patients who said that they had a lipogram at least once a year (data not included in a table) had lower total cholesterol levels than those who did not have the test annually (4.8 ± 1.0 vs 5.6 ± 1.4 , independent t-test, $p=0.012$)¹. While the cohort that tested annually also reflected improved levels for the constituent lipid fractions, these differences were not statistically significant. There were no significant differences in the lipid profiles of those patients who followed eating plans and those that did not.

Data not reflected in any table revealed that patients who used hipolipidaemic medication had non-significantly lower total cholesterol levels than those who used medication (4.8 ± 1.2 vs 5.1 ± 1.2 , independent t-test, $p=0.361$). There were no significant differences in either systolic or diastolic blood pressure correlated with any of the patient variables included in Table 8.5. Data not shown in any table revealed that, as would be expected, there was a significant difference in mean systolic blood pressure between those who used anti-hypertensive medication and those who did not (147 ± 17 vs 133 ± 16 , independent t-test, $p=0.003$). There was, however, no significant difference in diastolic blood pressure between these two groups of patients (82 ± 12 vs 70 ± 11 , independent t-test, $p=0.287$).

Although patients who had their blood pressure monitored at each diabetes consultation had both higher systolic and diastolic blood pressure (143 ± 18 and 82 ± 12) than did those who were not regularly monitored (139 ± 14 and 79 ± 13), the differences were not significant (systolic blood pressure, independent t-test, $p=0.546$ and diastolic blood pressure, independent t-test, $p=0.581$ respectively). No significant association with any of the patient characteristics were found for BMI.

8.5 Baseline and post-baseline clinical endpoints

8.5.1 Comparison of primary and secondary clinical endpoints

The results of the biochemical and other clinical variable tests and examinations conducted at baseline and post-baseline (Table 8.6) show that there were no significant differences for the primary endpoint or secondary endpoints at baseline or post-baseline for either the control or intervention patients. Similarly, there were no significant differences between the control and intervention groups for any of the endpoints at baseline or at post-baseline.

Table 8.6 Primary and secondary endpoints: control and intervention, baseline and post baseline								
Variable	Control		Intervention		p-values			
	Baseline	Post-baseline	Baseline	Post-baseline	Control Baseline v post-baseline	Intervention Baseline v post-baseline	Baseline Control v Intervention	Post-baseline Control v Intervention
					p-value ¹	p-value ²	p-value ³	p-value ⁴
HbA _{1c} (%)	7.3±1.2	7.6±1.6	8.2±2.1	8.2±1.8	0.295	0.815	0.046 ^a	0.226
Total-C (mmol/l)	4.9±0.8	4.7 ±0.9	5.1±1.5	4.9±1.2	0.123	0.351	0.490	0.375
HDL-C (mmol/l)	1.2±0.4	1.1±0.4	1.0±0.3	1.0±0.3	0.027 ^a	0.748	0.116	0.562
LDL-C (mmol/l)	3.0±1.0	3.0 ±0.7	3.2±1.2	3.0±1.0	0.775	0.308	0.590	0.584
Triglycerides (mmol/l)	2.3±1.7	2.2±1.1	2.1±1.1	2.2±1.2	0.632	0.291	0.689	0.966
S-creatinine (µmol/l)	88.2 ±30.6	88.0±26.1	80.7±16.8	84.0±15.8	0.086	0.065	0.172	0.611
Systolic BP (mm Hg)	139±14	138±16	141±19	139±19	0.659	0.445	0.320	0.765
Diastolic BP (mm Hg)	80±12	80±11	82±12	82±11	0.853	0.923	0.559	0.412
BMI (kg/m ²)	30.3±5.7	30.2±6.0	32.4±5.9	32.1 ±5.6	0.843	0.531	0.296	0.254
p-value ¹ and p-value ² – Dependent t-tests								
p-value ³ and p-value ⁴ – Independent t-tests								
^a Significant if p < 0.0083(Bonferroni adjustment)								

Table 8.6 shows that there was no real change in HbA_{1c} between baseline and post-baseline within the intervention group (8.2±2.0 to 8.2±1.8), and a small increase within the control group (7.3±1.2 to 7.6±1.6), and that these differences were not significant (independent t-test, p=0.514, Table 8.7). Similarly, evaluation of the secondary clinical endpoint data reveals that there were no significant differences between the control and intervention groups (Table 8.6) or within the individual clinical variables (Table 8.7).

Variable	N	Control Mean ±SD	N	Intervention Mean ±SD	p-value Independent t-test
Difference in HbA _{1c}	27	0.3±1.3	29	0.1±1.2	0.514
Difference in total-C	27	-0.2±0.7	30	-0.2±1.2	0.984
Difference in HDL-C	27	-0.1±0.2	29	0.0±0.2	0.040*
Difference in LDL-C	26	-0.1±0.8	27	-0.2±1.0	0.540
Difference in Triglycerides	27	-0.1±1.1	29	0.2±1.2	0.277
Difference in S-creatinine	24	3.6±9.9	27	0.3±8.9	0.901
Difference in Systolic BP	27	-1.7±19.4	30	-2.1±15.1	0.919
Difference in Diastolic BP	27	-0.4±12.4	30	-0.2±11.2	0.938
Difference in BMI	26	-0.1±2.1	29	-0.3±2.2	0.766

*Significant (p < 0.0083, Bonferroni adjustment)

8.5.2 Comparison of patients at goal for SEMDSA guideline for primary and secondary clinical endpoints

Table 8.8 shows that neither of the two groups demonstrated any significant difference between baseline and post-baseline in terms of patients being at goal for any of the clinical variables included in the SEMDSA guideline.

Table 8.8 Patients at goal for SEMDSA guideline baseline and post-baseline

Variable		Control		p-value	Intervention		p-value Chi-squared test
		Baseline	Post-baseline		Baseline	Post-baseline	
		N (%)	N (%)		N (%)	N (%)	
SEMDSA guideline							
HbA _{1c}	< 7%	11 (40.7)	11 (40.7)	1.000	9 (31.0)	9 (31.0)	1.000
Total cholesterol	< 5.0 mmol/l	10 (37.0)	15 (55.6)	0.125	12 (40.0)	16 (53.3)	0.344
HDL-cholesterol	> 1.2 mmol/l	8 (29.6)	5 (18.5)	0.375	5 (17.2)	6 (20.7)	1.000
LDL-cholesterol	≤ 3.0 mmol/l	12 (46.2)	15 (57.7)	0.375	10 (37.0)	15 (53.6)	0.125
Triglycerides	< 1.5 mmol/l	8 (29.6)	9 (33.3)	1.000	10 (34.5)	8 (27.6)	0.687
Systolic blood pressure	< 130 mmHg	5 (18.5)	5 (18.5)	1.000	9 (30.0)	6 (20.0)	0.375
Diastolic blood pressure	< 80 mmHg	15 (55.6)	7 (25.9)	0.021	13 (43.3)	12 (40.0)	1.000
Body mass index	< 25 kg/m ²	6 (22.2)	5 (19.2)	1.000	1 (3.4)	2 (6.9)	1.000

8.6 Post-baseline prescription data

Pharmacist-provided prescription data for anti-diabetic, hipolipidaemic and anti-hypertensive agents for the six month period 1 December 2006 to 31 May 2007 (Table 8.9) indicated no significant differences in prescription refill frequency between the control and intervention groups. Medication refill rates varied from a minimum of approximately 5.1 per 6 months for hipolipidaemic agents in the intervention group to a maximum of approximately 5.5 per 6 months for anti-hypertensive agents used by control patients.

Table 8.9 Prescribed medication refill frequency: post-baseline (N=57)				
Prescription refills 1 December 2006 to 31 May 2007	Number of observations	Number of refills in 6 months	Mean number of refills in 6 months	p-value Independent t-test
Oral anti-diabetic agents ^a				
Control	28	148	5.3±1.3	0.742
Intervention	52	280	5.4±1.1	
Hypolipidaemic agents ^a				
Control	15	81	5.4±1.4	0.579
Intervention	18	92	5.1±1.5	
Anti-hypertensive agents ^a				
Control	30	164	5.5±1.4	0.415
Intervention	35	182	5.2±1.2	
^a Pharmacological classification as per Monthly Index of Medical Specialities* 2007;47(9): 1-513				

During the study 13 patients (five control and eight intervention) had insulin added to their regimens (Table 8.10) and 14 patients (11 intervention and three control) had their oral anti-diabetic therapy adjusted during the study. Although more adjustments were made within the intervention group than within the control group, the test of significance was inconclusive possibly due to the small sample sizes. Therapeutic adjustments included increases in dosage, alternative oral agent prescribed or additional agent added to the regimen.

Table 8.10 Adjustments to diabetes pharmacotherapy: post-baseline N(%)			
Variable	Control N=23	Intervention N=31	p-value Chi-squared test
Increased dosage of oral anti-diabetic agent ^a	1 (4.3)	4 (12.9)	0.283
Alternative oral anti-diabetic agent prescribed	0 (0.0)	4 (12.9)	0.073
Additional oral anti-diabetic agent prescribed	2 (8.7)	3 (9.7)	0.902
Insulin added to regimen	5 (21.7)	8 (25.8)	0.730
^a Pharmacological classification as per Monthly Index of Medical Specialities 2007;47(9): 1-513			

8.7 Health-related beliefs, behaviours and knowledge

8.7.1 Comparison of baseline and post-baseline health-related beliefs and behaviours

Medication-related beliefs

Results for medication-related beliefs are presented as Necessity and Concerns scales which reflect adherence-related facets of patient beliefs concerning medication for personal use, and Overuse and Harm scales which considered aspects of patient beliefs about medicines in general. The mean Necessity and Concerns scale scores for both the control and intervention groups included in Table 8.11 reflect higher scores for Necessity than for Concerns at both baseline and post-baseline.

Table 8.11 Scale scores of medication-related beliefs ^a : baseline and post-baseline						
Scale items	Baseline			Post-baseline		p-value Independent t-test
	Control N=25 Mean±SD	Intervention N=28 Mean±SD	p-value	Control N=27 Mean±SD	Intervention N=30 Mean±SD	
Necessity(5)	20.3±3.1	19.3±3.5	0.280	20.2±3.4	19.1±3.6	0.250
Concerns (5)	12.6±3.7	13.2±3.6	0.518	14.5±3.1	13.3±3.9	0.206
NCD (5)	7.8±5.4	6.1±4.8	0.240	5.7±3.9	5.8±5.4	0.918
Overuse (4)	10.9±3.2	11.9±2.5	0.258	12.8±2.7	8.9±2.5	0.130
Harm (4)	9.0±2.8	9.6±1.9	0.364	11.5±3.3	9.7±2.4	0.212

^aBeliefs about Medicines Questionnaire³⁸⁴
Range 1-5: 1 = strongly disagree, 2 = disagree, 3 = uncertain, 4 = agree, 5 = strongly agree

Table 8.11 shows that while there were no significant differences between the control and intervention groups for the Necessity, Concerns and Necessity-Concerns Differential (NCD) scales at baseline or at the end of the study, there were positive differences in mean scale scores between the perception of necessity and concerns about the

prescribed therapy at baseline, and at post-baseline for the control and intervention groups. There were no significant differences between the control and intervention groups for the Harm and Overuse scales at baseline or post-baseline.

Table 8.12 confirms the importance patients attached to their belief about the necessity of using medication for DM2, with more than 90% of both control and intervention patients attaining scores above the scale midpoint at both baseline and post-baseline. Concerns and Overuse scores for control patients increased during the course of the study while Harm scores decreased for this cohort. For the intervention group, scores reflected very little change in perception for Necessity, Concerns and Overuse but a marked increase for Harm (from 28.6% to 46.7%). A substantially greater proportion of intervention patients attained scale scores above mid-point for Harm than did the control group at the end of the study (46.7% vs 18.5%).

Scale (items)	Baseline		Post-baseline	
	Control	Intervention	Control	Intervention
Necessity (5)	96.0%	96.4%	96.3%	93.3%
Concerns (5)	40.0%	42.9%	55.6%	40.0%
Overuse (4)	64.0%	67.9%	85.2%	70.0%
Harm (4)	24.0%	28.6%	18.5%	46.7%

Satisfaction with diabetes care

There was no significant difference between the control and intervention groups at baseline and post-baseline for patient satisfaction measures in terms of general diabetes care recently received (Table 8.13). In both groups post-baseline, patients 'agreed' or 'strongly agreed' that they were more satisfied with the level of recent care received (Item 1, control post-baseline 85.2%, intervention post-baseline 76.6%, Chi-squared test, $p=0.599$) than with care provided over the longer term (Item 3, control post-baseline 48.1%, intervention post-baseline 53.4%, Chi-squared test, $p=0.905$).

Table 8.13 General satisfaction with recent care ^a : baseline and post-baseline						
Item		Strongly Disagree N (%)	Disagree N (%)	Not Sure N (%)	Agree N (%)	Strongly Agree N (%)
Baseline						
1. "I'm very satisfied with the diabetes care that I receive"	Control	0 (0.0)	3 (12.5)	3 (12.5)	15 (62.5)	3 (12.5)
	Intervention p= 0.991 ^b	0 (0.0)	4 (14.3)	3 (10.7)	18 (64.3)	3 (10.7)
2. "Most people receive diabetes care that could be better"	Control	0 (0.0)	2 (8.7)	9 (39.1)	12 (52.2)	0 (0.0)
	Intervention p=0.741 ^b	0 (0.0)	2 (7.1)	13 (46.4)	12 (42.9)	1 (3.6)
3. "The diabetes care that I have received in the last few years is just about perfect"	Control	0 (0.0)	8 (33.3)	6 (25.0)	8 (33.3)	2 (8.3)
	Intervention p=0.450 ^b	0 (0.0)	4 (14.8)	8 (29.6)	13 (48.1)	2 (7.4)
4. "There are things about the diabetes care I receive that could be better"	Control	1 (4.2)	4 (16.7)	8 (33.3)	9 (37.5)	2 (8.3)
	Intervention p=0.352 ^b	0 (0.0)	3 (10.7)	11 (39.3)	14 (50.0)	0 (0.0)
Post-baseline						
1. "I'm very satisfied with the diabetes care that I receive"	Control	0 (0.0)	2 (7.4)	2 (7.4)	20 (74.1)	3 (11.1)
	Intervention p= 0.599 ^b	1 (3.3)	2 (6.7)	4 (13.3)	17 (56.6)	6 (20.0)
2. "Most people receive diabetes care that could be better"	Control	0 (0.0)	4 (15.4)	9 (34.6)	12 (46.2)	1 (3.8)
	Intervention p=0.689 ^b	1 (3.3)	2 (6.7)	9 (30.0)	17 (56.7)	1 (3.3)
3. "The diabetes care that I have received in the last few years is just about perfect"	Control	2 (7.4)	6 (22.2)	6 (22.2)	8 (29.6)	5 (18.5)
	Intervention p=0.905 ^b	1 (3.3)	8 (26.7)	5 (16.7)	11 (36.7)	5 (16.7)
4. "There are things about the diabetes care I receive that could be better"	Control	0 (0.0)	8 (29.6)	8 (29.6)	9 (33.3)	2 (7.4)
	Intervention p=0.104 ^b	3 (10.0)	5 (16.7)	4 (13.3)	17 (56.7)	1 (3.3)
^a Diabetes History Scale ⁴¹⁰						
^b Chi-squared test						

However, while few patients were dissatisfied with recent care received at the end of the study, about 30% expressed dissatisfaction ('strongly disagree' and 'disagree') with personal longer-term care (Item 3, control post-baseline 29.6%, intervention post-

baseline 30.0%), and approximately 20% (Item 3, control post-baseline 22.2%, intervention post-baseline 16.7%) were undecided ('Not Sure') about the level of long-term care received ($p=0.905$). Over a third of all patients (Item 2, control baseline 39.1%, intervention baseline 46.4%; Item 2, control post-baseline 34.6% and intervention post-baseline 30.0%) expressed uncertainty about the general level of care provided to all diabetics.

Close to 60% of all patients were satisfied with their healthcare providers (expressed as 'good', 'very good' or 'excellent', Table 8.14) at baseline and at the end of the study. This meant that approximately 40% of patients were unhappy with provider care, rating it as either 'poor' or 'fair'. There was no significant difference between the groups for any of the individual scale items reflected in Table 8.14, although patients were most satisfied when it came to knowing who to approach about aspects of diabetes care (Item 4, $\pm 70\%$) and least satisfied with the perceived level of interdisciplinary communication (Item 3, $\pm 50\%$).

Item		Poor N (%)	Fair N (%)	Good N (%)	Very good N (%)	Excellent N (%)
Baseline						
1. "Keeping you informed about what the next step in your care would be"	Control	6 (25.0)	5 (20.8)	6 (25.0)	4 (16.7)	3 (12.5)
	Intervention	6 (22.2)	5 (18.5)	7 (25.9)	7 (25.9)	2 (7.4)
	$p=0.921^b$					
2. "Different health care providers up-to-date on your current treatments and recent test results"	Control	4 (16.7)	4 (16.7)	12 (50.0)	4 (16.7)	0 (0.0)
	Intervention	9 (33.3)	7 (25.9)	6 (22.2)	5 (18.5)	0 (0.0)
	$p=0.196^b$					
3. "Communication between different health care providers caring for you"	Control	4 (16.7)	6 (25.0)	10 (41.7)	4 (16.7)	0 (0.0)
	Intervention	8 (29.6)	7 (25.9)	7 (25.9)	5 (18.5)	0 (0.0)
	$p=0.598^b$					
4. "Knowing who to ask when you had questions about your health"	Control	5 (20.8)	1 (4.2)	8 (33.3)	9 (37.5)	1 (4.2)
	Intervention	3 (10.7)	7 (25.0)	7 (25.0)	9 (32.1)	2 (7.1)
	$p=0.275^b$					

Table 14 continued						
Post-baseline						
1. "Keeping you informed about what the next step in your care would be"	Control	5 (18.5)	4 (14.8)	11 (40.7)	2 (7.4)	5 (18.5)
	Intervention	7 (23.3)	5 (16.7)	9 (30.0)	5 (16.7)	4 (13.3)
p= 0.756 ^b						
2. "Different health care providers up-to-date on your current treatments and recent test results"	Control	6 (24.0)	6 (24.0)	10 (40.0)	2 (8.0)	1 (4.0)
	Intervention	9 (30.0)	6 (20.0)	8 (26.7)	4 (13.3)	3 (10.0)
p=0.726 ^b						
3. "Communication between different health care providers caring for you"	Control	9 (34.6)	4 (15.4)	8 (30.8)	3 (11.5)	2 (7.7)
	Intervention	9 (30.0)	7 (23.3)	7 (23.3)	4 (13.3)	3 (10.0)
p=0.918 ^b						
4. "Knowing who to ask when you had questions about your health"	Control	2 (7.4)	4 (14.8)	14 (51.9)	5 (18.5)	2 (7.4)
	Intervention	5 (16.7)	4 (13.3)	11 (36.7)	3 (10.0)	7 (23.3)
p=0.311 ^b						
^a Diabetes History Scale ⁴¹⁰						
^b Chi-squared test						

Patient opinion about aspects of the diabetes care provided by their pharmacists (Table 8.15) revealed no significant differences between the groups for any of the items contained in the questionnaire. Patients appeared most likely to be satisfied ('agree' and 'strongly agree') with the notion that their pharmacists are equipped to provide diabetes care (Item 3, control baseline 73.9%, intervention baseline 85.7%, Chi-squared test, p=0.758; Item 3, control post-baseline 61.6%, intervention post-baseline 80.0%, Chi-squared test, p=0.406) and least satisfied with the perceived level of collaboration they believe exists between pharmacists and medical practitioners (Item 4, control baseline 47.8%, intervention baseline 57.2%, Chi-squared test, p=0.962; Item 4, control post-baseline 30.7%, intervention post-baseline 50.0%, Chi-squared test, p=0.482).

Table 8.15 Patient opinion of pharmacist diabetes care: baseline and post-baseline						
Item		Strongly disagree N (%)	Disagree N (%)	Not sure N (%)	Agree N (%)	Strongly agree N (%)
Baseline						
1. "My pharmacist provides me with a good level of diabetes care"	Control	2 (8.7)	2 (8.7)	3 (13.0)	13 (56.5)	3 (13.0)
	Intervention	0 (0.0)	9 (32.1)	1 (3.6)	15 (53.6)	3 (10.7)
	$p=0.127^a$					
2. "I would like my pharmacist to do more to help me manage my diabetes"	Control	0 (0.0)	7 (30.4)	5 (21.7)	10 (43.5)	1 (4.3)
	Intervention	1 (3.6)	9 (32.1)	2 (7.1)	11 (39.3)	5 (17.9)
	$p=0.308^a$					
3. "I think that my pharmacist is equipped to provide me with diabetes care"	Control	1 (4.3)	1 (4.3)	4 (17.4)	13 (56.5)	4 (17.4)
	Intervention	0 (0.0)	1 (3.6)	3 (10.7)	18 (64.3)	6 (21.4)
	$p=0.758^a$					
4. My pharmacist and doctor work together to provide me with diabetes care"	Control	1 (4.3)	7 (30.4)	4 (17.4)	9 (39.1)	2 (8.7)
	Intervention	1 (3.6)	7 (25)	4 (14.3)	12 (42.9)	4 (14.3)
	$p=0.962^a$					
Post-baseline						
1. "My pharmacist provides me with a good level of diabetes care"	Control	2 (7.7)	7 (26.9)	3 (11.5)	10 (38.5)	4 (15.4)
	Intervention	4 (13.3)	6 (20.0)	2 (6.7)	11 (36.7)	7 (23.3)
	$p=0.821^a$					
2. "I would like my pharmacist to do more to help me manage my diabetes"	Control	0 (0.0)	9 (36.0)	5 (20.0)	10 (40.0)	1 (4.0)
	Intervention	1 (3.3)	8 (26.7)	4 (13.3)	15 (50.0)	2 (6.7)
	$p=0.724^a$					
3. "I think that my pharmacist is equipped to provide me with diabetes care"	Control	0 (0.0)	2 (7.7)	8 (30.8)	12 (46.2)	4 (15.4)
	Intervention	1 (3.3)	1 (3.3)	4 (13.3)	18 (60.0)	6 (20.0)
	$p=0.406^a$					
4. "My pharmacist and doctor work together to provide me with diabetes care"	Control	2 (7.7)	7 (26.9)	9 (34.6)	5 (19.2)	3 (11.5)
	Intervention	4 (13.3)	5 (16.7)	6 (20.0)	9 (30.0)	6 (20.0)
	$p=0.482^a$					
^a Chi-squared test						

Adherence to self-management recommendations

Results for the diabetes self-management adherence items presented in Table 8.16 revealed no significant differences between the groups either at baseline or post-baseline. Overall approximately 60% of the control group said that they were always adherent to DM2 self-management recommendation, other than for the item relating to managing body mass, where 41.7% of patients said that they were able to keep their weight under control. Similarly, 38.5% of intervention patients claim to always to have their body mass under control with about 50% of this cohort always adherent to the remainder of the self-management recommendations .

Patients seldom reported 'never' being adherent, with body mass control presenting the greatest self-management challenge to both groups of patients (Item 2, 'always'). The intervention group found coping with their emotions more problematic than managing their body weight at the end of the study.

Table 8.16 Adherence to self-management recommendations ^a : baseline and post-baseline					
Item		Never N (%)	Sometimes N (%)	Always N (%)	Don't know N (%)
Baseline					
1. "I keep my blood sugar in good control"	Control	0 (0.00)	8 (33.3)	15 (62.5)	1 (4.2)
	Intervention	0 (0.00)	11 (42.3)	14 (53.8)	1 (3.8)
p= 0.807 ^b					
2. "I keep my weight under control"	Control	4 (16.7)	10 (41.7)	10 (41.7)	n/a
	Intervention	3 (11.5)	13 (50.0)	10 (38.5)	n/a
p=0.797 ^b					
3. "I do the things I need to do for my diabetes (diet etc.)."	Control	0 (0.00)	9 (37.5)	15 (62.5)	n/a
	Intervention	1 (3.8)	13 (50.0)	12 (46.2)	n/a
p=0.371 ^b					
4. "I handle my feelings (fear, worry, anger) about my diabetes fairly well."	Control	1(4.2)	8 (33.3)	15 (62.5)	n/a
	Intervention	1 (3.8)	12 (46.2)	13 (50.0)	n/a
p=0.649 ^b					

Table 8.16 continued					
Post-baseline					
1. "I keep my blood sugar in good control"	Control	0 (0.00)	9 (34.6)	17 (65.4)	0 (0.00)
	Intervention	1 (3.3)	9 (30.0)	20 (66.7)	0 (0.00)
		p= 0.618 ^b			
2. "I keep my weight under control"	Control	1 (3.7)	13 (48.1)	13 (48.1)	n/a
	Intervention	2 (6.7)	12 (40.0)	16 (53.3)	n/a
		p=0.768 ^b			
3. "I do the things I need to do for my diabetes (diet etc.)."	Control	0 (0.00)	8 (29.6)	19 (70.4)	n/a
	Intervention	0 (0.00)	13 (43.3)	17 (56.7)	n/a
		p=0.284 ^b			
4. "I handle my feelings (fear, worry, anger) about my diabetes fairly well."	Control	0 (0.00)	13 (48.1)	14 (51.9)	n/a
	Intervention	0 (0.00)	19 (63.3)	11 (36.7)	n/a
		p=0.249 ^b			
^a Attitudes Towards Diabetes Scale ³⁸⁵					
^b Chi-squared test					

8.7.2 Post-baseline health- related beliefs, behaviours and knowledge

The following health-related beliefs, behaviours and knowledge variables were only measured post-baseline for both control and intervention patients.

Patient empowerment

The combined scores for 'somewhat agree' and 'agree' in Table 8.17 ($\pm 80\%$ of patients) indicate that patients generally believe that they are empowered to provide the care they require in order to manage their DM2, with very little difference between the control and intervention groups for any of the items. Both groups viewed identifying specific areas of dissatisfaction with care (Item 1) as being more problematic than any of the other scale items. Patients appeared feeling most empowered about turning diabetes goals into action plans (Item 2).

Table 8.17 Patient empowerment in diabetes ^a : post-baseline						
Item		Strongly disagree N (%)	Somewhat disagree N (%)	Neutral N (%)	Somewhat agree N (%)	Strongly agree N (%)
<i>"In general I believe that I:</i>						
1...know what part(s) of taking care of my diabetes that I am dissatisfied with	Control	1 (3.8)	1 (3.8)	10 (38.5)	5 (19.2)	9 (34.6)
	Intervention	4 (14.3)	3 (10.7)	8 (28.6)	7 (25.0)	6 (21.4)
p=0.422 ^b						
2...am able to turn my diabetes goals into a workable plan	Control	1 (3.8)	0 (0.0)	0 (0.0)	13 (50.0)	12 (46.2)
	Intervention	1 (3.4)	0 (0.0)	0 (0.0)	15 (51.7)	13 (44.8)
p=0.990 ^b						
3...can try out different ways of overcoming barriers to my diabetes goals	Control	0 (0.0)	0 (0.0)	1 (3.8)	18 (69.2)	7 (26.9)
	Intervention	1 (3.4)	2 (6.9)	3 (10.3)	16 (55.2)	7 (24.1)
p=0.411 ^b						
4...can find ways to feel better about having diabetes	Control	0 (0.0)	1 (3.8)	5 (19.2)	13 (50.0)	7 (26.9)
	Intervention	3 (10.3)	1 (3.4)	5 (17.2)	8 (27.6)	12 (41.4)
p=0.252 ^b						
5...know the positive ways I cope with diabetes-related stress	Control	0 (0.0)	2 (8.0)	6 (24.0)	12 (48.0)	5 (20.0)
	Intervention	2 (6.9)	2 (6.9)	3 (10.3)	14 (48.3)	8 (27.6)
p=0.467 ^b						
6...can ask for support for having and caring for my diabetes when I need it	Control	0 (0.0)	2 (7.7)	1 (3.8)	10 (38.5)	13 (50.0)
	Intervention	1 (3.4)	1 (3.4)	3 (10.3)	9 (31.0)	15 (51.7)
p=0.668 ^b						
7...know what helps me stay motivated to care for my diabetes	Control	0 (0.0)	0 (0.0)	1 (3.8)	13 (50.0)	12 (46.2)
	Intervention	1 (3.4)	1 (3.4)	3 (10.3)	9 (31.0)	15 (51.7)
p=0.419 ^b						
8...know enough about myself as a person to make diabetes care choices that are right for me".	Control	0 (0.0)	0 (0.0)	1 (3.8)	14 (53.8)	11 (42.3)
	Intervention	0 (0.0)	1 (3.4)	2 (6.9)	10 (34.5)	16 (55.2)
p=0.428 ^b						
^a Diabetes Empowerment Scale –Short Form ⁴¹³						
^b Chi-squared test						

Adherence to pharmacotherapy

Self-reported medication adherence data for each of the five items included in Table 8.18 revealed a degree of non-adherence (i.e. < 100% for the 'Never' column) across all items.

Item		Always N (%)	Often N (%)	Sometimes N (%)	Rarely N (%)	Never N (%)
1. "I forget to take them."	Control	1 (3.8)	0 (0.00)	3 (11.5)	8 (30.8)	14 (53.8)
	Intervention	1 (3.3)	0 (0.00)	3 (10.0)	8 (26.7)	18 (60.0)
		p= 0.975 ^b				
2. "I alter the dose."	Control	0 (0.00)	0 (0.00)	3 (11.5)	4 (15.4)	19 (73.1)
	Intervention	0 (0.00)	0 (0.00)	3 (10.0)	5 (16.7)	22 (73.3)
		p=0.978 ^b				
3. "I stop taking them for a while."	Control	0 (0.00)	0 (0.00)	0 (0.0)	1 (3.8)	25 (96.2)
	Intervention	0 (0.00)	0 (0.00)	1 (3.3)	1 (3.3)	28 (93.3)
		p=0.641 ^b				
4. "I decide to miss out a dose."	Control	0 (0.00)	0 (0.00)	0 (0.0)	2 (7.7)	24 (92.3)
	Intervention	0 (0.00)	0 (0.00)	1 (3.3)	5 (16.7)	24 (80.0)
		p=0.366 ^b				
5. "I take less than instructed"	Control	0 (0.00)	0 (0.00)	2 (7.7)	5 (19.2)	19 (73.1)
	Intervention	0 (0.00)	0 (0.00)	3 (10.0)	0 (0.0)	27 (90.0)
		p=0.042 ^b				
^a Medication Adherence Report Scale ⁴²²						
^b Chi-squared test						

There was a significant difference between the control and intervention groups for Item 5, "I take less than instructed" (Chi-squared test, p=0.042), but no significant difference between the groups for any of the other items. The forgetfulness score (Item 1) for both control (53.8%) and intervention patients (60.0%) indicates that this factor was the main barrier to medication adherence (Chi-squared test, p=0.975). Overall, patients were least likely to use medication intermittently, i.e. "I stop taking them for a while" (Item 3, control 96.2%, intervention 93.3%, Chi-squared test, p=0.641).

Depression

Patients were screened for depression-related symptoms using the validated Major Depression Inventory⁴²⁸ (not reported in a table) where scores of between 20 and 24 may indicate mild depression, 25 to 29 moderate depression and over 30 severe depression. Patients in the control group achieved a mean total score of 7.5±5.5 and

those in the intervention group 8.7 ± 9.4 , with no significant difference between the two groups (independent t-test, $p=0.595$)

Self-monitoring of blood glucose (SMBG)

There were no significant differences between the two groups in terms of the items included in the SMBG scale (Table 8.19). Almost all patients monitored their blood glucose levels (Item 1, 92.3% of control and 86.7% of intervention patients, Chi-squared test, $p=0.496$), and over 80% in both groups used these data to inform self-management activities (Item 3, Chi-squared test, $p=0.623$), but fewer patients recorded these data (Item 2, 62.5% of control and 73.1% of intervention patients, Chi-squared test, $p=0.423$).

Approximately two thirds of patients said that their medical practitioners referred to their SMBG values (Item 4, 66.7% of control and 69.2% of intervention patients, Chi-squared test, $p=0.312$), whereas far fewer pharmacists appeared likely to review these data (Item 5, 16.7% of control and 30.8% of intervention patients, Chi-squared test, $p=0.213$). Data not included in a table revealed that there was no significant difference in HbA_{1c} between those patients who said that they monitored their blood glucose regularly and those who did not (7.8 ± 1.7 , 7.9 ± 2.0 , independent t-test, $p=0.863$).

Table 8.19 Self-monitoring of blood glucose ^a : post-baseline					
Item	Control		Intervention		p-value Chi-squared test
	N	%	N	%	
1. "Do you test your blood sugar?"	24	(92.3)	26	(86.7)	0.496
2. "Do you keep a record of your blood sugar results?"	15	(62.5)	19	(73.1)	0.423
3. "Do you use your blood sugar test results to assist you in the management of your diabetes?"	20	(83.3)	21	(80.8)	0.623
4. "Does your medical practitioner use your blood sugar test results in prescribing your diabetes therapy?"	16	(66.7)	18	(69.2)	0.312
5. "Does your pharmacist use your blood sugar test results to suggest adjustments to your medication therapy?"	4	(16.7)	8	(30.8)	0.213

^aAdapted from the Diabetes Care Profile³⁸⁵

Diabetes knowledge

The 14 item Diabetes Knowledge Test⁴³⁶ administered post-baseline (not reported in a table) revealed that there was no significant difference between the groups in terms of the mean total scores for the scale, with 26 control patients and 30 intervention patients achieving scores (in a range of 0 to 14) of 10.3 ± 2.5 and 10.4 ± 2.2 respectively (independent t-test $p=0.884$).

Self-rated understanding of diabetes

Table 8.20 presents the post-baseline scores for understanding management practices in DM2. A greater proportion of patients generally rated their understanding as 'Good' or 'Excellent' rather than 'Poor', with no important differences between intervention and control.

There was a good level of understanding in the key self-management areas of diet and glycaemic control, medication use, SMBG and less so with regard to physical exercise. There was a significant difference between the groups for the scale item relating to understanding the complications of diabetes with the intervention group demonstrating a significantly improved self-reported understanding of this aspect ($p=0.035$).

Table 8.20 Self-rated understanding of aspects of diabetes ^a : post-baseline				
Self-rated understanding of:		Poor N (%)	Good N (%)	Excellent N (%)
Diet and blood glucose control	Control	2 (7.7)	21 (80.8)	3 (11.5)
	Intervention p= 0.550 ^b	1 (3.4)	22 (75.9)	6 (20.7)
Weight management	Control	7 (26.9)	18 (69.2)	1 (3.8)
	Intervention p= 0.075 ^b	2 (6.7)	24 (80.0)	4 (13.3)
Physical exercise	Control	4 (15.4)	21 (80.8)	1 (3.8)
	Intervention p= 0.607 ^b	5 (17.2)	21 (72.4)	3 (10.3)
Use of medication	Control	2 (7.7)	18 (69.2)	6 (23.1)
	Intervention p= 0.114 ^b	0 (0.0)	17 (56.7)	13 (43.3)
Blood glucose testing	Control	1 (3.8)	17 (65.4)	8 (30.8)
	Intervention p= 0.896 ^b	2 (6.7)	19 (63.3)	9 (30.0)
Foot care	Control	6 (23.1)	16 (61.5)	4 (15.4)
	Intervention p= 0.314 ^b	3 (10.0)	19 (63.3)	8 (26.7)
Complications of diabetes	Control	6 (24.0)	19 (76.0)	0 (0.0)
	Intervention p= 0.035 ^b	5 (16.7)	18 (60.0)	7 (23.3)
Eye care	Control	6 (24.0)	13 (52.0)	6 (24.0)
	Intervention p= 0.769 ^b	5 (16.7)	18 (60.0)	7 (23.3)
Combining diabetes medication with other medication	Control	10 (38.5)	16 (61.5)	0 (0.0)
	Intervention p= 0.075 ^b	6 (20.0)	20 (66.7)	4 (13.3)
Alcohol use and diabetes	Control	4 (15.4)	16 (61.5)	6 (23.1)
	Intervention p= 0.687 ^b	6 (20.0)	15 (50.0)	9 (30.0)

^a Understanding Management Practices Scale adapted from the Diabetes Care Profile³⁸⁵
^b Chi-squared test

CHAPTER 9

DISCUSSION OF RESULTS

9.1 Introduction

Findings at the conclusion of the study indicate no significant differences between the control and intervention patients with regard to changes to the primary endpoint of HbA_{1c}, nor to any of the secondary biochemical or clinical markers, nor were there any significant differences between the two groups in terms of medication adherence and adherence to DM2 self-management recommendations. It may be concluded, therefore, that the intervention pharmacists showed no demonstrable influence on any of the intermediate health outcomes relating to metabolic control or on therapeutic adherence in DM2 that was significantly different from that exerted by the control cohort of pharmacists.

9.2 The challenge of recruiting pharmacists

The participation of only 16 pharmacists, all of whom were white and mostly female, did not adequately represent community pharmacy in South Africa. Recruiting pharmacists to the study proved problematic despite efforts to involve pharmacist organisations in the recruitment process. While the initial interest expressed by pharmacists was promising, many failed to participate for a number of reasons. The spectre of substantially reduced revenue and profit margins, which pharmacists believed would accompany the introduction of price control on medicines and corporate ownership of pharmacy in South Africa, impacted so negatively on community pharmacist sentiment that many in the profession questioned the continued viability of community pharmacy practice. This negative sentiment was reflected in the closure of some 150 pharmacies between 2004 and the end of 2006 with further pharmacy closures during 2007 (personal communication: Ms Sarah Nyama, Senior Registration Officer, South African Pharmacy Council, June 2008).

It is probable that the pessimism pervading community pharmacy impacted negatively on the study as it became evident during the recruitment process that the voluntary commitment of time and resources by pharmacists was by no means assured. As patient and pharmacist attrition levels were difficult to anticipate it was decided to canvass for pharmacist participation as broadly as was possible, given the limits imposed by available research resources. Similar barriers have been identified by other researchers as important impediments to the effective recruitment of pharmacists to practice-based research projects.¹⁸¹

It is possible that other factors affected participation including inadequate pharmacy infrastructure (e.g. absence of a separate patient counselling area), a perceived lack of capacity (i.e. skills, resources, support staff), confidence, and awareness of the purpose and value of research.^{181,529} It was beyond the scope of this study to investigate the reasons for pharmacist non-participation, but given the profession's stated commitment to practice-based research, and the professional imperative of using research to inform and guide education, training and practice,¹⁸⁶ this aspect warrants further investigation.

Pharmacists have often been compensated for participating in research,^{175,359} and some studies note that they have been specifically trained to implement interventions, or that they are credentialed to provide care for designated diseases.^{9,173,175} However, these potentially confounding influences are not always acknowledged or discussed when outcomes are reported.³⁸ It is probable that more pharmacists would have been recruited had there been a promise of compensation. However, it was felt that paying pharmacists to participate in intervention research could have introduced an element of bias as community pharmacists in South Africa are not generally paid to provide CPS.

The more successful diabetes-related pharmaceutical care interventions noted in the literature appear to be associated with specific training of specialist pharmacists and the intensive, ongoing support of these pharmacists.^{9,173,175} However, this approach does not satisfactorily emulate standard community pharmacy practice, as it is associated with a more controlled 'laboratory-style' research environment. Practising pharmacists may be reluctant to participate in research if they question the relevance of studies in the context of their own practice.¹⁸¹

The lack of face-to-face contact between the researcher and pharmacists may also have negatively affected pharmacist recruitment. Initially, a face-to-face recruitment and training strategy was mooted but logistical barriers prevented the adoption of such an approach mainly because the study was not restricted to any geographical area in South Africa and because most pharmacists were constrained by time and human resources which prevented attendance at after-hours training.

Recruitment by proxy and the use of a distance-learning training approach appeared to offer the next best option, especially since the continuing education programmes for pharmacists that are on offer from the Pharmaceutical Society of South Africa most often use distance-learning with written material as the method of instruction, and pharmacists are therefore familiar with such an approach. Poor communication between researchers and pharmacists has been identified as a major barrier to effective research.¹⁸¹ Reflecting on the recruitment process adopted in this study, far too much reliance was placed on the communication media of the various pharmacy organisations during the recruitment phase.

9.3 Patient participants

The patients recruited to the study may not have been fully representative of insured patients with DM2 in South Africa, as it is possible that there was a disproportionate representation of individuals who were already engaged with their care, i.e. there may have been little or no representation of those who were medically disengaged from care and who for this reason declined to participate. This impacts on the external validity of the study. The relatively high levels of adherence reported later in this chapter, in contrast to the findings contained in the WHO report on adherence to long-term therapies,¹ may support such an assumption.

Randomisation of the patient selection sequence reduced the potential for selection bias, although it was not possible to audit this process in the pharmacies.³⁵ The stratification of pharmacists to improve matching before the randomisation of pharmacists and their patients to control and intervention groups at pharmacy level, reduced bias and prevented contamination of the groups.^{35,359}

Demographically the only significant difference between the intervention and control groups was language. Neither group accurately reflected the ethnic composition of the South African population,⁵³⁰ although the sample did more closely represent the ethnicity of insured healthcare consumers whose prescriptions were filled by community pharmacists (personal communication M Willie Council for Medical Schemes 3 December 2008).

Patient participation may have been influenced by the socioeconomic conditions prevailing in South Africa as high levels of unemployment and poverty, especially amongst black individuals, prevent many South Africans from being able to access the insured healthcare sector.⁵⁰⁸ Another important barrier to patient use of community pharmacy for prescription medicines in this country is the high proportion of medical practitioners who dispense medicines to their patients.⁵¹⁶ Many black South Africans, especially those with few socioeconomic resources, prefer and rely extensively on culturally adroit traditional healers and their remedies for a range of physical and psychosomatic conditions.^{331,531,532} This also negatively influences the number of patients who receive medicines dispensed by community pharmacists.

As with the demographic data, there were no important differences between the two patient groups for other self-reported patient data,³⁵⁹ such as the length of time since first diagnosis of DM2 or level of medical care provided, that could have confounded the results.

9.4 Co-morbidities and complications

Despite the well-recognised role of glycaemic control in the prevention and arresting of diabetes-related complications,^{4,85} 50% of patients did not have their HbA_{1c} levels measured every six months, and a further 15% said that they did not know if this test had been done. This finding raises important questions relating to the quality of diabetes care, including the method of assessing the effectiveness of therapeutic interventions, if intermediate outcomes are not being measured. The old business management adage of “if you don’t measure you can’t manage” applies equally to managing glycaemia in evidence-based diabetes care.⁵³³

Hypertension was the most commonly reported co-morbidity and the 60% prevalence in both groups was not significantly different from the 70% reported in the literature.²⁵⁷ While the vast majority of patients had their blood pressure measured at each diabetes-related visit (>80% in both groups), less than 25% of all patients were at the SEMDSA guideline goal for systolic blood pressure.¹⁰⁵ This finding is in line with epidemiological data noted in the Hypertension Optimal Treatment (HOT) study,⁹⁷ and is a particular cause for concern as a hypertensive diabetic is particularly at risk for other diseases including cardiovascular disease, stroke, nephropathy and retinopathy.⁴

Cardiovascular disease accounts for between 50% and 80% of all diabetes-related deaths.^{4,41,101} A finding that should be of concern was that despite clear evidence of the association between dyslipidaemia, diabetes and cardiovascular disease,^{534,535} one third of all patients reported not having an annual lipogram and over 60% did not have an annual ECG. Furthermore, although the correlation between the anthropometric variables and cardiovascular risk is well established,^{49,116} less than 50% of patients stated that they were weighed at each diabetes consultation and less than 20% had their waist-hip circumference measured.

At the end of the study, 87% of study patients were classified as either overweight or obese in terms of the SEMDSA guideline, correlating closely with WHO data which shows that approximately 90% of individuals with DM2 are either overweight or obese.⁴⁹ One of the most challenging aspects of diabetes self-management relates to the control of body mass and a comparison of before and after data, which reveals very little change to BMI within or between the groups, bears witness to the difficulty of the problem.³⁶¹ However, in other studies, pharmacists have demonstrated an ability to successfully counsel patients for weight loss, and they are generally well positioned to provide weight reduction support.^{536,537}

Retinopathy, nephropathy and neuropathy are the most common microvascular complications of DM2 and, as a consequence, they make an important contribution to the patient's overall burden of disease.^{91,127,538} Approximately 60% of patients reported not having an annual eye examination, and although the screening prevalence reported in the study compares favourably with data forthcoming from a recent South African study where 5.2% of patients had a regular annual funduscopy,¹²⁶ it is possible that

patients under reported this complication,⁹¹ especially as retinopathy often precedes any loss of vision. Over 60% of patients did not have an annual kidney function test despite raised albuminuria in diabetes being associated with cardiovascular disease and the development of nephropathy.^{103,539,540} This reflects inadequate screening practices, especially as other South African data reveals nephropathy prevalence to be significantly greater than that reported in this study.^{541,542}

A similar situation exists for neuropathy which may be more prevalent than was reported given that approximately 60% of patients did not have an annual foot examination. Sexual dysfunction is a common and important complication of diabetes⁵¹⁵ but was not investigated in this study. This should have been included as pharmacists may be asked to counsel individuals on this condition, and as DM2, hypertension, heart disease and certain medications used to treat these conditions are associated with the complication.⁵⁴⁴

The overall 11.5% prevalence of depression in this study was lower than the 15%-20% reported in the literature.⁴²³ This lower prevalence may be due either to under-reporting by patients or may reflect the psychological profile of the patients who were willing to participate in the research. Concurrent depression has been shown to influence glycaemic control and self-management adherence negatively.⁵⁴⁵ Pharmacists have demonstrated that they are able to screen patients for depression using validated instruments and to refer identified patients for professional psychological evaluation.⁵⁴⁶

9.5 Changes to surrogate outcomes (primary and secondary clinical endpoints)

A comparative analysis of all the biochemical and clinical data, with the exception of serum creatinine, allows for an immediate visual 'picture' of a particular intermediate health outcome, for example an HbA_{1c} > 7.0 indicates the absence of glycaemic control.¹⁰⁵ Pharmacists, having been provided with clinical data at baseline, were positioned to easily identify patients not at guideline goal for HbA_{1c} and were therefore able to collaboratively tailor individualised remedial interventions.²⁰ The same principle holds true for blood lipid values and dyslipidaemia, blood pressure and hypertension and BMI and obesity. The serum creatinine value, while not providing an 'instant picture' of

an intermediate clinical outcome, is an essential element in calculating the glomerular filtration rate, which is considered to be the best index of renal function.¹²⁹

There were no significant differences in any of the clinical variables designated as primary and secondary endpoints, either between or within the groups at the end of the study. HbA_{1c}, lipid profiles, serum creatinine, blood pressure and BMI are all accepted surrogate markers or intermediate outcomes for the hyperglycaemia associated with DM2, dyslipidaemia, chronic kidney disease, hypertension and obesity, respectively.^{173,458}

A recent systematic review of pharmacist outpatient interventions in adults with diabetes, found that although there were very few RCTs of community pharmacist interventions, and despite studies often being limited by design flaws, there was some evidence of overall improvement in HbA_{1c}.⁴⁵⁸ A systematic review of the literature relating to the value of CPS provided in community settings between 1990 and 2002 identified six diabetes-related RCTs in which HbA_{1c} was used as a surrogate endpoint.¹² Of these only one study was able to show a significant improvement in HbA_{1c} in the intervention group, although patients were only followed for four months thus rendering any sustained improvement in HbA_{1c} uncertain.⁵⁴⁷ A Cochrane review that considered outpatient pharmacist impact on patient outcomes concluded that the quality of existing studies makes assessment of pharmacist effectiveness difficult.¹⁸³

9.6 Patients at goal for SEMDSA DM2 guideline

Given the evidence-based nature of the SEMDSA guideline and its role in promoting metabolic control in DM2,¹⁰⁵ an alternative method of evaluating the DCP intervention was to compare the percentage of patients at goal at baseline versus post-baseline. There were positive changes in the percentage of patients at goal for some of the lipid factors (i.e. total cholesterol and LDL-C) in both groups by the end of the study but there were no significant changes in the percentage of patients at goal for any of the other clinical variables including HbA_{1c}.

The study did not investigate patient knowledge of guideline recommendations, although the intervention pharmacists were provided with copies of the SEMDSA guideline and it

was suggested that they discuss the contents with their patients. A recent study relating to the prevention of coronary heart disease in DM2 demonstrated the utility of clinical practice guidelines in providing a basis for collaboration between pharmacists and medical practitioners.

9.7 Prescribed medication

Although there was no significant difference within or between the intervention and control groups for glycaemic control, the lower mean HbA_{1c} demonstrated by the control group both at baseline (7.3%) and post-baseline (7.6%), compared to the intervention group (8.2% at baseline and post-baseline) is a surprising finding given that the control patients had been diagnosed with DM2 for considerably longer than the intervention group (9 years vs 5 years), and given that DM2 is a progressive disease with insulin resistance and β -cell failure increasing over time resulting in an increased HbA_{1c}.⁵⁶ The control group appeared to have been subjected to more intensive therapy with over 40% of the group using insulin either alone or in combination with oral agents, whereas less than 20% of the intervention group used insulin and then only in combination with oral agents, which may explain the lower mean HbA_{1c} levels reported by the control group.

It is expected that therapy would be intensified with insulin being added to the regimen as glycaemic control decreased. This was confirmed in this study which revealed that the mean HbA_{1c} in patients using only oral anti-diabetic therapy was lower than for those patients on insulin alone or those who used a combination of insulin and oral agents.

Overall insulin utilisation by just over a quarter of study patients appears to be similar to that reported previously,⁵⁴⁹ and is commensurate with South African anecdotal data where it is estimated that 26% of DM2 diabetics use insulin (personal communication, Young Z, Novo-Nordisk (Pty) Ltd. 20 October 2008). The inadequacy of oral therapy occurs over time as a consequence of the progressive nature of DM2, and becomes evident once hyperglycaemia persists despite a regimen of two oral agents at maximum dose.⁵¹ In this study just under two-thirds of all patients using oral anti-diabetic agents were taking two agents, with the balance on monotherapy. It was not established if the maximum dose of the prescribed medication was being taken and it may be that dosages could be further titrated in order to improve glycaemic control.

Given that the mean HbA_{1c} of the dual oral therapy group (8.1%) exceeded the IDF threshold for initiating insulin therapy (>7.5%),⁴ it is probable that an additional number of patients should have been using insulin as well as oral therapy. The reluctance to use insulin both at a provider and a patient level has been described in the literature,⁵⁵⁰⁻⁵⁵² and may, in part, explain why less than 30% of all patients were at goal for HbA_{1c} at the end of the study. Previous research has shown that pharmacists who are prepared to develop skills relating to optimising insulin utilisation are able to assist patients and other providers in resolving common barriers to this essential therapy.⁵⁵³

The incidence of hypertension and anti-hypertensive medication utilisation reported in the study correlated with literature data.⁸⁹ It is unlikely that the anti-hypertensive regimens were optimised given that almost two thirds of patients were on monotherapy, whereas the UKPDS and the SEMDSA guideline suggest a two to three agent approach in managing hypertension in DM2.^{104,105}

The defined scope of practice of a community pharmacist provides for the appropriate monitoring of blood pressure.⁶ In addition to monitoring and advocating appropriate lifestyle and behavioural modifications,⁵⁵⁴ pharmacists may consider suggesting adjustments to antihypertensive therapy where goals are not being met,¹⁷⁴ especially with regard to the possible inclusion of agents from the ACE inhibitor and ARB classes, given the additional renal protection properties of these agents.⁵⁵⁵ Hypertension intervention studies have demonstrated cost-effective outcomes resulting from collaborative pharmacist interventions.^{359,556}

The self-reported prevalence of heart disease and dyslipidaemia closely correlated with pharmacy prescription data for hypolipidaemic agents. However, the relatively low level of statin utilisation indicates possible suboptimal use. While over a third of patients were taking a statin, utilisation was considerably lower than that recommended by the IDF,⁴ the Collaborative Atorvastatin Diabetes Study (CARDS)¹⁰⁰ and the Heart Protection Study⁹⁹ which suggest that all patients over the age of 40 should be considered for statin therapy.

The results demonstrating that only 57.7% of control patients and 53.6% of intervention patients met the SEMDSA guideline criterion for LDL-C (≤ 3.0 mmol/l) at the end of the study reflect the inadequacy of blood lipid control.¹⁰⁵ This result suggests that while it may appear that intervention pharmacists did little to influence lipid control, there is substantial potential for pharmacists to contribute to both the treatment and the prevention of cardiovascular disease via the medication review process. Such interventions should include non-pharmacotherapeutic as well as pharmacotherapeutic options.^{557,558}

While adjustments to glycaemia-related pharmacotherapy were noted at the end of the study, it was, however, not possible to ascertain from the data when the changes occurred or if any of the interventions were initiated as a direct result of pharmacist recommendations.

9.8 Health-related beliefs, behaviours and diabetes-related knowledge

Results relating to psychosocial variables revealed very little difference in control and intervention groups between baseline and the end of the study.

9.8.1 Medication-related beliefs, satisfaction with care and patient empowerment

Patients unequivocally indicated that they believed that the necessity of taking medication for DM2 far outweighed any concerns about the perceived adverse effects of these medicines. This finding is in line with that of a study that investigated patient beliefs concerning the role of medication in chronic disease management, where almost 90% of patients said that they believed that medication use was a necessary element of their care.⁵⁵⁹ The 'necessity' and 'concerns' beliefs about medication are closely associated with adherence to therapy,²⁷² and the reported positive necessity-concerns differential supported the high levels of adherence measured by patient self-report and prescription refill frequency data. Neither control nor intervention patients appeared overly concerned about the possible harm that medicines in general may do, or about the possibility that medical practitioners may overuse medication.²⁷²

At the end of the study the vast majority of both control and intervention patients (>80%) were very satisfied with their recent diabetes care, but substantially fewer (<60%) were similarly satisfied with their long-term care. However, it is possible that certain expectations arising from participation in the research may have influenced the 'recent care' scores. While a minority of patients, (22%) considered 12-month care specifically provided by their healthcare providers to be 'poor' either at baseline or post-baseline, a further 20% rated such care as 'fair'. These findings generally indicate a less than satisfactory state of affairs, as patient satisfaction is both a surrogate measure of the value patients place on services they receive,⁵⁶⁰ and is an important driver within the adherence dynamic.⁴⁰³

The relatively high level of patient dissatisfaction expressed with regard to longer-term care may have been influenced by the intrinsic nature of DM2,⁵⁶¹ i.e. it is a progressive chronic disease in which the prevalence of complications and associated co-morbidities are almost certain to increase over time and patients may experience frustration and a sense of powerlessness which may have fuelled their dissatisfaction with long-term care.¹⁹³ In addition, dissatisfaction may be associated with diabetes distress or with the embarrassment that some individuals feel about having diabetes.⁵⁶² Patient dissatisfaction with the perceived level of communication between healthcare providers speaks to the continued absence, at a systems level, of models of collaborative patient-centred diabetes care in South Africa.

The percentage of control patients who expressed satisfaction with their pharmacists declined by almost 16% during the study, while in the intervention group the percentage decline was in the order of 4%. The decline in satisfaction may be a reflection of unmet expectations arising from the research process, i.e. patients may have had unrealistic expectations relating to the purpose and processes involved in the research. This satisfaction differential may be attributed to the increased interaction between pharmacists and patients in the intervention group. Patients were particularly dissatisfied with the perceived level of communication between pharmacists and medical practitioners. Poor levels of communication between healthcare providers has been identified as an important barrier to optimising the medication utilisation process.¹⁶¹

Encouragingly, at the end of the study approximately 80% of the intervention patients continued to believe that pharmacists were equipped to provide diabetes care, while only 60% of control patients believed similarly. This finding correlates well with the findings of a recent systematic review of pharmacist interventions in diabetes, which endorses value-added roles for pharmacists in diabetes care,⁴⁵⁸ and this augurs well for pharmacist-delivered diabetes services as it indicates that intervention pharmacists were able to positively influence patient perception in this regard. Furthermore, it confirms the existence of a foundational basis for the future development of services in line with diabetes CPS provided elsewhere.¹⁷³

There was no significant difference between the control and intervention patients in terms of feeling empowered, with over 85% of patients stating that they 'agreed' or 'strongly agreed' that they were empowered to manage psychosocial aspects of their diabetes. The only areas where patients expressed uncertainty were in being able to identify specific aspects of care that caused most dissatisfaction, and in remaining positive about coping with diabetes and the stress that having the disease may cause. A Swedish diabetes education RCT found no significant difference between the groups in terms of patient empowerment,⁵⁶³ although the Asheville Project post-study focus group noted that patient diabetes empowerment perception improved as a result of the pharmaceutical care intervention.³²

9.8.2 Diabetes self-management adherence and depression screening.

Patients were largely adherent to both their prescribed medication therapies and to self-management recommendations, and no significant differences were identified between the control and intervention groups to indicate any intervention effect.

Despite being associated with a possible overestimation of adherence,³⁵⁰ the patient adherence self-report is nevertheless a useful tool for identifying barriers to self-management, which is the cornerstone of effective diabetes care.^{564,565} The results show that approximately 40% of patients said that they always managed to control their body mass and that between 50–60% of patients stated that they were adherent at baseline to self-management recommendations ranging from glycaemic and emotional control, eating appropriately, exercising, monitoring clinical variables, keeping appointments to

taking medication. One possible reason that the intervention group was not able to effect significant improvements in self-management adherence, when compared with those reported by the control group, may be the lack of sufficient emphasis within the DCP framework on the importance of adherence. Other reasons may include pharmacist uncertainty about what options to explore in developing adherence promoting interventions, and that an insufficient number of pharmacists with their patients developed and implemented interventions.

Studies of interventions aimed at improving medication adherence in patients with chronic diseases have not all demonstrated positive outcomes.^{324,343} An RCT involving 16 community pharmacies that compared patient adherence to therapies in two groups, one of which received comprehensive pharmaceutical care and the other traditional pharmacy services, found that although the intervention group was more satisfied with the level of care, adherence was not significantly different from that demonstrated by the control patients.⁴⁰⁵ A Cochrane review of interventions designed to enhance medication adherence, found that simple treatment regimens (e.g. a single dose of an agent once a day) and complex strategies, which could include comprehensive patient information, frequent counselling, follow-up and supervision of self-monitoring, and psychosocial support, were more likely to result in improved adherence and treatment outcomes than single component interventions. However, the reviewers note even complex strategies and interventions appear not be effective in the long term, in spite of the considerable time and effort required.³³⁰

A common denominator across successful interventions appears to be the improved and frequent interaction between provider and patient,³³⁰ which supports the nexus of the Chronic Care Model,¹⁵⁵ i.e. the productive interaction between prepared and proactive pharmacist and an informed and activated patient (Section 3.5.3). A pharmacist facilitated patient self-management programme described by Garrett and Blumi¹⁷⁶ was able to demonstrate improved patient adherence to treatment and improved clinical, economic and humanistic outcomes through a collaborative process of review, coaching and reinforcement. In contrast to this positive finding, a multi-clinic RCT of a pharmacist intervention in poorly controlled diabetics by Odegard et al³⁷ did not report significantly improved self-reported adherence, glycaemic control or changes in medication appropriateness. A systematic review of community pharmacist interventions

to improve patient adherence to chronic medication, noted that the paucity of well designed studies made it impossible to assess the effectiveness of such interventions.¹⁵³

The study indicated high levels of post-baseline adherence for all the pharmacological categories when assessed from prescription refill data with no significant differences between the control and intervention groups. Measuring medication adherence in practice remains problematic,³⁸⁰ and as no standard measure of medication adherence exists, various categorical cut-off points have been applied in defining the point below which the patient is considered to be non-adherent to a particular regimen. Some authors have suggested that patient self-assessment of adherence is most valid when non-adherence is defined as anything other than total or optimal adherence.³⁷⁶ Prescription refill or claims data, which serves as a surrogate measure of medication possession, is associated with clinical outcomes and has been used as a proxy measure of medication adherence, albeit that possession of medication does not guarantee that it is used or that it is used appropriately.^{348,376,380,566}

In addition to the prescription refill data, medication adherence at the end of the study was assessed by means of patient self-report using the Medication Adherence Report Scale.⁴²² Self-reported medication adherence was very high with an average of 23.5 out of a maximum score of 25, and this finding correlated with the prescription refill data which revealed a similar high level of adherence. As has been reported in other studies, patient self-report slightly overestimated adherence when compared to adherence assessed from the prescription refill data.^{376,567} Adherence levels ranged from a low of 54% to a high of 96% with both control and intervention patients identifying forgetfulness as the main cause of non-adherence, which correlates with findings of other studies.^{343,568,569} Overall adherence results agree with other studies, where adherence to oral anti-diabetic therapy was found to range from 36% to 93%.^{348,566}

It is possible that patients who participated in the study were largely adherent to pharmacotherapy at baseline and continued in this vein during the study, thus mitigating against being able to demonstrate any intervention effect. An RCT designed to improve patient medication adherence in DM2 by reducing self-reported adherence barriers found that the main reason for the lack of effect was the very high levels of adherence and low levels of barriers to adherence reported at baseline.⁴⁶⁴

Ideally the sample should have included patients with lower levels of baseline adherence. Paradoxically, it is these patients who may be at greatest risk for increased morbidity and are more likely to be disengaged from medical care who may be able to best demonstrate a positive intervention effect. However, it is possible that it is their very disengagement from care that prevents sustained participation in intervention studies. If pharmacists are specifically trained in recruitment techniques, including the way in which a study is described to patients, and if they are able to ensure that patients feel secure and see value in the research, then it may be possible for samples to be more representative of target patient populations.⁵⁷⁰

Despite the progressive nature of DM2, a number of major studies including UKPDS, DCCT and Steno-2 were able demonstrate improvements in hyperglycaemia, hypertension and dyslipidaemia using interventions that largely relied on pharmacotherapy.^{92,103,571} The close correlation of prescription refill data and self-reported medication adherence data indicated high levels of medication adherence, and yet only 30% of patients were at goal for the SEMDSA guideline for HbA_{1c}. Given that HbA_{1c}, blood pressure and blood lipids are particularly responsive to pharmacotherapy,^{92,103} this anomaly raises the question as to why more patients were not at goal at the end of the study. It is possible that the pharmacotherapy was not optimal with 'clinical inertia' being a contributing factor. Clinical inertia, has been identified as a critical barrier to the effective control of metabolic risk factors.^{572,573}

An analysis of the prescription data of 54 patients (23 control and 31 intervention) revealed that 50% of these patients had changes made to their anti-diabetic medication regimens during the 12 month period under review. Unfortunately, the data were incomplete in terms of when the changes were made, which prevented any evaluation of the impact of these changes on glycaemic control. Nevertheless, further investigation of the prevalence of clinical inertia in DM2 for all metabolic risk factors is warranted as the implications for patient health outcomes may be significant.⁵⁷³

The utility of pharmacist depression screening in patients with diabetes in a primary care setting has been demonstrated,⁵⁴⁶ although this should be confined to identifying patients who may be candidates for escalated psychological care.³⁶ The overall incidence of self-

reported depression decreased from seven at baseline to four post-baseline. Depression is an important co-morbidity in DM2 because it is associated with an increase in diabetic complications, reduced adherence to therapy and inadequate levels of self-management.⁴²³

9.8.3 Diabetes-related knowledge, understanding diabetes care and SMBG

At the end of the study, approximately 80% of control and 88% of intervention patients indicated that their understanding of key aspects of diabetes care was 'good' to 'excellent', with both control and intervention patients demonstrating equally that they had good levels of diabetes-related knowledge. Areas of diabetes care in which understanding could be improved included the concurrent use of antidiabetic medication with other medication, complications commonly associated with diabetes, eye care, foot care, body mass control and the use of alcohol in DM2. These more problematic areas of understanding diabetes care in some instances correlate with the relatively low prevalence of the corresponding SEMDSA guideline tests and examinations. For example, 64% of all patients said that had an annual eye examination and 41% an annual foot examination, suggesting that improving diabetes understanding of the relevance of eye care and foot care may result in increased numbers of patients being examined for potential microvascular complications associated with these variables.

Diabetes knowledge has been shown to be associated with improved glycaemic control.^{357,472} although this finding has not been unequivocal.⁴³⁵ Similarly, enhanced understanding of the key aspects of diabetes has been associated with improved metabolic control.⁴³⁰ Diabetes knowledge and understanding are foundational features of patient empowerment and of diabetes self-management education and have been associated with the resolution of barriers to care and thus are effective aspects of successful problem solving.^{392,574,575} A study that examined the association between patient knowledge of HbA_{1c} and diabetes care attitudes and behaviours found that only a quarter of participants knew their HbA_{1c} values. However, although those who knew their HbA_{1c} values were better able to assess their level of glycaemic control and had a better all-round understanding of diabetes care, this knowledge did not translate into improved self-management efficacy.³⁹⁸

Approximately 90% of all patients in this study self-monitored their blood glucose levels with very little difference in frequency between the intervention and control groups, and the results indicated that there was no significant difference in HbA_{1c} between those patients who self-monitored and those who did not. A disconcerting finding was that less than 20% of patients reported that their pharmacists referred to their SMBG readings and made suggestions regarding adjustments to therapy or self-management activities based on these data, with no evidence that the intervention pharmacists were more likely to engage with their patients than were the control group. The Asheville Project demonstrated that patients who engaged with pharmacists about their SMBG not only improved glycaemic control, but patient satisfaction with CPS was also enhanced.⁹

9.9 Study limitations

The study design was informed by *The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration*, which was published in 2001. Although attention was paid to a checklist of items that the Statement suggested should be included in reporting a RCT,³⁵ the study would have benefited had it been informed by guidelines specifically developed to assist researchers improve their understanding of the difficulties associated with developing and evaluating nonpharmacologic and complex interventions as can be found in two recent publications.^{294,296} The United Kingdom Medical Research Council first published a guideline for the development and evaluation of complex interventions in 2000 and revised this document with new guidance published in 2008.²⁹⁴ As the original CONSORT statement “*does not address some specific issues that apply to nonpharmacologic trials,*”²⁹⁶ the CONSORT group published their guideline for reporting nonpharmacologic RCTs in 2008.

A critical review of the design and methodology of the study, informed by the abovementioned reports and other literature relating to the development and evaluation of complex interventions, has identified the following limitations.^{294,296,576-578}

Theory

The theories and models used to support the pharmacist and patient health behaviour change were not adequately explored. The theoretical underpinning of behavioural change required additional discussion, especially as key aspects of the intervention

were informed by the 5 A's model for behavioural change²⁷⁵ and the counselling method of Motivational Interviewing,¹⁷¹ which in turn, is informed by behaviour-related theories and models including the TTM.⁵⁷⁹

Modelling.

The development of the DCP intervention would have been strengthened had there been consultation with a sample of pharmacists and DM2 patients, as envisaged by the Nominal Group Technique.⁵⁸⁰ By modelling the intervention in such a manner, essential elements such as desired patient outcomes, diabetes self-management needs, the relevance and practical implications of the various components of the intervention, as well as the training needs of pharmacists could have been better explored and addressed. This process may have led to a refining of the components of the intervention, and improved understanding of their interaction and the mechanism by which they affect outcomes.

Questionnaires and scales

Although the selection of psychosocial scales and questionnaires was informed by the 'Assess' provision of the 5 A's model (beliefs, behaviours and knowledge),²⁷⁵ neither pharmacists nor patients were consulted about the applicability of these instruments. The number and complexity of the questionnaires may have been inappropriate for this target patient population. For example, the relevance of the questionnaires could have been discussed in focus groups and further tested in a pilot study.

Collaboration and expertise

This study constituted a complex intervention and it would have benefited from collaboration with other investigators, such as a psychologist, sociologist, diabetologist and diabetes educator as effective diabetes care is best served by adopting a interdisciplinary approach.⁵⁶⁵ Furthermore, it would have been especially beneficial to have collaborated with a healthcare professional with expertise in the design of complex interventions. In particular, collaboration with such an expert would have aided the researcher in developing strategies to prevent the methodological difficulties which have become apparent.

Problems associated with the RCT

The methodological problems routinely associated with RCTs, especially in multisite pragmatic trials, may also have constituted limitations in this study. It was not possible to validate pharmacist measurement of the clinical variables and their reporting of prescription related data. There may have been an element of selection bias, i.e. only participants sufficiently interested in diabetes care may have participated in the study. The complex nature of behavioural change, with many possible interacting components, made the identification and management of confounding variables (e.g. changes in therapy) difficult, especially as this was a multisite trial. The overall lack of control by the researcher with regard to the actual implementation of the DCP in the trial meant that it was not possible to identify or assess the efficacy of the individual components of any applied intervention.

Details of the intervention and comparator

In a RCT, the ideal is to be able to precisely describe both the experimental treatment and comparator. In this study it was not possible to comprehensively describe the 'usual' care afforded patients by the control pharmacists as these pharmacists were merely requested not to provide their patients with a level of pharmaceutical care that differed from that which they traditionally provided. 'Usual care' potentially varied widely between the control pharmacists. There was no standardisation of the interventions as the DCP was intended to be pragmatically adapted by pharmacists for individual practice conditions and individualized for patients. While intervention pharmacists were provided with a suggested framework for individualized interventions (a DCP manual, Annexure 6.5), the detail of actual interventions applied was not recorded as the researcher was not able to authenticate such data.

Piloting the intervention

The intervention was not piloted and therefore neither the validity nor feasibility of the intervention could be determined prior to its implementation. The lack of an exploratory study precluded feedback on the components of the intervention and their subsequent refinement (including scales and questionnaires), the assessment of the likelihood of being able to recruit pharmacists and patients and their likelihood of adhering to the intervention protocol, or if due consideration should be given to an alternate design.

Practical considerations mainly relating to available resources mitigated against being able to conduct a meaningful exploratory study.

Recruitment and training of pharmacists

The study may have suffered as a result of the lack of face-to-face contact with the pharmacists, both in terms of recruitment and with regard to training for the delivery of the intervention. Improved contact and communication with pharmacists may have facilitated the resolution of some of the barriers preventing pharmacists from participating in practice-based research. It is possible that recruited pharmacists were not representative of community pharmacists in general, e.g. possibly only pharmacists with an interest in DM2 agreed to participate in the study, although this aspect was not investigated.

Pharmacist training using a distance learning approach is briefly mentioned above as a *Modeling* limitation. The distance learning method adopted in attempting to equip pharmacists for the delivery of individualized DCP interventions, did not result in any significant interaction between the researcher and the pharmacists, although assistance was offered to those who wanted further clarification or information. The development, organization and delivery of the training material (the DCP manual) would probably have benefited from further pharmacist consultation (e.g. using the Nominal Group Technique),⁵⁸⁰ and from the participation of an expert in the distance learning approach to the continuing education of health professionals. Despite distance learning with written material being the most common approach to pharmacist continuing education in South Africa, it may not be as effective as face-to-face training.^{581,582}

Pharmacist data

The pharmacist is an important variable in this study that should have been more intensively investigated. In particular, investigating pharmacist familiarity with the material provided, their confidence in their ability to develop and deliver the DCP, as well their actual expertise in delivering the intervention, could have provided valuable insight into key aspects of the intervention including the feasibility, validity and interdependence of the various components.

Blinding

Although blinding of the assessor (in this case the researcher) is a RCT recommendation, practical considerations mitigated against adherence to this item.

Sample size

The sample size calculation was based on detecting a 0.5% change in HbA_{1c}, whereas the literature most often refers to a 1% change as being significant. Had a sample size estimate been based on an absolute difference of 1% in HbA_{1c} change between the two groups, with a standard deviation of 1%, then a fixed sample size of 20 per group would yield a power of 88.54%.⁵¹⁷ The relatively small sample size (27 control and 31 intervention patients) impacted negatively on the quality of the study in terms of being able to adequately comment on the effect of the intervention on patient adherence. Haynes et al³³⁰ suggests that as a general guide for studies with a single intervention group and control group “...at least 60 participants per group are required in order to have at least 80% power to detect an absolute difference of 25% in the proportion of patients judged to have adequate adherence”. The small sample size exacerbated the problem relating to the representativity of both pharmacists and patients.

Pharmacist – medical practitioner collaboration

The study should have investigated collaboration or information sharing that may have taken place between medical practitioners and pharmacists given the emphasis placed on multidisciplinary collaboration in diabetes care.^{19,352,583}

Process evaluation

The lack of effect reported in the study may have been due to failure on the part of the pharmacists to implement the DCP adequately and for long enough rather than assuming ineffectiveness. The design lacked provision for in-process evaluation and as data were only collected at baseline and again post-baseline it was not possible to assess intervention fidelity or quality. This important limitation furthermore prevented the investigation and reporting of any short-term changes to endpoint variables that may have occurred between baseline and post-baseline.

Extensive use of self-reported data

This form of data collection has been associated with overestimation of adherence in other studies. It is also possible that patient responses, including those of the control patients, may have been influenced by the Hawthorne effect.⁴⁵³

Absence of a validated standard measurement for adherence

This is possibly the most commonly described limitation relating to adherence research.³³⁰

Cost-effectiveness evaluation

While the cost-effectiveness of an intervention is likely to be crucial to those charged with deciding whether or not to adopt research in practice, economic modeling and evaluation was not feasible given the available resources.

CHAPTER 10

GENERAL DISCUSSION: STUDY DESIGN, RESEARCH AND PRACTICE

10.1 Introduction

The study hypothesis was informed by a literature that generally supports extended roles for community pharmacists across the disease spectrum, including DM2.^{38,133,183} However, systematic reviews of pharmacist-directed interventions, while acknowledging the value of CPS interventions, invariably comment negatively on the paucity and methodological quality of such studies.^{133,183,456,584,}

The methodological limitations of the DCP trial were discussed previously (Section 9.9). In this chapter recommendations for an improved trial design are presented in the hope of informing future pharmacy practice research, especially research involving health-related behaviours. Implications of the study with regard to community pharmacy practice are discussed in a separate section, while the conclusion briefly summarises the main findings in terms of the research question and study objectives.

10.2 Methodological considerations for an improved DCP intervention

An improved design is discussed below in the context of evidence-based recommendations for the development and evaluation of behavioural change interventions where *“the science of intervention development remains at an early stage.”*⁵⁸⁵ Given the complexity of behavioural change interventions, it is strongly recommended that from the outset researchers collaborate with experienced others in conducting such research.

Three key elements of the process, namely Development, Feasibility/piloting and Evaluation (Figure 10.1), are considered.^{294,313,576,578,586} A fourth element, Implementation, which refers to the dissemination of the research for possible adoption in practice settings, is not addressed.

10.2.1 Development

The research problem, namely: “Are South African community pharmacists able to positively influence patient adherence and surrogate health outcomes in DM2?”, provides the focus for the literature review which informs the development of the intervention by identifying current evidence and appropriate theory.

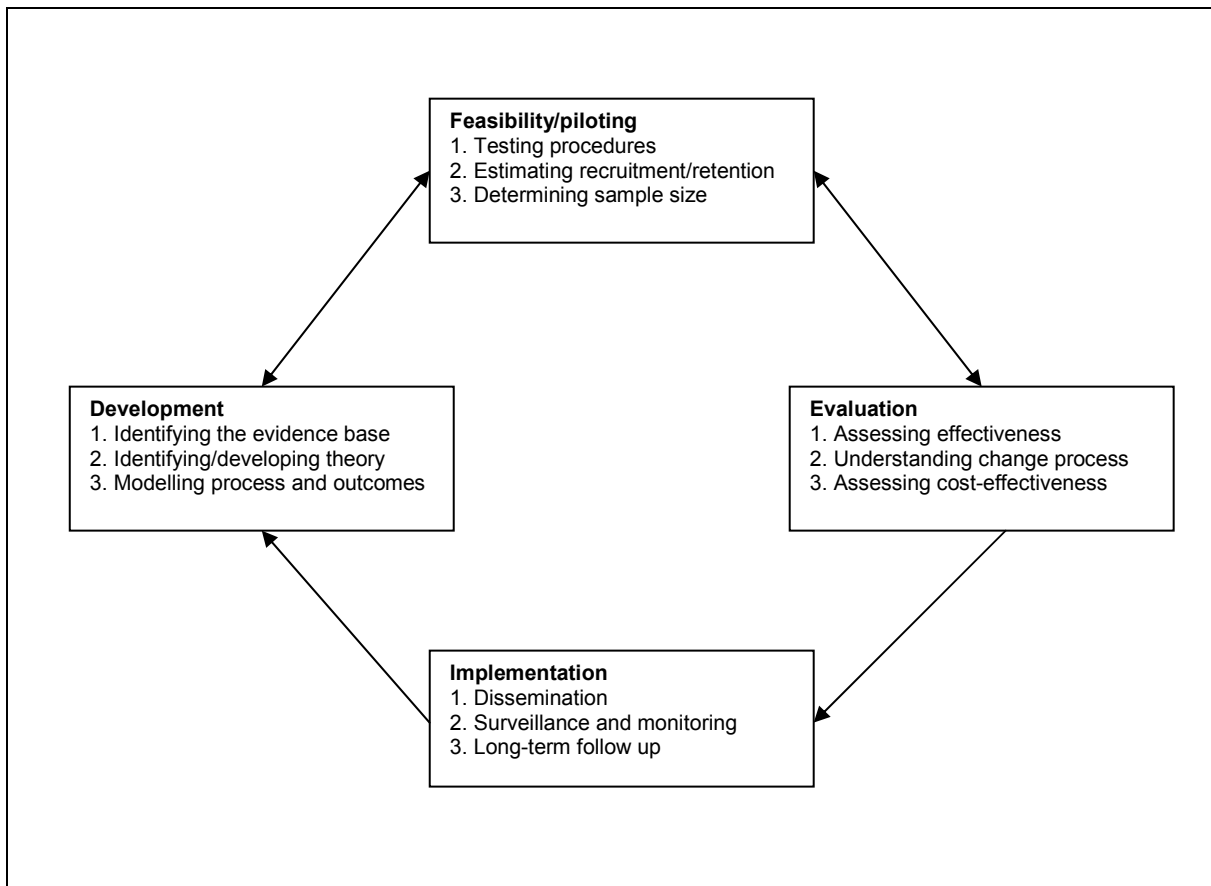


Figure 10.1 Key elements of the development and evaluation process²⁹⁴

Different levels of evidence may be considered, although systematic reviews are recommended. However, identifying appropriate reviews of complex interventions may prove problematic as the “*methodology of how to find, review and combine data from complex intervention studies is not yet fully developed*”.²⁹⁴

The literature review should identify the diabetes-related risk factors including health behaviours, clinical indicators, desired health outcomes and underpinning theory.²⁹⁴ Soliciting expert opinion prior to and during the literature review may assist the researcher in focusing this essential work. Key questions on which the literature review is premised are:²⁹⁴

- ❖ Is there clarity about the problem?
- ❖ Do evidence-based interventions exist that appear likely to answer the research problem or similar problems?
- ❖ Are the interventions based on sound theory and accepted models of behavioural change?
- ❖ What does the literature reveal about pharmacist and patient experience of these interventions?
- ❖ Are any identified interventions compatible with the practice of community pharmacy in South Africa?
- ❖ Can the interventions be adapted to facilitate acceptance and implementation by South African community pharmacists?
- ❖ Are the interventions likely to be accepted by patients?
- ❖ What are the appropriate outcomes measures?

The literature facilitates the theoretical link between the DCP intervention and the patient's health outcome,⁵⁸⁶ i.e. theory informs the process of defining the changes in behaviour likely to impact on the indicators designated as surrogate outcomes.^{294,313} Psychological theory identifies the drivers of the targeted behaviours and informs the selection of behavioural change methods. Theoretical or conceptual frameworks, such as the 5 A's Behaviour Change Model,²⁷⁵ are important in operationalising the intervention as they guide the actions that follow from answers to the questions of when, where, how and by whom should what be done?³¹³

Understanding patient diabetes-related needs, and the barriers preventing the patient from being able to satisfy these needs is essential for the development of an effective DCP intervention. Similarly pharmacists may not effectively deliver the intervention if their needs and any barriers to providing diabetes-related CPS are not adequately addressed.⁵⁸⁶ Fundamental to the development process of the intervention is the need for the researcher to gain insight with regard to the meaning and importance of the

research problem for both patient and pharmacist at an early stage as both the pharmacist and the patient will be involved in modifying health-related behaviour.⁵⁸⁶

Insight into the behaviours requiring change and any barriers to change may be elicited by engaging with patients and pharmacists in focus groups such as is envisaged by the Nominal Group Technique.⁵⁸⁰ Focus group discussions may be further informed by the findings of supplementary descriptive research.⁴⁴⁹ Additional qualitative research, i.e. conducting a problem and needs analysis by surveying larger numbers of pharmacists and patients and then discussing and refining identified issues in focus groups, may be required in order to fully explore the diverse and complex needs of pharmacists and patients alike as well as their likely response to the intervention.^{313,587} For example, insight into patterns of pharmacy practice as well as the targeting of pharmacist education and training to support behavioural change may be elicited using existing validated survey instruments adapted for local conditions.⁵⁸⁷ Such research allows for analyses that may be directed at specific aspects of the research problem, thus informing the development of each succeeding stage of the intervention.

An analysis of current practice should be conducted to identify interventions currently employed by pharmacists in day-to-day or real-life practice³¹³ as pharmacists may pragmatically provide CPS associated with diabetes care such as measuring the blood pressure of a DM2 patient each time the prescription is refilled.⁵⁸⁸ These interventions may develop by a process involving analytical reasoning and practical experience. Such accumulated practice experience may prove invaluable in developing practical evidenced-based interventions.

The theory, literature review, and the engagement with patients and pharmacists in focus groups establishes a basis for the diabetes self-management education of patients and the training of pharmacists to deliver the DCP intervention. Training methods should be selected and material prepared with the assistance of an expert in adult education and submitted to other experts in the field (e.g. diabetologist, health psychologist and diabetes educator) for further comment.¹⁷⁵ The material and training protocol may be further refined in pharmacist focus group discussions.

The individual components of the proposed DCP intervention should be identified and their interrelationship as well as their relationship to the selected surrogate outcomes defined. Interventions to be applied and which have been described in the literature should be prioritized in terms of proven efficacy and, if possible, their cost-effectiveness,⁵⁸⁶ The proposed DCP intervention should be critically discussed in the modelling phase of the development of the intervention by consulting with experts in the field as well as members of the focus groups (both patients and pharmacists) to ensure that it meets the requirements of scientific rigour as well as having practical relevance to both patients and pharmacists.¹⁸¹

Included in the modelling discussion with experts are matters relating to.^{294,296,}

- ❖ the financial and other resources required to effectively investigate the DCP intervention,
- ❖ the length of time of the study,
- ❖ obtaining ethical approval from the Rhodes University Ethics Committee,
- ❖ eligibility criteria for patients and pharmacists, including details of practice settings, any resource criteria, as well as qualifications, skill and competencies of pharmacists,
- ❖ methods to be used in recruiting patients and pharmacists,
- ❖ the sample size calculation (to be further informed by piloting phase) to ensure adequate statistical power,
- ❖ the design of the trial, ensuring RCT wherever possible,
- ❖ randomisation of participants including sequence generation
- ❖ allocation concealment of participants as well as the blinding of the researchers,
- ❖ being able to fully describe the intervention, which is based on the 5 A's Behaviour Change Model,²⁷⁵ including identifying the different components and, where possible, attempting to gauge the likely cost-effectiveness of the intervention,
- ❖ being able to adequately describe usual or standard care,
- ❖ methods of standardising the intervention,
- ❖ provisions for the recording of any allowable variation to the protocol,
- ❖ the training of intervention pharmacists, including any ongoing support to be provided,

- ❖ process evaluation, including timelines, assessment of adherence to the protocol and precise details of the individualised interventions and of the usual care provided,
- ❖ identifying relevant assessment instruments for the designated primary and secondary endpoints,
- ❖ data collection and statistical methods, including the methods to be employed, data collections intervals and, as the DCP involves multi-dimensional outcomes, consideration of the range of statistical options available,
- ❖ the overseeing or management of the evaluation, including the independent monitoring of data,
- ❖ agreeing on guidelines for the reporting of the trial in an accepted format.

The modelling process together with piloting the intervention furthermore assists in identifying weakness in the study design, i.e. areas that may require change or provide an indication that the trial is unwarranted.²⁹⁴

10.2.2 Feasibility/piloting

Before implementing the full-scale evaluation, the DCP intervention should be tested in practice with a pilot study (or a series of pilot studies) of DM2 patients and pharmacists to establish the likelihood of the evaluation being feasible, acceptable and replicable in the main trial.²⁹⁴

A pilot study is essential in order to be able address any uncertainties or problems that may have surfaced during the development process. Piloting also provides a basis for estimating the sample size and the likelihood of being able to recruit and retain participants, as well as providing some understanding of the dynamic of fostering pharmacist adherence to the protocol. It is imperative that every effort be made to evaluate each component as well as the total intervention, thus allowing for component as well as overall modification, should this be necessary.³¹³ These changes may be of such a nature that further exploratory work may be required before embarking on a full-scale trial.²⁹⁴

10.2.3 Evaluation

In addition to the precise details of the intervention and comparator, the context and environment in which the intervention is investigated should be described.²⁹⁶ In complex interventions, such as the DCP intervention, the definition of fidelity is not narrow, as interventions may have to be adapted for local conditions and changes may occur over time as a result of insight gained during the evaluation. The documentation of any variation to the intervention is thus essential in ultimately assessing effectiveness.²⁹⁴

While there are a number of study designs available that may be suitable for evaluating complex interventions, randomisation should always be considered because of its ability to prevent selection bias.²⁹⁴ Two experimental designs involving the randomisation of participants appear particularly suitable for evaluating the DCP intervention. The first is an individually randomized parallel group design, and the second a cluster randomized trial. The latter design is recommended should there be a likelihood of contamination of the comparator group, which could lead to biased estimates of effect size.²⁹⁴ Cluster randomized trials require larger sample sizes than parallel group RCTs in order to achieve similar statistical power, and they are more complex to design and require more complex analysis.⁴⁵⁵ In this study (the DCP intervention) such contamination is unlikely and the design of a randomized parallel group RCT, with pharmacists and their associated patients randomized to either control or intervention is an appropriate design.

Evaluation of the components of the intervention is crucial if the study design of a RCT is used, as this design allows for the investigation of the effectiveness of an intervention in totality. Without adequate insight at a component level *“it is not clear if and to what extent the individual interventions contribute to the effect”*.³¹³ Furthermore, sub-group analyses may be required to consider the source of any variation in outcomes.²⁹⁴

Further key aspects of the design of the evaluation include, the choice of outcomes measures (clinical primary and secondary endpoints as well as psychosocial measures), the inclusion of process evaluation and, where possible, an assessment of the cost-effectiveness of the intervention.^{294,296} The research problem and the evidence base together with other aspects of the preceding development work inform the surrogate

outcomes selected for the study. Including process evaluation in the trial allows for the assessment of pharmacist adherence to the DCP intervention protocol (i.e. assessing quality and fidelity),²⁹⁶ and may provide valuable insight as to why an intervention succeeds or fails, as well as contextualizing any variations in outcomes.²⁹⁴ Furthermore, it is essential for the intervention to be fully described and the procedures tested in order to ensure that the intervention may be replicated by others. Evidence of cost-effectiveness, while not assessed in this DCP intervention, is particularly relevant for decision-makers who may consider the implementation of evidence-based disease management programmes in the broader practice environment.²⁹⁴

The DCP trial should be reported in a manner that allows for the results to be assessed in the context of similar studies, should such evidence exist.²⁹⁴ The CONSORT group³⁵ recently published a revised checklist of items for reporting non-pharmacologic trials, including those involving behavioural change interventions,²⁹⁶ and it is suggested that this document be used as a template for reporting the DCP intervention.

While the RCT remains the ‘gold standard’ for reporting intervention trials,³⁵ extensions to certain of the methodological parameters governing traditional RCT’s have been advocated in order to adequately develop and evaluate complex interventions.^{294,296,589} Such trials may be referred to as pragmatic randomized trials. Hotopf M⁵⁸⁹ in a paper detailing key aspects of pragmatic randomised controlled trials makes it clear that the traditional approach to conducting a RCT may be criticised “*for failing to provide answers to relevant clinical problems of everyday practice*”.

Some of the key design features of pragmatic RCT’s include.⁵⁸⁹

- the need to reflect the heterogeneity of patients as encountered in clinical practice,
- selection criteria may be not as narrow as in traditional RCT’s,
- interventions are often complex and therefore greater flexibility in defining the interventions is required,
- “*there is tendency to deal with each treatment as a black box – usually the concern is not to try to understand specific ingredients within the box*”,
- usual care is difficult to define because it relies implicitly on the knowledge and skill of the provider delivering such care,

- blinding may not be possible,
- randomisation at the provider level is permissible,
- outcomes should reflect the ‘real world’ concerns of patients, providers and policy-makers.

10.3 Practice and research opportunities

This section discusses opportunities for community pharmacy practice and some potential areas of research arising out of the researcher’s observations during the study, reflection on the literature and personal experience as a community pharmacist.

Community pharmacy practice in South Africa has not been well researched.¹⁷ A Pubmed search using the term “community pharmacy AND South Africa AND pharmaceutical care OR cognitive pharmaceutical services” for the period 1985 to 2007 produced six articles, none of which were concerned with investigating the provision of CPS by community pharmacists.

It has been demonstrated that the most frequent healthcare encounter that a patient with diabetes who uses medication obtained from a community pharmacy is likely to have is an encounter with a pharmacist,³⁶ and this probably holds true for most other chronic diseases that include pharmacotherapy as a treatment option.^{1,595} The patient-pharmacist encounter, which is facilitated largely because of the prescription refill dynamic,¹¹ presents pharmacists with health promotion and disease monitoring opportunities,⁵⁹⁰ and they should be encouraged to develop care plans and deliver appropriate interventions based around these brief but potentially valuable healthcare encounters.^{171,265}

Pharmacists in community practice are charged with counselling chronically ill patients on the appropriate use of medication and yet they may do so without having access to the clinical data that informed the original selection and continued use of a given medicine.^{133,540} Similarly, pharmacists may not routinely assess patients using chronic medicines (e.g. by measuring blood pressure, BMI or blood lipids) despite there being good evidence to support this aspect of pharmaceutical care.^{173,470} As pharmacists expand their roles in the clinical arena it is incumbent upon them to ensure that their

support of patients is informed by appropriate, comprehensive information, including clinical data. Access to these data should be considered *de rigueur* in the practice of evidence-based pharmaceutical care.⁵⁹¹ Given the increasing ascendancy of patient-centred care, the effect of the collaborative sharing of appropriate patient data between providers requires investigation.^{155,592}

Studies conducted elsewhere have demonstrated that community pharmacists are able to engage with DM2 patients in order to measure and collect relevant biochemical and other clinical data.^{178,179} Patients at risk for hypertension or any of the elements of the metabolic syndrome should be screened at regular intervals and pharmacists are well positioned to play important roles in preventative screening.¹⁰⁵ For example, the progression of impaired glucose tolerance or impaired fasting glucose to diabetes may be forestalled by disease prevention programmes that are well within the scope of practice of a community pharmacist.^{6,561}

A large percentage of the SMBG metering devices and associated materials used by insured patients are acquired from community pharmacies. This presents community pharmacists with opportunities to develop diabetes practices that are anchored by SMBG and other elements of clinical monitoring, such as point-of-care cholesterol testing and blood pressure monitoring.⁹

Research indicates that a significant number of community pharmacists in South Africa either employ or are associated with registered nurses and this allows pharmacists to offer extended clinical services.¹⁶ Collaborative models of chronic care based on a pharmacist-nurse alliance are able to offer community-based chronic disease self-management programmes⁵⁹⁷ and pharmacists should be encouraged to develop expertise in this area.^{38,155,458} Not only could the pharmacist add value to patients as well as to the broader community, but may also contribute to the professionalisation of pharmacy practice.¹⁶³

The role of the pharmacist in patient-centred care and the promotion of chronic disease self-management may require the reorientation of pharmacy practice.^{158,229} Given the multidisciplinary approach advocated for the delivery of patient-centred diabetes care,¹⁵⁵ pharmacists should be encouraged to enter into collaborative practice arrangements with

medical practitioners and other allied healthcare professionals as there is evidence that such initiatives have resulted in improvements to the process of care and to patient health outcomes.^{8,556} Practical and effective strategies to accomplish this objective should be investigated.

Research has demonstrated the value of pharmacists in the academic detailing of medical practitioners and shown that adherence to clinical practice guidelines by medical practitioners significantly improved where pharmacists have been involved in advocacy programmes.⁵⁹⁴ The general acceptance of clinical practice guidelines by the medical profession should assist pharmacists contemplating collaborative interventions with medical practitioners as guidelines provide common ground for exploring care options.^{105,155}

Furthermore, adherence to the provisions of clinical practice guidelines by patients is a patient health outcomes factor that may be neglected in pharmacy practice.^{548,593} A common thread in many of the reviews relating to adherence is that despite improved adherence being associated with improved health outcomes, successful interventions have generally been multifaceted and complex making the sustained delivery of these interventions problematic in day-to-day pharmacy practice.^{38,330} This problem is further compounded by the complex nature of adherence which makes it difficult to identify and measure the individual components of interventions that may be effective.^{38,294,330} Practical, cost-effective and implementable adherence promoting interventions (i.e. pragmatic interventions), which fit seamlessly within day-to-day practice, such as patient reminders as well as telephonic and electronic follow-up of patients (email and cellphone short message service) appear likely to enjoy pharmacist and patient support,¹⁴² and should be investigated.^{330,366}

The growing acceptance of patient-centred care and the recognition of the key role of health-related behaviour in determining the course of chronic disease is influencing the way in which healthcare providers view caring for patients with chronic diseases.^{155,392} Consequently, there is increasing acknowledgement that no single component of care in diseases such as diabetes is more important than patient self-management.^{298,596} Studies have revealed that, with rare exception, chronically ill patients are responsible for almost all of the day to day care that they require,^{229,298} and that underpinning the

entire self-management dynamic are complex, interdependent and interacting health beliefs and behaviours.²⁷⁵ The practice of pharmaceutical care should therefore not be narrowly focused on the biomedical (provider-centred) aspects of care, but broadened to include psychosocial support for patient self-management efforts.^{229,298}

At a policy level there is consensus within organised pharmacy that practice research is essential for informing both the practice of pharmacy and the education of pharmacists.^{147,181} However, whether this commitment cascades down into community pharmacy and is being sufficiently reflected in professional practice activity, requires investigation. Wherever possible, practice research should report humanistic, clinical and economic outcomes,¹⁷⁶ as authors of systematic reviews and meta-analyses frequently comment on the dearth of comprehensive outcomes data.¹⁸³

There are a number of major challenges facing community pharmacists in providing care to the chronically ill. These include the development of a greater understanding of health behaviour change, together with the acquisition of the necessary skills to appropriately influence health behaviours.^{171,522,598} Further research relating to medicine-taking behaviour and other psychosocial imperatives in caring for individuals with chronic diseases such is suggested.^{153,155,599}

CHAPTER 11

CONCLUSIONS

This study, which was the first investigation of a South African community pharmacist intervention designed to influence patient health-related behaviour and outcomes for DM2, demonstrated that community pharmacists did not positively influence patient adherence or diabetes-related surrogate health outcomes. Such a finding, however, should be tempered by the limitations of the study, which were largely methodological in nature. For example, the power of the study would have been enhanced had more patients and pharmacists agreed to participate in the research, the educational intervention improved by involving an expert in the field of adult education or continuing medical education, and the overall design improved by accessing expertise in developing and evaluating pragmatic RCT's.

Both the consumer survey and the diabetes-related study itself demonstrated that a good foundational basis exists within the South African patient – community pharmacist dyad for the delivery of CPS. This is an important finding as the profession in South Africa did not previously have recourse to empirical data in this regard, but relied on anecdotal assumptions.

The survey of insured patients revealed that in general they were satisfied with the level of medication counselling and disease-related information provided by community pharmacists, and valued the CPS they received, although there appeared to be a problem related to pharmacist accessibility which requires further investigation. The diabetes-related study generally demonstrated patient acceptance and satisfaction with the diabetes care provided by pharmacists.

The design of this study, as a RCT, presented many challenges in implementation, and problems were encountered in the adaptation of this study design to the complex “real-world” setting of community pharmacy practice. Perhaps the most important lesson learnt in developing and evaluating the intervention was the need for a multidisciplinary team approach when attempting a project of this magnitude and complexity. There is no doubt that the study would have benefitted had such an approach been taken.

A valuable aspect of this study is the critical evaluation and reflection on study design that it has demanded, and the consequent insight developed into the methodological constraints associated with conducting community pharmacy practice-based research in which complex interventions are developed and evaluated. In particular, while the choice of a RCT study design is advocated as the 'gold standard' for intervention-based research, there were considerable constraints associated with this design in its original or traditional clinical format.

The traditional RCT, with its narrow, prescriptive and often single component intervention focus appears not to offer the best solution for research problems that are complex, and where, by definition, there may be a number of interacting and mutually influencing components. This has been acknowledged by both CONSORT²⁹⁶ and UKMRC²⁹⁴ in guidelines published in 2008, the year in which this DCP study was completed. Fortunately for future researchers wishing to investigate non-pharmacologic complex interventions using the design of a RCT, there is growing recognition of the need to adopt a more pragmatic approach to these trials than with traditional RCTs of pharmacologic interventions. For example, the UKMRC guideline suggests that in certain circumstances *"Fidelity is not straightforward in relation to complex interventions...some interventions are deliberately designed to be adapted to local circumstances...Limiting variation in treatment may be desirable in an efficacy trial, but in a pragmatic, effectiveness study the statistical advantages and gain in 'internal validity' need to be weighed against the loss of generalisability or 'external validity'."*²⁹⁴

Given that the study was concerned with effectiveness and not efficacy, its value in terms of adding to the body of knowledge may, therefore, not lie solely in the empirical data produced, which may be of limited value, but rather in serving to inform further pragmatic practice-based research, especially that concerned with evolving patterns of community pharmacy practice, and in promoting patient health-related behavioural change.

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STEP 1 Assess

- ### MAJOR RISK FACTORS
- Levels of systolic and diastolic BP.
 - Smoking.
 - Dyslipidaemia:
 - total cholesterol > 6.5 mmol/L, OR
 - LDL > 4 mmol/L OR
 - HDL men < 1 and women < 1.2 mmol/L
 - Diabetes mellitus.
 - Men > 55 years.
 - Women > 65 years.
 - Family history of early onset of cardiovascular disease:
 - Men aged < 55 years
 - Women aged < 65 years.
 - Waist circumference - abdominal obesity:
 - Men > 102cm;
 - Women > 88cm.
 The exceptions are South Asians and Chinese: Men: > 90cm and Women: > 80cm.

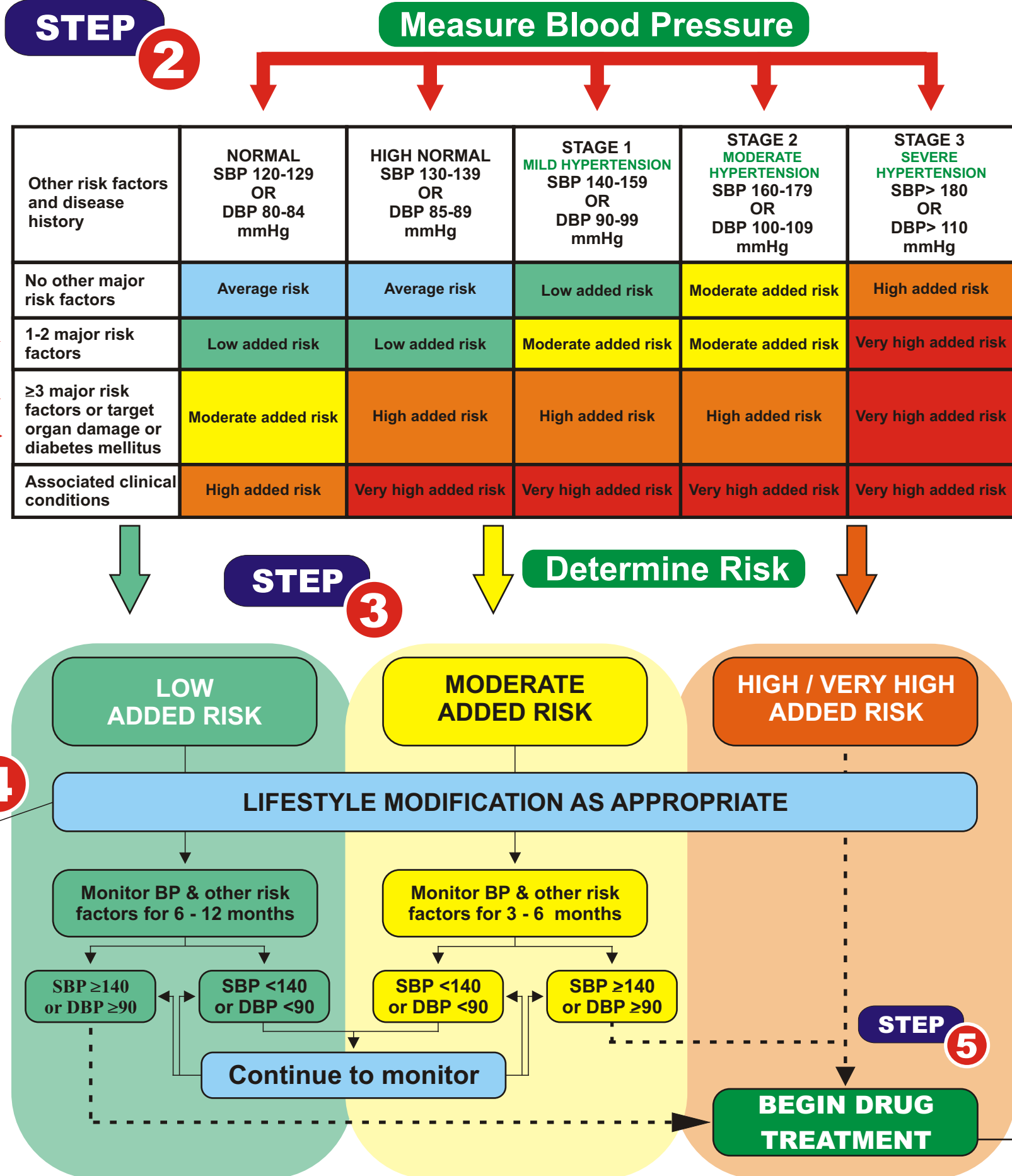
- ### TARGET ORGAN DAMAGE
- Left ventricular hypertrophy: based on ECG
 - Sokolow-Lyons - S in V1 plus R in V5 + V6 ≥ 38mm
 - Cornel - (S in V3 + R in avL + 6 in females) X QRS duration > 2440mm.ms
 - Microalbuminuria: albumin creatinine ratio 3-30 mg/mmol.
 - Slightly elevated creatinine:
 - men 115-133 μmol/L;
 - women 107-124 μmol/L

- ### ASSOCIATED CLINICAL CONDITIONS
- Coronary heart disease.
 - Heart failure.
 - Chronic kidney disease: albumin creatinine ratio > 30mg/mmol.
 - Stroke or transient ischaemic attack.
 - Peripheral arterial disease.
 - Advanced retinopathy:
 - haemorrhages OR exudates, papilloedema.

- ### LIFESTYLE MODIFICATION
- Weight reduction
 - Dietary sodium reduction
 - Restrict alcohol consumption
 - Limit total fat intake
 - Increase fruit and vegetable consumption
 - Limit free sugars
 - Physical activity
 - Stop using all tobacco products



HYPERTENSION MANAGEMENT ALGORITHM



STEP 9 BP targets

TARGETS FOR BP-LOWERING TREATMENT

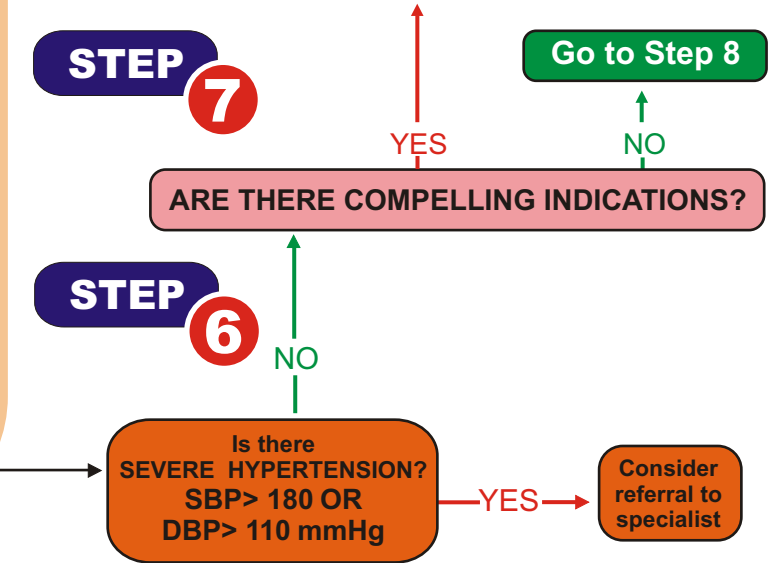
Ideally these targets should be reached in 3 months

Stage	BP level (mmHg)
All stages	< 140/90
Isolated Systolic Hypertension	Do not lower the DBP to < 65
High-risk patients	< 130/80

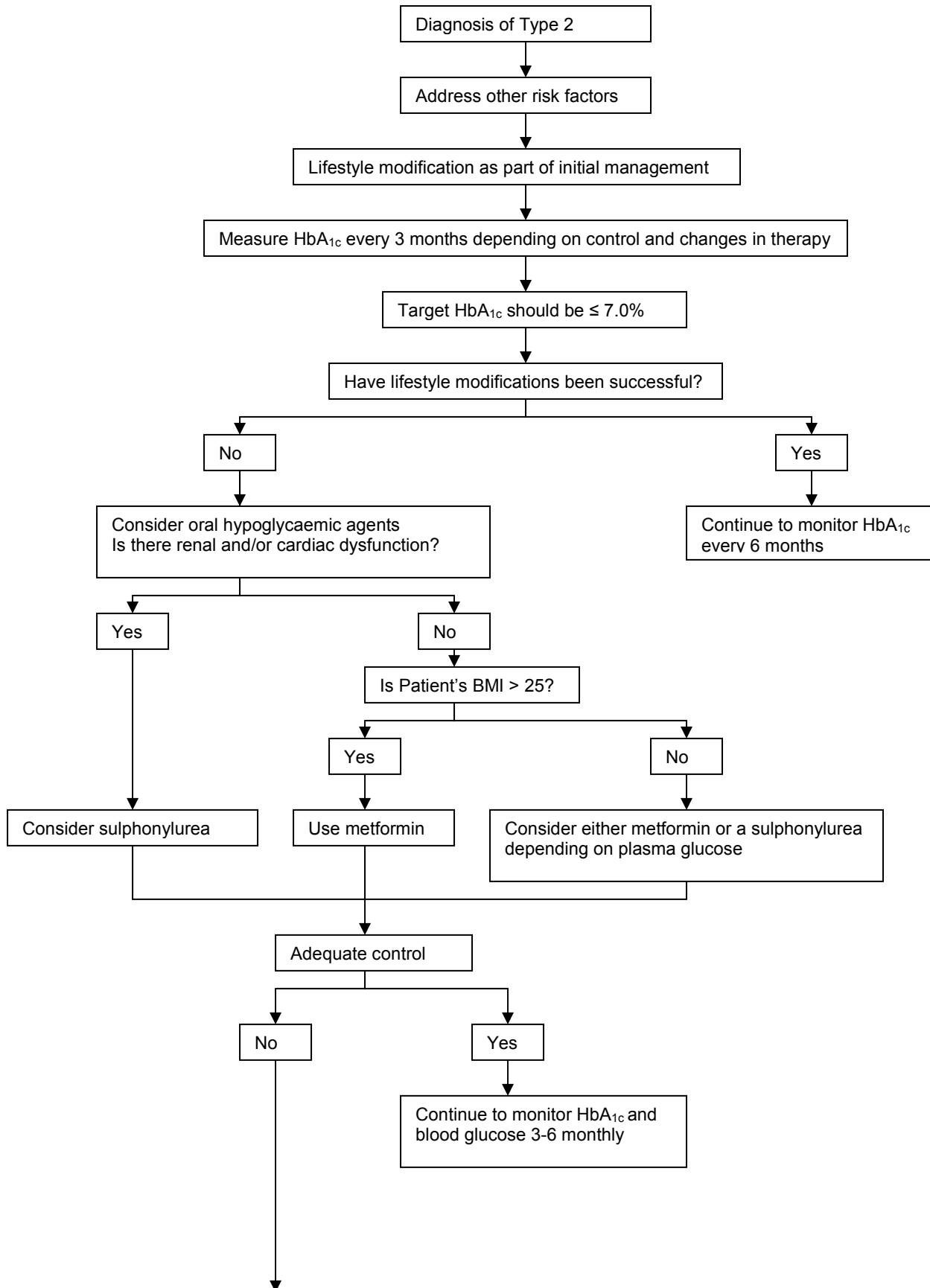
STEP 8 Routine Management

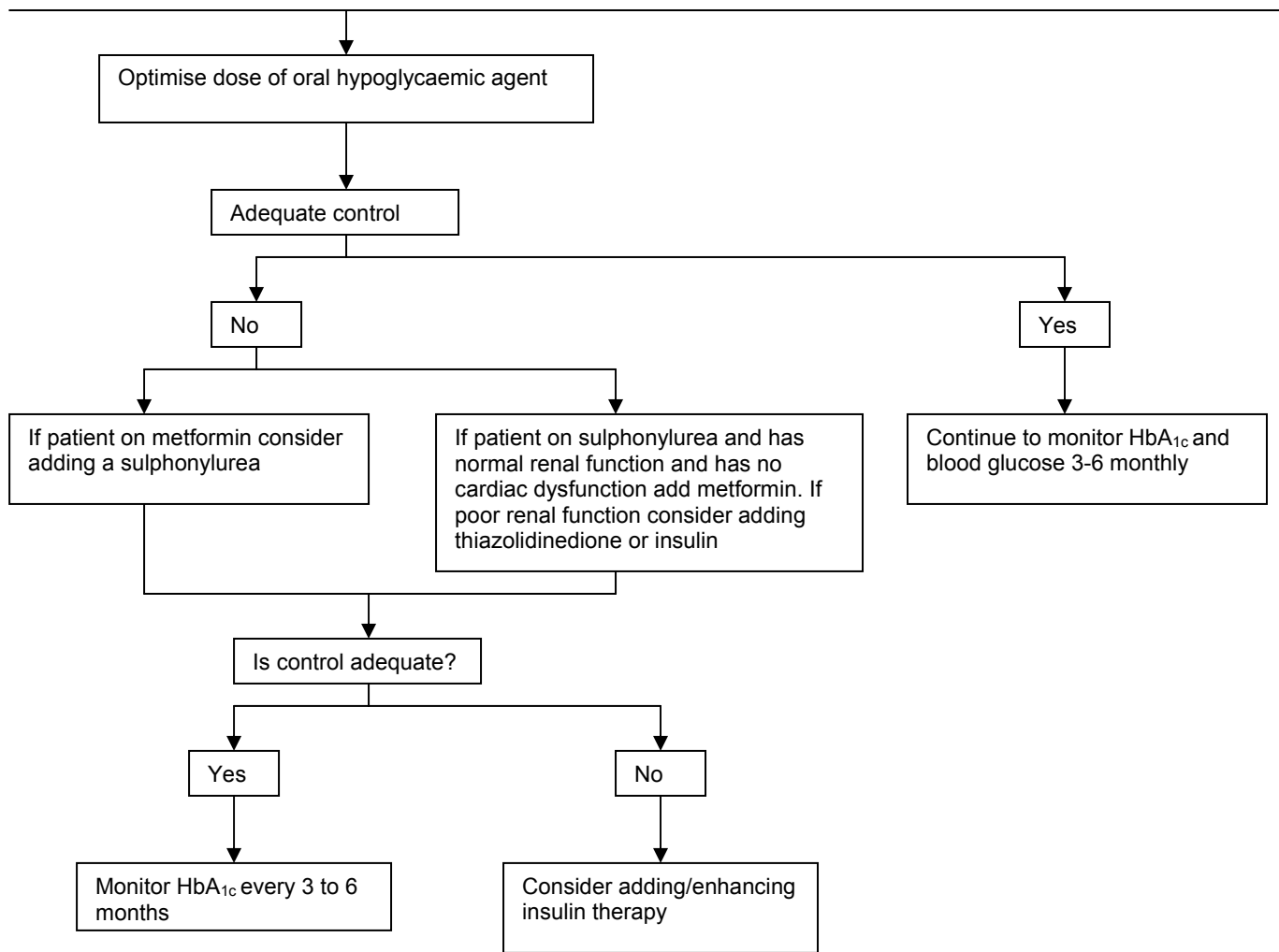
STEP 1:	Low-dose hydrochlorothiazide (12.5 mg preferred up to max 25mg) OR thiazide-like diuretic.
STEP 2 AND STEP 3:	ACE-I (in ACE-I intolerance use ARBs); OR CCB long-acting dihydropyridines OR non-dihydropyridines.
STEP 4 RESISTANT HYPERTENSION:	Direct vasodilators: hydralazine, minoxidil; Centrally acting drugs: methyldopa, moxonidine; Alpha blocker: doxazosin; Beta blockers: many cardio-selective agents are available; Aldosterone antagonist.

COMPELLING INDICATIONS	DRUG CLASS
Angina.	Beta-blocker OR CCB (rate lowering preferred.)
Prior myocardial infarct.	Beta-blocker AND ACE-I (ARB IF ACE-I intolerant) Verapamil if beta-blockers contraindicated. If heart failure see below.
Heart failure.	ACE-I (ARB if ACE-I intolerant) AND certain beta-blockers AND aldosterone antagonist. For combination ARB AND ACE-I see guideline. Loop diuretics for volume overload.
Left ventricular hypertrophy (confirmed by ECG).	ARB (preferred) OR ACE-I
Stroke: secondary prevention.	ACE-I plus diuretic OR ARB
Diabetes type 1 or 2 with or without evidence of microalbuminuria or proteinuria.	ACE-I OR ARB - usually in combination with a diuretic
Chronic kidney disease.	ACE-I OR ARB - usually in combination with a diuretic
Isolated systolic hypertension.	Low-dose thiazide or thiazide-like diuretic OR long-acting CCB.



DIABETES MELLITUS TYPE 2





Annexure 3.2 Council for Medical Schemes algorithm for Type 2 diabetes

Community Pharmacist Survey

Annexure 5.1

Section 1: Respondent Demographics

1.1 Gender:

1.2 Ethnic Group:

1.3 Age:

1.4 Medical Aid Membership:

1.5 Occupation Classification:

Section 2: Community Pharmacist related questions

2.1 Have you received prescription medicines

2.1.1 Do you get your prescription medicines:

2.2 If you get your prescription medicines from a pharmacy, did a pharmacist:

2.2.1 Counsel you on the use of your prescription medicines:

2.2.2 Provide you with information on your disease or condition:

2.3 If you get your prescription medicines from a doctor, did the doctor;

2.3.1 Counsel you on the use of your prescription medicines

2.3.2 Provide information on your disease or condition

2.4 If you visit a pharmacy;

2.4.1 How often do you so

2.4.2 What do you purchase

2.4.2.1 Prescription medicines

2.4.2.2 Over the Counter medicines

2.4.2.3 Other Goods

2.5.1 Does the pharmacy have a clinic

2.5.2 Does the pharmacy have a nurse

2.5.3 Have you had any of the following tests/procedures done in a pharmacy

2.5.3.1 Blood Pressure Monitoring

2.5.3.1.1 If Yes by whom

2.5.3.2 Cholesterol Monitoring

2.5.3.2.1 If Yes by whom

2.5.3.3 Blood Glucose Monitoring

2.5.3.3.1 If Yes by whom

2.5.3.3 Vaccinations (including Influenza)

2.5.3.3.1 If Yes by whom

2.5.3.4 Body Mass Monitored (weighed)

2.5.3.4.1 If Yes by whom

2.5.3.5 Other tests or procedures

2.5.3.5.1 If Yes by whom

2.6 Have you ever consulted a pharmacist on health related matters

2.6.1 If Yes, do you think the advice the pharmacist gave you was:

2.6.1 If No, would you ever consider consulting a pharmacist on health related matters

Do you suffer from a chronic illness (a disease such as high blood pressure, diabetes, asthma, high cholesterol, epilepsy or any other disease that requires the ongoing use of medicines)

2.7.1 If Yes -

2.7.1.1 has a pharmacist given you additional advice on dealing with and controlling your condition / disease

2.7.1.2 if a pharmacist has not given you additional advice on dealing with and controlling your condition / disease, would you like a pharmacist to do so

2.7.2 If No - and you were to become chronically ill in the future, would you like a pharmacist to give you additional advice on dealing with and controlling your condition / disease

2.8 Do you think that pharmacists should be paid for providing professional services, namely:

"Counseling patients on the correct use of their medicines and giving additional advice on dealing with and controlling their conditions / disease"

2.8.1 If Yes - who should pay:

2.9 Is your relationship with your pharmacist;

Good

I know his/her name; he / she knows mine; I trust the health related advice given to me; I feel I can speak to him / her at any time about my health problem; I see him /her as 'my' pharmacist

Average

I know his / her name but I doubt he /s he knows mine; I may or may not trust the health related advice given to me depending on the circumstances; I would probably visit the same pharmacy most of the time

Poor

We don't know each other; I am seldom if ever given health related advice and I may or may not trust the advice, I will use the pharmacy most convenient at the time that I need to make a purchase

No relationship

I never visit a pharmacy nor do I consult with a pharmacist.

2.10 Which health care professional is most accessible to you; (conveniently situated, readily available to talk to, gives free advice or advice that you may be willing to pay for):



RHODES UNIVERSITY

Grahamstown • 6140 • South Africa

FACULTY OF PHARMACY ☐ Tel: (046) 603 8381 • Fax: (046) 636 1205

Dear Colleague,

Re: Pharmacy Practice Research

I am writing to you to enquire if you would be willing to take part in a community pharmacy disease management study. The study is aimed at testing the hypothesis that trained community pharmacists are able to positively influence adherence to therapies by patients with Type-2 diabetes mellitus. Professor Ros Dowse of the faculty of pharmacy at Rhodes University will supervise the study.

Research has shown that patient adherence to therapy by the chronically ill falls far short of what is considered to be ideal- with less than 50% of patients in the developed world being considered adequately adherent to long-term therapies. Therapeutic adherence levels in the developing world are considered by the WHO to be far worse than those of the developed world. The impact of less than ideal levels of therapeutic adherence by chronically ill patients results in poor healthcare outcomes- both from a patient health related quality of life and a health economics perspective.

In a report published by the World Health Organisation in January 2003, A.J.M. Hoek, General Secretary of the International Pharmaceutical Federation (FIP) had the following to say about the role of the pharmacist in improving patient adherence to long-term therapies:

“ Pharmacists are well positioned to play a primary role in improving adherence to long-term therapy because they are the most accessible health care professionals and because they have extensive training in pharmaceuticals. ”

I understand that some of you may question the appropriateness or need for pharmacy practice research at a time when the very existence of community pharmacy in South Africa is under threat. I believe that the nature of the threat and the reality of the changed community pharmacy environment is cause enough for the profession to explore ways to re-invent itself. The changing dynamic supports the premise that we are no longer trading professionals but rather professionals who trade. Thus it has become important and urgent that we scientifically prove to healthcare stakeholders that we can and do add value to the healthcare chain.

The literature reveals that community pharmacists in a number of countries are able to add value to healthcare by providing professional cognitive pharmacy services to patients. The position in South Africa remains less definite because of a paucity of valid local pharmacy practice research to support similar claims to this effect.

In addition to being reimbursed for the act of dispensing medicines, as legislated by the Medicines and Related Substances Act (No.101 of 1965) as amended, our right to be reimbursed for providing pharmaceutical care to patients is included in the provisions of the suspended South African Pharmacy Council Board Notice 94 of 2003. This notice sets out the “rules relating to the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees.” In order to unlock the reimbursement potential inherent in the provision of pharmaceutical care the profession will have to demonstrate to healthcare stakeholders, especially the funders of healthcare, that the provision of pharmaceutical care by community pharmacists results in tangible value for patients and funders alike. I believe that the proposed study will go some way towards achieving this objective.

The proposed study design is that of a randomised control trial. The pharmacists who will be randomised to the intervention cohort will be provided with both type-2 diabetes disease state management and adherence promoting intervention training and on-going support. The intervention cohort will thus be required to provide their associated type-2 diabetes patients with enhanced care. The control cohort will consequently provide their associated type-2 diabetes patients with usual care. Key adherence variables and disease risk indicators in both the intervention and control cohorts will be measured and studied.

It is hoped that the study will prove the hypothesis that trained community pharmacists are able to collaborate with type-2 diabetes patients and assist them to improve their levels of adherence to therapies. If the study results in such an outcome, then I believe that valid scientific evidence will exist that will support those community pharmacists wishing to establish themselves as healthcare providers of value-added professional cognitive pharmacy services.

The profession needs your active participation in the study. Those pharmacists who respond positively to this request by completing the attached form will be provided with additional information on the study including a proposed role-out action plan with time-lines.

I look forward to working with you. Any questions or suggestions then please contact me by email at peterhill@intekom.co.za

Peter Hill
PO Box 75
Molteno
5500

COMMUNITY PHARMACY DISEASE MANAGEMENT STUDY

If you would like to participate in this study, please complete the form and email to me at peterhill@intekom.co.za

Participating Pharmacist's Details			
Pharmacy Name:			
Pharmacist's Surname:		Pharmacist's First Name:	
Telephone No:	Work:	Cell:	Email:
Physical Address:		Postal Address:	
RAMS/BHF No:			



RHODES UNIVERSITY
Grahamstown • 6140 • South Africa
FACULTY OF PHARMACY

Annexure 6.2

Type 2 Diabetes Mellitus Research

PO Box 275
Port Alfred
6170

5 March 2006

Dear *name of pharmacist*

Enclosed please find the Patient Study Packs – one for each of the T2DM patients that you recruited to the study. I have written to each recruited patient [see attached] thanking them for agreeing to participate in the study and provided some information on the process going forward. I suggest that you contact your patients as soon as possible and arrange to meet with them to discuss the contents of the enclosed packs. It is crucial that patients understand the importance of completing the questionnaires and of having the baseline clinical variables measured.

I would appreciate it if these documents could be returned to me in the self-addressed postage paid envelopes as soon as possible. The due date for the return of the documentation to me is 31 May 2006.

Patient Study Packs

Each pack contains the following:

- Patient profile [to be completed by the patient and returned to me].
- Baseline clinical data form [items 4 - 7 to be completed by you and returned to me. Note if the patient has had a Lipogram, HbA_{1c}, or serum creatinine measured within 60 days you may use those results, in which case please include such values on the form].
- Ampath form for the required biochemical tests [please complete the form selecting the boxes that correspond to the required tests].
- Medical practitioner information letter [to be completed by you and forwarded to the patient's medical practitioner].
- Beliefs about medicines questionnaire [to be completed by the patient and returned to me].
- Patient satisfaction questionnaire [to be completed by the patient and returned to me].
- Diabetes care questionnaire [to be completed by the patient and returned to me].
- Self-care adherence questionnaire [to be completed by the patient and returned to me].
- Self-addressed and postage paid envelope.
- A copy of the International Diabetes Federation's desktop Guide to Type 2 Diabetes [provides you with a type 2 diabetes reference resource].

Language

We respect the rights of both pharmacists and patients to be addressed in an official language of their choice, however, the study is being conducted in English for two main reasons:

- All of the scientifically validated questionnaires and scales that will be used in this study have been published in English. Translation of these instruments into other languages would not only be time consuming but would require re-validation due to the possible effect of bias brought about by translation. Re-validation of these instruments is beyond the scope of this research.
- Although we have a number of official languages in South Africa in addition to English, it is the language of use in most of the published literature relating to the topic.

Thanks once again for your valuable participation and please pass on my thanks and appreciation to your patients.

Kind regards

Peter Hill
Faculty of Pharmacy
Rhodes University
Grahamstown
046 6243575
0829285020



RHODES UNIVERSITY
Grahamstown • 6140 • South Africa
FACULTY OF PHARMACY

Type 2 Diabetes Mellitus Research

PO Box 275
Port Alfred
6170

Dear *name of patient*

Thank you once again for agreeing to participate in the research project aimed at finding ways for pharmacists to help people with Type 2 diabetes improve the care and management of their condition.

We are now ready to move to the next phase of the research and this is going to require you to go into your pharmacy during the months of April and May 2006 to have some tests and measurements done.

Certain of the measurements will be done in the pharmacy and others will require a blood test. The measurements that are to be done by your pharmacist in the pharmacy are the following:

1. Blood Pressure.
2. Urine test.
3. Body Mass Index (weight and height).
4. Waist and hip measured.

A blood test is required for the following important information about the state of your diabetes:

5. Glycated haemoglobin or HbA1c- this is a measure of the average blood glucose level over the past 2-3 months.
6. Lipogram- a full Cholesterol test.
7. Creatinine- a kidney function test.

If you have had any of the above blood tests done (tests 5, 6 and 7) within the past 2 months then you do not have to repeat the tests now- all you have to do is hand copies of the results to your pharmacist. Please note that even if you have recently had the abovementioned blood tests done, you will still have to have the other measurements/tests (tests 1, 2, 3 and 4) done in the pharmacy during April/May

I have arranged with the Ampath pathology group to do the blood tests for you at a reduced cost.

The blood tests will have to be done at the beginning (April/May 2006) and again at the end of the project (April/May 2007), as will the tests and measurements that will be performed by your pharmacist (blood pressure, body mass index, waist-hip and urine test)

Some of you may question the need for the tests. The International Diabetes Federation, a world authority on diabetes care, stresses the need for regular testing, as mentioned above, if diabetes care is to be optimised. It is very important that you have the tests done as it is impossible to manage diabetes unless certain measurements and tests are regularly performed and the results assessed. This research is aimed at finding ways to help you improve your diabetes care and the results of your tests will contribute significantly to this goal.

I have written to your pharmacist and asked him/her to contact you to make an appointment for the measurements and blood test. In addition to the abovementioned set of tests, please complete the form entitled 'Patient Profile' together with questionnaires that your pharmacist will hand to you. These forms have been designed to help us identify possible problem areas in your diabetes care. This information, as is the case with your test results, is very important to finding ways of improving diabetes care. When you receive the form and questionnaires, please complete them as soon as possible and then return them to me in the self-addressed postage paid envelope that I will provide.

If you have any questions or suggestions, please do not hesitate to contact your pharmacist.

Your contribution to improving diabetes care is invaluable and very much appreciated.

kind regards

Peter Hill
Faculty of Pharmacy
Rhodes University
Grahamstown
046 6243575
0829285020

Type 2 Diabetes Mellitus Research Project

Annexure 6.2

NB Please print clearly

Name of your pharmacy :	
Your surname and initial:	
Your diabetes research identity number:	

Patient Profile -please tick the box corresponding to your answer

Gender	M	F		
Age (years)				
Ethnic group	Black	White	Coloured	Asian
Marital status (M=married or living with a partner; S = single living alone)	M	S		
Education-highest level of education completed	Primary	Secondary	Tertiary	No School
Home language	isiZulu	isiXhosa	Afrikaans	Sepedi
			English	Setswana
			Sesotho	Other
Duration of diabetes-how long since you were first diagnosed with Type 2 diabetes (years)				
Medical care-how often do you see your doctor about your diabetes? (times a year)				
-and do you see your GP or a specialist (endocrinologist or diabetologist)?	GP	Specialist		
Family history of diabetes-is there a family history of diabetes?	Y	N	Not sure	
Diabetes education-have you ever received diabetes education?	Y	N		
Diet-has a dietician ever advised you on meal planning?	Y	N		
-do you follow a diabetes friendly meal plan?	Y	N		
Exercise-has your doctor or any other health care professional advised you to exercise?	Y	N		
-do you exercise regularly (3-5 times a week)	Y	N		
Social support-do you receive support from family and or friends in managing your diabetes?	Y	N		
Medicines for diabetes-do you take medicine and/or use insulin to treat your diabetes?	Y	N		
-are your diabetes medicines taken orally, injected (insulin) or both?	Oral	Injected	Both	
Other chronic conditions-do you have any of the following conditions?				
-do you have heart disease?	Y	N		
-have you had a stroke?	Y	N		
-do you have high blood pressure?	Y	N		
-do you have high cholesterol?	Y	N		
-are you depressed (diagnosed by a doctor)?	Y	N		
-do you have kidney disease?	Y	N		
-do you have blood circulation problems? ('Diabetic foot')	Y	N		
-do you have eyesight problems related to diabetes?	Y	N		
Medicines for other chronic conditions-do you take prescription medicines for the following chronic conditions				
-heart disease?	Y	N		
-high blood pressure?	Y	N		
-high cholesterol?	Y	N		
-any form of depression?	Y	N		
Do you have any of the following tests and examinations?				
-do you have your HbA1c (glycated haemoglobin) monitored at least once every 6 months ?	Y	N	Not sure	
-do you self-monitor your blood glucose ?	Y	N		
-if yes, then how often ?	Daily	Weekly	Monthly	
-do you have your cholesterol monitored at least once a year?	Y	N		
-do you have your blood pressure monitored at every diabetes consultation**?	Y	N		
-do you have your kidney function monitored at least once a year?	Y	N		
-do you have your weight monitored at every diabetes consultation**?	Y	N		
-do you have your waist and hip measured regularly?	Y	N		
-do you have you feet examined at least once a year?	Y	N		
-do you have an eye examination at least once a year?	Y	N		
-do you have a yearly ECG?	Y	N		
Complementary Medicines-do you use homeopathic or herbal medicines to treat your diabetes?	Y	N		
Tobacco use-do you smoke tobacco?	Every day	Occasionally	Never	
Alcohol use -do you consume alcohol?	Y	N		
-if yes, and you have a drink every day-how many drinks do you have each day?				
-if yes, and you do not have a drink every day-how many drinks do you have each week?				

** consultation= whenever you consult a doctor, nurse, pharmacist about your diabetes

This information will be treated as confidential and is for research purposes only

Type 2 Diabetes Mellitus Research**Baseline Clinical Data Form**

Name of Pharmacy.....

Laboratory: Ampath Other laboratory Pharmacy laboratory

Patient Surname.....Initials..... Research ID No.....

Test	Result	Date
1. Glycated haemoglobin – HbA _{1c} (%)		
2. Lipogram (mmol/l)		
2.1 Total Cholesterol		
2.3 HDL Cholesterol		
2.4 LDL Cholesterol		
2.5 Triglycerides		
3. Serum Creatinine (mmol/l)		
4. Proteinuria (urine dipstick-positive[+ve] or negative [-ve])		
5. Blood Pressure (mmHg)		
4.1 Systolic blood pressure		
4.2 Diastolic blood pressure		
6. Body Mass Index-BMI (mass in kg/ height in m ²)		
7. Waist-Hip Ratio		

All patient information provided in the course of this research will remain confidential.

Please fax the completed form to Peter Hill at 046 6243575



RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

Dear Doctor

Re: Pharmacy Practice Research

Improving Patient Adherence to Self-care Recommendations in Type 2 Diabetes Mellitus: a Community Pharmacist Randomised Controlled Cluster Trial

This letter serves to advise you that *name of participating patient* has agreed to participate in a Rhodes University, Faculty of Pharmacy endorsed research project aimed at testing the hypothesis that community pharmacists are able to assist patients with Type 2 diabetes mellitus improve their adherence to long-term therapies and other diabetes self-care recommendations.

Project Overview

Patient Adherence to Long-term Therapies.

The World Health Organisation (WHO) published a report in January 2003 entitled “Adherence to long-term therapies: evidence for action”.¹ The report is an extensive review of the published literature on patient adherence to long-term therapies. Research has shown that there continues to be an epidemiological shift along the disease continuum from acute to chronic. Furthermore, therapeutic adherence amongst the chronically ill has been shown to fall far short of what is considered to be ideal with the level of adherence to long-term therapies being no better than 50% in developed countries and certainly less than 50% in developing countries.¹ The result is that so-called ‘therapeutic failure’ is not an uncommon phenomenon, especially amongst patients in the developing world²

The WHO report endorses the view held by Hayes, an internationally acknowledged researcher on adherence, that “increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments”⁵

Studies referred to in the report show that poor levels of therapeutic adherence by chronically ill patients result in poor health outcomes, both from a patient health-related quality of life and a health economics perspective.¹

Type 2 Diabetes Mellitus

Diabetes mellitus is a group of highly prevalent diseases affecting approximately 150 million people worldwide and this number is predicted to double within the next 22 years. It is estimated that by 2025, 75% of patients with diabetes will be living in developing countries.³ Type 2 diabetes mellitus accounts for about 90% of all diagnosed cases of the diabetes mellitus.¹ It is an insidious condition as it has been shown to be associated with the silent downstream development of serious co-morbidities especially coronary heart disease, hypertension and hyperlipidemia.⁴

It follows, therefore, that therapeutic adherence by patients with Type 2 diabetes mellitus is of crucial importance not only in managing the primary condition but also in preventing or arresting the development of very important microvascular and macrovascular complications. The 1991 United Kingdom Prospective Diabetes Study revealed that around 50% of patients had already developed certain of the complications associated with diabetes mellitus by the time they were first diagnosed with Type 2 diabetes.⁶

The Role of the Community Pharmacist

The WHO and other authorities have identified the community pharmacist as one of the health care professionals ideally positioned to impact positively on patient adherence to long-term therapies.^{1,5,7} Worldwide, the profession is increasingly emphasizing the importance of providing pharmaceutical care to patients.^{8, 9} SA legislation too has recognized the changing dynamic as evidenced by the publishing by the SA Pharmacy Council of mandatory Rules governing Good Pharmacy Practice.¹⁰

Study Design

The study is a national multi-centre Randomised Controlled Trial designed to test the hypothesis that the intervention cohort of community pharmacists are able to positively influence Type 2 diabetic patient adherence to therapies and key self-care recommendations.

Each participating pharmacist will recruit 10 Type 2 diabetic patients randomly selected from the pharmacy's prescription database. We will measure all participants for identified clinical indicators and psychosocial variables at baseline then randomise the pharmacists and their associated patients to control (usual care) and intervention (enhanced care) and again measure the variables 12 months post baseline. The intervention pharmacists will be provided with a diabetes care plan framework after randomisation. The primary endpoint is HbA_{1c} which, in addition to being an intermediate health outcome, serves as a surrogate marker for adherence. Other clinical and psychosocial indicators will be secondary endpoints.

Dr Ros Dowse, Associate Professor in the Faculty of Pharmacy, Rhodes University, Grahamstown, is supervising the research. Professor Dowse may be contacted at telephone 046 603 8399 or email r.dowse@ru.ac.za.

Patient Information letter

Prospective participating patients have been provided with study information letters and consent forms which set out that:

- the reason for the research programme is to determine if pharmacists can assist diabetic patients improve their adherence to diabetes self-care recommendations;
- improved adherence to self-care recommendations in Type 2 diabetes helps to prevent the development of diabetes-related complications which, in turn, translates into improved health-related quality of life;
- the programme supports and does not interfere with treatment prescribed by their doctor or any other health care professional;
- all they have to do is complete short questionnaires and to have certain clinical indicators measured at the beginning of the programme (baseline), again after 12 months;
- all information provided will be treated confidentially;
- their right to discontinue participation in the study at any time and without prejudice is recognised.

Patient-centred care

In keeping with the collaborative patient-centred approach to health care that is increasingly finding favour with health care consumers and progressive health care professionals around the world, it is the intention of the research to support the relationship between pharmacist and medical practitioner as this is a key component of collaborative patient-centred care.

Accordingly we affirm that:

- the study supports accepted national and international treatment guidelines for Type 2 diabetes;
- it is not our intention to interfere with prescribed therapy but rather to support the practice of evidence-based care in type 2 diabetes;
- all adherence promoting interventions applied in the intervention cohort are based on evidence contained in the literature;
- patients participate in the study of their own free will and may discontinue their participation at any time and without prejudice;
- the Ethics Committee of Rhodes University has approved the research in terms of the Medical Research Council's guidelines for human subject research

We value your support of the research and welcome any contribution that you might care to offer.

kind regards

Name of -Study Pharmacist

Peter Hill-Researcher

References

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5. Haynes RB. Interventions for helping patients to follow prescriptions for medications. *Cochrane Database of Systematic Reviews, 2001, Issue 1.*
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8. Cipolle RJ, Strand LM, Morley PC. *Pharmaceutical Care Practice*. 1998 McGraw-Hill Health Professions Division
9. Martin S. Traditional value, innovative practices: Pharmacists who provide cognitive services. *Am Pharm* 1990; NS30(4):22-27
10. The Pharmacy Act No. 53 of 1974



Type 2 Diabetes Mellitus Research Project Questionnaire* No. 1

* Reproduced with the permission of Professor Robert Horne, University of Brighton

Your research identity number: _____

Your views about medicines prescribed for you

- We would like to ask you about your personal views about all the medicines prescribed for you.
- These are statements other people have made about their medicines.
- For each of the statements, please tick the box that is closest to your opinion

There are no right or wrong answers. We are interested in your personal views

	Views about medicines prescribed for you:	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
1	My health at present, depends on my medicines					
2	Having to take medicines worries me					
3	My life would be impossible without my medicines					
4	I sometimes worry about the long-term effects of my medicines					
5	Without my medicines I would be very ill					
6	My medicines are a mystery to me					
7	My health in future will depend on my medicines					
8	My medicines disrupt my life					
9	I sometimes worry about becoming too dependant on my medicines					
10	My medicines protect me from becoming worse					
11	These medicines give me unpleasant side effects					

Your views about medicines in general

- These are statements other people have made about medicines in general.
- For each of the statements, please tick the box that is closest to your opinion

	Views about medicines in general	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
1	Doctors use too many medicines					
2	People who take too many medicines should stop their treatment for a while every now and again					
3	Most medicines are addictive					
4	Natural remedies are safer than medicines					
5	Medicines do more harm than good					
6	Most medicines are poisons					
7	Doctors place too much trust in medicines					
8	If doctors had more time with patients they would prescribe fewer medicines					

Please return the completed questionnaire in the self-addressed postage paid envelope provided.

Thank you for completing the questionnaire



Type 2 Diabetes Mellitus Research Project Questionnaire* No.2

* Reproduced with the permission of the University of Michigan Diabetes Research and Training Center

Your research identity number: _____

These statements reflect on the diabetes care you have received recently. For each of the statements, please tick the box that is closest to your opinion .

Q1	Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree
A. I'm very satisfied with the diabetes care that I receive					
B. Most people receive diabetes care that could be better					
C. The diabetes care that I have received in the last few years is just about perfect					
D. There are things about the diabetes care I receive that could be better					

Q2. Who currently provides your main diabetes health care? (Tick only one box)

- Generalist (your GP, or a nurse,)
- Specialist (a diabetologist, endocrinologist, or nurse working with a diabetologist or endocrinologist)
- Other (please specify): _____
- No one- I do not have a regular health care provider who provides my diabetes care

Q3. Thinking back over the past 12 months, how would you rate the diabetes care you have received with regard to:

(Tick only <u>one</u> box in each line)	Poor	Fair	Good	Very Good	Excellent
A. Keeping you informed about what the next step in your care would be.					
B. Different health care providers being up-to-date on your current treatments and recent test results					
C. Communication between different health care providers caring for you					
D. Knowing who to ask when you had questions about your health					

Please return the completed questionnaire in the self-addressed postage paid envelope provided.

Thank you for completing the questionnaire



Type 2 Diabetes Mellitus Research Project Questionnaire No. 3

Your research identity number: _____

Q1	Have you set diabetes-related goals for yourself?	Yes	No	
		Yes	No	Not Sure
Q2	Do you have a diabetes care plan?			
Q3	Did a health care professional (e.g. doctor, nurse, or pharmacist) assist you with the development of a diabetes care plan?			
Q4	Does your diabetes care include the regular monitoring by a health care professional of the following, your:			
	a. self monitored blood glucose test results			
	b. HbA1c (Glycosylated haemoglobin) levels			
	c. weight			
	d. exercise programme			
	e. medication use			
	f. blood pressure			
	g. cholesterol levels			
	h. kidney function			
	i. eye sight			
	j. blood circulation ('diabetic foot')			
	k. use of alcohol*			n/a
	l. use of tobacco*			n/a
	m. diabetes-related stress			
	n. family or social support			

***Note:** If you do not use alcohol or tobacco please tick the n/a blocks

These statements consider the role of your pharmacist in your diabetes care plan.

For each of the statements, please tick the box that is closest to your opinion .

Q5	Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree
a. My pharmacist provides me with a good level of diabetes care					
b. I would like my pharmacist to do more to help me manage my diabetes					
c. I think that my pharmacist is equipped to provide me with diabetes care					
d. My pharmacist and doctor work together to provide me with diabetes care					

Please return the completed questionnaire in the self-addressed postage paid envelope provided.

Thank you for completing the questionnaire



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FACULTY OF PHARMACY

Annexure 6.2

Type 2 Diabetes Mellitus Research Project Questionnaire* No. 4

* Reproduced with the permission of the University of Michigan Diabetes Research and Training Center

Your research identity number: _____

For each of the statements, please tick the box that is closest to your opinion .

		Never	Sometimes	Always	Don't know
Q1	I keep my blood sugar in good control				

		Never	Sometimes	Always
Q2	I keep my weight under control			
Q3	I do the things I need to do for my diabetes (diet, medicine, exercise, etc.)			
Q4	I handle the feelings (fear, worry, anger) about my diabetes fairly well			

Please return the completed questionnaire in the self-addressed postage paid envelope provided.

Thank you for completing the questionnaire

Guidelines for Diabetes Care

A Desktop Guide to Type 2 Diabetes Mellitus

*European Diabetes Policy Group
1998-1999*

[Add
IDF logo
here]

**International Diabetes Federation
European Region**

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A Desktop Guide to Type 2 Diabetes Mellitus

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Preface

A desktop guide

In 1989 the European NIDDM Policy Group published its first Desktop Guide for the management of Non-insulin-dependent (Type 2) Diabetes, and in 1993 that document was revised on behalf of the St Vincent Declaration Initiative.

The current Desktop Guide builds on those guidelines, in the light of newer understandings, and attempts to provide a more direct and more accessible format. Our aim here is to provide Guidelines which can offer easy access to high quality and better integrated care, while reducing health inequalities.

The greater emphasis on arterial risk factor management, rather than just good blood glucose control, is given particular prominence.

Furthermore, this time language that can be followed by the educated person with diabetes has been used, remembering that “the primary resource for diabetes care is the person with diabetes themselves, supported by enthusiastic and well-trained professionals”.

Evidence

In an attempt to maintain clarity, accessibility and usefulness, the current Desktop Guide remains didactic in its approach. However, a source document to be published later will go further than the previous guidelines in referencing the evidence and strength of the recommendations given here.

Aims of diabetes care

The aim of these Guidelines is to enable people with diabetes to have a life of normal length and fulfilment through :

- provision of skills to adapt life-style to ensure optimum health;
- development of understanding to allow coping with new challenges, and to give maximum flexibility;
- control of risk factors for arterial disease, and for eye, kidney and nerve damage;
- early detection and management of any existing vascular damage.

A way forward

The 1998-1999 European Diabetes Policy Group has worked on both the major types of diabetes – the sister publication on Type 1 diabetes appeared last year. The working group came from richer and poorer nations throughout Europe, and included people with diabetes, as well as members of multi-disciplinary teams.

European Diabetes Policy Group, 1999

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Electronic file : Download as Word 97 document, or HTML (web browser) files from : <http://www.staff.newcastle.ac.uk/philip.home/guidelines>

1 Diagnosis of Hyperglycaemic States

Management classification – hyperglycaemic states

Diagnostic background

The purpose of diagnosis is to identify those at risk of developing the complications of diabetes, both arterial (macrovascular) and microvascular, as well as to deal with any symptoms

The levels of blood glucose vary for these different risks, and determine management

1. Symptomatic (biochemically confirmed) ⇒ "Diabetes"
2. At risk of arterial and microvascular damage ⇒ "Diabetes"
3. At risk of arterial damage from hyperglycaemia and of progression to diabetes ⇒ "Impaired Glucose Tolerance (IGT)" ⇒ "Impaired Fasting Glycaemia (IFG)"

Diagnostic algorithm

1. Symptomatic or glycosuria or incidental hyperglycaemia

- ⇒ Check random venous plasma glucose (see below for capillary / venous equivalents)
 - If >11.0 mmol/l (≥ 200 mg/dl) ⇒ "Diabetes"
 - If >5.5 mmol/l (≥ 100 mg/dl) then proceed to next step (2.) (and review cause of symptoms)

2. Random or fasting screening glucose >5.5 mmol/l (≥ 100 mg/dl)

- ⇒ Check fasting venous plasma glucose
 - If ≥ 7.0 mmol/l (>125 mg/dl), repeat and if confirmed ⇒ "Diabetes"
 - If >6.0 mmol/l (≥ 110 mg/dl) do oral glucose tolerance test (OGTT)
 - If >5.0 mmol/l (>90 mg/dl), consider yearly reassessment of arterial risk factors, including plasma glucose

OGTT (venous plasma glucose) :

- If 2-h >11.0 mmol/l (≥ 200 mg/dl) ⇒ "Diabetes"
- If 2-h ≤ 11.0 mmol/l (< 200 mg/dl) and ≥ 7.8 mmol/l (≥ 140 mg/dl) ⇒ "IGT"
- If fasting >6.0 mmol/l (≥ 110 mg/dl) and 2-h < 7.8 mmol/l (< 140 mg/dl) ⇒ "IFG"

Diagnostic equivalents for plasma and blood

	Plasma glucose*		Whole blood glucose	
	Venous* mmol/l mg/dl	Capillary mmol/l mg/dl	Venous mmol/l mg/dl	Capillary mmol/l mg/dl
Fasting				
"Diabetes"	≥ 7.0 >125	≥ 7.0 >125	> 6.0 ≥ 110	> 6.0 ≥ 110
"IFG"	> 6.0 ≥ 110	> 6.0 ≥ 110	> 5.5 ≥ 100	> 5.5 ≥ 100
OGTT 2-h				
"Diabetes"	>11.0 ≥ 200	≥ 12.2 ≥ 220	≥ 10.0 ≥ 180	>11.0 ≥ 200
"IGT"	≥ 7.8 ≥ 140	≥ 8.9 ≥ 160	≥ 6.7 ≥ 120	≥ 7.8 ≥ 140

* preferred measure

OGTT: 75 g glucose in 300 ml water over 3-5 min

See cautions on next page

Diagnostic aids and cautions

1. **Fasting glucose estimations** require a certainty of no previous calorie intake
 - be suspicious if HbA_{1c} not consistently elevated
 - if suspicious repeat after 2-h supervision, or consider OGTT
 - diagnosis cannot be based on a single abnormal glucose estimation in the absence of symptoms
2. Venous plasma glucose estimation is preferred
 - for convenience, equivalents for **whole blood and capillary glucose estimations** are given on previous page
3. **HbA_{1c}** (glycated haemoglobin) can be useful in clinical diagnosis
 - provided that confirmatory venous plasma glucose estimations are obtained
 - provided the assay is DCCT standardized, an HPLC chromatogram is reviewed for presence of abnormal haemoglobins, and erythrocyte turnover is not abnormal
 - approximately, HbA_{1c} >7.5 % ≈ fasting plasma glucose ≥7.0 mmol/l (>125 mg/dl)
>6.5 % ≈ fasting plasma glucose >6.0 mmol/l (≥110 mg/dl)
4. Diagnostic procedures should not be performed :
 - in the presence of **acute illness or after trauma or surgery**
 - during short courses of **blood glucose raising drugs**
5. Diagnostic tests should be interpreted with reservation :
 - in people on long-term **blood glucose raising drugs**
 - in people with reversible **endocrine conditions**
 - in **pregnant women** (*see section 20*)
6. If suspicion or high risk of diabetes, but fasting glucose normal, do OGTT, particularly in the elderly
7. The above procedures are not applicable to people with **hepatic cirrhosis** or other extreme forms of peripheral insulin resistance
 - in people with normal fasting but elevated post-prandial glucose levels, diagnose according to 2-h OGTT criteria

2 Framework of Diabetes Care

A framework for quality diabetes care

Ensure provision of the following :

- **A diabetes team** (professionals) with up-to-date skills, including :
 - doctors
 - diabetes nurse specialists/assistants and educators
 - nutritionists (dieticians)
 - podiatrists (chiropodists)
- **A solid infrastructure**
 - easy access for people with diabetes
 - protocols for diabetes care
 - facilities for education and foot care
 - information for people with diabetes
 - structured records
 - recall system for Annual Review / eye surveillance
 - access to quality-assured laboratory facilities
 - database / software for quality monitoring and development
 - continuing education for professional staff
- **A range of services**
 - for regular review (often 3-monthly)
 - for Annual Review
 - for education
 - for foot care
 - for eye surveillance
 - emergency advice line
 - access to heart, renal, eye, vascular specialists
 - joint obstetric service
- **A system of quality development**
 - feedback from people with diabetes on service performance
 - regular review of service performance (*see section 5*)

3 The Diabetes Consultation

Consultation infrastructure

Make available for consultations the following :

- diabetes team members
- time and space
- printed information for the individual with diabetes
- records and means of communication to other health professionals

Consultation process

Include the following :

⇒ Welcome

Friendly greeting and early establishment of rapport

⇒ Problems review

- Identification of :
- recent life-events / new symptoms
 - new difficulties in self-management of diabetes
- Review of :
- self-monitored results; discussion of their meaning
 - dietary behaviours, physical activity, smoking
 - diabetes education, skills, and foot care
 - blood glucose, lipid and blood pressure therapy and results
 - other medical conditions and therapy affecting diabetes
- Management of :
- arterial / foot risk factors identified at Annual Review
 - complications and other problems identified at Annual Review

⇒ Analysis and planning

- Agreement on :
- main points covered
 - targets for coming months
 - changes in therapy
 - interval to next consultation

⇒ Recording

- Completion of :
- structured record / patient-held record

Annual Review

Include additionally, at Annual Review, surveillance of the following :

Symptoms	ischaemic heart disease, peripheral vascular disease neuropathy, erectile dysfunction (<i>see section 19</i>)
Feet	footwear, deformity / joint rigidity, poor skin condition, ischaemia, ulceration, absent pulses, sensory impairment (<i>see section 18</i>)
Eyes	visual acuity and retinal review (<i>see section 17</i>)
Kidney damage	albumin excretion and serum creatinine (<i>see section 16</i>)
Arterial risk	blood glucose, blood pressure, blood lipids, and smoking (<i>see section 8</i>)
Attendance	podiatry / ophthalmology / other, as indicated

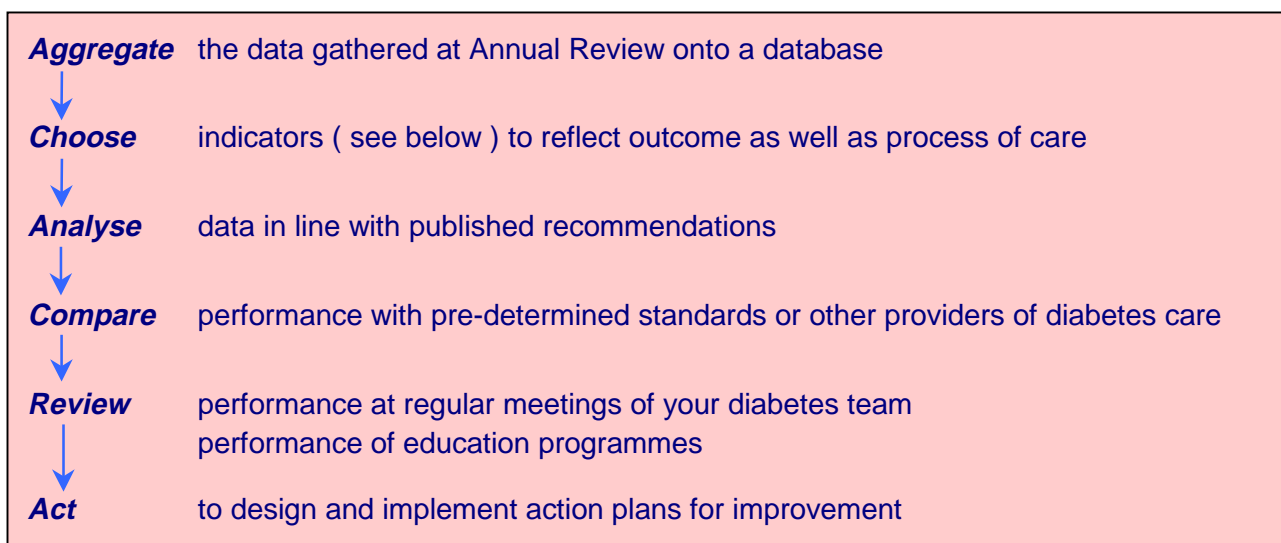
4 Organization of Clinical Monitoring

Schedule for clinical monitoring at different types of visit

<i>Review topics</i>	<i>Initial review / referral</i>	<i>Regular review</i>	<i>Annual Review</i>
Background history			
Social history / life-style review			
Long-term / recent diabetes history			
Complications history / symptoms			
Other medical history / systems			
Family history diabetes / arterial disease			
Drug history / current drugs			
Current skills / well-being			
Diabetes self-management			
Self-monitoring skills / results			
Vascular risk factors			
HbA _{1c} (glycated haemoglobin)			
Lipid profile		If problem	
Blood pressure		If problem	
Smoking		If problem	
*Urine albumin excretion		If problem	
Examination / complications			
General examination			
Weight / body mass index			
Foot examination		If problem	
Eye / vision examination		If problem	
Urine protein			
Serum creatinine		If problem	
<i>* not required if proteinuria</i>			

5 Monitoring Quality of Care

Protocol for quality development and monitoring of performance



Examples of indicators for quality development and monitoring

Measure :	Calculate :
Intermediate outcomes	
HbA _{1c}	Percent with HbA _{1c} >7.5 and >6.5 %
Albumin excretion	Percent with abnormal albumin excretion
Eye damage	Percent with retinal damage
True outcomes	
Amputation above ankle	Incidence
Myocardial infarction	Incidence
Stroke	Incidence
Foot ulceration	Incidence
Risk factor control	
Hypertension	Percent with blood pressure ≥140/85 mmHg
Smoking	Percent people still smoking
Process of care	
Eyes screened	Percent people examined in year
Education performed	Percent people seeing nurse educator in year
Feet examined	Percent people examined in year
<i>These are examples; many other indicators are possible</i>	

6 Patient Education

It is the responsibility of the diabetes team to ensure that the person with diabetes can follow the life-style of their educated choice, achieved through the three elements of empowerment: knowledge, behavioural skills, and self-responsibility

Patient education – *Taking responsibility*

Assess whether the person with diabetes :

- has the knowledge and behavioural skills necessary for optimum self-care
- makes early and effective responses to everyday problems
- has the confidence to obtain the best input from the diabetes health-care team

Ensure that empowerment is :

- a primary objective of your consultations and education programme
- supported by availability of diabetes publications and other information sources
- the active policy of your diabetes service

Provide :

- positive encouraging responses to requests for information and understanding
- a copy of the European Patients' Charter or a similar national or local statement of rights and roles
- a copy of the person's diabetes health-care record
- information on the results and meaning of all investigations

Consider :

- need for assisted self-care for those with cognitive or physical impairment

Patient education – *Assessment*

Use :

- review of diabetes skills (self-monitoring, food identification)
- biomedical measures (changes in body weight, glycated haemoglobin)
- evidence of appropriate behaviours (footwear, physical activity, smoking cessation, membership of diabetes associations)
- assessment of life-style, emotional adjustment, and perceptions of barriers to life-style activities and self-care
- perceptions of desired short-term goals (glucose control, weight), and long-term vulnerability (to arterial disease)
- knowledge (as a basic measure)
- diabetes-specific well-being and health profile assessments (as global measures)

Perform assessment :

- as part of routine care visits, by direct enquiry
- more formally, as part of Annual Review, or on first contact

Patient education – Goals

Aim to optimize :

- knowledge of diabetes, its progressive nature, and the aims of its management
- ability to define personal health-care targets
- motivation and attitudes to self-care
- behaviours which interact with diabetes management
- empowerment in using the skills of health-care and other professionals

Aim to provide skills to :

- | | |
|---|---|
| ➤ manage nutrition and physical activity | ➤ monitor and use the results of therapy |
| ➤ understand and agree health-care targets, and develop strategies for meeting them | ➤ avoid self-destructive behaviours and deal adequately with stress |
| ➤ manage complications of therapy including hypoglycaemia | ➤ ensure appropriate use of glucose-lowering therapies |
| ➤ use the professional members of the diabetes care team effectively | ➤ empower self-management during intercurrent illness |
| ➤ respond to new problems in diabetes care | ➤ cope appropriately with the late tissue damage of diabetes |

Patient education – Provision

Integrate education into regular clinical care by providing your own curriculum and programme

Ensure that the diabetes team has personnel adequately trained in patient education

Assess special needs of each individual (see above)

Be aware of needs of special groups (language problems, physical / mental disabilities)

Provide education within three time frames :

- At and shortly after diagnosis :
 - basic information on healthy eating, physical exercise, and smoking cessation
 - supportive information on the nature and outcomes of diabetes
 - the minimum skills to obtain control over the new situation
- In the months following diagnosis :
 - a comprehensive coverage
 - topics covered previously, plus
 - targets of therapy, eating at home and away
 - complications of diabetes, arterial risk factors, foot care
 - employment, insurance, driving and travel
- In the long term :
 - reinforcement periodically after annual evaluation (see previous page)

Include carers and family members as appropriate

Use group education to uncover problems and provide solutions and behavioural change through peer example

Review, evaluate, and improve the impact of your education programmes regularly

Patient education – *Life-style issues*

Assessment

Ask regularly about diabetes interfering with :

- employment
- social and leisure activities
- travel

Topics

Employment

Provide :

- individualized advice
- counselling and contacts for those affected by a change to insulin therapy

Insurance and driving licences

Be aware of where appropriate and up-to-date premiums can be obtained

Provide :

- advice to patients wishing to enter into insurance contracts
- rapid and appropriate reports on request
- informed comment and advice on legal restrictions on licences

Travelling

Provide advice :

- on the need for valid travel insurance
- on special health risks in visited countries
- as appropriate for those using insulin (see *Desktop Guide to Type 1 Diabetes, 1998*)

Review coping skills for acute illness, especially gastroenteritis, and hypoglycaemia

The aims of patient education and training are to provide information in an acceptable form, in order that people with diabetes develop the knowledge to self-manage their diabetes and to empower them to make informed choices in their lives

7 Self-monitoring of Blood Glucose Control

Use and assessment of self-monitoring

Advise use of self-monitoring for :

- education on effects of diet and physical activity on blood glucose
- assurance of satisfactory blood glucose control
- coping with illness and new situations
- insulin dose adjustment and hypoglycaemia management where relevant

Assess skills (and meters if used) yearly or if problems with self-monitoring

Evaluate reliability of self-test results (if indicated) by :

- ⇒ consistency with the results of glycated haemoglobin estimation
- ⇒ comparison with acute results obtained at consultation
- ⇒ review of the quality of self-test record diaries

Achieving effective self-monitoring

Use :

- for all people with Type 2 diabetes
- blood reagent strips / meters, or self-urinalysis according to individual need

Provide appropriate training and regular review of technique

Recommend :

- ⇒ results are recorded (with date and time)
- ⇒ different patterns of testing according to need :
 - urine glucose post-prandially 1-7 times a week if results consistently negative and glucose control targets met (*see section 8*)
 - blood glucose 1-4 times a day according to need if glucose control is deteriorating or if using insulin therapy (*see Desktop Guide to Type 1 Diabetes, 1998*)
 - blood glucose 4-8 times a day during illness, life-style changes, in pregnancy
- ⇒ tests 1-2 h after meals and not just pre-prandially
- ⇒ testing to cope with variations in eating or activity
- ⇒ urine glucose testing if blood glucose monitoring is indicated but not possible, or if the patient does not wish to continue with it

8 Assessing Blood Glucose, Blood Lipid, and Blood Pressure Control

Using assessment levels to set targets

Use the assessment levels (next page) for glucose, lipids, and blood pressure :

- as an integral part of diabetes care – do not manage diabetes on symptoms alone
- to indicate need for further intervention
- as the basis for short-term and longer-term individualized targets
- as an educational tool to help the person with diabetes

Ask yourself the following at consultations :

- ⇒ Is it possible for the individual to approach each target more closely, without a counterbalancing deterioration in quality of life?

Be concerned about targets :

- ⇒ Failure to attempt to reach agreed targets is inadequate care, unless this would lead to deterioration in quality of life

Assessment of blood glucose, blood lipid, and blood pressure control

Measure :

- ⇒ glycated haemoglobin 2-6 monthly
- ⇒ the blood lipid profile (total, LDL, and HDL cholesterol, and triglycerides) 2-6 monthly if previously above assessment levels (see next page), otherwise annually
- ⇒ blood pressure at each consultation unless known to be below assessment levels

Use the assessment levels (next page) to set individual blood glucose, blood lipid and blood pressure targets, depending on overall risk and what it may be possible to achieve within a foreseeable time period

Modify individual targets at least yearly in the light of past success, and if any change in clinical circumstances

Smoking target : Stop, or reduce to as low as possible

Identify smoking habits :

- at diagnosis / referral and Annual Review

Emphasize importance :

- at diagnosis and if critical events occur
- at every appropriate opportunity

Provide information on :

- health risks and benefits of stopping / reducing
- techniques for reducing tobacco consumption
- use of pharmacological substitutes
- formal smoking cessation programmes

Blood glucose control assessment levels

	Low risk	Arterial risk	Microvascular risk
HbA _{1c} (DCCT standardized) %Hb	≤6.5	>6.5	>7.5
Venous plasma glucose			
Fasting/pre-prandial mmol/l	≤6.0	>6.0	≥7.0
mg/dl	<110	≥110	>125
Self-monitored blood glucose			
Fasting/pre-prandial mmol/l	≤5.5	>5.5	>6.0
mg/dl	<100	≥100	≥110
Post-prandial (peak) mmol/l	<7.5	≥7.5	>9.0
mg/dl	<135	≥135	>160

Fasting capillary blood glucose is around 1.0 mmol/l (18 mg/dl) lower than venous plasma; post-prandial capillary blood glucose is the same as venous plasma

Blood lipid control assessment levels

	Low risk	At risk	High risk
Serum total cholesterol			
mmol/l	<4.8	4.8-6.0	>6.0
mg/dl	<185	185-230	>230
Serum LDL cholesterol			
mmol/l	<3.0	3.0-4.0	>4.0
mg/dl	<115	115-155	>155
Serum HDL cholesterol			
mmol/l	>1.2	1.0-1.2	<1.0
mg/dl	>46	39-46	<39
Serum triglycerides			
mmol/l	<1.7	1.7-2.2	>2.2
mg/dl	<150	150-200	>200

Blood pressure control assessment level

Low risk (mmHg)	<140/85
-------------------	---------

9 Providing Nutritional Advice

Reviewing dietary management

Review dietary management regularly :

- ⇒ Is healthy eating (see box) a normal part of life-style?
- ⇒ Is calorie intake appropriate to desired body weight?
- ⇒ Is alcohol intake moderate? Could it be exacerbating hypertension or hypertriglyceridaemia? Could it be contributing to early or late hypoglycaemia? Is this understood by the person with diabetes?
- ⇒ Is money being spent unnecessarily on special 'diabetes' food products?
- ⇒ Does calorie distribution reflect the patient's life-style and preferences, as well as glucose lowering therapy and regional eating habits?
- ⇒ Do raised blood pressure or kidney damage suggest a benefit from special recommendations (protein intake <0.8 g/kg, salt intake <6 g/day, respectively)?

Make recommendations and review eating :

- at diagnosis
- at each consultation if overweight or vascular risk factor control sub-optimal
- formally every other year as a routine, or more often as required
- on beginning insulin therapy
- on request

Nutritional management is an integral part of initial and continuing education programmes

Healthy eating

Advise carbohydrate intake should be higher, and fat intake lower than that of most Europeans, but not different from recommendations for the population in general :

- Saturated fat : <10 % of calories
- Polyunsaturated fat : <10 % of calories
- Carbohydrate : use foods containing soluble fibre in a carbohydrate rich diet
- Simple sugars : need not be rigorously excluded from the diet, but should be limited
- Protein : <15 % of calories
- Monounsaturated fat : use to maintain palatability and balance calorie intake
- Total calories : as required for normal body mass index
- Fresh fruit / vegetables : encouraged as part of meal-time calorie intake
- Alcohol : if desired, as part of total daily calorie intake

Individualize intake to match needs, preferences and culture

10 Physical Exercise

Assessment of physical activity

Review :

- activity at work, and in getting to and from the workplace
- physical activity practice and opportunities in domestic activities and hobbies
- the possibility of formal physical exercise on a regular basis

Examples :

- ⇒ brisk walking 30 min per day
- ⇒ active swimming for 1 h three times a week

Management

Advise that physical exercise :

- can benefit insulin sensitivity, blood pressure, and blood lipid control
- should be taken at least every 2-3 days for optimum effect
- may increase the risk of acute and delayed hypoglycaemia

Manage physical exercise using :

- ⇒ formal recording of levels of physical activity
- ⇒ identification of new exercise opportunities (see box above), and encouragement to develop these
- ⇒ appropriate self-monitoring, additional carbohydrate, and dose adjustment of glucose lowering therapy for those using insulin or insulin secretagogues
- ⇒ warnings :
 - about delayed hypoglycaemia, especially with more prolonged, severe, or unusual exercise for those using insulin therapy
 - that alcohol may exacerbate the risk of hypoglycaemia after exercise
 - about risks of foot damage from exercise
 - need to consider ischaemic heart disease in those beginning new exercise programmes

Dietary management, physical activity, and drug therapies are partners in the battle to achieve and maintain low risk blood glucose, blood lipid and blood pressure levels

11 Therapy for High Blood Glucose Concentrations

Life-style management of raised blood glucose levels should be given a good trial before beginning glucose lowering drugs

- ⇒ Patient education : see section 6, page 11
- ⇒ Self-monitoring : see section 7, page 14
- ⇒ Blood glucose targets : see section 8, page 16
- ⇒ Dietary management : see section 9, page 17
- ⇒ Physical exercise : see section 10, page 18

Using oral glucose-lowering drugs (for *insulin therapy* see next page)

Begin oral agent therapy when :

- an adequate trial of life-style intervention / education has been given
- *either* (usually) :
HbA_{1c} >6.5 %, fasting venous plasma glucose >6.0 mmol/l (≥110 mg/dl)
- *or* (occasionally) if thin and no other arterial risk factor :
HbA_{1c} >7.5 %, fasting venous plasma glucose ≥7.0 mmol/l (>125 mg/dl)

Use :

- metformin
- insulin secretagogues (sulphonylureas and repaglinide)
- α-glucosidase inhibitors
- thiazolidinediones and related PPAR_γ-agonists

Choice of agents

Metformin : strong evidence base in the overweight, lowers LDL cholesterol, but gastrointestinal side effects in some patients; dose titration may help tolerance

- * *contraindicated (risk of lactic acidosis)* if renal impairment, overt liver disease, or severe cardiac failure; monitor renal function at least yearly

Sulphonylureas : good evidence base, provided patient has useful islet B-cell function

- * *hypoglycaemia a significant problem* glibenclamide > glipizide ≡ chlorpropamide > gliclazide > tolbutamide (some other agents lack data); avoid glibenclamide / chlorpropamide particularly if renal impairment or in the thin insulin-sensitive patient (especially if elderly)

Repaglinide : new rapid-acting insulin secretagogue; possible advantage in hypoglycaemia avoidance and control of post-prandial glucose excursions

α-Glucosidase inhibitors : effective control of post-prandial hyperglycaemia, but poorly tolerated by many patients; dose titration may help tolerance

PPAR_γ-agonists : new agents, offering effective glucose-lowering particularly in combination with insulin and insulin secretagogues

- * *contraindicated* if any history of liver disease, and require organized monitoring of liver function tests until hepatic safety assured

A number of new drugs are currently entering clinical practice; we anticipate the need to modify the above advice as the role of such drugs becomes better understood

Maintaining good blood glucose control with oral glucose-lowering drugs

Expect :

- ⇒ continuous deterioration of glucose control with time
- ⇒ a need to increase therapy and add new agents with time
- ⇒ insulin therapy to be needed in many patients after a variable number of years

Monitor (see section 4, *Clinical monitoring – page 9*) :

- dietary quality and quantity, physical exercise level
- HbA_{1c} (or fasting venous plasma glucose), and self-test results
- body weight
- other vascular risk factors (blood lipids, blood pressure)

Adjust therapy :

- ⇒ Increase dose of individual agent at each visit up to maximum tolerated / effective dose, if targets are not met
- ⇒ Decrease dose of individual agent, if therapy-related problems arise, or if glucose control well into the non-diabetic range

Combination therapy

- ⇒ Add another agent of therapy when maximum dose of current drugs reached
- ⇒ Use triple therapy when control targets cannot be reached on maximum tolerated doses of two agents

(For combination therapy with **insulin** see next box)

Insulin therapy in Type 2 diabetes

Begin when HbA_{1c} has deteriorated to >7.5 % after maximum attention to dietary control and oral glucose-lowering therapy (unless poor life-expectancy and asymptomatic)

- ⇒ Arrange dietary review when starting insulin therapy
- ⇒ Review (or start) self-monitoring of blood glucose before starting insulin
- ⇒ Continue therapy with metformin / insulin secretagogues / PPAR_γ-agonists

Use :

- NPH insulin at night with oral glucose-lowering drugs in people with good insulin secretory reserve
- pre-mixed insulin twice daily in the majority of people
- twice daily NPH insulin in people with high pre-breakfast blood glucose concentrations relative to their HbA_{1c}

Adjust therapy :

- frequently at first, using self-monitored results, until insulin dose is adequate to reach blood glucose targets (see section 8), or hypoglycaemia becomes a risk
- ⇒ Consider more intensive insulin regimens
 - in the more active patient if control remains sub-optimal
 - if control remains sub-optimal due to hypoglycaemia (but not if due to insulin insensitivity)
 - to assist achievement of more flexible life-styles

See *Desktop Guide to Type 1 Diabetes, 1998*

12 Therapy for Abnormal Blood Lipid Concentrations

Life-style management of abnormal blood lipid profiles should be given a good trial before beginning lipid lowering drugs

- ⇒ Patient education : see section 6, page 11
- ⇒ Blood lipid targets : see section 8, page 16
- ⇒ Dietary management : see section 9, page 17
- ⇒ Physical exercise : see section 10, page 18

Using blood lipid lowering drugs

Monitor (see section 4, *Clinical monitoring – page 9*) :

- dietary quality and quantity (including alcohol)
- physical exercise level
- body weight
- blood glucose control
- lipid profile including triglycerides and LDL cholesterol

Begin :

- ⇒ Optimize blood glucose control as far as is possible
- ⇒ Establish lipid profile before beginning a trial of therapy

Use :

- a statin *if*: LDL cholesterol ≥ 3.0 mmol/l (≥ 115 mg/dl)
 (>4.0 mmol/l (>155 mg/dl) if low risk including thin elderly)
- a fibrate *if*: triglyceride >2.2 mmol/l (>200 mg/dl)
 and LDL cholesterol <3.0 mmol/l (<115 mg/dl)
- a fibrate first if triglyceride markedly elevated (>6.8 mmol/l (>600 mg/dl)); check thyroid, renal, and liver function (and apoE genotype if available); consider combination therapy with a statin if LDL cholesterol remains elevated
- combination therapy beginning with statin for high LDL cholesterol and triglyceride

Choice of agents

Statin : choice will usually be determined by relative cost-effectiveness locally

Fibrates : ciprofibrate and fenofibrate are probably more effective than bezafibrate in lowering triglycerides

Other drugs : in general not recommended, unless severe hyperlipidaemia and intolerance to statins and/or fibrates

13 Therapy for Raised Blood Pressure

Life-style management of raised blood pressure should be given a good trial before beginning anti-hypertensive drugs

- ⇒ Patient education : see section 6, page 11
- ⇒ Blood pressure targets : see section 8, page 16
- ⇒ Dietary management : see section 9, page 17
- ⇒ Physical exercise : see section 10, page 18

Using anti-hypertensive drugs

Monitor (see section 4, *Clinical monitoring* – page 9) :

- dietary quality and quantity (including alcohol), physical exercise, body weight
- sitting blood pressure (after 5 min rest, 1st and 5th phase)
 - ⇒ Use : family doctor / occupational health services to obtain monthly records
 - patient-held record card to provide cumulative record of progress
 - self-monitoring devices if available

Use :

- single agent therapy at rising doses until target achieved (or intolerance)
- multiple therapy if targets not reached on maximum doses of single agents
- once daily drug administration regimens

Available drug classes

ACE-inhibitors : good evidence base in diabetes, advancing renal disease, cardiac failure

- * monitor renal function / K^+ (risk of renal artery stenosis with arterial disease)

β -Adrenergic blockers : good evidence base in diabetes and useful where angina or previous myocardial infarction

- * avoid combination with thiazides (metabolic deterioration), and if peripheral vascular disease. Ask about tiredness and impotence

Calcium channel antagonists : some evidence base in diabetes and in advancing renal disease

- * use only long-acting preparations
- * fluid retention a problem with some agents (avoid if history of foot ulceration)

Thiazides : some evidence base in diabetes

- * use low doses only and avoid combination with β -adrenergic blockers (metabolic deterioration). Ask about impotence

Loop diuretics : useful synergistic action with ACE-inhibitors

α -Adrenergic blockers : effective blood pressure lowering and metabolically beneficial

- * use only long-acting drugs (postural hypotension)

Angiotensin II receptor blockers : no special advantages

Choice of agents – summary

Multiple therapy is often required; add loop diuretic to ACE-inhibitor, and avoid thiazides with β -adrenergic blocker; otherwise most combinations neutral

Many older and less expensive agents are as effective as newer agents

If abnormal albumin excretion, particularly if progressive, begin with ACE-inhibitor, or calcium channel antagonist if ACE-inhibitor not tolerated

If ischaemic heart disease, consider β -adrenergic blocker first

14 Managing Arterial Risk Factors

Integrated management of arterial risk

Arterial damage is the major cause of death and disability in people with Type 2 diabetes

Review arterial risk factors :

- * blood glucose
 - * blood lipids
 - * blood pressure
 - * smoking
 - * body weight / abdominal adiposity
 - * family history
 - * albumin excretion rate
 - * arterial / heart symptoms
- at diagnosis
 - yearly
 - more frequently if abnormal or treated

Define risk level as :

- ⇒ **Average risk** : any one arterial risk factor
- or **High risk** : established disease, or any two arterial risk factors
- or **Very high risk** : established disease + any arterial risk factor
or any three arterial risk factors

Manage as follows :

- If **High risk** manage blood glucose, blood lipids, blood pressure to assessment levels
- If **Very high risk** manage blood glucose, blood lipids, blood pressure to lowest possible risk levels
- If **Smoking** manage problem aggressively (see box, section 8)

Educate people :

- ⇒ about the risks of heart disease / stroke from the time of diagnosis
- ⇒ about not smoking and smoking cessation programmes (see box, section 8)
- ⇒ about healthy eating (see box, section 9)

Prescribe :

- ⇒ a programme of regular physical exercise (see section 10)
- ⇒ glucose, lipid, and blood pressure lowering therapy as indicated
- ⇒ low-dose aspirin for those in the *High risk* or *Very high risk* categories
- ⇒ selective β -adrenergic blockers if known ischaemic heart disease

Consider :

- ⇒ hormone replacement therapy post-menopausally (if agreed)

Diagnose :

- ⇒ silent myocardial ischaemia in higher risk patients (see section 15)

15 Ischaemic Heart Disease

Ischaemic heart disease develops in over three-quarters of people with Type 2 diabetes, and kills half of them.
It is often silent, often accompanied by cardiac failure, and is less amenable to surgical intervention than usual

Assessment and diagnosis

Investigate if :

- classical angina or suspicious symptoms
- unexplained breathlessness
- cardiac failure, cardiomegaly, or cardiac rhythm disorder
- arterial thrombotic event

The threshold for investigation is lower if albumin excretion rate is abnormal

Investigate by :

- standard 12-lead ECG and chest X-ray
- cardiac ultrasound scan
- exercise stress ECG
- angiography / stress echo if indicated

Management

Intensify :

- management of arterial risk factors (*see section 14*)
- education on life-style management including smoking (*see sections 6, 8-10*)

Review :

- choice of blood pressure lowering drugs (indication for β -adrenergic blockers)
- use of aspirin / other anti-thrombotic therapy (all patients)
- use of cardiac failure drugs (indication for ACE-inhibitors)

Advise :

- early coronary bypass therapy / angioplasty / stenting if indicated

Use :

- intravenous insulin to control blood glucose levels after admission for myocardial infarction

Consider :

- hormone replacement therapy in post-menopausal women (if agreed)

16 Kidney Damage

Detection and surveillance

Raised albumin excretion rate in Type 2 diabetes is often a sign of general vascular damage rather than specific renal damage. It is a useful arterial risk marker

Abnormal serum creatinine in Type 2 diabetes is often due to renal arterial disease and/or diuretic therapy for cardiac failure rather than to diabetic nephropathy

Detection and surveillance of specific kidney problems therefore depends on identifying progression of albumin excretion rate and serum creatinine, in the absence of other causes

Check for proteinuria yearly using reagent strips

Measure urinary albumin excretion yearly (if not proteinuric) using :

- pre-breakfast albumin:creatinine ratio, or
- pre-breakfast urinary albumin concentration
- ⇒ *If* ratio >2.5 mg/mmol (>30 mg/g) in men or >3.5 mg/mmol (>40 mg/g) in women
or concentration >20 mg/l :
 - repeat to confirm
 - monitor any progression of kidney damage by more frequent measurement

Check for infection and **consider** other renal disease if proteinuria positive

- ⇒ exclude infection with leucocyte/nitrate strips and microscopy / culture if positive

Measure serum creatinine yearly (more often if abnormal, or if rising and metformin-treated)

Measure blood pressure yearly for surveillance purposes (sitting, after 5 min rest, 1st/5th phase)

Management if raised albumin excretion rate

If serum creatinine normal :

- ⇒ monitor albumin excretion rate yearly to detect progression suggestive of specific diabetic kidney damage
- ⇒ intensify management of modifiable arterial risk factors (glucose, lipids, blood pressure)

If serum creatinine abnormal :

- ⇒ review other possible causes of renal impairment (recurrent infection, renal arterial / hypertensive damage, loop diuretic therapy / cardiac failure, glomerulonephritis)
- ⇒ monitor albumin excretion and serum creatinine more frequently to detect progression of renal damage

If specific diabetic kidney damage (diabetic nephropathy) suspected :

- ⇒ treat blood pressure aggressively with a target of <130/80 mmHg
 - ⇒ reduce salt intake
 - ⇒ use ACE-inhibitors as first-line drug therapy
 - ⇒ add loop diuretics, other agents if necessary
- ⇒ reduce protein intake with target of <0.8 g/kg
- ⇒ maintain good blood glucose control and tight arterial risk factor control (see above)
- ⇒ treat urinary infections aggressively; consider papillary necrosis if recurrent
- ⇒ arrange evaluation by a nephrologist before creatinine rises to 250 µmol/l (3.0 mg/dl)

17 Eye Damage

Detection and surveillance

Detection and surveillance of eye problems are a routine part of Annual Review

Organize a recall system to ensure it occurs regularly for every individual

Measure or assess yearly :

- visual acuity (glasses or pinhole)
- the lens and vitreous (ophthalmoscopy)
- the retina (dilated pupils, retinal photography or skilled ophthalmoscopy)
- related factors (smoking / blood pressure)

Reassess after shorter interval (3-6 mo) if :

- pregnant (see section 20)
- new or progressive early or moderate non-proliferative retinopathy
- blood glucose control recently improved in people with retinopathy

Eye disease management

Refer to ophthalmologist if :

- severe non-proliferative retinopathy
- proliferative retinopathy
- macular oedema or exudative maculopathy
- visual disability from cataract
- unexplained deterioration of visual acuity
- other eye disease of visual significance
- unrecognized eye lesions

Review and intensify management of :

- diabetic kidney disease
- blood pressure (target <140/85 mmHg)
- blood glucose control
- blood lipid control (if hard exudates)
- smoking

Attend to the psychological and social aspects of visual impairment where it develops

The primary management of diabetic eye disease is by careful attention to blood glucose control targets from the time of diagnosis

18 Foot Problems

Detection and surveillance

Detection and surveillance of foot problems are a routine part of Annual Review

Organize a recall system to ensure it occurs regularly for every individual

Examine yearly :

- foot shape, deformity, joint rigidity, and shoes
- foot skin condition (fragility, cracking, oedema, callus, ulceration)
- foot and ankle pulses
- sensitivity to monofilament or vibration, and pin prick

Assess yearly :

- history of foot problems since last review
- visual and mobility problems preventing self-care of feet
- self-care behaviours and knowledge of foot care (including carer if appropriate)

Categorize as :

- ⇒ **Foot ulcer** : active foot ulceration
- or **High risk** : neuropathy or vascular disease or previous ulcer or Charcot foot
- or **At risk** : deformity or self-care problem or simple skin problem
- or **Low current risk**

Monitor related factors (blood glucose control, claudication, drug therapy, smoking)

Foot management – preventative

High risk foot

Involve a specialist in diabetes foot care

Provide :

- regular foot assessment
- local preventative attention to callus
- relief of pressure using foam spacers, made-to-order shoes, customized insoles
- regular foot care education – the commandments of foot care
- vascular referral if symptoms or critical arterial supply

At risk foot

Provide :

- routine foot care according to need
- advice on appropriate footwear
- foot care education at routine visits
- advice to carers

Foot management – advanced disease***Established foot ulceration / infection***

Involve your local diabetes foot team without delay

Use local measures including :

- debridement and trimming of callus
- dressings to absorb exudate
- foot casts to relieve pressure
- surgical drainage

Use systemic and proximal measures including :

- intravenous or oral antibiotic therapy – usually staphylococcal coverage, plus wider spectrum, anaerobes, or streptococcal as specifically indicated
- vascular referral, investigation, and reconstruction / angioplasty if indicated

Reserve amputation for :

- uncontrolled pain (secondary to vascular disease)
- debilitating, long-term, non-healing ulceration
- a useless and disabling infected or Charcot foot

19 Nerve Damage

* for *Foot problems* see previous section

Detection and surveillance

Detection and surveillance of nerve damage are a routine part of Annual Review

Enquire yearly for :

- painful and other symptomatic neuropathy
- erectile impotence in men

Enquire for other manifestations of autonomic neuropathy if :

- other complications (especially kidney)
- before anaesthesia
- erratic blood glucose control

Management of painful neuropathy

Counsel for the depressing and disabling nature of the condition

Consider initially :

- ⇒ bed foot cradles for night-time problems
- ⇒ simple analgesia taken in advance of diurnal symptoms
- ⇒ contact dressings

Consider therapeutic trials of :

- ⇒ tricyclic drugs (amitriptyline)
- ⇒ carbamazepine at high doses (600-1200 mg/day)

Management of autonomic neuropathy

Erectile impotence

- ⇒ sildenafil may be helpful if not contraindicated (beware of nitrate therapy)
- ⇒ intracavernosal / intraurethral alprostadil can be useful in some men
- ⇒ referral to professionals with specialist expertise can be useful for :
 - advice on vacuum devices, or mechanical or surgical prostheses
 - vascular investigation and reconstruction
 - psychological assistance

Gastroparesis

- ⇒ investigation using radiological or radioisotope methods may help in diagnosis
- ⇒ investigation of cardiovascular autonomic neuropathy may help diagnosis
- ⇒ cisapride and domperidone are worth a trial

Diabetic nocturnal diarrhoea

- ⇒ investigation must exclude other causes of intestinal upset
- ⇒ may be helped by high doses of codeine, loperamide or diphenoxylate, or by erythromycin / tetracycline

Gustatory sweating

- ⇒ explanation and counselling are often required
- ⇒ try topical or oral anticholinergic agents

20 Pregnancy and Contraception in Women with Type 2 Diabetes

Women of child-bearing age with Type 2 diabetes are almost invariably overweight and have a high relative risk of arterial damage / thrombotic problems

Women who develop diabetes in pregnancy and revert to normal after delivery (gestational diabetes) are at high risk of developing Type 2 diabetes in later life

Contraception / pre-pregnancy management

Enquire :

- as to need for contraceptive advice if pregnancy not intended
- as part of Annual Review as to pregnancy intentions

Advise :

- on barrier methods, or low-dose oral contraceptives if low arterial risk (see above)
- not to discontinue contraception until adequate metabolic control achieved
- repeatedly the need for pregnancy planning
- on the intensity of diabetic pregnancy management, and the risks to the fetus

If pregnancy is intended :

- ⇒ start folic acid
- ⇒ stop oral glucose-lowering drugs (consider insulin therapy)
- ⇒ stop statins
- ⇒ optimize blood glucose control :
 - self-monitoring targets : pre-prandial 3.5-5.5 mmol/l (65-100 mg/dl)
post-prandial 5.0-8.0 mmol/l (90-145 mg/dl)
- ⇒ assess and normalize (<130/80 mmHg) blood pressure :
 - ⇒ replace ACE-inhibitors with methyldopa / nifedipine / labetalol
- ⇒ assess retina and treat as indicated
- ⇒ review education and repeat as needed
- ⇒ urge to stop smoking

Diagnosis of diabetes in pregnancy

If venous plasma glucose >6.0 mmol/l (≥110 mg/dl) at any time :

- ⇒ perform 75 g oral glucose tolerance test
- ⇒ manage as diabetes :
 - if* fasting plasma glucose ≥7.0 mmol/l (>125 mg/dl)
 - or* 2-h plasma glucose ≥7.8 mmol/l (≥140 mg/dl)

Pregnancy care

Organize joint obstetric care in a designated centre

- include a diabetologist, a diabetes teaching nurse, a dietician, an obstetrician, a midwife, and a neonatologist

Provide support for continuing good blood glucose control :

- ⇒ frequent review (every 1-2 weeks)
- ⇒ appropriate educational support
- ⇒ regular self-monitoring of blood glucose with reliable system
- ⇒ target blood glucose as close to normal as possible, while avoiding hypoglycaemia
 - self-monitored blood glucose fasting : 3.5-5.5 mmol/l (65-100 mg/dl)
 - post-prandial : 5.0-7.5 mmol/l (90-135 mg/dl)
 - glycated haemoglobin close to the upper limit of normal
- ⇒ food intake
 - weight controlling but adequate to maintain maternal and fetal nutrition
 - frequent small meals may facilitate improved blood glucose control
- ⇒ insulin therapy if blood glucose control remains above targets

Examine eyes each trimester

Provide regular obstetric care :

- ⇒ ultrasound examination early and repeated for dates and fetal malformation
- ⇒ fetal monitoring in later stages
- ⇒ frequent antenatal review

Provide a normal safe delivery :

- ⇒ deliver at term unless obstetric or diabetes risk
- ⇒ deliver vaginally unless obstetric or diabetes risk
- ⇒ provide optimal neonatal care :
 - access to specialized neonatal intensive care
 - neonatologists warned of expected delivery
- ⇒ good blood glucose control during / after labour
- ⇒ IV infusion of glucose and insulin if necessary with frequent blood glucose measurement
- ⇒ cessation of insulin therapy at delivery if started during pregnancy (and no suspicion of Type 1 diabetes)

If diabetes before pregnancy provide advice for post-pregnancy blood glucose control

If diabetes diagnosed in pregnancy :

- ⇒ confirm remission at post-natal follow-up
- ⇒ advise patient / family doctor of need for regular arterial risk factor review for rest of life

Evaluate quality of care

- ⇒ monitor outcomes of pregnancy of women with diabetes
- ⇒ compare outcomes with other diabetes services
- ⇒ review any need for improvements in pregnancy care

21 Management of Diabetes during Surgery

Organization

- Prepare** a local care protocol
- Disseminate** the protocol to relevant professionals

Management

- Optimize** blood glucose control pre-operatively (see section 8)
- Delay** major surgery if possible when :
 - HbA_{1c} >9.0 %, or
 - fasting blood glucose >10.0 mmol/l (>180 mg/dl), or
 - post-prandial >13.0 mmol/l (>230 mg/dl)
- Screen** for complications which may affect surgery risk; alert the surgical team :
 - heart or kidney problems
 - autonomic or peripheral nerve damage
 - proliferative retinopathy
- Manage** blood glucose :
 - ⇒ If diet / oral agents and good blood glucose control and minor surgery :
 - ⇒ omit therapy on morning of surgery
 - ⇒ restart when eating normally (metformin only after renal function check)
 - ⇒ avoid glucose-containing IV infusions
 - ⇒ If insulin therapy or unsatisfactory blood glucose control or major surgery :
 - ⇒ use IV glucose-insulin-potassium infusion (GIK)
 - ⇒ start at 0800 h and continue until eating normally
 - ⇒ monitor blood glucose before, during, and after (1-4 hourly) surgery
 - use a quality-assured method
 - ⇒ aim for blood glucose levels of 6.0-10.0 mmol/l (110-180 mg/dl)
- Encourage** supervised self-management while in hospital

Surgical glucose-insulin-potassium (GIK) regimens

- ⇒ Use 500 ml 10 % (100 g/l) glucose (dextrose) containing :
 - unmodified (soluble, regular) human insulin 16 U
 - potassium chloride 10 mmol
 Infuse at 80 ml/h from a volumetric pump
- ⇒ Consider higher dose (20 U) if obese, or initial blood glucose high
- ⇒ Consider lower dose (12 U) if very thin, or usual insulin dose low
- ⇒ Decrease dose by 4 U if glucose falling and normal or low
- ⇒ Increase dose by 4 U if glucose rising or high
- ⇒ Continue the GIK infusion until 30-60 min after first meal
- ⇒ Use higher strength glucose solutions if water volume a problem
- ⇒ Check for dilutional hyponatraemia daily

European Diabetes Policy Group 1998-1999

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Statement of Duality of Interest

A number of members of the Policy Group, personally or through their employers, hold research contracts with, or provide consultation to, governmental and commercial organizations (including the sponsors) with an interest in areas covered by these Guidelines.

While travel and subsistence costs of the Policy Group's consensus meeting were covered by a grant to the University of Newcastle upon Tyne by the sponsors, no member of the Group has received any fee in connection with this activity. A fee commensurate with the editorial work performed was however received by the spouse of one of the Chairmen.

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DIABETES TYPE 2 DESKTOP GUIDELINES

EUROPEAN DIABETES POLICY GROUP 1999

Diabetes Care Research Programme- Patient Information

I am happy to announce that *Name of Pharmacy* and researchers from the Faculty of Pharmacy at Rhodes University will be working together on a research programme aimed at assisting Type 2 diabetic patients improve their diabetes management.

As you are probably aware diabetes is very often associated with other serious conditions such as coronary heart disease, high blood pressure, high cholesterol, eye and foot problems and kidney failure. Diabetes specialists worldwide agree that doing everything possible to prevent or slow down the development of these serious conditions is very important. Our diabetes research programme is designed to help patients with Type 2 diabetes improve the management of their condition. We will work with patients, their doctors and other health care professionals to identify and address important diabetes-related issues in order to ensure that patients are able to maximize the benefits of their treatment.

Our programme will run for 12 months and during this period participating patients will be required, from time to time, to have their body mass index (weight to height ratio), waist-hip, blood glucose, blood pressure and total cholesterol measured. Patients will also be asked to complete questionnaires that will help the researchers measure other important aspects of their treatment. All the information provided, together with the results of the tests will be regarded as confidential.

I hope that you will agree to take part in this programme. I want to help you manage your condition and I know that by working together as a team we can go a long way towards getting the best out of your treatment. If you would like to take part in this research then please complete and sign the attached Patient Consent form and hand it back to me.

Please note that your participation in this programme is voluntary and that you may withdraw from this programme at any time.

Name of Pharmacist



RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

Diabetes Care Research Programme- Patient Consent Form

Patient's Surname:		Initials:
Postal Address:		Postal code:
Telephone (daytime):	Code:	Cellphone number:
Fax:	Code:	
Email:		ID Number:
Gender: Male <input type="checkbox"/>	Female <input type="checkbox"/>	Age:

Patient

I, _____ being the abovementioned patient, hereby agree to participate in this research programme on the understanding that any and all personal information provided by me or my pharmacist or medical practioner to the researcher will be provided in the interests of furthering this research and will remain confidential. Furthermore, I understand that I may withdraw from the research programme without prejudice at any time.

Signature _____ **Date** _____

Witness _____

Pharmacist

I, _____ being the registered pharmacist agree that any and all patient information provided to me in the course of this research will remain confidential.

Signature _____ **Date** _____

Researcher

I, Peter William Hill being the researcher approved by the Faculty of Pharmacy of Rhodes University Grahamstown, agree that any and all patient information provided to me in the course of this research will remain confidential.

Signature _____ **Date** _____



Patient adherence in type 2 diabetes mellitus: a South African community pharmacist diabetes care intervention.

8 November 2006,

Dear *name of pharmacist*

Further to my email of 6 August 2006, I would like to confirm that you and your associated patients have been randomised to the **intervention** arm of the study.

As you are no doubt aware, practice conditions vary from pharmacy to pharmacy, and both pharmacists and patients, as individuals, are unlikely to approach adherence or any aspect of diabetes care on a “one-size-fits-all” basis. Furthermore, your rights and obligations as a registered healthcare professional are recognised. Therefore, I have not prescribed precise stage-specific diabetes care interventions, but rather wish to encourage you to collaborate with your patients in developing interventions to suit individual patient needs within the reality of your specific practice situation.

An intervention framework in the form of a manual will be sent to you by registered mail during the first week of December 2006. The intervention document, IDF guidelines and any published article or paper I send you are resource material and provide a framework or guide for individualized diabetes care plans that I trust you will develop with each of your patients. But, and this is important, it's up to you to decide on how you go about working with and assisting your patients.

The intervention is an individualized pharmacist-directed diabetes care plan [DCP]. In essence, the DCP requires you to:

- Conduct medication reviews to assist in the identification of actual or potential medication related problems.
- Assess patient diabetes-related needs and goals.
- Discuss and agree strategies to address the needs and goals [within your scope of practice as a pharmacist].
- Implement any agreed interventions [you are to use your initiative and professional judgment in deciding on the actual interventions].
- Monitor patient diabetes-related clinical and psychosocial indicators.

- Discuss the findings with your patients and agree remedial action [including referral to other healthcare professionals].
- Regular review and appropriately modify the DCP.

The DCP is comprised of two main elements:

- a clinical intervention and
- a patient education and counseling intervention [PEC].

The Clinical Intervention

The clinical intervention requires that you pay particular attention to the issue of medication-related problems. In this regard I suggest that you refer to the *ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling 2001*, a copy of which is included in the manual. Also please refer to your copy of the IDF's *A Desktop Guide to Type 2 Diabetes Mellitus*, which I previously sent you. Included too you will find copies of the *Revised SEMDSA Guidelines for the diagnosis and management of type 2 diabetes mellitus for primary health care in 2002*, The South African Council for Medical Scheme's *Algorithm for Diabetes Mellitus Type 2*. Please don't forget to refer to your copy of the South African Pharmacy Council's publication, *Good Pharmacy Practice in South Africa*, as this publication deals with the statutory requirement of providing pharmaceutical care. I suggest that you refer to the SEMDSA and IDF guidelines to inform your discussions about diabetes-related goals, tests and examinations, monitoring indicators and general self-care recommendations. Remember it's really important to monitor because the cliché: "if you can't measure you can't manage", most certainly applies to diabetes care.

The PEC Intervention

The patient education and counseling (PEC) intervention is an important component of the DCP for two reasons:

- The potential for PEC is not limited to structured appointments only as pharmacist-patient dialogue can take place in a range of circumstances using various methods of communication.
- It is the intervention concerned with reinforcing the pre-eminent role of patient self-care in Type 2 diabetes.

The PEC intervention is based on the counselling model of Motivational Interviewing and adapted for use in community pharmacy. I understand that community pharmacists in practice do not have much time to spend with each patient and so I have suggested an MI design that is brief. However, I assume that you will use your professional judgment in

deciding how much time you will need to spend with each patient. As mentioned above, I will be posting you a fairly detailed framework for the diabetes care plan and I will also let you have published literature to augment the main document. If however, you feel you need help in a particular area then please don't hesitate to contact me and I will make every effort to assist you.

Remember the research hypothesis is that community pharmacists are able to assist patients with Type 2 diabetes improve their adherence to therapies and self-care recommendations and, by inference, improve patient health outcomes. As previously mentioned individual pharmacists working with other individuals [patients] suggests that there can be no one-size-fits-all solution to the problem of adherence. There are, however, a number of true-north principles underpinning therapeutic adherence:

- Patients must have access to an appropriate healthcare system [including healthcare professionals and affordable medicines].
- They need to have a basic understanding of their disease and how to use their medicines correctly.
- They need to be able to motivate themselves to follow agreed therapy and self-care recommendations.
- They need to convert motivation into behaviours that include medicine taking and lifestyle modifications, and then they need to sustain the changed behaviour.
- They should be encouraged to accept that through self-care they alone hold the key to successful chronic care.
- Healthcare providers should support chronic care models that recognise the pre-eminent and defining role of patient self-care.

Given the realities of working in a busy practice, I suggest you use the patient interaction opportunity created by the script refill encounter to review pharmacotherapy [check for any medication related problems], monitor key indicators [measure blood pressure, body mass, waist-hip, check on their SMBG values etc.] and discuss findings. This is also an ideal time to re-enforce self-care behaviours. Telephonic follow-up between pharmacy visits has been shown to be very useful in promoting adherence and in building relationships with patients.

The study will run for 12 months post-baseline (May 2006 to May 2007) and the intervention during the 6-month period December 2006 to May 2007. During May 2007 identified clinical and disease-risk indicators together with other qualitative variables will be measured for patients in both the intervention and control groups.

Thank you once again for your very valuable contribution to this research.

Kind professional regards

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**The South African Community Pharmacist and Type 2 Diabetes Mellitus: A
Pharmaceutical Care Intervention.**

Diabetes Care Plan Intervention

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The South African Community Pharmacist and Type 2 Diabetes Mellitus: A Pharmaceutical Care Intervention.

EXECUTIVE SUMMARY

1. The intervention is a pharmacist scope of practice patient-centred Diabetes Care Plan (DCP) involves the documented processes of:

Assessment: identify diabetes-related needs, goals and problems.

Planning: patient and pharmacist (and other health care providers) collaborate to develop strategies and interventions required to address the needs, goals and problems.

Implementation: patient and pharmacist implement agreed interventions.

Monitoring: pharmacist and patient monitor key variables underpinning patient goals.

Review: pharmacist and patient review monitoring results and other data at agreed intervals. Adjustments to therapy and onward referral based on evaluation of the data forthcoming from the monitoring and review process.

2. The DCP consists of two main elements :
 - a Patient Education & Counselling intervention (PEC) (page 12 – 19).
 - a Clinical intervention (page 20 – 23).
3. The patient education & counselling intervention involves:

- Diabetes-related education designed to improve patient knowledge and understanding of key aspects of Type 2 diabetes (DM2) as per the International Diabetes Federation (IDF) Global guidelines for Type 2 Diabetes.
 - Counselling for patient self-management based on the Motivational Interviewing model.
4. The clinical intervention essentially involves : (i) medication review, (ii) self-management assessment, (iii) agreeing diabetes-related goals (iv) monitoring of key clinical and disease-risk variables, (v) evaluation of data.

4.1 Medication review

- Conduct medication review informed by American Society of Health-System Pharmacists (ASHP) guidelines on pharmacist-conducted patient education and counseling, revised Society for Endocrinology Diabetes and Metabolism of South Africa (SEMDSA) guidelines for diagnosis and management of type 2 diabetes mellitus for primary health in 2002, and The Council for Medical Schemes diabetes mellitus type 2 algorithm.
- Measure medication adherence by reviewing prescription refill data.
- Measure patient self-reported adherence using Medication Adherence Report Scale.
- Identify and resolve/refer any other medication related problems.
- Refer to medical practitioner for adjustment to pharmacotherapy where required.
- Identify and resolve/refer medication access problems.
- Conduct medication appropriateness evaluation for self-medication (OTC's).

4.2 Self-management assessment

- Using the questionnaires provided establish baseline values for psychosocial variables.
- Use the clinical and disease-risk indicator data collected to establish baseline values.

4.3 Establish desired and realistic diabetes-related goals informed by SEMDSA guidelines for :

- Blood Glucose – to achieve and maintain guideline glycaemic levels.
- Blood Pressure – to achieve and maintain guideline blood pressure levels.
- Lipid profile – to achieve and maintain guideline lipid levels.
- Body Mass Index – to achieve and maintain guideline BMI.
- Any other scope of practice diabetes-related goals the patient may identify.

4.5 Intervention

- Provide appropriate diabetes education to ensure adequate knowledge base.
- Identify and enlist patient's social support structures (family, friends).
- Discuss, agree and plan interventions required for the realisation of patient diabetes-related goals.
- Identify and attempt to resolve barriers to patient self-management.
- Refer appropriately to other health care providers (including for psychosocial investigation).
- Agree date and times for follow-up consultations (more frequently for high-risk patients e.g. elderly, multiple co-morbidities, poor glycaemic control).

4.4 Monitoring of the clinical and disease-risk indicators and other variables

- Refer to the monitoring schedule (page 21-23).
- Follow-up telephonically between face-to-face consultations.

4.5 Evaluation

- Review the patient's health status.
- Refer to results of the monitoring process and discuss and agree to modify strategies and interventions and escalate the diabetes care (refer to other healthcare professionals) where necessary.
- Review and reinforce self-management activities.

- Reward achievement and encourage where there has been regression.

The following documents are included in the manual in support of the DCP intervention :

Patient Education & Counselling Intervention	Content
Motivational Interviewing	Motivational interviewing helps patients confront change. Berger B US Pharmacist Assessing and interviewing patients for meaningful behavioral change. Part 1 Berger B The Case Manager Assessing and interviewing patients for meaningful behavioral change. Part 2 Berger B The Case Manager Motivational interviewing in health settings: a review. Britt E et al. Patient Education an Counseling
Communication	Persuasive communication. Part 1 Berger B US Pharmacist Persuasive communication. Part 2 Berger B US Pharmacist
Change	Change is a multistep process. Berger B Us Pharmacist Helping patients face change. Berger B US Pharmacist
Clinical Intervention	
Diabetes education	Education: IDF global guidelines for type 2 diabetes. IDF
Guideline and medicine review	Revised SEMDSA guidelines for diagnosis and management of type 2 diabetes mellitus for primary health in 2002 Council for medical schemes algorithm for diabetes mellitus type 2 ASHP guidelines on pharmacist conducted patient education and counseling. American Journal of Health-System Pharmacists
Self-management adherence	Improving adherence to diabetes self-management recommendations. Schechter CB and Walker EA. Diabetes Spectrum
Diabetes-related knowledge	Diabetes knowledge questionnaire: assesses patient's day-to-day knowledge of diabetes
Self-management: SMBG	Self-monitoring of blood glucose questionnaire: assesses SMBG practices
Self-efficacy	Diabetes empowerment (DES-SF) questionnaire : assesses patient self-efficacy
Self-management: understanding	Understanding self-management questionnaire: assesses patient's understanding of self-management practises
Self-management: medication adherence	Medication Adherence Report Scale (MARS): assesses patient adherence to medication therapy

Depression	Major depression inventory (MDI): a depression assessment tool (for possible referral)
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Note: In addition to the abovementioned please refer to the copies of the following which were completed by each of your patient's at baseline and which I forwarded to you:

- Patient Profile
- Clinical Data Form
- Beliefs about Medicines Questionnaire
- Patient Satisfaction Questionnaire
- Diabetes Care Plan Questionnaire
- Self-care Adherence Scale

In addition it is recommended that pharmacists consult the excellent and comprehensive resource, IDF Global Guideline for type 2 Diabetes available free-of-charges on-line at www.idf.org/webdata/docs/IDF%20GGT2D.pdf

Conclusion

The DCP is designed to provide pharmacists participating in the study with resource material and a suggested framework on which to base **individualised** diabetes care plans. Pharmacists are not compelled to use any specific intervention and are free to use their professional judgement (as you do in day-to-day practice) in deciding on the interventions to be used and how they are to be applied. However, in keeping with good pharmaceutical care practice it is suggested that pharmacists record any such interventions and the clinical and other data in a manner that allows for easy referral.

The intervention will run for 6 months starting in January 2007 and ending in June 2007. Please remind your patients that we will need to re-measure them for the clinical and disease-risk indicators that we measured at baseline in April/May 2006 (HbA_{1c}, Lipogram, Serum creatinine, Waist-Hip, BMI, and BP) in June 2007. At the end of the study period I will ask you to forward all outstanding patient data to me.

Please contact your patients as soon as possible to arrange for the initial interview which should ideally take place at your earliest convenience **during December/January**. I suggest that you have your patients complete the questionnaires **in the pharmacy** during the initial interview. Please score questionnaires once they are completed, make copies

for your file and then post the originals to me using the self-addressed postage paid envelopes provided.

Once again, thank you for your participation and I look forward to working with you during this intervention phase. Do not hesitate to contact me by email if you need clarification on any issue.

I would also like to wish you a merry and Blessed Christmas and a Happy New Year.

Kind regards

Peter Hill

Overview

Introduction

The pharmacist intervention for the study takes the form of an agreed (between patient and pharmacist), evidence-based DCP appropriate to the scope of practice of a pharmacist. The DCP has been developed from the literature and from own past experience as a community pharmacist.

A role for the patient in diabetes care

The patient is not a passive recipient of diabetes care but is actively involved in all aspects of the DCP, including defining diabetes-related needs, discussing and agreeing strategy, implementing interventions and monitoring outcomes. This collaborative approach is founded on the pre-eminent role that self-management plays in chronic care.

Self-management in DM2 is based on the following true-north principles:

- that the day-to-day therapeutic (e.g. take medicine), lifestyle (e.g. exercise) and behavioural (e.g. self-monitor blood glucose) decisions are made by the person with diabetes;
- that self-management can never be practiced in isolation and that collaborative support that allows patients to make the best possible decisions about their care is a patient right;
- that almost all of the barriers to self-management can only ever be resolved by motivated and empowered patients themselves;
- that the consequences of diabetes care, i.e. patient outcomes, are born by the patients and their immediate social circle and not by healthcare providers.

A role for the pharmacist in diabetes care

The DCP embodies the following principles of care delivery identified by the IDF as essential for the provision of quality, patient-centred and evidence-based care to people with DM2.

- i. Offer care, with sensitivity to cultural wishes and desires, to people with DM2.
- ii. Organise care around the person with diabetes.
- iii. Encourage a collaborative relationship by actively involving the person with diabetes in the development of the DCP and, at each consultation, create opportunities for them to ask questions and express concerns. Ensure that issues important to the person with diabetes are addressed.
- iv. Agree and document an individualised DCP with each person:

- Use diabetes care interventions that are protocol and guideline-driven to deliver the DCP.
 - Review key elements of the DCP at agreed fixed date and time intervals ('appointments') based on patient-risk evaluation, cost and convenience.
 - Modify the DCP according to changes in findings, wishes & circumstances.
 - Review the entire DCP at six monthly intervals.
- v. Offer surveillance, appropriate to the scope of practice of a pharmacist, of all aspects of diabetes control and complications to people with DM2 . These aspects include:
- Self-management knowledge and beliefs
 - Lifestyle adaptation and wishes (including nutrition, exercise, smoking)
 - Body weight trends
 - Psychological status (e.g. depression/diabetes distress)
 - Cardiovascular risk
 - Self-monitoring skills and equipment
 - Medication review
 - Blood glucose control
 - Blood pressure control
 - Blood lipid control
 - Kidney function
 - Vision (eye)
 - 'Diabetic foot'
 - Erectile dysfunction
- vi. Refer, where required, to members of a multidisciplinary care team with specific diabetes-related expertise.
- vii. As a minimum, ensure that at each prescription refill diabetes care is reinforced.
- viii. Provide urgent access to diabetes healthcare advice for unforeseen problems.
- ix. Consider how people with diabetes, acting as expert patients, and knowing their limitations, together with other interested parties might be involved in supporting the pharmacist-directed care delivery.
- x. Access decision support systems and resources to enhance care delivery.
- xi. Follow up by maintaining contact with patients between appointments and other unscheduled encounters and use the data gathered in routine care to support quality assurance and intervention-related activities.

The main thrust of the DCP lies in providing patients with appropriate information and support in an effort to enable them to achieve their diabetes-related healthcare goals. The process of diabetes care in its entirety is complex and requires a collaborative multifaceted approach beyond the scope of practice of a pharmacist alone. However, pharmacists because of the frequency of contact with their DM2 patients, most of whom rely on pharmacotherapy, are positioned to significantly contribute to the overall objective of improved patient outcomes.

The proposed DCP consists of two interrelated interventions, one of which is predominately psychosocial in nature and the other biomedical or clinical. The psychosocial intervention is a patient education and counselling intervention, (see the following section entitled “Patient Education & Counselling”). The biomedical or clinical intervention is described in the section entitled “Clinical” which follows the patient education and counselling section of this document. Although the patient education and counselling intervention and the clinical intervention are referred to separately in this manual the two are interdependent with many of the clinical activities being subject to psychosocial drivers and vice versa.

Patient Education & Counselling intervention (pages 12 – 19)

The patient education and counselling intervention consists of two components namely, ‘education’ and ‘counseling’ that are distinct in purpose but interdependent. **Patient education** is aimed at addressing deficiencies in patient knowledge about DM2, any co-morbidity, and any other issue that may impact on the management of diabetes, in order to ensure that the patient has a clinical foundation adequate for the effective self-management of the disease. **Patient counseling** differs from patient education in that, while education is more biomedically focused, counseling takes a psychosocial approach to aspects of diabetes care. In this context, counseling has a broader reach than education as it is less concerned about the transfer of empirical knowledge between pharmacist and patient and more focused on encouraging the patient to make informed decisions about self-management behaviour.

Patient counseling by the pharmacist has a number of secondary outcomes designed to support the main objective of informed decision-making and these include:

- fostering of caring patient relationships through concordant alignment of vision, expectation, contribution and commitment;
- elucidating and discussing patient needs, diabetes-related goals and desired health outcomes;

- empowering patients to take ownership of their diabetes care and at the same time reassuring them of continued pharmacist support;
- reinforcing the appropriate use of medication, nutrition and exercise therapies, given patient health and medication beliefs and the effect of cultural imperatives on patient choice of therapies and lifestyle practices;
- encouraging adverse medication event reporting;
- identifying possible diabetes-related distress or depression with possible referral for professional psychological evaluation and support;
- resolving, where possible, issues relating to patient access to the healthcare system and, where needed and possible, providing assistance through a referral process;
- involving spouse, partner or close family member in diabetes care;
- where required, facilitating patient enrolment in smoking cessation programmes;
- improving patient adherence to therapies and self-management recommendations by suggesting mechanisms to overcome barriers to adherence, encouraging the use of adherence promoting aids, and the use of patient self-report tools to self-monitor adherence to therapies.

Clinical intervention (pages 20-23)

Monitoring is a key aspect of the clinical intervention in diabetes care. The management maxim of “If you can’t measure it, you can’t manage it” certainly applies to diabetes care. The pharmacist is able to measure many of the key clinical and disease-risk variables associated with diabetes care (HbA_{1c}, blood pressure, blood lipids, aspects of renal function, BMI, medication adherence) and qualitatively measure certain important psychosocial variables, such as patient satisfaction, self-management adherence and diabetes empowerment using validated scales. Data such as these when viewed in conjunction with evidence-based disease management protocols and accepted guidelines for the treatment of DM2, could be used to inform both the overall diabetes care plan and, most importantly, the patient’s self-management plan. In broad terms the monitoring intervention involves the following:

- Collection, interpretation and discussion of the data.
- Evaluation of the effectiveness of the DCP interventions by benchmarking the results obtained against accepted guidelines and the patient’s own goals.
- Referring patients where necessary and with their approval, to other healthcare providers for further evaluation and possible intervention.

Patient Education and Counselling Intervention

The PEC intervention is based on the model of Motivational Interviewing (MI) developed by Miller and Rollnick underpinned by the South African Pharmacy Council's Good Pharmacy Practice Standards and the SEMDSA and IDF guidelines. MI was developed as a patient-centred counselling tool for use with patients suffering from addictions but has subsequently been adapted for use in other healthcare settings, including chronic disease care. Additional resource material in the main in the guise of 'practical' articles by Professor Bruce Berger are attached to the executive summary of this manual.

Acute care vs. Chronic care

The acute care or biomedical model presupposes a dynamic in which the expert healthcare provider interacts with the naïve patient. The chronic care model first proposed by Wagner¹ recognised that a different approach to caring for people with chronic diseases was required as *"patients and families struggling with chronic illness have different needs, and these needs are unlikely to be met by an acute care organisation and culture"*

Wagner proposed that chronically ill patients required, inter alia:

- planned and regular contact with their healthcare professionals in order to systematically and continually assess progress in terms of accepted treatment guidelines;
- interventions focused on addressing exacerbations and complications of their diseases;
- behavioural support for their role as self-managers of their disease;
- regular and continuous follow-up;
- that the entire chronic care process should be documented using a clinically appropriate information system.

Implicit in the model is the recognition of the key role of patient self-care or self-management, and that the healthcare provider in the context of chronic care is the entity created by the collaborative partnership between the patient and healthcare professional.

Patient self-management

Patient self-management has a pre-eminent role to play in the treatment and management of DM2². Patients who do not achieve desired health outcomes do so largely because their therapeutic goals have not been achieved, and not because of incorrect diagnosis or therapy. The self-management recommendations that will drive HbA_{1c} and other disease-risk and clinical indicators to levels that meet national or international guideline targets for DM2 include:

- lifestyle modifications (smoking cessation, diet and exercise);
- self-monitoring of blood glucose;
- adherence to prescribed therapies;
- regular attendance at appointments with healthcare professionals;
- having essential tests and examinations done as per guideline recommendations.

Patient behaviour: readiness to change

Patient behaviour is the main driver underpinning self-management in DM2². Resistance to change or having mixed feelings (ambivalence) about the necessity to change behaviour can only be resolved by the patient and never by the healthcare professional. Resolving resistance to change or ambivalence requires motivation to change on the part of the patient, and motivation in the context of MI is viewed as readiness to change rather than as a personality trait³. This, in effect, means that motivation is not 'fixed' but is rather a state that is open to change.

The pharmacist in applying the principles of MI acts as a facilitator of behavioural change by helping patients to recognise and resolve their resistance to change or ambivalence³. This is very different from the traditional view of pharmacist counselling which is based on giving advice or providing information in the hope that patients will change health behaviours. While this approach may work with some patients, research shows that only about 5-10% of patients will undertake behavioural change as a result of such an intervention³. Many patients do not want to be given advice in a way that may seem prescriptive especially if the healthcare provider only emphasises the benefits of change without taking into consideration the personal cost to the patient of the behavioural change. Such an approach is likely to increase resistance to change or ambivalence rather than to lead to the removing of any barriers to change. To illustrate this point, telling an obese patient to lose weight without attempting to address the psychosocial drivers behind the patient's obesity is probably futile and may well increase patient resistance or even be perceived as confrontational by the patient.

Motivational Interviewing

Motivational Interviewing employs a counselling style that is *"quiet and facilitative, and where the relationship is more like a partnership or companionship than an expert/recipient one."*³ The strategy used in the application of MI has 3 core elements,⁴ and for each of the core elements 5 clinical principles apply³

The 3 core elements are:

(i) Elicitation

This is asking the patient to provide information about the issue under discussion by using open-ended questions that do not allow for 'Yes' or 'No' answers. In other words, the patient is encouraged to identify both a need and the barrier(s) that prevents the need from being met (the cause of the resistance to change or the nature of the ambivalence). For example, if discussing non-adherence to pharmacotherapy with a patient, the pharmacist could ask the patient a question along the lines of, *"You say that you do not always take your medicines as prescribed-why do you think this happens?"* The patient has identified the problem – does not take medication regularly- but has not yet identified the reason for the behaviour. The pharmacist in asking the question, *"why do you think this happens?"* is directing the patient to identify the reason for the resistance or ambivalence, and so it is important that the pharmacist have a clear goal in mind when exploring a patient's ambivalence.

(ii) Provision

The pharmacist must accept that resistance to change or ambivalence with regard to therapy is a 'normal' behaviour. Research has shown that patients weigh up the pros and cons of pharmacotherapy by considering their need to take medicines versus their concerns about any perceived negative aspect of the therapy⁵. Having listened to what the patient has had to say, the pharmacist should use the opportunity to provide information and answer questions in a manner that is directional but without being dictatorial. For example, continuing with the non adherence theme, the patient may have said that he finds taking a once-a-day dose before breakfast makes him nauseous and so he consciously does not take the medicine every day. This is an adverse-effect issue and the pharmacist might suggest that the patient try taking the medicine last thing at night as a way of overcoming this barrier to adherence. In doing so the pharmacist accepts the patient's ambivalence and then is directive in suggesting the change in the timing of the dosage.

(iii) Elicitation

The pharmacist restates the problem and the patient's agreed solution or decision and then asks if there are any other issues that require clarification. As a result of providing information and answering questions it is possible that other concerns may surface in the patient's mind and so it is important that patient's be encouraged to raise any further issues.

An important technique used in providing information in MI is to seek the patient's permission before offering advice, especially if the information could be construed as

dictatorial 'advice'. In the abovementioned example, the pharmacist in changing the timing of the dose from morning to night might be drawing on past experience either with other patients or from information contained in the literature. In this case it may be helpful to say something like, *"If I may, I'd like to share something of my experience with others patients who had a similar problem?"* before going on to suggest the change. Seeking the patient's permission to provide solutions to a problem demonstrates the pharmacist's willingness to collaborate and encourages the patient to make decisions.

The 5 clinical principles of Motivational Interviewing

In applying the MI strategy of Elicitation- Provision- Elicitation, five principles or skills are used to effect behavioural change through a process of self-motivation. These principles are:

(i) Roll with resistance

If a patient seems ambivalent or is resisting any aspect of their therapy then instead of confronting the patient's resistance head-on, use the central theme of the resistance or ambivalent statement to support the provision of information and create what is referred to as dissonance (or clashing of ideas) in the patient's mind³.

Consider the following hypothetical example of a patient who smokes and who has previously been counselled on the health issues relating to smoking. The interview reveals that the patient is aware that smoking causes lung cancer and that it plays a role in the development of other serious diseases. This realisation, even if unspoken, creates dissonance (current health-related behaviour [smoking] versus other behaviour [not smoking] required to achieve the patient's desired health outcomes). It is believed that dissonance motivates the patient to change behaviour. The pharmacist must work with or exploit the dissonance that the patient self-realises in order to encourage the patient to shift perception.

Advice that the patient may perceive as confrontational may simply reinforce resistance to change. For example, if the patient was defensive about smoking and said something like, *"I enjoy smoking and besides I am concerned about putting on weight if I stop"*. An answer along the lines of *"Well being fat is better than being dead from lung cancer"* is likely to be viewed as confrontational and increase resistance.

Rolling with resistance would mean a comment by the pharmacist that would recognise the patient's concern about gaining weight, *"I can understand that you are reluctant to stop*

smoking because of the possibility of gaining a few kilos”, offer encouragement, “but in my experience this does not always happen and in any event I am able to help you if this should happen”, and at the same time raise the possibility of a more serious health outcome if they continue to smoke, “I would like to suggest, however, that if you decide to keep smoking, it might be an idea to have your lungs and heart checked out more frequently because as you know there are very real health risks associated with smoking”. Finally, the pharmacist should recognise the patient’s right to make their own decisions about their health care⁶, “I’d like to add that I respect your right to make your own decision about whether or not you stop smoking.”

(ii) Express empathy

This is a sincere attitude born out of the acceptance on the part of the pharmacist of the reality that self-management is the primary determinant of patient health outcomes in DM2. Being able to express empathy is a very important MI skill as it demonstrates the pharmacist’s capacity for care. Furthermore, it supports the development of trust, and both underpins the patient-pharmacist relationship and facilitates behavioural change by the patient. Being empathic also means being non-judgemental and empathy shows the patient that although the pharmacist may not have diabetes there exists an acceptance and understanding of the problems associated with the day-to-day issues of living with this chronic disease. Referring to the smoking example above, the comment, “*well being fat is better than being dead from lung cancer*” does not reflect empathy whereas, “*I can understand that you are reluctant to stop smoking because of the possibility of gaining a few kilos, but in my experience this does not always happen and in any event I am able to help you if this should happen*”, is an empathic reply.

(iii) Avoid arguments

If in trying to breakdown resistance or resolve ambivalence and an argument between the patient and pharmacist develops then the patient is likely to become defensive and resistance to change may become entrenched. Avoiding arguments signals to the patient that the pharmacist is on the patient’s side. That is not to say that MI is non-confrontational, to the contrary the model allows patients to be confronted about their aberrant behaviour but in a manner that is not argumentative.

Consider an example of a female hypertensive patient whose blood pressure remains uncontrolled despite being prescribed medication known to be effective in controlling the condition. A review of the patient’s medication history reveals that the patient has been having her prescription refilled every 45 days instead of every 30 days or so. The pharmacist in counselling the patient on non-adherence says the following, “*I see that you*

have missed quite a number of doses of your Renitec over the past two months. You realise that you are acting irresponsibly by putting yourself at risk for a stroke or heart attack". Such a statement by the pharmacist may well be considered to be argumentative. The following alternative approach, while still confronting the patient about the possible serious consequences of her non-adherence does not invite argument. *"From my records it looks as though you are not taking your Renitec every day. As you know keeping your blood pressure under control is essential if you are to minimise the chances of a stroke or heart attack and this means taking your medicine every day. If you would like to tell me why you have missed doses then perhaps we can work together and find a solution so that you are able to minimise the risk of something serious happening to you"*. This statement is empathic, non-judgemental, seeks to understand why the patient is not being adherent and offers meaningful help to overcome the problem.

(iv) Develop Discrepancy

This principle creates dissonance as a result of the misalignment of the patient's current health-related behaviour and their desired health outcomes. Simply put if, for example, a patient has a stated health-related goal of meeting an acceptable blood pressure target but does not take the antihypertensive medication as prescribed, and the non-adherence is raised appropriately, then the patient is likely to realise that a discrepancy exists between what they desire from a blood pressure perspective and what they are doing to support this goal. Motivation that is effective and sustainable must be self created. Put another way, motivation must arise from within the patient and this is what dissonance does – it fosters readiness to change.

Again considering the non-adherent antihypertensive patient, the pharmacist might facilitate dissonance by saying something along the lines of, *"I notice that you have missed some doses of your Renitec since your last repeat. What are your thoughts on how this might affect your risk of suffering a stroke or a heart attack?"* The pharmacist can facilitate the creation of dissonance in two ways: Firstly, by eliciting information about the patient's hypertension-related goals, for example *"The ideal blood pressure for someone of your age is around 130 over 80. What would you like to aim for?"* Secondly, having established a blood pressure goal the following question should focus on the behavioural changes needed to realise the patient's stated goal *"Taking your Renitec regularly every day will certainly help you reach your blood pressure goal, so what do you think you need to do to help you ensure that you don't miss a dose?"*

(v) Support Self-Efficacy

Patients not only have to believe that their therapy will improve their chances of preventing the downstream development of diabetes-related complications but, importantly, that they are also capable of effecting the required changes in behaviour. Pharmacists should notice and encourage not only the actual changes in behaviour but also any contemplated changes. For example should a patient say, “ *I have been giving some thought to stopping smoking*” then an appropriate response by the pharmacist would be something along the lines of, “*That’s really good news. If you don’t mind telling me, how do you plan to stop?*”

Changes in behaviour that lead to the realisation of diabetes-related goals should be rewarded with praise, “*Great- your blood pressure is spot on this month. You obviously have been taking your meds every day and cutting back on the salt. Well done and keep it up!*” Patients must be encouraged when targets are missed, “ *Don’t worry, I know that you can do this. What do you think you need to change to get there?*” Pharmacists should think innovatively and access outside expertise where needed, provided the patient is in agreement.

Conclusion

Chronic diseases, with interrelated and sometime conflicting biomedical, psychological and social drivers, are by nature complex⁷. It follows, therefore, that the solutions to managing these diseases must be complex. DM2 presents a special set of challenges because it is a disease where treatment and care are largely reliant on patient self-management behaviour. Furthermore, it is a disease very often clustered with other serious chronic disease states which require focused self-management. Pharmacists are encouraged to reflect on how best to influence patient health-related behaviour within the scope of practice of a pharmacist. Motivational Interviewing, while not a universal panacea for poor patient health-related behaviour, is an approach well worth considering.

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The Clinical Intervention

The review and monitoring of diabetes-related variables is key to optimising diabetes care and thus a very important part of the DCP. Diabetes care is founded essentially on patient self-management of lifestyle (mainly diet and exercise) and pharmacotherapy, as approximately 95% of the care required by a diabetic is provided by themselves or members of their family. Eating correctly, exercising adequately and taking medication appropriately are all behavioural activities. Measuring and monitoring these activities adds a crucial clinical dimension as it is difficult to conceive of managing without measuring.

Monitoring therapy and clinical and disease-risk indicators and other variables allows the patient and pharmacist to confirm that the therapy and self-management behaviours, that are aimed at optimising patient economic, clinical and humanistic outcomes, are having the desired effect. If patient outcomes are being compromised then monitoring provides the basis – the evidence – for the initiation of remedial action.

Monitoring need not be time consuming, and an ideal time to undertake some of the more frequent monitoring activities (e.g. BP, SMBG review, BMI, medication adherence) is during the prescription refill encounter. Furthermore, simplifying regimens, providing prescription refill reminders and telephonic follow-up between patient visits to the pharmacy have been shown to be very effective adherence promoting and monitoring interventions.

The monitoring schedule below is informed by the clinical monitoring schedule contained in the IDF's Desktop Guide to Type 2 Diabetes Mellitus which was provided to study pharmacists earlier in the year. It is suggested that pharmacists refer to this resource and to other guidelines [IDF's Global guidelines for Type 2 Diabetes, National Institute for Health and Clinical Excellence's Type 2 diabetes clinical guideline (www.nice.org.uk), American Diabetes Association's Standards of Medical Care in Diabetes 2006. Diabetes Care 2006; 29(suppl 1):S4 – 42]

The schedule summarises suggested monitoring activities for Type 2 diabetes patients participating in the study. The frequency with which the various elements of a monitoring programme are implemented are dependant on the risk profile of the patient (patients whose disease-risk indicators indicate that they are well controlled will require fewer

monitoring encounters than those who are not well controlled) and the time available to the patient and pharmacist. It is suggested that pharmacists structure fixed time appointments for the initial visit and for subsequent planned encounters (more frequently in the case of those patients who are particularly at risk – e.g. the elderly, multiple co-morbidities, polypharmacy). Pharmacists should discuss and agree an individualised monitoring schedule with each patient.

Monitoring Schedule

Domains	Baseline evaluation	Interim evaluation	12 month evaluation
Background history and medication review			
Social history/lifestyle review	√		
Social support status: family/friend involvement	√	If required	
Lifestyle practices: current exercise, diet, smoking status	√	√	
Long-term and recent diabetes history	√		
Complications: history and symptoms	√	If required	
Medical history (refer Patient Profile)	√		
Medication review of prescribed therapy: <ul style="list-style-type: none"> • Appropriateness evaluation as per national algorithm • Pharmacotherapy, names of medicines, dosages and side-effects • Medication related problems including adverse effects • OTC and CAM use 	√	If required	
Diabetes knowledge and self-management			
Diabetes disease and therapy related knowledge <ul style="list-style-type: none"> • Basic pathophysiology • Complications, and co-morbidities • Disease-risk and clinical indicators • Self-care recommendations • General diabetes-related knowledge 	√	If required	
Self-monitoring skills/results especially: <ul style="list-style-type: none"> • Self-monitored blood glucose • Blood pressure • Cholesterol • Body mass index (BMI) • Waist-hip ratio 	√	If required	
Self-care recommendations awareness of the need for: <ul style="list-style-type: none"> • Lifestyle modification especially diet, exercise, smoking • Foot care • Medication adherence • Attendance at regular examinations • Measurement of clinical indicators 	√	If required	
Key clinical indicators			
Review and refer in terms of SEMDSA guidelines for :			
• Glycated haemoglobin (HbA _{1c})	√		√
• Lipid profile	√		√
• Blood pressure	√	√	√
• Proteinuria	√		√

• BMI and waist-hip ratio	√	√	√
Provider referral			
General examination by medical practitioner and referral to diabetologist/endocrinologist for at-risk patients	√	If required	
Foot examination- podiatrist referral	√	If required	
Eye- ophthalmologist referral	√		
ECG- physician referral	√		
Behavioural indicators	√		
Smoking	√	If required	
Alcohol consumption	√	If required	
The Beliefs about Medicines Questionnaire	√		√
The Satisfaction with Diabetes Scale	√		√
Diabetes Care Plan Questionnaire	√		√
The Self-care Adherence Scale	√		√
The Brief Diabetes Knowledge Test			√
The Self Monitoring Blood Glucose Scale			√
The Diabetes Empowerment Scale Short Form			√
The Understanding Self-care Practices Scale			√
The Medication Adherence Report Scale			√
The Major Depression Inventory			√

Notes to the monitoring schedule:

- “If required”, indicates that the pharmacist may want to revisit those aspects identified during the initial consultation and which may require follow-up.
- The medical history is contained in a Patient Profile self-report completed by each patient at baseline.
- The practice of pharmaceutical care demands that the pharmacist (as the ‘medicine expert’ on the diabetes healthcare team) pay particular attention to assisting the patient to resolve any medicine related problems.
- Research shows that while diabetes related knowledge is seldom enough to guarantee good patient outcomes it is an important aspect of diabetes care.
- There is a strong correlation between regular self-monitoring, especially self-monitored blood glucose (SMBG) and the optimisation of therapy. Adjustments to dosages, food intake and exercise require accurate blood glucose levels. Patient’s must monitor blood glucose regularly and use the values to aid in their decision making. The same holds true for other important indicators.
- The most important aspect of diabetes care is patient self-management.
- Patients and pharmacist should know what the guidelines suggest in terms of key clinical and disease-risk indicators (Society for Endocrinology Metabolism and Diabetes of SA guidelines for Type 2 diabetes).
- The UKPDS (United Kingdom Prospective Diabetes Study) Risk Engine is a cardiovascular and stroke risk assessment web-based tool developed by the Diabetes Trials Unit at Oxford University to risk rate Type 2 diabetes patients for non-

fatal and fatal coronary heart disease and stroke. Pharmacists wishing to use the tool can do so by copying the following website address to their Internet browsers <http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/index.php> and then select 'download' following the links. Patient data is entered in the specified fields and the relative risk is calculated. The tool is useful both as a referral indicator and in assisting patients understand their possible risk of experiencing a cardiovascular event and or stroke.

- The IDF and SEMSDA guidelines for Type 2 diabetes suggest certain medical examinations be done at specified intervals.

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Motivational Interviewing Helps Patients Confront Change

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This last article in the series on change considers motivational interviewing. Motivational interviewing was originally developed by Miller and Rollnick¹ as a complementary process to the Transtheoretical Model of Change (see U.S. Pharmacist, October 1999). It was first targeted toward people with addictive behaviors, but with the development of brief motivational interviewing, it is now being used to assist healthcare providers in managing patients with other illnesses.²

Motivational interviewing was developed as a strategy for assisting patients in making a commitment to change. It combines Rogers' client-centered approach³ to therapy and more directive approaches for helping people to make changes. The basic idea behind motivational interviewing is that for any number of reasons patients are often ambivalent about change. They may not be aware that a change is truly needed. Or, patients may have misinterpreted the seriousness of the condition. Alternatively, patients may understand the treatment regimen, but cannot see any way to carry it out without great difficulty. As a result, they're not sure they have "what it takes" to control their illness.

Ambivalence affects motivation and readiness to change and inhibits a patient's ability to adapt coping strategies for change. An important aspect of motivational interviewing is to start with an assessment of the patient's readiness to change. Knowing what stage a patient is in will assist a practitioner in defining coping strategies to promote change. For example, individuals in the precontemplation stage may not be aware that there is a problem. They need objective, nonjudgmental information. On the other hand, people in the action stage are ready for change. For these individuals, the pharmacist may want to check the accuracy of the information so that coping strategies are appropriate. In addition, these patients have made a commitment to change and therefore, encouragement and assisting in defining strategies work well.

Motivational interviewing is extremely useful because it teaches the healthcare provider to explore the patient's understanding and concerns. It focuses its attention on dealing with resistance and on helping patients to move through the stages of change.

The Menu of Strategies

The following menu of strategies is the process the pharmacist may use to identify the stage of readiness of the patient and create a climate for change. It is modified from the work of Rollnick and colleagues.² A skilled provider can use the entire menu in no more than 5–15 minutes with a patient. Each patient may require some or all of the items,

depending on where the patient is in the process. Each time the patient is seen, some or all of the strategies will be employed. After the menu of strategies is discussed, specific skills will be addressed.

1. Opening strategy—lifestyle: This strategy involves talking in general about the patient's lifestyle from his or her own perspective. Does the patient view it as healthy or unhealthy? What does he or she like or dislike about it? Are there aspects that need to change? This opening strategy is to give the pharmacist a general picture of the patient's health habits (or lack of them) and desire to change unhealthy habits or take on new behaviors.

2. A typical day: Knowing what a typical day is like for the patient allows the pharmacist to do a better job of realistically tailoring medication regimens (or exercise, etc.) to fit the patient's daily routines. Tailoring can greatly improve treatment adherence since patients can attach medication taking to a behavior or activity they are used to doing. Also, knowing how the patient's day is structured can help with better planning. There is no need to tell a patient to monitor her blood glucose at three in the afternoon when that is a busy time for her each day. This strategy also helps to build rapport with the patient.

3. The good things and less good things: Here the pharmacist continues to build rapport and explores how a patient represents his or her illness and its treatment. Patients with misconceptions about an illness or its treatment may treat the illness inappropriately. By asking questions such as, "What does having diabetes mean to you?" the pharmacist is able to determine which beliefs are accurate and which need to be corrected. In discussing the good things and less good things, the pharmacist can also ask patients about what they perceive as barriers and facilitators to treating their illness. All of this gives the pharmacist the opportunity to listen to the patient and demonstrate understanding by empathic responding. Identifying barriers and facilitators of behavior change will also allow the pharmacist to more accurately determine the patient's stage of readiness. Barriers to change are much more prominent in earlier stages of readiness. Finally, knowing the good things and less good things gives the pharmacist the opportunity to develop discrepancies between old, unwanted behaviors and new, desired behaviors. This is an effective skill for moving patients forward.

4. Providing information: This strategy is really aimed at exchanging further information. This is an important point. First, the pharmacist should ask if the patient wants additional information about the illness and its treatment (or, e.g., smoking cessation). If the patient is not ready for more information, it is wise to note this and provide a leaflet only. It does not make sense to try to tell patients more when they are not ready to hear it. If the patient is ready for additional information, it should be provided in an unbiased, nonjudgmental manner. The information provided should assist patients in taking their medications appropriately. The point is that patients should leave the pharmacy with a clear understanding of what to expect and what to do if the expected doesn't occur. For a thorough discussion of the kind of information to be provided, see *U.S. Pharmacist*, February 1999, pp. 64–73.

5. **The future and the present:** The intention of this strategy is to allow patients to discuss what they want to have happen as a result of treating the illness (taking medication, losing weight, etc.). Usually, any concerns or dissatisfaction on the part of the patient will come out here and should be addressed in a compassionate, nonjudgmental manner.

6. **Helping with decision-making:** Lastly, the pharmacist should assist patients in making decisions about managing their illnesses. Patients should be asked questions such as, “What are your thoughts about managing your diabetes” or “Where does this leave you now?”² These are neutral, nonjudgmental questions. It is very important for the pharmacist to be patient during this time of questioning. Patients may vacillate between changing and staying the same.

The Five Principles

Five general principles are used to support the menu of strategies.¹

1. Express empathy
2. Develop discrepancy
3. Avoid argumentation
4. Roll with resistance
5. Support self-efficacy

What follows is a rationale for each principle. A dialogue between a pharmacist and a patient is also presented which will incorporate these five general principles.

Express empathy: Practitioners who are judgmental, perceive the patient as lazy or uncooperative, or are impatient, are likely to fail in assisting a patient with change. The pharmacist who sees the patient as one who is struggling with the process of change and respects the patient and the struggle, will be far more successful. What you are observing with a patient who seems uncooperative, uninterested, or resistant is that patient’s way of coping with the situation. It may not be productive, but it is the only way that the patient knows how to cope at the time. One of the roles of the HCP is to identify and understand the reasons for the resistance from the patient’s perspective. Only then can other, more productive ways of coping be identified. The tools successful therapists use to initially assess a patient are open-ended questions, reflective listening and empathic responding. For a more thorough discussion of this topic, see U.S. Pharmacist, October 1998, pp. 69–76.

Develop discrepancy: Because patients are often ambivalent about change, initiatives must be taken to begin to move the patient in the direction of the desired change. While persuasive strategies may work very well for patients in the later stages of change, they generally fail miserably when patients are in the precontemplation or contemplation stages. Generally, persuasive strategies are met with resistance in these early stages. So, what does one do? It has already been suggested that expressing empathy is critical early on. The next step is to develop discrepancies between a patient’s present behavior and the behaviors desired. People are much more highly motivated to change when discrepancies

exist between current behavior and desired personal goals.²

Motivational interviewing attempts to create these discrepancies without making the patient feel threatened or pressured. Through effective questioning, the skilled interviewer attempts to identify discrepancies that already exist within the patient, rather than impose external pressures. If done properly, it will be the patient who will come up with the reasons that the change is necessary.

Avoid argumentation: As stated by Miller and Rollnick, “Motivational interviewing is confrontational in its purpose: to increase awareness of problems and the need to do something about them.”¹ However, this kind of confrontation is different than arguing with the patient, trying to convince patients they have a problem when they are not ready to accept this, or labeling patients (overweight, diabetic, hypertensive, anorexic, uncooperative) in order to promote change. Arguing tends to increase resistance rather than increasing motivation to change.¹

Roll with resistance: When dealing with patients who do not want to change, are overwhelmed, or won’t take their illnesses seriously, there is a tendency to become frustrated or angry. This frustration or anger often leads to increased efforts at trying to persuade patients that they have a problem, they should take it seriously, and make a more committed effort to adhere to instructions (“to get with the program”). When patients make statements that indicate resistance (“But I just can’t remember to take it three times a day,” “Yeah, it’s easy for you to say...you don’t have high blood pressure,” “I just don’t understand what the big deal is...I feel fine”), they are providing valuable insight into where the problems lie. For example, a less complicated regimen, identification of low-salt foods that can be eaten, or clarification of information may be solutions to the identified problems. Nonetheless, communication that expresses understanding of the problems that the patient encounters will go much further than brow-beating or arguing. Ultimately, it will be the patient’s job (with your support and assistance) to solve the problems presented. You may be able to decrease the complexity of the regimen, but the patient will still have to take the medication. You may be able to suggest foods that do not contain sodium, but the patient will still have to avoid high-sodium foods.

Support self-efficacy: Patients have to believe that they have the knowledge and skills or abilities to carry out the treatment plan. The pharmacist can greatly assist the patient in developing self-efficacy about carry out the treatment plan. Pharmacists can help by: 1) providing and clarifying information; 2) offering realistic hope and expressing confidence in the patient’s ability to succeed; 3) noticing successful attempts at adherence, even if they are short-lived; 4) praising ideas from the patient to solve problems; and 5) continuing to emphasize and support the responsibilities that both the patient and provider have in improving treatment adherence and treatment outcomes.⁴

Conclusion

Motivational interviewing and the stages of change are useful concepts and processes for

meeting patients where they are in their readiness to manage their illnesses. They provide pharmacists with stage-specific skills and strategies for assisting patients with change. This approach requires that the pharmacist view his or her job as serving the needs of the patients, not vice versa. When this can be achieved, better outcomes are more likely to occur.

A PHARMACIST-PATIENT DIALOGUE

This dialogue involves a pharmacist who has been trained in motivational interviewing and a patient who is having a difficult time accepting that she has asthma. Mrs. Jones has been diagnosed with asthma and has brought in several prescriptions.

Mrs. Jones: "Here."

Pharmacist: "You seem a little down today, Mrs. Jones" (expressing empathy).

Mrs. Jones: "Well, look at these prescriptions."

Pharmacist: "Looks like you have asthma."

Mrs. Jones: "So now you know why I'm so down."

Pharmacist: "You are down because you just found out and it came unexpectedly" (expressing empathy).

Mrs. Jones: "Well, yes. I mean, I get winded sometimes but I didn't know I had asthma."

Pharmacist: "Asthma sounds bad to you" (expressing empathy).

Mrs. Jones: "Sure. You have to take medicine for it. I have to stop smoking. I found out my cat's hair might be a problem. That doesn't sound bad to you?"

Pharmacist: "It sounds like a lot of change at one time" (expressing empathy and avoiding argumentation).

Mrs. Jones: "You're darn right. I might quit smoking, but I've had my little Chubbers for seven years and I'm not giving her up. I love that cat."

Pharmacist: "It sounds like you have a lot of difficult decisions to make" (expressing empathy). "What did the doctor tell you about asthma?"

Mrs. Jones: "Not much—he just said that I need to use these medicines, stop smoking and get rid of the cat. He's got some nerve—get rid of the cat!"

Pharmacist: "You didn't like his advice" (expressing empathy, rolling with resistance and avoiding argumentation).

Mrs. Jones: "Not one bit."

Pharmacist: "I know that you don't want to get rid of your cat, Chubbers. What do you think about quitting smoking?"

Mrs. Jones: "I don't know. It relaxes me a lot, but Dr. Carroll says it's bad for my asthma. Is that true?"

Pharmacist: "Smoking does make asthma worse. It does increase your risks associated with asthma."

Mrs. Jones: "That's what Dr. Carroll said, too. I guess it's true."

Pharmacist: "So, on the one hand you're telling me that smoking relaxes you, but you also seem to be saying that you realize that smoking will make your asthma worse" (developing discrepancy).

Mrs. Jones: "Yeah, I guess so. I need to go home and sort all of this out. Just fill my prescriptions."

Pharmacist: "It must seem somewhat overwhelming right now" (expressing empathy).

Mrs. Jones: "Yes."

Pharmacist: "I'll get these prescriptions filled and then we'll talk about how to use these properly so you will get the most benefit from them."

Mrs. Jones: "All right."

Pharmacist: "Has Dr. Carroll talked to you about a peak flow meter?"

Mrs. Jones: "A what?"

Pharmacist: "A peak flow meter to tell how your breathing is doing?"

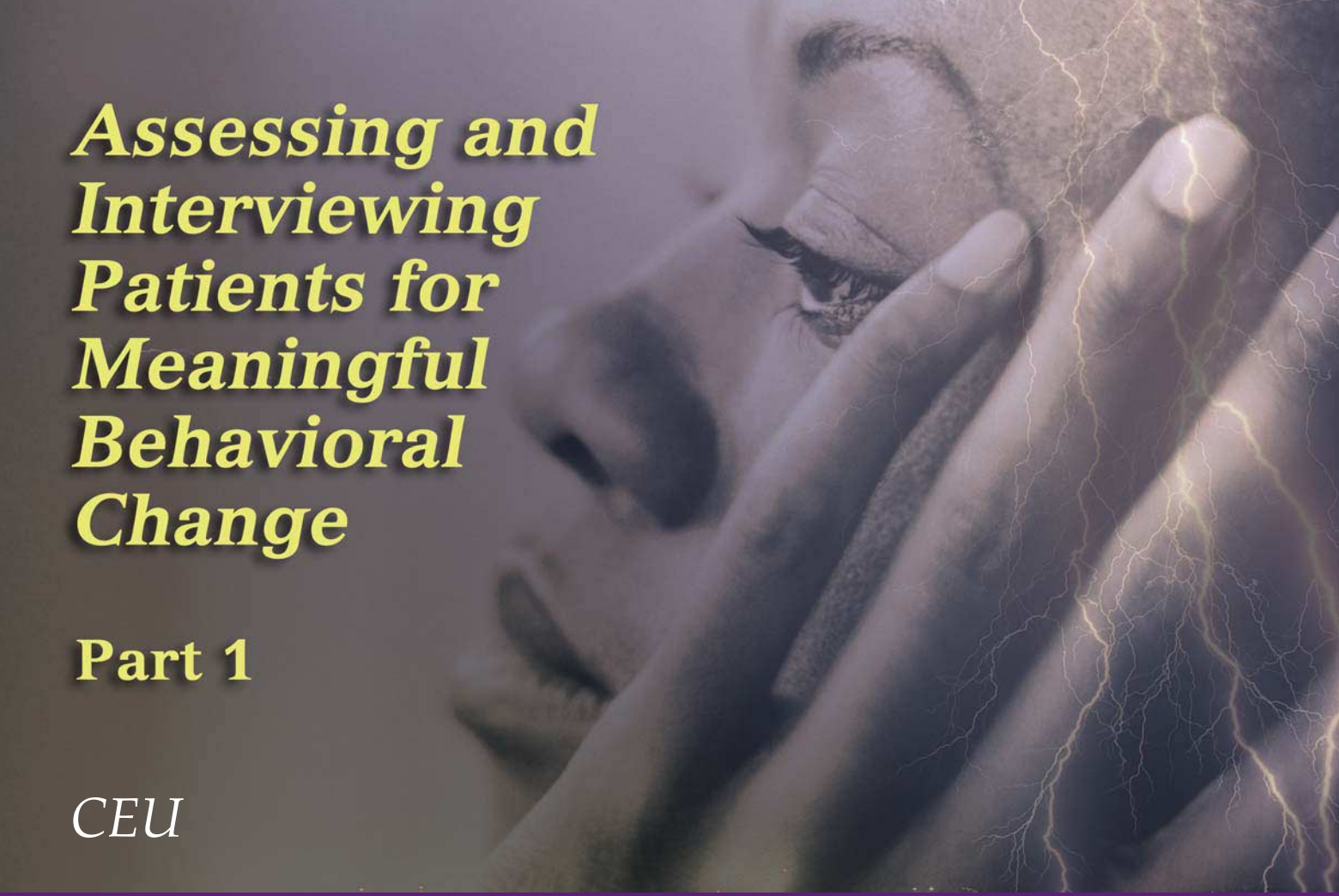
Mrs. Jones: "Look, I can't handle anything else right now. Could you just get my prescriptions filled?"

Pharmacist: "Sure, we can talk about the peak flow meter another time" (rolling with resistance, expressing empathy).

ANALYSIS

It seems clear from this dialogue that Mrs. Jones is not ready to accept her asthma and the things she may need to do to get it under control. The pharmacist is patient and caring and does not try to push the patient too fast. The pharmacist does not insist on talking to the patient about peak flow because she is not ready to hear about this yet. She is ambivalent about what to do and needs some time to sort things out. The pharmacist uses many of the principles of motivational interviewing in this dialogue. A key point is this: Even though everything did not get covered and all of the steps of the menu of strategies were not employed, no bridges were burned and no added resistance occurred because the pharmacist did not rush things. The pharmacist realized that this is a process, and other opportunities to talk to Mrs. Jones about her asthma will arise.

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Assessing and Interviewing Patients for Meaningful Behavioral Change

Part 1

CEU

Bruce A. Berger, PhD, RPh

Nurse case managers are in a unique position to help patients move toward healthy behaviors and outcomes. Compliance is the extent to which patients follow advice given to them by health care providers, whether the advice concerns taking medications, making lifestyle changes, or other interventions. While some studies estimate that 50% to 60% of patients are noncompliant with their medication regimens, compliance with lifestyle changes is even lower, at 30%.¹ "Of all patients, 30% to 40% fail to follow preventive regimens, and 20% to 30% fail to follow curative (relief of symptoms) medication regimens. Moreover, when long-term medication is prescribed, 50% fail to adhere."²

Each year millions of people suffer from drug-related morbidity and mortality as a result of noncompliance. Especially when it comes to taking medication and lifestyle changes, noncompliance can result in increased health care costs. For example, noncompliance with medication regimens and the needed lifestyle changes for diabetes patients can result in gangrene, neuropathies, even death. Not only does this underutilization of medication decrease pharmacy revenues, it also increases overall health care costs, because an estimated 11% to 20% of hospital admissions, emergency room visits, and repeat doctor visits may be results of noncompliance.^{3,4}

Compliance Interventions

Because noncompliance is complex, multiple approaches to improving compliance may be necessary. A patient taking more than one drug may have trouble remembering to take one and may not believe in the efficacy of the other. Therefore, patient-specific approaches

are needed. Please keep in mind that different compliance studies use different measures and methods so that rates are not always the same or comparable. The following steps have been proven to increase compliance by:⁵

- Assessing the patient's understanding and then educating about the disease state and the treatment regimen
- Tying the medication-taking process to other daily routines (tailoring)
- Using compliance aids, such as medication organizers or charts
- Simplifying medication regimens
- Providing human support within the health care team (listening and empathic understanding from the health care providers are essential)
- Recognizing poor coping skills and other sociobehavioral issues within the patient
- Developing a client-centered approach

Why have rates of noncompliance remained so high, despite years of research and convenient daily and weekly drug therapy? While there has been an increasing emphasis on patient counseling in the health professions, counseling has been confused with the simple provision of information. Although information provision is a prerequisite, it has not been shown to predict compliance, because often the information is provided in ways that are ambiguous or don't allow the opportunity for the patient to ask questions and to express concerns.

Information provision is a provider-centered approach rather than a client- or patient-centered approach to improving compliance. Client-centered approaches have been found to be more effective in promoting compliance. A client approach is "one where the client collaborates with the provider in helping to identify treatment goals, choose treatment options, monitor symptoms, and evaluate and revise regimens if problems occur."⁶

Failing to take appropriate medications correctly is a complex process that goes beyond patients simply forgetting to take their drugs. Several conditions must exist to increase the probability that the patient will be compliant. Compliance requires that a patient:

- Understand and believe the diagnosis
- Be interested in his/her health
- Correctly assess the impact of the diagnosis
- Believe in the efficacy of the prescribed treatment
- Know exactly how to take the medication and the duration of therapy
- Know how long it will take for the medication to start working and how to know it is working
- Find ways to incorporate the medication regimen into his/her daily routine to minimize the negative impacts on his/her life
- Value the outcome of treatment more than the "cost" of treatment
- Believe that he/she can exert some degree of control over the illness by carrying out the treatment plan
- Believe that the health care practitioners involved in the treatment process truly care about him/her as a person and do not just view the patient as a disease to be treated⁷
- Be assessed for the readiness to manage the illness and take the medication⁸

In a client-centered approach, these factors are assessed by the nurse case manager. For example, the nurse case manager asks the patient to state in her own words her understanding of the illness and what the medicine will (or won't) do relative to the illness. In addition, efforts are made to address the patient's questions or concerns. What barriers does the patient foresee? Does the patient believe the medicine will work (if not, why not, and what would the patient need to know to be more confident) and what value does the medicine have for the patient?

Counseling is an exchange of information so that clear treatment goals and expectations are explored. Information provision is unidirectional and does not allow for this interaction. For example, what does "Take 1 tablet twice a day" mean to the patient? If the patient is supposed to take it every 12 hours, is that time frame communicated clearly to him? Does he know how long it will take for the medicine to work? Can he work the medicine into his daily routine? Because of the visibility and the accessibility of nurse case managers,

they have the potential to play a major role in improving patient compliance or persistence with drug therapies. The ability to do so requires an understanding of why noncompliance occurs and the communication skills to interact with patients so that problems may be identified and resolved.

In the psychology literature, the terms "therapeutic alliance," "working alliance," or "helping alliance" have been used to describe the necessary relationship that must exist between a counselor or a psychotherapist and a client (nurse case manager and patient) for positive therapeutic change to take place. Specifically, a therapeutic alliance is defined as "the observable ability of the therapist and the patient to work together in a realistic, collaborative relationship based on mutual respect, liking, trust, and commitment to the work of treatment."⁹ Some researchers have gone so far as to say that the therapeutic alliance is the collaboration exhibited by the patient.¹⁰ The quality of the alliance is a function of the extent to which the patient and the therapist agree about the goals and tasks of psychotherapy.

As one can see, this agreement would also be critical to pharmaceutical care because effective pharmacotherapeutic goals and outcomes, and the behaviors needed to carry them out, must be negotiated between the nurse case manager and the patient if treatment has any chance of being effective. Therefore, compliance requires a partnership. While it is ultimately up to the patient to decide if he or she is going to be compliant with a medication regimen, the relationship or collaborative alliance between the nurse case manager and the patient is the key predictor of success.¹¹

Motivational Interviewing

Managing an illness, particularly a chronic illness, is complex. Changes in many behaviors may be involved. Some habituated behaviors may have to be given up (smoking), whereas other new behaviors may need to be added. Medication regimens must be worked into daily routines. Sometimes regimens don't fit very well into an individual's lifestyle, but taking medication must become habituated along with other

TABLE 1. THE BIOMEDICAL MODEL OF CARE VERSUS THE PSYCHOSOCIAL MODEL OF CARE

Biomedical	Psychosocial
Practitioner centered	Patient centered
Information giving	Information exchange
"Save" the patient	Patient "saves" self
Dictate behavior	Negotiate behavior
Compliance	Adherence
Authoritarian (parent to child)	Servant
Motivate the patient	Assess and explore motivation
Persuade, manipulate	Understand, accept
Resistance is bad	Resistance is information
Argue	Confront
Respect is expected	Respect is earned

routines. Often changes in lifestyle must occur—weight must be lost and kept off, or diets must be changed. Exercise may have to be initiated or increased.

While health care providers can certainly describe for the patient what needs to be done, ultimately, it is the patient who must manage her own illness. The best that health care providers can do is to make an accurate diagnosis, prescribe the appropriate treatment, give proper information, answer questions, and create a nurturing environment in which patients feel safe enough to discuss their concerns (more on this later). And while these things are vitally important, it is still patients who must decide if they want to or can regulate their illnesses. This point is critical to understand.

It is unfortunate that providers often use single strategies to address problems of patient adherence to medication regimens. They assume that patients who fill prescriptions are ready to take their medication properly and to manage their illnesses. However, research examining changes in health behaviors indicates that only 30% of all patients with a new chronic illness may be ready to take their medicine properly and to manage their illness.¹² In fact, different interpersonal skills and strategies need to be used, depending on how ready patients are to take action to take their medicines and to regulate their illnesses.¹³ For example, patients who resist taking their medication properly and/or managing their illness require different communi-

cation strategies and interventions than patients who try to maintain healthy behaviors.

Last year in the United States, we spent more than \$1 trillion for health care. According to the World Health Organization, approximately 51% of these costs were behavioral in nature; that is, these costs required patients to engage in a behavior (such as taking medication) or ceasing a behavior (such as smoking). Our current way of talking to patients only affected 2% of these costs. The estimated cost of drug-related morbidity and mortality—this is for legitimate drug therapy—is nearly \$100 billion. These costs include avoidable hospitalizations, emergency room visits, and physician visits. All of these costs accrued because patients did not properly use their prescribed therapy (if at all). Simply put, for every dollar we spend on the drug itself, we have to spend another dollar to deal with the health-related problems resulting from improper use of that drug. Something is terribly wrong, and current approaches are not nearly effective enough.

Motivational interviewing is a psychosocial or sociobehavioral approach to patient care that contrasts with the traditional biomedical approach shown in [Table 1](#). This process was developed to help health care providers assess a patient's readiness to comply with a treatment regimen. The biomedical approach has not been successful in assisting patients with sustained behavior change.

Note the major differences in these models. The biomedical model is practitioner centered, whereas the psychosocial model is patient centered. The psychosocial model stresses that the patient's needs and concerns must be appropriately addressed; otherwise, noncompliance may occur. Asking what questions or concerns the patient may have about the illness or treatment is a proactive way of assessing this possibility.

While the biomedical model has the health care expert telling the patient what to do, the psychosocial model views an encounter between patient and health care provider as a meeting of experts. The nurse case manager may be an expert in helping the patient with disease management, but patients are experts on themselves and how they are affected by the proposed changes in their lives. In the psychosocial model, our job is to assist patients in saving themselves. It is their decision (with our input) to choose healthy or unhealthy behaviors. Remember, patients manage their illness, not us. However, we can create an environment through caring, sufficient information, and understanding to improve the chance that the patient will manage the illness.

Behaviors need to be negotiated, not dictated. In the psychosocial model, adherence implies that both the health care provider and patient take responsibility for improved outcomes. Failure is not just the patient's to take on. We are there to serve, within reason, the needs and the concerns of the patient, not vice versa. We do not motivate patients; we assess their motivation and then apply the appropriate skills and strategies to address their readiness. This point is critical. Patients vary in their readiness to take their medicines, make lifestyle changes, etc., so they must be assessed to determine how prepared they are to do what is needed. How important do they think the changes are? Are they ready to make them? Are they confident they can do so? Will they need help? Do they understand the benefits? What barriers do they perceive? How will they reduce them?

Based on this assessment, different skills and strategies will be needed to assist

patients in identifying and implementing their change processes. This is the heart of motivational interviewing. Our job is to understand and to accept the patients' needs and concerns, not to try to talk them out of these things. In this approach, resistance is seen as information, not as something bad. Resistance is simply the patient's way of expressing that something is wrong or uncomfortable. More on this idea later.

Consequently, we don't argue with patients; we address and explore their concerns. There is a difference between chastising the patient by saying, "Mrs. Jones, how many times have I told you how important it is to take your medicine every day?" versus addressing the problem by saying, "Mrs. Jones, I notice that you haven't been taking your blood pressure medicine every day. Can you tell me if there is a problem?" The former is argumentative and judgmental and will not allow the patient to express the reasons for noncompliance without defensiveness. The latter is non-judgmental and invites the patient to openly express the reasons for her noncompliance. The former closes down any talk about noncompliance; the latter opens up productive talk about the problem that may lead the patient to a solution for her problem.

Finally, in the psychosocial model, respect is earned, not expected. The health care provider needs to earn the respect and the trust of the patient by being competent and caring.

Change and Resistance

Change and resistance are opposite sides of the same coin. Change often evokes resistance because change inherently questions our motivation and ability to do what is needed. Resistance is a person's way of saying, "I don't like the proposed change," or "I don't know if I can handle the proposed change."

Resistance behavior is the person's signal of a disturbance in the relationship—it is a disturbance in rapport. This is not necessarily a bad thing. When people resist change, they feel out of kilter. This is when they are most likely to do something if they perceive that the

benefits of the change outweigh the downside of the change. People have an internal "decisional balance" about any change under their control. If the pros of the change outweigh the cons, they make the change. A skilled health care provider can help "tilt" the pros in favor of the change and help the patient overcome the cons.

On the other hand, ambivalence kills change. When people are ambivalent, they do nothing. The pros and cons of the change seem the same. For example, when they are unclear about what to do or if they doubt they have the necessary skills, patients often choose to do nothing.

Simply put, for every dollar we spend on the drug itself, we have to spend another dollar to deal with the health-related problems resulting from improper use of that drug. Something is terribly wrong, and current approaches are not nearly effective enough.

ing. The same is true if patients doubt that the medicine will actually work. Resistance is a person's way of saying, "I need to explore this and see if it works for me." Understanding is needed in response to resistance, not persuasion nor criticism.

Resistance behavior can take many forms. Patients can negate things you say by blaming, disagreeing, excusing, minimizing, etc. They may argue with you by challenging you, discounting what you say, or becoming hostile or agitated. They may resist by interrupting frequently or ignoring things you say. The point is that sensitive health care providers listen for resistance, which is a signal that there is a disturbance in rapport that needs to be addressed and explored, not squashed. A change is needed in the way we are communicating with the patient. When the patient says, "I just don't know if I can do this," rather than saying, "Sure you can. It's not so hard," we could say instead, "Tell me what makes it seem so difficult for you," or "What would make you feel more confident that you could do this?" These latter responses explore the patient's concerns and reveal infor-

mation that can be used to help the patient overcome barriers.

"Yes, but" communication and argumentative tactics are not the solution to resistance. A common trap is to respond to your patient in the following way:

Patient: "I just don't like taking medicine."

Case manager: "Yes, but you want to get your cholesterol under control, don't you?" or, "Don't you think it's important to stay healthy so you can see your kids graduate?"

Neither of these responses explores the problem the patient presents. Both responses ensure more resistance. Understanding, exploration, and patience are the keys to managing resistance. If we try to move people too quickly toward a behavior, they will dig in and resist even more. A better response to the patient saying she doesn't like taking medicine would have been, "What bothers you the most about taking this medicine?" This way the patient can explain herself, and you can specifically address the concern.

Motivational interviewing is a patient-centered, directive method of communicating for enhancing a person's intrinsic (internal) motivation to change by exploring and resolving ambivalence and resistance. This means that we use our communication to stimulate the patient's internal processes of motivation. We do not motivate. We assess motivation and stimulate the patient's internal processes to increase their own intrinsic motivation. Because the process is directive, it takes less time than simply allowing patients to talk about anything.

Before talking about dissonance, a distinction between ambivalence and resistance is needed. When someone is ambivalent about doing something, he may not know what to do, how to do it, understand why it needs to be done, does not yet believe it needs to be done, or doubts his own ability to carry out what is needed. Ambivalence shuts down motivation for change and, therefore, needs to be addressed. Resistance occurs because the person does not like the proposed changes, is unwilling to make the necessary changes, etc. A person may be resistant because he does not accept the proposed changes as being needed. However, resistance is a more active choice about staying the same than ambivalence. In either case, the ambivalence or resistance must be explored if behavior is to change.

Dissonance

Motivational interviewing is used to create dissonance in a person. Dissonance, an inconsistency between two behaviors, attitudes, values, etc., creates discomfort that is motivating. For example, if a person's attitudes are inconsistent with his behaviors, dissonance occurs, and the person is likely to try to reduce it because it is uncomfortable. A person may say that he is generous but will experience dissonance if it is pointed out that he frequently turns down giving to charitable organizations.

For our purposes, we want to create dissonance about noncompliant behavior. We want our patients who don't take their medicines as they should to feel dissonance between their goals and their noncompliant behaviors. We want them to resolve this dissonance by identifying future behaviors that are more beneficial than their present noncompliant behaviors.

The spirit of motivational interviewing is collaboration, evocation, and autonomy. That is, we desire a relationship with the patient in which we collaborate on mutually agreed goals. We ask questions to understand the patient's resistance or ambivalence; the patient knows the answers, not us. And finally, we believe that patients must make informed choices. It is not enough to

simply provide information. We need to make sure that the patient understands the information, knows how to use it, and feels confident in his ability to do what is needed. This includes assessing the patient's understanding of the illness and its treatment.

Motivational interviewing was developed by psychologists William Miller and Stephen Rollnick to assess a patient's readiness for change (take their medications; make a lifestyle change, etc.). Patients vary in their readiness to carry out a treatment plan. If we assess their degree of readiness, we can choose specific communication skills and appropriate strategies. We will discuss this in more detail later. Motivational interviewing is used to create a favorable climate for change—problems are attacked, not people—and it is nonjudgmental. As stated previously, motivational interviewing addresses ambivalence and resistance. It is designed to take 3-5 minutes per session with the patient.

So how does motivational interviewing work? Motivational interviewing uses the general process of elicit–provide–elicit. That is, we elicit information from patients to better understand them and what they already understand (what do they already know about the illness and its treatment); then we provide the necessary information (and interventions) to assist our patients in moving forward with the treatment plan; then we elicit information again to check for concerns or questions that new information may have brought up.

Specifically, motivational interviewing uses a menu (or a sequence) of strategies and a set of specific skills to accomplish its goals. The menu is the specific process used to elicit and to provide information. The 5 principles that follow the menu of strategies are specific skills used to support the menu and to allow us to address ambivalence and to resistance and to create dissonance as the basis for change. Along with the principles are specific assessments called readiness rulers and the envelope, which are used to assess a patient's readiness to manage a behavior (take a drug, lose weight) and to identify barriers

impeding them from doing so. We will discuss these items in the second article. □

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Assessing and Interviewing Patients for Meaningful Behavioral Change

Part 2

CEU

Bruce A. Berger, PhD, RPh

Editor's note: This article is the second in a two-part series on motivational interviewing to effect change in patients to improve their health. The first dynamic article emphasized that the spirit of motivational interviewing is collaboration, evocation, and autonomy. That is, we, as case managers, desire a relationship with the patient in which we collaborate on mutually agreed goals. We ask questions to understand the patient's resistance or ambivalence. And finally, we believe that the patient must be allowed to make his or her own choices but must be given sufficient information to do so. Furthermore, we need to make sure that the patient understands the information, knows how to use it, and feels confident in his ability to do what is needed. This includes assessing his understanding of the illness and its treatment. This article outlines strategies for achieving these goals.

Let's look at the menu of strategies in motivational interviewing. The menu is the specific process used to elicit and provide information. Keep in mind that not all of the steps are needed with each patient; only certain steps may be needed, depending on how well you already know the patient. Let's start by assuming that we have a new patient with a new prescription for high blood pressure.

The Opening Strategy

The opening strategy with a new patient is to elicit information. This strategy builds rapport and helps to relax the patient. The information gathered is often very useful when tailoring taking of medication to the patient's daily routines. Tailoring has been shown to increase compliance. The opening strategy simply asks the patient to talk about his or her lifestyle—eating habits, nutrition, exercise, for example. This information can be incorporated into counseling that involves changes in eating habits, exercise, and so forth. It is good to start with an understanding of the patient's perspective. Ask the patient:

- How do you view the changes we have discussed? What are your thoughts?
- Tell me about your eating habits.

- Tell me about how much you exercise. Do you think you get as much exercise as you need?

A Typical Day

Next ask the patient about a typical day:

- Tell me about your daily routine.
- Do you eat 3 meals a day? When?
- When do you get up? When do you go to sleep?

This information could be extremely important to scheduling medication doses around or with activities the patient already does, which can improve compliance. Moreover, it does not make sense to tell a patient to take a dose in the morning if he or she works the night shift and is asleep during that time.

The Good Things and Less Good Things

Assuming that a diagnosis has been made and that medication is being prescribed, the next step is to elicit the patient's thoughts on the illness and its treatment. At this point, ask the patient to state in his own words what the condition means to him.

- What is your understanding of the consequences of not treating your high blood pressure?
- Do you believe the medicine prescribed will help you?
- Do you believe the diagnosis?
- Can you do what is being asked? What will get in the way? What will help?
- What are the positive aspects of treating the illness? Negative aspects?
- What is your overall goal in using this medicine? What do you want to see happen?

This is a time to let the patient speak and for you to *really* listen. If he cannot see anything positive to what is happening, say, "May I tell you what other patients have said? What do you think of that?" Concerns need to be explored through evocative, open-ended questions. It is especially important to listen to discrepancies in what the patient says. For example, we should ask patients what their goals are as a result of treating their condition. What do they want to happen?

One patient may say that, as a result of lowering cholesterol, he wants to reduce his risk of a heart attack as a goal. However, when asked about the downside of

treatment, he says, "I just don't like taking medicines. Besides, I feel fine." It is important to point out this apparent contradiction in a matter-of-fact way by saying, "On the one hand you want to reduce your risk of heart attack by lowering your cholesterol, but you don't like the idea of taking medicine and you feel fine." Follow this with, "I am concerned that if you don't take this medicine, your cholesterol will remain elevated, and you will be at greater risk for a heart attack. This worries me."

Pointing out the discrepancy and demonstrating caring creates dissonance for the patient. Dissonance is motivating. It throws the patient's system out of kilter. No one likes to be seen as irrational or inconsistent.

What if the patient does not believe the diagnosis or does not feel confident the medicine will work? Instead of trying to convince the patient, simply ask, "What would you need to know to feel confident that the doctor made an appropriate diagnosis?" or "What makes you doubt the diagnosis?" or "What information would you like to have to feel confident that this medicine will work?" We deal with resistance by asking evocative questions, not through persuasion or trying to squash it.

It is critical to make sure that the patient understands the benefits of medication. This is done simply by asking, "What do you see as the benefits of using this medicine?" The patient's positive answers should be praised or encouraged. If the patient cannot articulate any benefits or does not mention several important aspects, ask, "May I tell you some other benefits that my other patients have mentioned?" It is important to ask permission to allow for respect and patient autonomy. Next, ask what barriers the patient anticipates in taking the medicine. Then ask what he plans to do to reduce or eliminate them. If the patient does not know, say, "May I tell you what other patients have done to overcome this barrier?"

Remember, it is vital to make sure that the patient's decisional balance tilts toward healthy behavior by making sure the benefits outweigh the risks. This is done by emphasizing the bene-

fits and discussing how to reduce the risks.

Providing Information

After eliciting information from the patient, the next step is to provide information about the drug therapy, including the name of the drug, dosing information, onset of action, what effects the patient can expect, and some unwanted side effects and how to treat them. Dosing information should not be taken for granted. One tablet twice a day may not mean approximately every 12 hours to the patient. This timeframe needs to be made explicit. Also, the onset of action is critical information. How long will it take for the drug to have an effect, and what is that effect? The patient will not be able to feel lowered blood pressure, so it may be wise for him to purchase a blood pressure cuff and learn how to use it.

Finally, the patient should be alerted to the two or three most common side effects and how to minimize them. If they will go away in time, the patient should be told what to expect, whether 1 week, 2 weeks, or more. If side effects do not go away or if they become bothersome, patients should be told to contact their doctor or nurse case manager. If the side effects can be reduced by certain actions (take medicine on a full stomach), the patient should be told.

Rechecking for Concerns

After information has been provided, new concerns that it may raise should be addressed. These new questions can be elicited by asking:

- What are your thoughts now about managing your high blood pressure?
- Where does this leave you now in managing your diabetes?
- Do you anticipate needing any help?

The overall process in motivational interviewing is *elicit-provide-elicite*. First, ask patients about themselves and their initial concerns, then provide new information, then recheck for new concerns.

The Five Principles

Throughout the menu of strategies, motivational interviewing uses five principles or major skills to assess and create motivation within the patient.

- Roll with resistance
- Express empathy
- Avoid arguments
- Develop discrepancy
- Support self-efficacy

The first letter of each skill forms the acronym READS to help you remember the five principles. Let's look at each skill in more detail.

Roll with Resistance

Rolling with resistance is a matter of ignoring any antagonistic elements in the patient's comments to focus on the important underlying issues. In this sense, rolling follows the central direction of the patient's resistance. For example, the patient says, "Look, I haven't had any real problems with my smoking so far, so don't worry about it." Instead of rejecting this comment by saying, "If you continue smoking, I can assure you that you *will* suffer some major consequences," the health care provider can roll with the expressed resistance by saying, "I hope your health continues to stay that way. I would like you to consider getting your lungs checked because early stages of cancer and lung disease may not have symptoms. That way, you can make a better decision about whether you want to keep smoking. I am worried that your smoking is going to make your heart disease much worse in the future. However, the decision to smoke or quit smoking is yours." Here the provider has not only followed the direction set by the patient but has extended the issue to create a discrepancy. This response respects the patient, creates some dissonance, and allows the patient to hear information without being chastised.

Express Empathy

Probably the most important skill in motivational interviewing is expressing empathy, because it is the primary skill for demonstrating caring and understanding. The definition of empathy is an objective identification with the affective state of another (not his or her experience). We identify with the patient's affect (emotions), not with the experience. We need not have high blood pressure to identify the fear some patients may have about a chronic illness. Empathy is objective; we do not

pass judgment on people's feelings. We attempt to understand them instead.

Empathy is shown throughout the motivational interviewing process to identify and to understand resistance and reasons for unhealthy behaviors (for example, noncompliance). It is nonjudgmental and creates a climate for change through trust. Here is an example. One of your patients smokes, and you want him to quit. You ask him what he likes about smoking, and he says it relaxes him. Instead of creating defensiveness by asking, "Can't you think of something else to relax you?" you state empathically, "It would be difficult to give up something that was relaxing." As a result, the patient is now in a much better position to hear what you have to say next. The patient sees you as an advocate, not someone who is going to beat him up about his smoking.

Advice giving, probing, and warning may be necessary at times. For example, it may be completely appropriate to warn our patients or give advice, praise their behavior, or point out unhealthy habits. However, these responses are not listening or empathic responses. If a patient says, "I just can't believe that my cholesterol is that high!" responding with, "Well, you need to take this medicine as prescribed, regardless" does not address her concern. While the directive may be true, it does not promote the relationship.

A more appropriate response might be, "You are having some difficulty accepting that your cholesterol is high. What concerns you the most?" This response acknowledges the concern and explores it further. This response may be followed by, "I really do want you to get your cholesterol under control by taking this medicine as prescribed," but only after the patient has had her concern addressed.

Avoid Arguments

Avoiding arguments is a powerful skill, because we do not add to a person's resistance by forcing the patient to defend the behavior we are trying to change. By avoiding arguments, the patient is more likely to see us as being on her side. It is important to note that

motivational interviewing *is* confrontational, however. It is acceptable to say, "Mrs. Jones, I see that you have been getting your refills about every 40 days or so, but you receive only a 30-day supply. Can you tell me what happened?" or "Mrs. Smith, I have noticed that you get your refills like clockwork. I am happy to see that you are taking your medicine regularly to get your cholesterol under control." Both statements confront the patient. Neither is argumentative or judgmental.

Finally, it should be noted that feelings that a patient may express (for example, fear, concern) are not arguable. They are real for the patient. Here is an example of avoiding arguments about a patient's feelings. The patient says, "Taking medicine for depression makes me feel like I can't even control my own problems." The health care provider responds, "You feel like you have to depend on a medicine instead of yourself to feel better. I hope you come to see the medicine as something that will allow you to do that. What are your thoughts?" Notice that this response is empathic, addresses the patient's concern, and asks for more input.

Develop Discrepancy

An extremely important skill in motivational interviewing is developing discrepancy. This skill, more than any other, is used to create dissonance and can be achieved in two major ways. First, ask the patient about the good things and the less good things or the pros and the cons about the changes that are needed and then listen carefully for discrepancies that allow for the creation of dissonance. Remember, dissonance is motivating. We develop discrepancies by repeating back the pros and the cons stated by the patient.

Second, we develop discrepancies by asking the patient to discuss his or her goals relative to the treatment. For example, we say, "What do you want to happen as a result of taking this medicine for your blood pressure?" Establishing this goal is critical. It not only gives taking medicine a specific, definable purpose, it also allows us to ask patients about behaviors that do not support the goal.

Case Study

Try to identify how the case manager's comments in the first scenario close down the dialogue by inadvertently encouraging defensiveness in the patient. See if you can figure out how the strategy and the principles of motivational interviewing could open up the dialogue and could prompt the patient to consider whether his behavior is consistent with his values and goals.

Richard Stallings is a 57-year-old man who smokes close to a pack of cigarettes each day and who has high blood pressure. While he is not overweight, he does not exercise because "he gets winded easily." He has received a prescription drug to treat his high blood pressure. His case manager calls him to find out how he is doing.

Case manager: Mr. Stallings. Hi, this is Nancy. I'm calling back to see how you are doing on your blood pressure medicine.

Mr. Stallings: Doing just fine. Taking it every day.

Case manager: Good. Are you taking your blood pressure like we discussed?

Mr. Stallings: Now and then.

Case manager: Mr. Stallings, we talked about this last time—what's the point in having a blood pressure cuff if you aren't going to measure your blood pressure?

Mr. Stallings: Don't worry, I'm doing fine. I take the medicine every day.

Case manager: Yes, but you need to see if the medicine is lowering your blood pressure. Have you thought any more about what we talked about last time concerning your smoking?

Mr. Stallings: Nope. Not ready to quit.

Case manager: Mr. Stallings . . .

Mr. Stallings (interrupts): OK, stop right there. I am not ready to quit smoking. I take my blood pressure medicine every day. Leave it alone.

Case manager: Well, all right. It's your life.

Mr. Stallings: That's right, it's my life.

Case manager: OK, well, I really wish you would think about quitting, that's all. It's not good for you.

Mr. Stallings: (sarcastically) Whatever you say.

Case manager: It's gonna make your high blood pressure worse, but it's your decision.

Mr. Stallings: Right. OK, are we done?

Case manager: Yes. Keep taking your medicine.

Mr. Stallings: Got it!

Discussion

Mr. Stallings is not ready to conform to this case manager's idea of what a "good patient" should be. She is very parental in her approach—she does not explore Mr. Stallings' resistance to taking his blood pressure or to quitting smoking. She does not praise his compliance with his blood pressure medication regimen; she only admonishes the patient for what he is not doing. She uses "yes, but" communication and tries to "fix" or to save the patient instead of demonstrating any patience or understanding. The only thing she demonstrates is her intolerance. What is sad is that she thinks she is trying to help this patient, when in reality she is alienating him because she is so fixated on pushing her agenda (and her needs) instead of trying to better understand this patient. Let's look at a dialogue that incorporates motivational interviewing.

Case manager: Mr. Stallings. Hi, this is Nancy. I'm calling back to see how you are doing on your blood pressure medicine.

Mr. Stallings: Doing just fine. Taking it every day.

Case manager: Great, that's terrific! I wish more of my patients were as conscientious as you. How are you doing on taking your blood pressure?

Mr. Stallings: Taking it now and then.

Case manager: How often is that?

Mr. Stallings: Oh, about once a week.

Case manager: And how is it doing?

Mr. Stallings: Last time I took it, it was 150 over 95.

Case manager: I see. That's still a little high. Have you thought about taking it more often to see if it fluctuates during the week?

Mr. Stallings: Not really.

Case manager: I would like you to consider taking it more often so we can get a better picture of how your blood pressure is doing during the week. Would you consider doing that?

Mr. Stallings: I don't know. I'm not sure.

Case manager: What would make you decide to take your blood pressure more often?

Mr. Stallings: I'm not sure.

Case manager: Okay. Well, I would really like for you to consider taking your blood pressure every day so we can get a better picture of how your medicine is working.

Mr. Stallings: I'll think about it.

Case manager: Good, that's all I can ask. Have you thought any more about quitting smoking?

Mr. Stallings: Not much.

Case manager: Smoking is your decision. I am concerned that your smoking is going to make your high blood pressure worse. You told me last time we talked that your goal is to get your blood pressure down to normal to reduce your risk of stroke or heart attack. Smoking increases that risk. What are your thoughts on that?

Mr. Stallings: I don't know. I'm just not ready to quit. I'll take the medicine, and I'll think about taking my blood pressure more often, but I'm not ready to quit. It relaxes me.

Case manager: It would be very difficult to give up something that is relaxing. You have been asked to make a lot of changes at one time. If you get to the point where you think you may want to quit, I would like to help. I am worried about your smoking and heart disease.

Mr. Stallings: I hear ya. I'll let you know.

Case manager: Good. Well, keep up the good work on taking your medicine. I will check back on you soon. If you have any questions, don't hesitate to call.

Mr. Stallings: OK, goodbye.

Discussion

The case manager's communication in this scenario is patient and caring. How is caring communicated? The case manager listens to Mr. Stallings without judging him or his decisions. She lets him know that she understands that he is being asked to do a lot at once and that quitting is not easy. She does confront the patient and create dissonance by bringing up an established goal and the conflict between that goal and his smoking. She lets him draw his own conclusion and does not rush to a decision. She realizes that change is a process that must not be forced. As a result, the patient stays open to change. While the patient has not yet decided to quit smoking, the case manager's communication did not force him to defend his behavior. This leaves the patient open to change.

For example, you notice that Mr. Jones does not take his blood pressure medicine daily as prescribed. You say, "Mr. Jones, I have noticed that you skip doses of your blood pressure medicine. What are your thoughts on how this

might affect your goal of reducing your risk of stroke or heart attack?" Notice that the question is nonjudgmental and allows the patient to draw his own conclusions. Nevertheless, asking the question creates dissonance. It is important

to ask the patient to elaborate on discrepancies between stated goals and behaviors that contradict them. Change is motivated by a perceived discrepancy between present behavior and important personal goals or values.

Support Self-Efficacy

A person's belief in the possibility of change is an important motivator. Supporting self-efficacy is a key skill. Health care providers need to support, to notice, and to encourage thoughts and behaviors that indicate that the patient not only wants to move toward the target behavior (such as taking a medicine correctly) but also believes that she can accomplish this change. It is important to notice not only actual changes in behavior but also contemplated changes expressed in positive statements, such as, "I have been thinking more about my diet and lowering my cholesterol." Let the person know you have noticed. Say something like, "That's great. Tell me more about what you have been thinking." For the patient who gets her medications filled on time, you could say, "Mrs. Smith, I think it's terrific that you take your blood pressure medicine each day the way we discussed. Keep it up!"

Remember, the patient, not the health care provider, is responsible for choosing and carrying out change. In addition, the provider's own belief in the patient's ability to change becomes a self-fulfilling prophecy. Let clients know how you feel. Praise the behavior, not the person, and continue to support self-efficacy throughout the process. Here's another example, "I really like it that you have been seriously thinking about lowering your cholesterol." To support self-efficacy, you have to look for opportunities to praise the change efforts of your patients.

Readiness Rulers

Before summarizing motivational interviewing, I would like to discuss readiness rulers. They are used along with the five principles to elicit change talk and are especially useful when you encounter resistance. They are a quick and an effective way for eliciting change talk from your patients and for determining what else needs to happen for the patient to make a greater commitment to change. Readiness rulers measure two concepts: how important the change (e.g., taking the medicine) is to the patient and how confident the patient is that he or she can do what is needed.

If you sense some ambivalence or resis-

tance on the part of your patients about taking medicines, here is what you do. Look at the patient and say, "On a scale from 1 to 7, where 1 is not at all important and 7 is extremely important, how important is it for you to take your _____ (drug name) each day as we have discussed?" Let's say the patient responds, "3." Instead of asking, "Why 3, not 7?" (this response would cause patients to talk about why they cannot take the medicine), say, "Why 3, not 1?" This question elicits positive change talk; it allows patients to state reasons why they think taking the drug is important.

Reflect back on what you have heard, then say, "Other patients have also stated these reasons . . . Do these fit you?" Again, let the patient respond, then say, "What would have to happen for you to say 4 or 5?" This asks the patient to think about incremental change. We do not want to ask about "7" because that moves the patient too fast from the initial response. Even if the patient cannot come up with something right now, ask him to think about it and to let you know. You are planting the seeds of dissonance to create change.

Do the same thing with the readiness ruler for confidence about taking the drug. With a few readiness ruler questions, you can elicit a great deal of information.

We also have a method called the envelope, which can be used to gather information. Here is how it works. A patient states, "I don't know. I just don't want to quit smoking." You say, "If I were to hand you an envelope, what would the message inside have to say for you to think more about quitting?" Listen carefully to the patient's answer. Usually she will give you some hook to grab onto. In addition, the exercise gets the patient thinking. This method is very effective.

What happens if you use the envelope query and the patient says, "There is nothing in that envelope that would make me want to quit smoking"? Remember, the decision to use medicine, to quit smoking, to start exercising, and so forth, is the *patient's* decision. If you have given the patient objective information about the behavior change and you still meet with resistance, do not

argue. Simply say, "Mr. Jones, it sounds like you are not ready to quit smoking. If you decide to quit, let me know because I have some things that can help. I do want you to know that I am going to be concerned about you. I do believe that the smoking will make your heart disease worse, much sooner. It is your decision, though. I would recommend that you get your lungs checked if you have not done so to be sure you are okay." Even if the patient does not respond, you have created dissonance.

Conclusion

In summary, motivational interviewing is a process to address resistance and ambivalence and to create dissonance. We use evocative questions to elicit change talk and to explore concerns and the pros and the cons of change. We encourage patients to elaborate on their concerns and what they see as the benefits of the change. We elicit information from the patient, then provide information, then recheck for new concerns or questions. We are directive insofar as we keep the dialogue centered on exploring how the goals and the values of the patient relate to the treatment and the patient's behaviors.

We do all of this with empathy and understanding to allow the patient to feel safe and cared for in the relationship. Skillful and caring case managers may be able to assist their patients in making dramatic improvements in their health. It is hoped that this will be satisfying and rewarding for both patients and case managers. □

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Motivational interviewing in health settings: a review

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Abstract

There is evidence that patient-centred approaches to health care consultations may have better outcomes than traditional advice giving, especially when lifestyle change is involved. Motivational interviewing (MI) is a patient-centred approach that is gathering increased interest in health settings. It provides a way of working with patients who may not seem ready to make the behaviour changes that are considered necessary by the health practitioner. The current paper provides an overview of MI, with particular reference to its application to health problems.

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1. Introduction

Many health problems are related to lifestyle factors such as diet, exercise, and smoking. Changing such behaviours is difficult, requiring time, considerable effort and motivation. Furthermore, ambivalence about behaviour change is a common problem in health care consultations [1].

Traditionally, health practitioners have encouraged patients to make such changes through the provision of advice (i.e. information giving with direct persuasion) about behaviour change [2]. While this works with some patients [3], the evidence of the effectiveness of advice giving about lifestyle change is not strong [4], with success rates of only 5–10% [5,6].

Furthermore, there is evidence that patients do not necessarily want advice if it is provided in a style that is perceived as being “told what to do” [7]. Additionally, advice giving can develop into non-constructive disagreement, with the health practitioner placing emphasis on the benefits of change while undervaluing the personal costs, and the patient looking closely at the personal implications of change and the immediate costs while minimising future benefits [2]. The risk of such an encounter is that the patient becomes resistant to change or resistance, if already present, is increased [8].

In contrast, there is evidence that more patient-centred approaches produce better outcomes [9–11]. The essential features of these patient-centred approaches are that the patient does most of the talking, and that there is a ‘meeting between experts’ [2], with the concept of reciprocity in the consultation [12]. However, patient-centred counselling has not been developed into a replicable method specifically geared towards negotiating behaviour change in health consultations [13].

Motivational interviewing (MI), which evolved from Miller’s experience with the treatment of problem drinkers [14], and was later elaborated by Miller and Rollnick [8], is a patient-centred approach that has been gathering increased interest in health settings [13]. Miller conceptualises motivation as a state of readiness for change, rather than a personality trait [14]. As a state, motivation may fluctuate over time or from one situation to another, and can be influenced to change in a particular direction [15]. Thus, lack of motivation (or resistance to change) is not seen as inherent within the patient but rather something that is open to change. The main focus of MI is facilitating behaviour change by helping patients to explore and resolve their ambivalence about the behaviour change [16].

This conceptualisation of motivation as a state which is open to change is a sharp contrast to traditional approaches which view motivation as an attribute of personality, and denial or resistance as something to be dealt with through aggressive confrontation [17–20]. In fact, Miller and Rollnick suggest that adopting an aggressive and/or confrontational style (as in traditional approaches) is likely to produce

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responses from the patient (such as arguing) which may then be interpreted by the practitioner as denial or resistance [8], thus creating a “self-fulfilling prophecy” (p. 10).

While MI is patient-centred in that it focuses on the patient's wants, thinks and feels, and it is the patient that does most of the talking, MI differs from other patient-centred approaches in that it is directive. That is, in MI there is the clear goal of exploring the patient's ambivalence in such a way that the patient is more likely to choose to change his or her behaviour in the desired direction, and systematic strategies are used in order to achieve this [8].

2. MI principles and techniques

Rollnick and Miller distinguish between the “spirit” (p. 326) of MI and specific MI techniques [16]. Within the spirit of MI, readiness to change is not seen as a patient trait, but a “fluctuating product of interpersonal interaction” (p. 327), and motivation to change is viewed as something which is evoked in the patient, rather than imposed [16]. It is the patient's task (not the practitioner's) to articulate and resolve his or her own ambivalence. It is the practitioner's task to expect and recognise ambivalence, and to be directive in helping the patient to examine and resolve the ambivalence.

Miller and Rollnick suggest the following clinical principles upon which MI is based: express empathy, develop discrepancy, avoid argumentation, roll with resistance, and support self-efficacy [8].

An empathic style is seen as fundamental to MI. The underlying attitude must be one of acceptance, and belief that ambivalence is normal. Within this empathic style it is the practitioner's task to create and amplify any discrepancy between the patient's present behaviour and important goals, so that the patient presents the argument(s) for change.

Argumentation or direct persuasion is considered counterproductive and is to be avoided, as it is likely to produce defensiveness or resistance. Instead, the style is generally quiet and facilitative, and the relationship is more like a partnership or companionship than an expert/recipient one.

Resistance, on the other hand, is seen as a signal to change strategy. It is not opposed, but rather acknowledged and explored, with the view to shifting the patient's perceptions.

In supporting self-efficacy, the patient is seen as a valuable resource in finding solutions to problems. The patient is seen as responsible for choosing and carrying out personal change, but at the same time he or she must have a belief in his or her ability to change.

Rollnick and Miller describe specific, trainable techniques, which are characteristic of a MI style [16]. Seeking to understand the patient's frame of reference, particularly via reflective listening, and expressing acceptance and affirmation are techniques of MI borrowed from Rogers' non-directive patient-centred therapy [21,22]. MI techniques of evoking and selectively reinforcing the patient's

own self-motivational statements, monitoring the patient's readiness to change, ensuring that resistance is not generated by jumping ahead of the patient, and affirming the patient's freedom of choice and self-determination, are techniques which distinguish MI from other patient-centred approaches [8].

The techniques of MI are applied within the context of the ingredients for effective brief interventions, using the acronym FRAMES [8,23], namely Feedback, Responsibility for change lies within the individual, Advice giving, Menu of change options, Empathic style, and Self-efficacy is enhanced. In MI, however, advice is not given without the patient's permission, and when given, is accompanied by actively encouraging the patient to make his or her own choices.

MI therefore is not being practised when the practitioner argues that the patient has a problem and needs to change, or offers direct advice, or prescribes solutions to the problem without the patient's permission or without actively encouraging the patient to make their his or her choices. MI is also not being offered if the practitioner takes an authoritative/expert stance, leaving the patient in a passive role, or functions as a unidirectional information delivery system. The MI practitioner should not do most of the talking, impose a diagnostic label, or behave in a punitive or coercive manner towards the patient.

Within MI, there are a number of strategies that may be used to help build and strengthen motivation for change. They should be used flexibly to fit with each patient's situation and state of change and are discussed in order according to degree of readiness to change.

The patient is encouraged to talk about their typical day, and thereby talk about their current behaviour in detail within a non-pathological framework. For example, “can we spend the next 5–10 min going through a typical day from beginning to end. What happened, how did you feel, and where did your diabetes fit in?”

The patient is encouraged to make decisions about where to take the consultation by the use of agenda setting, used to structure the initial discussion. This may take the form of an agenda setting chart, with diagrams or words representing key areas which may be useful to explore (e.g. smoking exercise, alcohol, weight, etc.), and can be introduced as: “These are some of the things which we could talk about. What about you today? Would you like to talk about any of these, or do you have something else (pointing to the blank spaces) you would prefer to talk about?”

The personal dissonance strategy aims to create dissonance between the patient's positive image of themselves as a person on the one hand and a negative image of themselves on the other. A suggested line of questioning is: “Give me some words that describe your positive points as a person. Now give me some words that describe you as you have been with your drinking. How do these two fit together?”

The patient is invited to outline the positive things about continuing as they are and then conversely the negative

things. Some suggested questions are: “What are the good things about smoking. Let’s flip the coin. Tell me about the not so good things about smoking.”

The patient is encouraged to talk about specific individualised problems and concerns they have about their behaviour. A suggested line of questioning is: “What problems are you experiencing because of your weight? What concerns do you have about your weight? What else, what other concerns, do you have?” This strategy ends with a summary which highlights not only these problems and concerns, but also the positive benefits of continuing as they are currently (i.e. not changing).

Patients are encouraged to think about their current satisfaction with life and what the future looks like both if they continue as they are and if they change their behaviour. Suggested questions are: “How have things changed for you because of your high blood pressure? What will happen if you continue as you are now? If things are to improve, what needs to be different?”

The patient is invited to weigh up the pros and cons of changing his or her behaviour. Suggested questions are: “What would be some of the costs of changing? What would be the benefits of changing?”

The patient is encouraged to construct decisional balances, which involves generating the pros and cons of change options generated as a result of earlier questioning. These may be written down in the form of balance sheets and given to the patient, and should include: reasons to continue as before and reasons to change; short- and long-term positive and negative consequences of changing or staying the same; positive and negative consequences for self and for others, and self-approval rating for self and from others. In each of these balances the factors which support change are to be emphasised over those that may maintain the status quo.

When the patient indicates some desire to make a decision to change, the practitioner can help with decision making by the following: “Where does that leave you now?”, which can then be followed up by questions which elicit, rather than impose, possible solutions/targets for behaviour change, such as: “There is no one solution to this problem, but many. I can tell you about what has worked for others, but in the end, you will be the best guide of what is going to work for you. Shall we look at some of the options together? What might work for you?”

These strategies should not be used in isolation. Rather, they should be used within the context of the ingredients for effective brief intervention and alongside the MI techniques mentioned earlier, with particular reference to the patient’s readiness for change.

3. Theoretical basis

MI was not based on any specific theory. Rather, Miller drew from social psychology [14], applying processes such as attribution [24], cognitive dissonance [25], and

self-efficacy [26,27], and empathic processes from the methods of Rogers [21,22].

Despite the lack of empirical data, considerable interest in MI was shown, mostly within the addictions field, after Miller’s initial article [14]. Because of this interest, Miller began to research the processes and outcomes of MI, and as result, his initial model was elaborated and further developed by Miller and Rollnick [8,16].

A major development was to link MI to the transtheoretical model of change [28,29], with the transtheoretical model providing a framework for understanding the change process itself, and MI providing a means of facilitating this change process [30]. Within this framework readiness for change is seen as the extent to which the patient has contemplated the need for change, having considered the pros and cons of change. Lack of motivation can therefore be viewed as a “perceptual” (p. 115) problem, in which the patient sees no (or insufficient) need to change, whereas others (e.g. health professionals) do perceive a problem and a need for change [14].

MI aims to alter how the patient sees, feels about, and means to respond to the problematic behaviour. Ambivalence is seen as the key to this. It is resolved by focusing on the patient’s wants, expectations, beliefs, fears and hopes, with particular emphasis on the inconsistencies between these and the problematic behaviour.

The concept of readiness to change might help explain why simple advice giving is limited in effectiveness [4], as the patient may not be ready to change, and so any advice given is unlikely to be acted upon. Concrete behaviour change should not be the only goal. Instead, the practitioner might aim to increase the patient’s readiness for change through the use of MI. The concept of readiness to change also provides the possibility of tailoring interventions to suit the degree of readiness for change of the patient, which should ensure greater parity between the agendas of the practitioner and the patient, and therefore minimise resistance and improve the effectiveness of intervention.

The principles of MI have been related to the principles of cognitive dissonance [31]. That is, MI’s emphasis on resolving ambivalence by focusing on inconsistencies is creating dissonance. The techniques of MI (e.g. reflections, summarising) function to arouse cognitive dissonance. MI, then, is seen as producing a dissonant state (by focusing on ambivalence or inconsistencies) and then controlling the direction chosen for the dissonance resolution through the skilful use of MI techniques.

MI appears consistent with a number of models of health behaviour, such as Locus of Control [32], Theory of Reasoned Action [33], Social Cognitive Theory [34], Decisional Balance [35], Health Belief Model (HBM) [36], Health Action Process Model [37], Self-determination Theory [38] and Self-regulatory Model [39]. All of these models, despite differences in their terms and emphasis, share three common constructs [40], which are the focus of MI. These are the patient’s expectations about the consequences of engaging

in the behaviour, the influence of the patient's perception of, or beliefs about, personal control over the behaviour, and the social context of the behaviour.

The Health Belief Model, for example, suggests that health behaviour change depends on the simultaneous occurrence of: first, the belief that one is susceptible to a health threat or the medical or social consequences of the health threat; second, sufficient health concern to make the issues relevant; and third, the belief that a particular health recommendation would be beneficial in reducing the perceived threat at an acceptable cost [41]. MI appears to be a process by which the preceding three factors for health behaviour change, as postulated by the HBM, can be created or enhanced in the patient by the health practitioner.

Additionally, it has been suggested that the HBM could be improved by drawing upon Bandura's self-efficacy theory [26,42]. According to this theory, the degree to which an individual develops the expectancy that they will be able to perform desired behaviours (i.e. self-efficacy) is an important factor in behaviour change [26].

Self-efficacy has been used to predict health behaviours such as smoking cessation, weight reduction, exercise, and cardiac rehabilitation [43]. As mentioned earlier, self-efficacy is an important aspect to MI, with MI attempting to increase the patient's belief in his or her ability to change his or her behaviour (self-efficacy).

4. Specific interventions

The principles of MI have been incorporated into a brief intervention (called the Drinker's Check-up or DCU) for problem drinkers [44,45]. This is an assessment based strategy, involving a comprehensive assessment of the patient's drinking and related behaviours, followed by systematic feedback to the patient of findings using a MI communication style.

Motivational Enhancement Therapy or MET [46] is a four session adaptation of the Drinker's Check-up, which was developed as one of three interventions for alcohol abuse and dependence evaluated in Project MATCH [47]. It aims to motivate patients to make changes rather than provide detailed step-by-step advice about behaviour change, using a MI style.

Brief motivational interviewing (BMI) [1] consists of a set (or menu) of techniques, which follow the spirit and practice of motivational interviewing. It was designed for use in a single 40 min session in primary health care settings, with non-help-seeking problem drinkers.

Studies are evaluating whether the spirit of MI can be captured in even briefer (e.g. 5–10 min) encounters [48]. Rollnick et al. present a method focused on behaviour change in health settings, designed for brief consultations [49]. This comprises readily teachable brief strategies that follow the main goals of MI, but are more suited to health care practitioners, who have less time to acquire listening skills re-

quired for MI and who often have limited time with patients. While Rollnick et al. caution that the method they present should not be equated with MI [49], the method draws heavily from MI and the transtheoretical model of change.

MI has been provided by telephone consultation [50] and in a group format [51–53]. However, a group format, while more efficient, may compromise the effectiveness of MI as the intervention will not be able to be targeted at each individual's specific need as it is likely that different members of the group will be at different stages of change, at different times during the group. Studies are also currently underway exploring other formats for MI, such as computerised or paper self-help manuals.

MI in its various forms (MI style, DCU, MET, and BMI) has been applied both as a stand-alone intervention and as a preparation for treatment, and in a range of settings. This includes health settings such as the general hospital ward [54], emergency department [55], and general medical practice [48,56,57].

5. Efficacy of MI

Many studies reporting on the outcome of MI do not provide adequate information on what the intervention involved, or how it may have been modified for the particular target problem or client population, which makes it difficult to draw conclusions or make comparisons. However, there have been studies, particularly within the alcohol abuse field, which have utilised a specific MI intervention, such as the DCU or MET, and which have made attempts to ensure that the therapists adhere to the intervention protocol by evaluating the therapist's behaviour as well as client outcome.

The greatest support for MI comes from the treatment of problem drinkers, particularly Project MATCH [47]. This study represented the first test of MI as a stand-alone treatment for alcohol problems in a clinical population. In this comprehensive randomised controlled trial (RCT), 1726 alcohol-dependent participants were randomly assigned to one of three outpatient treatments: MET, Twelve Step Facilitation, or Cognitive Behavioural Coping Skills Training. On all measures (self-report, collateral, and biochemistry) MET was found to be more effective than the two longer (12 sessions) outpatient treatments.

Similarly, Sellman et al. compared MET with a similar brief intervention, Person Centred Therapy (PCT), and found MET to be more effective [58]. In this study, 122 participants with mild to moderate alcohol dependence were randomly assigned to one of three groups: MET, PCT, or a control group who received no further counselling. The MET group showed significantly less heavy drinking at 6 weeks and 6 months follow-up than the other two groups.

Furthermore, in a re-analysis of the Project MATCH data, MET was found to be most effective for those individuals with a higher level of anger [59]. Additionally, Heather et al., in a study of 123 heavy drinkers randomly assigned to one of

three groups: brief MI, skills-based brief counselling, or no intervention, found that MI was most effective for individuals who were least motivated, as measured by self-report and collateral measures of alcohol consumption [54]. These findings, then, provide evidence that MET may be most effective for patients who may be perceived as most resistant to change.

In a slightly different study, Handmaker et al. [57] evaluated the efficacy of MI as an intervention for pregnant drinkers in order to reduce the risk of fetal alcohol effects. In this pilot study, 42 pregnant drinkers were randomly assigned to receive written information about the effects of drinking during pregnancy (control group) or a 1 h MI session. Results indicate that women who reported the highest blood alcohol concentration (BAC) levels in early pregnancy showed significantly greater reduction in their estimated BAC later in pregnancy if assigned to the MI group rather than the control group.

Pilot studies suggest that MI can be successfully used with other substance abuse problems, such as heroin [60–62], cocaine [63] and marijuana [64], as well as with substance abusers with dual diagnoses [65]. However, the conclusions that can be drawn about the generalisability of MI from alcohol abuse to other substance abuse problems, or substance abusers with dual diagnoses, are limited as these studies are either single case reports, have combined MI with some other intervention, or the exact nature of the MI intervention utilised is unclear.

It has been suggested that MI could usefully be applied to health problems [66] and health promotion [67]. Furthermore, it has been suggested that MI might be particularly useful in the management of chronic illness [68] such as pain management [69], cardiac rehabilitation [70], diabetes [71], weight loss [72], and HIV risk behaviour [73,74]. However, there are few studies investigating the efficacy of MI applied to health problems.

The greatest support for the efficacy of MI applied to health behaviour change is from smoking cessation studies. For example, Stotts et al. examined the efficacy of MI as a late pregnancy smoking cessation intervention for resistant pregnant smokers [75]. In this study, 269 women who were still smoking at 28 weeks gestation were randomised to either an experimental group who received MI adapted from MET, or to a control group who received no further intervention apart from usual pregnancy care. MI was conducted in two sessions over the telephone, with a personalised feedback letter mailed following the first call. The results suggest that 43% of the women who received the full MI intervention ($n = 175$) were not smoking (i.e. no cotinine in urine samples) at the 34th week of gestation compared to 34% of the control group, and that 6 weeks post-partum 27.1% of the full intervention group reported to be either abstinent or light smokers, compared to only 14.6% of the control group. Similar support for the efficacy of MI in maternal smoking cessation is provided by Valanis et al. [76] using a quasi-experimental prospective cohort

design, with regression analysis showing statistically significant quit rates during pregnancy and smoking abstinence 6–12 months post-partum for the intervention women, although they relied entirely on self-reported smoking.

In another RCT ($n = 291$), Emmons et al. [77] evaluated the efficacy of MI (based on MET) for smoking parents of young children (under 3 years of age) in reducing household passive smoke exposure. Participants in the MI condition received one MI session in their home, followed by four follow-up telephone calls, whereas participants in the self-help group received information on quitting smoking in the mail. The results again lend support to the efficacy of MI, with 6-month nicotine levels significantly lower in the MI households compared to the self-help households.

There has also been increasing interest in the use of MI in the treatment of anorexia nervosa and bulimia nervosa, with the recognition that ambivalence about treatment is common with eating disorders [77–82]. However, there are few studies evaluating the efficacy of MI applied to the treatment of eating disorders.

Treasure et al. [83] in an RCT, in which 125 female patients with bulimia nervosa received four sessions of either MET or cognitive behavioural therapy (CBT), found MET to be as effective in the short-term (i.e. over 4 weeks) as CBT in reducing symptoms of binge eating, vomiting and laxative abuse. However, because patients were randomised to treatment blind of stage of change, some of the power of MET may have been lost, as MET might be expected to be particularly effective with patients in the precontemplation and contemplation stages of change.

Further, preliminary evidence that MET could be a useful treatment for eating disorders comes from a pilot study in which 19 patients with eating disorders received a group form of MET [84], with results suggesting that the participants' motivation to change increased following the intervention, along with decreases in depressive symptomatology and an increase in self-esteem. The results of these two studies suggest that further research into MET applied to the treatment of eating disorders is warranted.

MI has been receiving increased interest as a means of promoting treatment adherence in diabetes [48,71,85]. Smith et al. [72], in a pilot study, investigated whether the addition of three motivational interviewing sessions (conducted by psychologists) to a standard (16 weeks) behavioural weight reduction program for 22 obese women with Type 2 diabetes would increase adherence to treatment and improve glucose control. The MI group demonstrated better adherence to the program, as evidenced by higher attendance, more diaries turned in, and more frequent monitoring of their blood glucose levels. Furthermore, both groups reduced their average weight to a significant degree, but the MI group also achieved better glucose control. While the relatively short follow-up (4 months) and small sample size limit the conclusions that can be drawn, the results suggest that MI may contribute to increased efficacy of behavioural weight control programs.

Stott et al. [71] in an RCT with 200 patients with Type 2 diabetes with general practice doctors and nurses being trained in MI report that the general practice doctors and nurses were keen to learn new techniques, and found the MI techniques acceptable and useful, particularly the agenda setting chart, with over 70% of the health care practitioners reporting to frequently use it. However, patient outcome data were not reported.

Another area of treatment adherence in which it has been suggested that MI may be useful is psychiatric patient compliance with treatment [86], given that one of the main barriers to effective care of the long-term mentally ill is the poor compliance of many patients with recommended treatment, including compliance with prescribed medication regimes [87]. However, again, there are few empirical studies investigating this application of MI.

Swanson et al. in a study that randomised 121 psychiatric inpatients to either standard treatment (ST), which included pharmacotherapy, individual and group psychotherapy, activities therapy, milieu therapy and discharge planning, or to ST plus MI, found that significantly more patients who received ST plus MI attended their first outpatient appointment [87]. In another pilot study, Hayward et al. compared MI focused on medication self-management, for 21 patients with non-organic psychotic illnesses, to a control group, and found that the MI group showed positive changes in their attitude towards medication and insight into their illness, but the difference between the two groups was not statistically significant [87].

There are isolated studies which apply MI to other health behaviour, such as physical activity and dietary change. An RCT in which patients with hypertension were randomised to one of three groups: control, or low level or high level (MI) counselling conducted by nurse counsellors in a general practice setting, found that the MI group produced significant decreases in both weight and blood pressure over 18 weeks [88].

In another RCT, Harland et al. [89] examined the effectiveness of MI in promoting physical activity among adults aged 40–64 years attending a general medical practice. Participants ($n = 523$) were randomised to one of four groups or a control group: brief (one session) or intensive (six sessions over 12 weeks) MI, with or without financial incentive (vouchers for free access to leisure facilities). Although the results rely on self-report (exercise in the previous 4 weeks) they indicate that the intensive MI intervention (six sessions plus vouchers) was the most effective for promoting the adoption of exercise at 12 weeks, but that no intervention promoted long-term (12 months) adherence to exercise.

A form of BMI (three telephone counselling calls) was used to promote fruit and vegetable intake among African American church goers after they received an educational package focused on the 5 A Day message [90]. Participants receiving the MI calls had the largest increase in fruit and vegetable intake, with group \times time effects significantly different from group 1 who received the educational package

alone or group 2 who received the educational pack, plus one telephone call to cue the use of the material presented. However, in addition to the study relying solely on self-reported fruit and vegetable intake, it is unclear whether the MI per se resulted in the dietary changes, or whether the effect was simply due to the increased number of telephone calls.

One of the main issues when considering MI for use in health settings is the amount of training that might be required for health professionals to use MI and whether MI can fit within the demands of busy health settings. As mentioned earlier, Rollnick et al. [49] have begun to address this issue through the development of readily teachable brief strategies that follow the main goals of MI, which are suited to health care practitioners, who may have less time to acquire the skills required for MI and who often have limited time with patients. Additionally, there are reports of MI applied to health settings, which suggest that it may be feasible and relevant to health behaviour change [91–94], and that the techniques may be considered acceptable by health practitioners [71]. However, it is unclear how much training is required for competent use of MI. It seems that developing the attitude and knowledge necessary may not be too time consuming, but that the skills required for effective MI may take longer to develop, depending on the type of MI to be practised (e.g. BMI or MET) [92,95].

6. Conclusions

MI appears to hold substantial promise for health behaviour change. It is consistent with the call (from patients, and health researchers and practitioners) for more patient-centred approaches in health care in which the health practitioner–patient relationship is seen as a partnership, rather than an expert–recipient one. MI also provides health practitioners with a means of tailoring their interventions to suit the patient's degree of readiness for change. In particular, it provides practitioners with an effective means of working with patients who are ambivalent about, or not ready for, change.

Despite the promise which MI holds for promoting health behaviour change, there are few controlled studies evaluating the efficacy of MI with health problems, with clinical innovation remaining ahead of scientific evaluation [13]. Continued outcome research into MI applied to health behaviour change is required.

Additionally, it remains unclear as to how MI has its effect and what elements of MI are essential [96]. Further research needs to establish the process of MI and its key components. For example, little is known about what is the best way to structure sessions, or which are the optimal methods for responding to resistance.

It is also unclear which patients would benefit most from MI and which specific motivational intervention (i.e. DCU, MET, BMI or even briefer motivational consultations) would be of most benefit for which patients. For example, it is

unclear how a patient's level of motivation and other characteristics may influence the effectiveness of MI.

The challenge is to develop MI interventions that are useable in health consultations (which tend to be brief), are teachable, and are sufficiently specific to enable proper evaluation [4]. With such interventions, patients are likely to feel listened to and understood by their health practitioner. Health practitioners, on the other hand, are likely to gain a greater sense of achievement from recognising change in patients' readiness as important progress, rather than seeing concrete behaviour change as the only goal. Thus, MI interventions are likely to contribute to a greater sense of satisfaction for patients and practitioners, as well as helping promote health behaviour change.

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Persuasive Communication

Part 1

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At one time or another all of us have probably tried to persuade someone to do something. And, most likely, we have all met with varying degrees of success. For persuasive communication to be effective, certain principles must be followed or the attempt can backfire and cause more resistance to engaging in the target behavior. Much research has been done on persuasive communication. In the next two articles in this series, persuasive strategies will be discussed and illustrated to help improve pharmacists' "powers of persuasion."

What is Persuasive Communication?

Communication that is persuasive is directed toward changing or altering another person's beliefs, attitudes, and, ultimately, behaviors. Generally speaking, attitudes are composed of three components:

- (1) cognitive—the manner in which the attitude object is perceived,
- (2) affective—feelings of like or dislike toward the object, and
- (3) behavioral—action tendencies toward the attitude object.¹ The cognitive component is the person's belief about the attitude object. The idea is that beliefs affect attitudes, which affect behaviors. Change a person's beliefs or attitudes, and you change their behaviors. However, while there are relationships between beliefs, attitudes and behaviors, these relationships are not always straightforward. A few examples will help clarify this.

Example 1

Mrs. Jones is 80 years old. She knows that many people take medicines and that they are helped by them. However, she doesn't like to put any kind of medicine in her body. She believes that medicine can help other people, but she does not like (affective component) medicines; therefore, she won't take them.

Example 2

Mr. Smith thinks that Mercedes makes a great car (belief), and he really likes the way they look and perform (affective component); however, he isn't going to buy one because he can't afford it.

Example 3

Mr. Taylor, age 20, believes that medicines can really help people, has taken medicine for illnesses, but because of his busy schedule he has compliance problems.

Each of the people mentioned above is positive in his beliefs about medicine, but their attitudes and behaviors are different. Positive beliefs don't necessarily produce positive behaviors and resulting action. For Mr. Smith, an intervening variable (money) precluded him from purchasing (the behavior) a Mercedes, even though he believes they are good cars and he likes them. Therefore, different strategies are needed to change behavior. One size does not fit all.

While influence and persuasion are often used interchangeably, there is a distinction between the two. When someone is influenced by another, there is often a change in the person's beliefs, attitudes or behavior. This sounds a lot like persuasion. However, we can influence people without consciously attempting to do so.² For example, a parent could positively (or negatively) influence the behavior of his or her child by the way the parent interacts with others. The parent may not be consciously aware that the child is watching and learning, but the influence is there nonetheless. Persuasion, on the other hand, is a conscious, volitional attempt to influence someone else.

Influences on Persuasive Messages

Many factors determine the effectiveness of a persuasive message. Four major factors are: 1) the message source, 2) believability of the message, 3) environmental factors, and 4) comprehension and retention of the message. It should be noted that these factors overlap a great deal.

Message Source

For a persuasive message to have its intended impact, the message source (the pharmacist) must be seen as credible. Credibility involves recognized expertise, a desire to do what is right, a desire to serve the patient, and to be warm and fair. Therefore, expertise is not enough. The patient must perceive that the pharmacist's expert power is being used not to manipulate or control, but to do what is best for the patient. Of course, this involves finding out from the patient's perspective what he/she thinks is best, too. It is important to note that expertise is not simply ascribed to a pharmacist because of a societal role. It must be demonstrated and done so in a way that supports the patient. Expertise that "puts the patient in his place" is not generally persuasive. A few examples will illustrate this point. Mrs. Jones enters the pharmacy to have her antihypertensive medication refilled.

Example 1

Pharmacist: Hello, Mrs. Jones, how are you today?

Mrs. Jones: Just fine. Couldn't be better.

Pharmacist: Great! I'll go refill your prescription.

Pharmacist: (a few moments later) Mrs. Jones, I noticed that your blood pressure medicine should have run out several weeks ago. Are you taking your medicine the way you're supposed to take it?

Mrs. Jones: Oh sure, every time I get a headache.

Pharmacist: That doesn't make any sense. How often is that?

Mrs. Jones: Oh, maybe once a week.

Pharmacist: Mrs. Jones, that's not how you're supposed to take it at all. Where did you get such an idea? Didn't you read the label instructions? It says take it every day.

Mrs. Jones: What's your problem? Just give me my medicine! (Grabs the bag.) Put it on my account (she exits the pharmacy).

Pharmacist: But you're not taking it the right way.

The pharmacist is in no position to have influence here because of the approach taken. He will probably have to call Mrs. Jones later and get this situation straightened out. Rather than taking a calm approach, he berates Mrs. Jones. She is unwilling to listen and leaves without finding out what the problem is. Let's see an alternative approach.

Example 2

Pharmacist: Hello, Mrs. Jones, how are you today?

Mrs. Jones: Just fine. Couldn't be better.

Pharmacist: Great! I'll go refill your prescription.

Pharmacist: (a few moments later) Mrs. Jones, I noticed that your blood pressure medicine should have run out several weeks ago. Can you tell me how you're taking it?

Mrs. Jones: Oh sure, every time I get a headache.

Pharmacist (calmly): So you take it when you get a headache because you believe that you have headaches when your blood pressure is up?

Mrs. Jones: Exactly!

Pharmacist: That makes sense. However, we should have done a better job of explaining to you how to take this medicine.

Mrs. Jones: What do you mean?

Pharmacist: While it is certainly true that people with high blood pressure sometimes get headaches, it is usually stress, not your high blood pressure that is causing them. It is really very difficult, if not impossible, to tell when your blood pressure is up without measuring it. The medicine should be taken once a day for you to get the most benefit from it.

Mrs. Jones: Once a day? I didn't realize that.

Pharmacist: Well, let's have you start taking it once a day from now on, even if you don't have a headache. I want to make sure your blood pressure stays controlled.

Mrs. Jones: So do I. I never knew.

Pharmacist: I know. Again, I sure can understand the confusion.

This pharmacist took responsibility and because he did not blame or berate the patient, she was willing to listen. She was able to be influenced because she felt understood. The

pharmacist's communication was directed toward solving a problem, not ascribing blame. Even though he knew the label directions were not being followed, he felt no need to point this out and risk her embarrassment.

Believability of the Message

The believability of the message is very much related to the credibility of the message source. Also, does the message fit with the patient's belief system? Some patients may find it very hard to believe (and understand) different concepts that pharmacists take for granted. For example, potency is often a difficult concept for patients. A patient may have been taking a tablet for pain relief. This tablet was taken twice a day and was quite large, but the patient got no relief despite the fact that he was taking it properly. The physician prescribes another medication that is more potent, is taken less often and is much smaller in size. It may be difficult for some patients to accept that this smaller tablet is going to help if the larger one taken twice as often did not help. As a result, the patient may not even try the new medicine unless he is persuaded by the pharmacist. To be persuasive, the pharmacist will first have to acknowledge and objectively reflect back an accurate understanding of the patient's beliefs. Then, factual information about potency will have to be given that makes sense to the patient. Analogies may need to be used to allow the patient to understand the concept of potency. One such analogy that might make sense to a patient is that of black pepper versus cayenne pepper. The idea being that smaller amounts of cayenne pepper are more potent in their effects in the mouth than larger amounts of black pepper.

Gender Differences

There is a great deal of literature on male and female differences in persuasive communication. While there is literature to support the idea that men and women use different persuasive strategies, the literature is inconsistent in trying to identify exactly what those strategies are or whether they result from gender differences or differences in roles. For example, some literature reports that women use a more democratic and participative leadership style to have influence while men tend to be more autocratic and directive.³ However, other research attributes these differences more to role in the organization than to gender differences. That is, as women move higher in the organization, their communication tends to be more autocratic and directive.

Gilligan found that "men employ a 'justice' orientation in reasoning about moral choices by emphasizing the importance of rights, respect, and impartiality, while women employ a 'care' orientation in their moral reasoning by emphasizing mutual participation, cooperation, and attention to individuals' feelings and needs."⁴ Men are most likely to influence by focusing on rights and responsibilities, while women are likely to influence emphasizing issues relating to

Another issue patients may have difficulty grasping is that many drugs have multiple indications at various dosing schedules. For example, diazepam can be used for anxiety, epilepsy, and muscle relaxation. It is often very difficult for patients to understand how this can

feelings and caring.⁵ These influence foci are not right or wrong, they are simply the way many men and women attempt to influence others. The key point is that these strategies do work, but only for individuals who orient in the same way. Both men and women need to be flexible enough to realize that “appeals to justice” also work for many women and “appeals to emotions and caring” also work for many men.

A flexible set of influence strategies is needed.

occur. Therefore, when a patient asks, “What’s this medicine for?” the best answer is, “Could you tell me what caused you to see the doctor?” rather than, “It’s for numerous things, like anxiety, epilepsy and muscle relaxation.”

Environmental Factors

In a pharmacy, environmental factors are related to issues of privacy, noises, interruptions, and distractions that can affect whether a message is heard and understood. It is especially important when attempting to deliver a persuasive message that it be done in an environment free from (as much as possible) noises, distractions and interruptions. Each time these events occur, the likelihood of message comprehension and retention decreases. Therefore, the pharmacist should do as much as possible to create private areas to talk to patients. If this is not possible, then attempts to pull patients away from sources of noises, interruptions, and distractions should be made.

Comprehension and Retention

Obviously, for a persuasive message to be effective it must be understood and recalled. Another key factor that affects comprehension of the message is the language level of the message. Is the message conveyed in language that is understood by the receiver of the message? Too often in health care, providers use jargon that is common to medicine and pharmacy, but not to patients. For example, a 67-year-old woman came into a pharmacy and asked a pharmacist how her methyldopa lowered her blood pressure. She was told that it was a dopa decarboxylase inhibitor. The woman looked confused, but said, “Oh, OK,” and then left the pharmacy. She most likely found the message believable. However, she may not have understood a word the pharmacist said. It is vitally important to use language the patient can understand. It is better to say “high blood pressure” than “hypertension.”

Another problem regarding comprehension of the message has to do with the receiver interpreting the meaning of the message. Sometimes, a pharmacist’s communication with patients seems clear to him or her, but is open to interpretation by the patient. For example, when the pharmacist tells a patient to “take one tablet twice a day” he or she means that the patient should take a tablet approximately every 12 hours. But, if this meaning is not made explicit, problems may occur. Similarly, how are the directions,

“Take one tablet after meals and at bedtime” interpreted? It largely depends on how many meals you eat a day. A patient with diabetes may eat 6–7 mini-meals each day and take 7–8 tablets. If this response is not correct, then pharmacists need to be much more explicit in their directions.

Finally, the only way to know if a message is understood and can be recalled is for the pharmacist to ask patients to repeat back their understanding of the message.

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Persuasive Communication—Part 2

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The pharmacist may use direct or indirect persuasive strategies when trying to influence a patient's behavior.

The previous article on persuasive communication noted that persuasion was a conscious effort to influence the belief, attitudes, and ultimately, the behaviors of another person. It also covered factors affecting persuasive communication, such as message source and believability of the message. In this article, direct and indirect persuasive strategies will be discussed.

Direct Strategies

Consciousness-raising: One direct strategy is consciousness-raising. With respect to the pharmacist-patient relationship, this involves (1) providing information about the patient's illness and treatment in a straightforward, objective way or (2) helping the patient become more aware of healthy or unhealthy behaviors (or beliefs or attitudes) in which they are currently engaged. In either case, exerting influence is the objective. While providing information seems straightforward, the way in which pharmacists communicate information may either result in clarity or cause confusion. Therefore, the language used must be clear and easy to understand. Helping the patient become more aware of healthy or unhealthy behaviors is less straightforward.

Example

Pharmacist: Mr. Johnson, I am concerned about the fact that you continue to smoke even though you have asthma.

Patient: I feel O.K.

Pharmacist: That's great. I hope you do. Over time, cigarette smoking will continue to compromise your lungs, and your breathing will become more and more difficult. I would hate for you to have to go to the emergency room or be hospitalized. Also, smoking puts you more at risk for other illnesses.

Patient: I just didn't know that asthma was that serious.

Pharmacist: It can be if it's not controlled, and it's almost impossible to control if you continue to smoke. That concerns me a great deal.

Patient: I need to give this some serious thought.

Pharmacist: I know of several products and smoking cessation programs that are helpful. Give me a call when you're ready.

This pharmacist confronted this patient about his smoking and used consciousness-raising to address the problem directly. The pharmacist was able to have influence on this patient's beliefs because he was objective and demonstrated caring.

Messages that Arouse Fear: Research supports the view that a message can be persuasive if it arouses fear. The idea is that avoiding problems is rewarding. Messages that arouse fear can promote a change in health behavior if they meet the following conditions: (1) the message provides a strong argument that the recipient will suffer a negative consequence if the recommendations are not accepted; and (2) the message provides strong assurance that adoption of the recommendations will eliminate the negative consequences.¹ Two studies evaluated the effects of fear-arousing health messages in women. One involved cancer in general, and the other, breast cancer and breast self-examination. The fear-arousal messages did increase participation in preventive measures.¹ The key is that after hearing the fear-arousal message, the patient must believe that his/her actions will lead to a reduction of the threat.

Example

Pharmacist: Mrs. Ackerman, I am quite concerned that you are only taking about 30% of your doses for your high blood pressure. Given that your blood pressure is 170/110, I am very concerned about you having a stroke or heart attack.

Patient: Don't you think you're overreacting? I feel just fine.

Pharmacist: That's part of the problem. People can't tell when their blood pressure is up by how they feel. Most patients feel just fine even when their blood pressure is dangerously high. You are still putting a strain on your heart. It is very important that you take your medicine every day, as prescribed, to get your blood pressure down and reduce your risk of a stroke or a heart attack.

Patient: Can you guarantee that that will keep me from having a heart attack?

Pharmacist: I can guarantee that you will greatly reduce your risks and that you are asking for trouble if you don't take your medicine as prescribed, each day. Is remembering to take it once a day a problem for you?

Patient: Not really—I just didn't know I was at such high risk.

Pharmacist: This is really very important.

Patient: O.K.

Pharmacist: Please let me know if you have any problems.

This pharmacist used a fear-arousing appeal. It worked because the pharmacist expressed caring and concern. The patient finally understood that she really was at risk, and now believes that she can do what is necessary to reduce the risk.

Use of Vivid Information: Particularly in fear-arousal appeals, research supports the use of vivid information versus abstract information.² Vivid information uses emotional appeals and examples that the patient can relate to. These could be examples of other people the patient's age (famous or otherwise), etc. It is the use of any kind of concrete example that helps the patient take abstract information and make it more real to them. In the above example of the patient with hypertension, if the pharmacist could have pointed out another patient who recently had a stroke because of uncontrolled blood pressure (without mentioning the patient's name), this could help this patient understand the problem more clearly.

In general, the research on negatively framed appeals (fear-arousal) versus positively framed appeals has supported negative appeals in promoting health behaviors to avoid risk (e.g., of cancer, osteoporosis).¹ More research is needed to evaluate these findings. Moreover, telling patients the benefits of taking their medicine properly and of their engaging in healthy behaviors is also vitally important.

Linguistic Binds: One last category of direct persuasive appeals requires caution. Linguistic binds are discussed in the persuasion literature and could have relevance to pharmacy practice. However, there is an element of deception in the use of linguistic binds. Binds create the illusion of choice by using language that appears to offer a choice; however, either choice the listener chooses, he or she is still going along with what the speaker wants.³ Linguistic binds cause one to walk a fine line between influence and manipulation.

Example

Pharmacist: Mrs. Smith, I note from this new prescription that you are newly diagnosed with high blood pressure.

Patient: Yes, I just came from the doctor.

Pharmacist: The medicine the doctor prescribed is very effective if taken correctly.

Patient: Oh, believe me—I'll take it correctly. I don't want to have a stroke.

Pharmacist: Great! Dr. Stevens probably told you that the only way that we can really know if your blood pressure is being controlled is to take regular readings using a blood pressure cuff.

Patient: Yes, he did say I should take my medicine even if I feel fine.

Pharmacist: Good. Since you will only be seeing Dr. Stevens every 3 months, I would like to either show you a blood pressure cuff for home use or I have a monitoring service that costs \$30 per month for unlimited readings that I will fax to your doctor every 2 weeks. Which would you prefer?

Patient: Uh, I guess I would rather have the monitoring service.

Pharmacist: Great. Would you like to go ahead and set up your first appointment now, or, when is a good time for you to meet to take your blood pressure? (pharmacist has pen in hand to jot down a time)

Patient: I guess Friday mornings.

Pharmacist: Good, 10 a.m. this Friday?

Patient: O.K.

Several issues need to be discussed here. First, offering to sell a patient a blood pressure cuff or providing a monitoring service certainly is appropriate for any patient with high blood pressure. If patients with high blood pressure had their blood pressure regularly monitored, far fewer strokes or heart attacks would probably occur. When the pharmacist uses the linguistic bind both times, the “illusion of choice is presented. In the first bind, the pharmacist wants to sell a product or a service, either of which would benefit the patient and the pharmacist. The choice that is left out is to buy neither. In the second bind, the illusion of choice is setting up the first appointment. It is hard to argue against monitoring of high blood pressure. It is a good thing for the patient to do. However, what concerns some people about linguistic binds is the element of confusion or deception created. It seems to be not quite honest. The expert authority the pharmacist has is being

used to “force” a choice. Here, linguistic binds are being used to benefit the patient and the pharmacist. Binds that only benefit the pharmacist at the expense of the patient are not appropriate and are ethically questionable.

Indirect Persuasive Attempts

Despite following all of the above guidelines, there are times when persuasive strategies don’t work or aren’t very effective. Generally speaking, when people strongly resist change, direct persuasive strategies are very ineffective. These direct strategies often take the form of advice giving or “yes, but” communication.

Example

Pharmacist: Mr. Johnson, you really need to quit smoking because of your asthma.

Mr. Johnson: (yes, but) I’m really not ready to quit. I like it too much. It relaxes me.

Pharmacist: (yes, but) Don’t you think your health is important?

Mr. Johnson: (yes, but) Why don’t you let me worry about that?

Pharmacist: (yes, but) I don’t think you understand how serious this is.

Mr. Johnson: (yes, but) I don’t think YOU understand how serious I am!

This could go on and on, and usually does. The “yes, but” the pharmacist is using actually force the patient to defend the very behavior the pharmacist is trying to change. Remember, persuasion involves a conscious attempt to influence, not an attempt to coerce or convince. To influence people, it is especially important that they feel they are not being coerced or manipulated and that they have choices. Otherwise, especially for resistant people, they dig in further. The work of Miller and Rollnick⁴ and Prochaska and colleagues⁵ has added much to our understanding of patient resistance. Ambivalence is often the cause of such resistance.⁴ When people are ambivalent they tend to do nothing. Therefore, one approach is to provide objective, nonjudgmental information. If patients are informed, but not ready to change because they are ambivalent about their ability to make the necessary changes, different strategies are needed.

One strategy involves attempting to see the world as the patient sees it and then clearly defining the choices that need to be made.

Example

Pharmacist: I’m very concerned that you are continuing to smoke, because of your asthma.

Patient: I’m just not ready to quit. It really relaxes me.

Pharmacist: It would be hard to give up something that was relaxing.

Patient: Yeah, no kidding. You ever tried to quit smoking?

Pharmacist: No, but I know that it is very hard for most people. I wanted you to know that I am concerned because smoking can make your asthma much worse. I do have some smoking cessation products that could help when you are ready to quit. The choice really is up to you.

Patient: I appreciate that. I’m just not ready.

Pharmacist: I understand. If you haven’t had a chest x-ray lately, you might consider

that just to make sure everything is O.K. At least it would give you additional information to make an informed decision. Let me go ahead and show you how this asthma inhaler works.

This pharmacist was informative, but did not try to coerce this patient into quitting. We cannot make people change their behavior. The pharmacist opened a door for future conversation and keeps it open by nonjudgmentally directing his communication at what is appropriate for this patient.

Self-persuasion and Cognitive Dissonance: Another strategy that often works for resistant patients involves self-persuasion and the use of cognitive dissonance. Cognitive dissonance theory states that a feeling of dissonance or distress occurs in people when they do or say something that runs in direct opposition to their beliefs or self-concept. To reduce the dissonance produced, people will try to reduce the disparity.⁶ It has been found that dissonance is very self-motivating. Therefore, if pharmacists can create dissonance in communicating with patients, this will stimulate patients to persuade themselves to do something to reduce the dissonance.

Example 1

Patient: I'm just not ready to quit smoking. I find it very relaxing.

Pharmacist: What would you tell your teenage daughter, Sara, about smoking?

Patient: I'd tell her not to do it.

Pharmacist: Because?

Patient: For obvious health reasons, cost, and the like.

Pharmacist: Your smoking and the advice you would give seem a little inconsistent.

Patient: I suppose they are.

Example 2

Patient: I'm just not ready to quit smoking. I find it very relaxing.

Pharmacist: It would be hard to give up something you find relaxing. What else do you like about smoking?

Patient: It gives me something to do with my hands and I especially like lighting up after a meal. It's very relaxing. It also helps me keep weight off.

Pharmacist: Those things are important. Do you see any downside to smoking?

Patient: Oh sure, the usual health reasons, plus my wife says my breath and clothes smell. And it's become more and more expensive.

Pharmacist: So on the one hand, smoking relaxes you, gives you something to do with your hands, and keeps you from gaining weight, but on the other hand you realize that it is very bad for your health, your wife says your breath and clothes smell, and it's expensive.

Patient: Right.

Pharmacist: I did want you to know that I am concerned about your smoking, but I won't bug you about it. I do have some things that can help you stop if you get to that point.

In example 1, the pharmacist creates dissonance by creating a discrepancy between the patient's beliefs or values and what he actually does. In example 2, the dissonance is created by repeating back what the patient says is positive and negative about smoking. The dissonance becomes the stimulus for change. It is important to note that in both examples, the pharmacist is nonjudgmental and does not attempt to move the patient along too quickly. This would only create more resistance (see U.S. Pharmacist, October 1999, "Change is a Multi-Step Process?").

Conclusion

Whether using direct or indirect forms of persuasive communication, the emphasis in either case has been on using influence strategies that benefit the patient and enhance patient care. Pharmacists are encouraged to try out several of these strategies, because patients will respond differently to different forms of influence.

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Change is a Multistep Process

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The first article of this three-part series examined people's emotional reactions to change and why they have these reactions. This article will examine change from the perspective of the patient's readiness to change in order to manage an illness, particularly a chronic illness. Managing an illness often requires changes in multiple behaviors. For example, patients with diabetes will need to use their medicine(s) correctly, exercise, change their diet, and monitor their blood glucose. They will not necessarily engage in each of these behaviors equally well, nor are they likely to engage in each of the behaviors with the same degree of motivation or commitment. This article will examine a model of change and discuss how pharmacists and other healthcare providers can assist patients in managing their illnesses.

The Transtheoretical Model of Change (TMC)

During the 1970s and 1980s Prochaska and colleagues carried out an exhaustive examination of the literature on change.^{1,2} They looked at why and how people change in psychotherapy, why they did not change, and why and how they changed outside of therapy. The objective was to develop a comprehensive model of change that could be used to predict how ready an individual was for change and how to intervene to assist the individual in making the change.

As a result of their extensive research, Prochaska and colleagues developed the Transtheoretical Model of Change. They identified five stages of readiness for change ([see Table 1](#)) and ten processes of change ([see Table 2](#)) that individuals use to move from one stage of readiness to the next. In other words, change is not an either/or process.^{3,4} People often cycle through five stages of change (or readiness) before the change is internalized and habituated. The first three stages are cognitive—that is, people think about the change and weigh the pros and cons of making the change. They also make decisions about whether they think they have the skills and/or resources to make the necessary changes (self-efficacy).

Table 1 Stages of Change and Pharmacist Support		
STAGE	CHARACTERISTICS	SKILLS/INTERVENTIONS BY PHARMACIST
Precontemplation	Unaware, unwilling, too discouraged, have not tried anything, cons outweigh pros, not ready to try anything within next six months	Listening and empathic responding, effective questioning, identifying barriers to change, nonjudgmental approach needed. Persuasive strategies are generally ineffective. Avoid argumentation in all stages
Contemplation	Open to information, education, thinking about trying something within six months, low self-efficacy, high perceived temptations to stay the same	Listening and empathic responding, educational interventions, emotional support, social support, effective questioning, discussion of strategies to remove barriers, developing discrepancies
Preparation	Ready to engage in behavior(s) in the next month, have made at least one prior attempt in the past year, beginning to set goals and “psyche” themselves up	Listening/empathy. Praise for their readiness to manage illness, help to set goals, discuss their plan of action with them, identify possible pitfalls, ask if they have the support of others
Action	Taking steps, fighting “coercive forces,” engaging will power, developing a sense of autonomy, improved self-efficacy, but may also experience guilt, failure, limits of personal freedom; very stressful stage	Listening/empathy. Reinforce self-efficacious behavior, encouragement, continued emotional support is important, especially if relapse occurs; identify reasons for relapse. Confrontation may be necessary. Avoid argumentation
Maintenance	Has been engaged in new behaviors for at least six months, person senses that “I am becoming more like the person I want to be.” Is able to more clearly identify situations and self-defeating behaviors that encourage relapse	Listening/empathy. Open assessment of situations likely to produce relapse, continue to apply counter-conditioning and stimulus control, continue supportive role and provide positive reinforcement

Within each stage of readiness people use different internal processes ([Table 2](#)) to move to the next stage of readiness. It is the healthcare provider’s task to assess the patient’s readiness to manage the target behaviors. Next, the healthcare provider should use stage-specific skills and strategies to stimulate the internal processes needed to motivate change

and help the patient move to the next stage of readiness. Notice that the task is not necessarily to move the patient directly to action; it is to assist the patient in moving to the next stage. One internal process is consciousness raising. It is the most-used process of change. For example, increasing the information available to the patient can help the patient make better choices. In order for patients with diabetes to manage their illness they must first know enough about the illness and how to control it to be successful. Therefore, their understanding of the illness and its treatment must be assessed and then appropriate information communicated. While education does not predict adherence, it is vital that patients assimilate accurate information so that they have a reasonable chance to succeed. Education can stimulate the internal process—consciousness raising—in the patient.

Table 2 Characteristics of the Processes of Change	
PROCESS	PEAK STAGE
Social liberation Noticing that others with a similar condition in their environment are changing behaviors	Contemplation and preparation
Dramatic relief Becoming upset or emotional in response to information about the hazards of not changing	Precontemplation and contemplation
Helping relationships The existence of meaningful others who provide support for one's efforts to change	Prepar., action, and maint.
Consciousness-raising Gaining and thinking about information that is relevant to one's health maintenance behaviors	Precontemp., contemp.
Environmental reevaluation Recognizing the harmful effects of not taking care of one's physical and social needs	Contemplation
Reinforcement management Rewarding oneself or being rewarded by others for healthy behaviors	Action and maintenance
Self-reevaluation Cognitively evaluating one's attitudes toward healthy and unhealthy behaviors	Contemplation
Stimulus control Altering or manipulating the environment to remove cues that trigger relapses in behaviors, and introducing cues to facilitate healthy behaviors	Action and maintenance
Counterconditioning Developing and engaging in new behaviors to take the place of old, unhealthy ones, e.g., overeating	Action and maintenance
Self-liberation Realizing that one is capable of successfully engaging in healthy behaviors if he or she chooses to	Preparation

This model is very powerful, yet sometimes it presents difficulties for healthcare providers who have a strong need for control or who believe that they manage the patient’s illness. In reality, we cannot control, motivate or save the patient.

Nor do healthcare providers manage an illness. Patients manage illnesses—or they don’t. What healthcare providers can do is offer sufficient, understandable information in a caring, trusting context in which patients feel safe enough and free enough to discuss their successes and problems in managing their illnesses. In addition, providers can use patient-specific skills and strategies to assist patients in moving towards healthy behaviors. [Table 3](#) contrasts the Biomedical (Paternalistic) Model of care with a Socio-Behavioral Model of Care. The Biomedical Model is one in which the healthcare provider is in “control,” whereas the Socio-Behavioral Model places the patient and provider as partners who negotiate care. The Biomedical Model works in settings in which the patient is nonambulatory (for example, hospitals, nursing homes). However, it does not work well at all when the patient is ambulatory and can choose whether to follow a treatment regimen or not. This is where Socio-Behavioral Models work best. The Transtheoretical Model is a Socio-Behavioral Model of care.

Table 3 Traditional versus Empowerment Model of Care	
BIOMEDICAL MODEL (PATERNALISTIC)	SOCIO-BEHAVIORAL MODEL
Practitioner-centered	Patient centered
Information giving	Information exchange
Practitioner must “save” the patient	Patients must save themselves
Dictate behavior	Negotiate behavior
Compliance	Adherence
Authoritarian (parent-child) relationship	Servant
Motivate the patient	Assess the patient’s motivation
Persuade, manipulate	Understand, accept
Resistance is bad	Resistance is information
Argue	Confront
Respect expected	Mutual respect is assumed

Some Important Contrasts

Before examining the stages of change, some important contrasts need to be considered (see [Table 4](#)). When people are faced with change, initially, the change may seem foreign to them. This is especially true when they are told they have a chronic illness to manage. They may say, “It is not happening to me” or “It is not really that serious.” In other words, they do not accept what is happening to them. Until the change or illness is internalized or integrated, becoming part of the person’s sense of self, the change is unlikely to take place. Through empathy, understanding and education, the process of internalization can be assisted.

Ambivalence is a major reason why people don't change. If they do not know what to do, how to do it, or do not believe they have the skills or resources to do what is necessary, change usually does not occur. Therefore, interventions that help people understand what is needed and the resultant benefits are often useful. In addition, creating dissonance is a powerful tool to promote change. If people believe that staying the same will create more problems than changing, they will be more likely to change. Dissonance stimulates the process of self-reevaluation. In other words, in order to change, the patient must decide that he will like himself more as a result of the changes. People are less likely to change if they feel coerced or as if their freedom is being impinged on; they are more likely to change when they believe that the decision to do so is theirs. The ability to make good decisions is aided by accurate, nonjudgmental information, empathic understanding, and stressing the positives of making the change.

Finally, helping relationships are far more likely to move people toward change than will treating patients like children. Helping relationships do the following: they involve the patient in the decision-making, they respect that this change is only part of what is occurring in their lives, and they allow the patient to express fears, doubts or concerns. Helping relationships serve to stimulate, among other processes, self-liberation, in which patients feel free to make better choices. Having said all of this, there are patients who want to be told exactly what to do and when. However, even this is a choice the patient—not the healthcare provider—is making.

The Stages of Change

Precontemplation: Individuals approach change with varying degrees of readiness. Precontemplation is considered the first stage of readiness. Individuals in this stage are either unaware, unwilling, or too discouraged to change. For the precontemplator who is unaware, the best strategy is education. For example, people with diabetes cannot effectively manage their illness if they do not understand the illness or its treatment.

For patients who are aware of negative consequences but are unwilling to change, a different approach is needed. Many smokers are aware of the dangers of smoking, but continue to do so for other reasons. Here, the strategy is to ask the smoker what he/she likes about smoking. If the smoker says, "It relaxes me," a helpful response is, "It would be hard to give up something that is relaxing." This response does not put the patient on the defensive and in fact, demonstrates nonjudgmental understanding. After asking what else the smoker likes about smoking, asks what he/she sees as the downside of smoking. Summarize all that you have heard. Saying, "So, on the one hand you like smoking because....while on the other hand, you see the downside of smoking as..." This is called developing discrepancies. Saying the pros and cons of a behavior out loud creates dissonance, and the dissonance creates motivation for change. To assess just how resistant to change the patient is, the "envelope" method is recommended. Using our smoking example, you would say, "Mr. Smith, if I were to hand you an envelope, what message would have to be inside of it for you to consider quitting?" Very resistant precontemplators will tell you, "There isn't any message that could get me to quit." Some patients will have no intention of changing in our lifetime. We cannot save them. To them we would say, "Mr. Smith, it sounds like you're not ready to quit smoking. I am

concerned that your smoking increases your chances for a stroke or heart attack because of your high blood pressure, but it really is up to you if you want to quit. If you get to the point where you are considering quitting, let me know and I would be glad to help you with some methods for doing so.”

On the other hand, when asked about the envelope, some patients might say, “I guess I would consider quitting if I found out that I had early warning signs of problems.” Now you have an opening to ask the patient to consider getting his or her lungs checked so he or she can make a better decision about whether to consider quitting.

For the patient who is too discouraged to attempt to change, identifying any successes they have had in past attempts at change is very helpful. Often identifying what worked, if even for a short period of time, helps the patient repeat these actions for longer periods.

Contemplation: In this stage, patients are more open to information and want to learn more. They are thinking of changing within the next six months. Providing objective, nonjudgmental information is very important in this stage. Noticing the patient’s statements, indicating a shift in his/her stage of readiness, is also important. Asking the patient what he/she anticipates will be the greatest obstacles to overcome and what the patient perceives as the benefits of the change is very useful.

Preparation: In the preparation stage, the patient is getting ready to try something within the next 30 days. It is not until this stage that any action-oriented strategies are considered. Setting small goals and removing barriers to change are very important in this stage. Discussing the patient’s plan for action and praising the patient’s readiness are very important.

Action: The action stage is critical. A great deal of effort is being made. The patient has now engaged in the behavior(s), but for less than six months. Often, once the patient engages in action, healthcare providers think their work is done. However, it is really just beginning. Patients need to be noticed and the new behaviors need to be reinforced. Some encouragement and social support is essential. It is unfortunate that major improvements may go unnoticed because healthcare providers and family may say, “Why should I praise them for doing what they’re supposed to be doing?” The answer is simple: you want them to keep doing it. Statements such as, “Mr. Jones, I noticed that you were right on time for your blood pressure medicine this month. That’s great. How have you been able to get yourself on track? I’d like to be able to pass this on to other patients” are very helpful.

Table 4 Important Contrasts in the Process of Change	
Foreign	Internalization
Ambivalence	Dissonance
Coercion	Decision-making
Paternalism	Helping relationship

Maintenance: In the maintenance stage, the patient has been engaged in the target behavior(s) for at least six months. Again, noticing these positive changes is very important. Preventing relapse is an important focus of this stage. At some time or another, patients may relapse: the smoker may smoke, the patient with diabetes will go off his diet, etc. The key is to stay focused on targeting problems, not people. For example, the pharmacist may inquire about the relapse in a tactful, respectful manner:

Pharmacist: “Mrs. Jones, what happened to cause your blood glucose to go up?”

Mrs. Jones: “Seems like we had a rash of birthdays at work—you know, cake, ice cream, the works. I overindulged.”

Pharmacist: “O.K., that happens now and then. Since you were doing a great job of keeping your diabetes under control, I know that you’ll get back on track. What is your plan?”

Mrs. Jones: “I plan to eat a smaller piece of cake, and no ice cream next time.”

Summary

The Transtheoretical Model of Change helps to convey that change is a process and that each stage of the process requires different skills and strategies to effectively help the patient. At all times, the pharmacist’s communication is supportive, encouraging and nonjudgmental.

Editors’ Note: We welcome your feedback. You can e-mail the author at uspharmacist@jobson.com.

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Helping Patients Face Change

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Change is one of the few constants in life. Yet, most of us are not completely comfortable with change. Individuals differ in their comfort and tolerance level toward change, with different kinds of changes producing different responses. John Galbraith once stated that when people are given a choice between changing and proving that change is not necessary, most get busy with the proof. Given their current level and response to stress (change), people use their best problem-solving strategies to get their needs met, even if these strategies are dysfunctional. People do what they know until they learn something new. Managing an illness requires behavior change. For example, to manage diabetes, patients must take their medicine properly, monitor their blood glucose, often change their eating habits, and get sufficient exercise. These changes are not easy. In the face of such changes, people often avoid the critical choices they need to make.

Massive changes are taking place in healthcare and in pharmacy. Changes are required of patients when they have to manage an illness. Given these realities, this column will explore issues surrounding change. This and future articles will discuss the emotional responses people have to change, the behavioral responses, the internal processes people use to change, the stages of change that people go through, how we can assist people with change, how to assess a person's readiness for change, how to choose appropriate skills and intervention strategies to match a person's readiness to change, and, lastly, a process for improving patient readiness to manage their illness.

Emotional Responses to Change

Table 1 summarizes the different emotional reactions people have to change. Table 2 summarizes reasons for these reactions. Let's examine each reaction and their reasons, and note effective responses.

Table 1
Intrapersonal Aspects of Change:
Why Change is So Difficult

FEELINGS
Fear, anxiety, ambivalence
Anger, blaming, scapegoating
Going numb, avoidance
Excitement, joy, relief
Frustration
Depression - both existential and clinical
Out of control
Shame/guilt
Being alone in the world

Table 2
Intrapersonal Aspects of Change:
Why Change is So Difficult

<p>REASONS</p> <p>Lack of confidence in ability to make the transition (“Do I have the skills?” “Can I really do this?”)</p> <p>Lack of understanding (vision) of what is needed</p> <p>Lack of involvement</p> <p>Cannot see personal or professional benefits of the change</p> <p>“What’s wrong with the way things are?”</p> <p>“Have I done something wrong?”</p> <p>“I’m too old for this.”</p>

Fear, Anxiety, Ambivalence: When faced with the need to change, some people become anxious or frightened. Change calls into question our capacity and ability to make changes. A person faced with change may wonder: Do I have the necessary skills? Do I know what is required of me? Is the change really going to be beneficial to me? Will training be available if I need it? Will others think I’m stupid (inept, clumsy, etc.) if I have difficulties at first? All these issues can cause us to feel fearful or anxious. In fact, if these questions are not adequately answered, people experience ambivalence.

Ambivalence is the primary reason people will not make a change or engage in a change. They do not know what to do, how to do it, or are not sure if they have the capacity to do it. Ambivalence shuts people down, causing them to proceed with great caution, or not at all. When people are ambivalent, they often maintain old behaviors because of familiarity. Therefore, anyone interested in helping someone to change must help the person address these issues for that person to move forward. Listening and empathic responding are very important (see U.S. Pharmacist, October 1998). People’s fears and concerns must be taken seriously and responded to in a respectful way. Fear or anxiety need to be honored (“So, you are concerned that you may not have all of the resources that you need to make the necessary changes”), not obliterated. Attempting to minimize the fear (“Oh come on, it’s not so bad”) is not effective in gaining trust. Comparing the person to others (“Other patients haven’t had difficulties with this”) is also not effective.

Anger, Blaming, Scapegoating: It is not unusual for people to become angry or defensive when faced with change, particularly if they have not been involved in the decision-making process. Therefore, participation and feedback are essential. In addition, anger is an emotion that is often used to mask another emotion, such as fear, anxiety, or frustration (see U.S. Pharmacist, March 1999). Rather than admit they feel afraid in confronting change, people often convert that fear to anger, because anger feels more powerful. What sometimes follows this angry response is blaming, scapegoating or some form of discounting. People begin to blame someone or something for why the change is

silly and/or unnecessary, why they cannot make the change, or why it will not work. They may discount the importance of the change so that they do not have to act. The key is to understand that these responses indicate that people feel threatened and anxious about the change. Therefore, perceived threats need to be explored and understood rather than minimized. Individuals need to be respectfully confronted with statements such as: “From what you have said, you don’t believe the change is necessary. Tell me why. I’d like your input,” or “Given the problem we are having, what would you propose instead?” The key is to make the person responsible for his/her statements and behavior without being punitive or shaming.

Going Numb: One response to change is to simply avoid it altogether, to go numb, act like nothing is different. The thought behind this is, “If I don’t think about it, it will go away.” Most of us would agree that this approach is unhealthy, but it is still a way to cope when feeling threatened. Going numb can also mean deciding to do nothing rather than enact a change, for others have also done nothing, even though all involved know that this decision may be harmful to themselves or others.

Excitement, Joy, Relief: Some patients may experience these emotions when diagnosed with an illness. For example, the patient who finds out she has diabetes may experience relief at finally knowing why she has felt so badly for so long. Knowing that the illness is controllable, she experiences relief and a sense of being in charge of her life again. For many people, change can be exciting if it clearly represents something better for them, whether that be working conditions, technology, health, etc.

Positive reactions to change should also be noticed. If a patient is doing a particularly good job of managing his/her illness, this should be acknowledged (“I like that you are refilling your medicine on time and regularly monitoring your blood pressure”) so that desired behaviors are repeated. It is unfortunate that we often focus on what people do that we do not like, rather than seeing the things they do that we like. We sometimes have the mentality, “Why should I praise someone for doing what they’re supposed to be doing?” The answer is simple: We want them to keep doing it. All of us like to be recognized for our accomplishments.

Frustration: This is a common response to change. For reasons similar to those describing anger, change can be very frustrating when people affected by the change are not involved in the decision-making process and have not been solicited for feedback. Again, the reasons for the frustration need to be explored rather than minimized.

Depression (existential and clinical): This sometimes occurs when people are faced with change, even if they can see its benefits. This is particularly true when people find out they have a chronic illness that will have to be treated for life. Many times, the chronic illness is a harsh reminder that they are not immortal or that they are growing older. This is difficult for most of us to accept immediately. It is unfortunate that when patients begin to express this sense of loss, which is healthy, too many healthcare providers and others often try to fix the problem rather than being emotionally available to the person. This fixing results in statements such as: “Cheer up, at least you know what

it is,” “It’s not so bad, millions of people have diabetes (high blood pressure, asthma, etc.) and it’s treatable,” etc. These statements minimize the importance of the patient’s present feelings about the illness. Listening to the patient and showing understanding would be far more powerful.

A distinction needs to be made between existential depression and clinical depression. Existential means that the feeling moves the patient forward. It promotes existence. When faced with change, even if it is positive, we must give up a part of what we used to be to become something new. This creates a sense of loss that can be experienced as depression. If one has ever been in a funk for a day or two and could not explain why, chances are very good that some important change was taking place in that person’s life. Clinical depression is much more severe. Clinical depression can result from major changes in a person’s life. It needs to be taken seriously by healthcare providers and treated by a therapist and/or drug therapy.

Out of Control: When faced with change, particularly sudden or chaotic change, people often feel out of control. In order to feel more in control, they revert back to familiar behaviors, numb out, blame someone, discount the change, or, hopefully, make the change. To encourage the person to make the change, understand the person’s reasons for feeling out of control and examine ways he or she might feel more in control of what is happening.

Shame/Guilt: Some people feel ashamed or guilty when faced with change. If the change is threatening, such as a chronic illness or a modification in job description, some feel the change is a result of past sinful behavior. They believe they deserve the punishment being inflicted on them. This is unfortunate, because these thoughts are irrational and cannot be dealt with through reasoning. Listening and empathy are important. Staying focused on the task at hand is also vital. For example, Mrs. Jones states, “I just know I got diabetes because I ate too many sweets as a kid.” The helpful pharmacist replies, “Let’s see what we can do to get your diabetes under control so that you can live a long, healthy life,” rather than, “Oh, Mrs. Jones, I’m sure that has nothing to do with this.”

Being Alone in the World: Even when people realize they need to change, it can feel very lonely. Our primary fear is being alone in the world. One of the most powerful things pharmacists can do to help patients make necessary changes is to be emotionally available and reflect back their understanding. If a problem can be understood, it can be solved. This provides hope. Hope provides energy for change. If the change ultimately must be made, the person’s resistance to the change should be explored to determine how he or she can be helped to change.

Global Guideline for Type 2 Diabetes



Global Guideline

for Type 2 Diabetes



Website and other versions of this document

This document is also available at www.idf.org

Versions of this document aimed at other audiences are planned, in particular a series of articles in *Diabetes Voice* (2006).

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Other IDF publications, including *Guide for Guidelines*, are available from www.idf.org, or from the IDF Executive Office: International Diabetes Federation, Avenue Emile De Mot 19, B-1000 Brussels, Belgium. communications@idf.org

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Preface

There is now extensive evidence on the optimal management of diabetes, offering the opportunity of improving the immediate and long-term quality of life of those with the condition.

Unfortunately such optimal management is not reaching many, perhaps the majority, of the people who could benefit. Reasons include the size and complexity of the evidence-base, and the complexity of diabetes care itself. One result is a lack of proven cost-effective resources for diabetes care. Another result is diversity of standards of clinical practice.

Guidelines are one part of a process that seeks to address those problems. Many guidelines have appeared internationally, nationally, and more locally in recent years, but most of these have not used the rigorous new guideline methodologies for identification and analysis of the evidence.

Increasingly, national organizations have sought to use these new approaches, which are described in the IDF publication *Guide for Guidelines*. It was noted in that document that many countries around the world do not have the resources, either in expertise or financially, that are needed to promote formal guideline development. In any case, such a repetitive approach would be enormously inefficient.

Accordingly the International Diabetes Federation (IDF) has developed a global guideline. For reasons of efficiency the current initiative has chosen to use the evidence analyses of prior national and local efforts. This should also help to ensure a balance of views and interpretation.

A global guideline presents a unique challenge. Many national guidelines address one group of people with diabetes in the context of one health-care system, with one level of national and health-care resources. This is not true in the global context where, although every health-care system seems to be short of resources, the funding and expertise available for health care vary widely between countries and even between localities.

Published national guidelines come from relatively resource-rich countries, and may be of limited practical use in less well resourced countries. Accordingly we have also tried to develop a guideline that is sensitive to resource and cost-effectiveness issues. Despite the challenges, we hope to be found to have been at least partially successful in that endeavour, which has used an approach that we have termed 'Levels of care' (see next page).

Funding is essential to an activity of this kind. IDF is grateful to a diversity of commercial partners for provision of unrestricted educational grants.

Levels of care

All people with diabetes should have access to cost-effective evidence-based care. It is recognized that in many parts of the world the implementation of particular standards of care is limited by lack of resources. This guideline provides a practical approach to promote the implementation of cost-effective evidence-based care in settings between which resources vary widely.

The approach adopted has been to advise on three levels of care:

■ Standard care

Standard care is evidence-based care which is cost-effective in most nations with a well developed service base, and with health-care funding systems consuming a significant part of national wealth.

Standard care should be available to all people with diabetes and the aim of any health-care system should be to achieve this level of care. However, in recognition of the considerable variations in resources throughout the world, other levels of care are described which acknowledge low and high resource situations.

■ Minimal care

Minimal care is the lowest level of care that anyone with diabetes should receive. It acknowledges that standard medical resources and fully-trained health professionals are often unavailable in poorly funded health-care systems. Nevertheless this level of care aims to achieve with limited and cost-effective resources a high proportion of what can be achieved by *Standard care*. Only low cost or high cost-effectiveness interventions are included at this level.

■ Comprehensive care

Comprehensive care includes the most up-to-date and complete range of health technologies that can be offered to people with diabetes, with the aim of achieving best possible outcomes. However the evidence-base supporting the use of some of these expensive or new technologies is relatively weak.

Summary of the Levels of Care structure

Standard care

Evidence-based care, cost-effective in most nations with a well developed service base and with health-care funding systems consuming a significant part of their national wealth.

Minimal care

Care that seeks to achieve the major objectives of diabetes management, but is provided in health-care settings with very limited resources – drugs, personnel, technologies and procedures.

Comprehensive care

Care with some evidence-base that is provided in health-care settings with considerable resources.

Methodology

The methodology used in the development of this guideline is not described in detail here, as it broadly follows the principles described in *Guide for Guidelines*.

In summary:

- The process involved a broadly based group of people, including people with diabetes, health-care professionals from diverse disciplines, and people from non-governmental organizations (see *Members of the Guidelines Group*).
- Within the Group, a number of people had considerable experience of guideline development and health economics, and of health-care administration, as well as of health-care development and delivery, and of living with diabetes.
- Geographical representation was from all the IDF regions, and from countries in very different states of economic development (see *Members of the Guidelines Group*).
- In general the evidence analyses used were published evidence-based reviews and guidelines from the last 5 years; those used are referenced within each section. However, members of the Group were asked to identify any more recent publications relevant to the section of the guideline allotted to them, and encouraged to review details of papers referred to in the published guidelines. Key evidence-based reviews and meta-analyses are also referenced.
- The whole Group met to hear the synthesis of the evidence for each section of diabetes care, to address what recommendations should be made, and to make recommendations over what should be in each *Level of care* for each section.
- The results from the meeting were synthesized into written English by a scientific writer with a knowledge of diabetes, with the assistance of the initiative's chairmen; those drafts were then reviewed by the members of the Group who originally worked on each section, and amendments made according to their suggestions.
- The whole draft guideline was sent out for wider consultation to IDF member associations, IDF elected representatives globally and regionally, interested professionals, industry sponsors (of the guideline and of IDF generally), and others on IDF contact lists, a total of 378 invitations. Each comment received was reviewed by the two chairmen and the scientific writer, and changes were made where the evidence-base confirmed these to be appropriate.
- The revised and final guideline is being made available in paper form, and on the IDF website. The evidence resources used (or links to them) will also be made available. Versions are also being made available in descriptive form (in *Diabetes Voice*), and in language made accessible to people without technical medical training.
- Past experience of international diabetes guidelines is that they have a useful lifespan exceeding 5 years. IDF will consider the need for review of this guideline after 3-5 years.

Members of the Guidelines Group

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Comments on the draft were received from all IDF regions, coming from national associations, individuals, industry, non-governmental organizations, and IDF officers. All are thanked for their time and valuable input.

Duality of interest:

Members of the Guidelines Group and consultees are acknowledged as having dualities of interest in respect of medical conditions, and in relationships with commercial enterprises, governments, and non-governmental organizations. No fees were paid to Group members in connection with the current activity. A fee commensurate with the editorial work was however paid to the spouse of one of the chairmen.

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Recommendations

■ Standard care

- SD1 Each health service should decide whether to have a programme to detect people with undiagnosed diabetes.
- This decision should be based on the prevalence of undiagnosed diabetes and on the resources available to conduct the detection programme and treat those who are detected.
 - Universal screening for undiagnosed diabetes is not recommended.
 - Detection programmes should target high-risk people identified by assessment of risk factors.
- SD2 Detection programmes should use measurement of plasma glucose, preferably fasting.
- For diagnosis, an oral glucose tolerance test (OGTT) should be performed in people with a fasting plasma glucose ≥ 5.6 mmol/l (≥ 100 mg/dl) and < 7.0 mmol/l (< 126 mg/dl).
- SD3 Where a random plasma glucose level ≥ 5.6 mmol/l (≥ 100 mg/dl) and < 11.1 mmol/l (< 200 mg/dl) is detected on opportunistic screening, it should be repeated fasting, or an OGTT performed.
- SD4 The WHO 1999 criteria [1] should be used to diagnose diabetes; these include the importance of not diagnosing diabetes on the basis of a single laboratory measurement in the absence of symptoms.
- SD5 People with screen-detected diabetes should be offered treatment and care.

This guideline does not deal with lesser degrees of hyperglycaemia detected on screening.

■ Comprehensive care

SD_c1 Resources should be available for diabetes detection programmes.

SD_c2 Investigations to classify type of diabetes (e.g. islet-cell related antibodies, C-peptide, genotyping) should be available.

■ Minimal care

SD_M1 Detection programmes should be opportunistic and limited to high-risk individuals.

SD_M2 Diagnosis should be based on fasting laboratory plasma glucose (preferred) or capillary plasma glucose.

SD_M3 If blood glucose testing is not available, the presence of glycosuria, especially with classical symptoms, may be used to diagnose diabetes.

Rationale

Screening for Type 2 diabetes has important implications for individual health, day-to-day clinical practice, and public health policy. While the early detection and treatment of diabetes seems logical in terms of minimizing complications, there is currently no direct evidence as to whether or not this is beneficial to individuals. Despite this lack of direct evidence, early detection through screening is taking place and is recommended by a number of organizations throughout the world.

The decision about conducting a detection programme should be based on the following considerations [2]:

- **epidemiological** - prevalence of undiagnosed Type 2 diabetes
- **health systems** - capacity to carry out the screening, provide care for those who screen positive, and implement prevention programmes in those at high risk of future development of diabetes
- **population** - acceptability and likely uptake of the screening programme
- **economic** - cost of early detection to the health system and to the individual, and relative cost-effectiveness of early detection compared with improving care for people with known diabetes.

Evidence-base

Diabetes is associated with a range of serious complications which result in reduced quality of life and premature mortality. Early detection and treatment is one strategy proposed for reducing this burden.

Screening / early detection

Type 2 diabetes has a long asymptomatic pre-clinical phase which frequently goes undetected. At the time of diagnosis, over half have one or more diabetes complications [3]. Retinopathy rates at the time of diagnosis range from 20 % to 40 % [4,5]. Since the development of retinopathy is related to duration of diabetes, it has been estimated that Type 2 diabetes may have its onset up to 12 years before its clinical diagnosis [4].

Of people with Type 2 diabetes, the proportion who are undiagnosed ranges from 30 % to 90 %. Overall, data from countries as diverse as Mongolia [6] and Australia [7] demonstrate that for every person with diagnosed diabetes there is another who has undiagnosed diabetes. Other countries have even higher rates of undiagnosed diabetes – 80 % in Tonga [8] and 60-90 % in Africa [9-11]. However, in the USA only 30 % are undiagnosed [12].

Although there is considerable evidence supporting the benefits of improved blood glucose, blood pressure and blood lipid control in Type 2 diabetes, no randomized controlled studies have assessed the potential benefits of

early diagnosis on outcomes in screen-detected diabetes. Therefore there is only limited indirect evidence suggesting that early detection may be beneficial.

Schneider et al. [13] performed an analysis of a mass-screening programme based on urinary glucose levels, conducted in the former East Germany in the 1960s and 1970s. It suggested that people found to have diabetes by screening had an improved outcome compared with those presenting spontaneously with diabetes.

Fasting plasma glucose (FPG) at diagnosis might serve as a surrogate for the duration of diabetes. A post-hoc analysis of UKPDS showed that the frequency of subsequent complications was related to FPG at study entry [14]. The group with an initial FPG <7.8 mmol/l (<140 mg/dl) had significantly lower rates of all major end-points compared with the ≥ 10.0 mmol/l (≥ 180 mg/dl) group and also had significantly lower diabetes-related death rates and myocardial infarction rates compared with the 7.8 to <10.0 mmol/l (140 to <180 mg/dl) group. These findings suggest a benefit of intervening either at lower FPG levels or earlier in the natural history of diabetes, and may be consistent with a benefit derived from early detection.

Studies in progress which may contribute to the knowledge-base on early detection of diabetes are the 'Inter99' study in Copenhagen county, Denmark [15] and the (Anglo-Danish-Dutch) ADDITION study [16].

Screening for diabetes will also identify individuals with lesser degrees of hyperglycaemia who may benefit from interventions to prevent or delay progression to diabetes, and to prevent cardiovascular disease.

Screening strategies

There are several options for strategies to screen for undiagnosed diabetes. The ultimate choice is based on available resources and a trade-off between sensitivity (the proportion of people with diabetes who test positive on the screening test), specificity (the proportion of people who do not have diabetes who test negative on the screening test), and the proportion of the population with a positive screening test which needs to proceed to diagnostic testing.

Most screening strategies include risk assessment and measurement of plasma glucose, performed either sequentially or simultaneously. Screening tests are followed by diagnostic tests (fasting plasma glucose (FPG) and/or an oral glucose tolerance test (OGTT)) in order to make the diagnosis. References 2 and 17 provide a detailed review of screening options. Combined screening strategies have a

sensitivity and specificity in the order of 75 %, and 25 % of the population require diagnostic testing. People who screen negative will need re-testing after 3-5 years. These people should also be offered lifestyle advice to minimize their risk of developing diabetes.

Although the usefulness of urine glucose as a screening test for undiagnosed diabetes is limited because of low sensitivity (21-64 %) [17], specificity is high (>98 %), so it may have a place in low-resource settings where other procedures are not available.

Diagnosis

Following a positive screening test, diagnostic testing is required. This may either be a confirmatory FPG (≥ 7.0 mmol/l, >125 mg/dl) or an OGTT. The diagnostic criteria for diabetes adopted by the WHO [1] and American Diabetes Association (ADA) [18] are accepted internationally.

Consideration

The place of screening for undiagnosed diabetes as part of an overall strategy to reduce the health burden of diabetes is not established. However, many organizations recommend it. The choice of whether to screen or not, and the screening strategy, must be made locally taking into account local considerations.

Implementation

A clear and transparent decision should be made about whether or not to endorse a screening strategy. If the decision is in favour of screening, this should be supported by local protocols and guidelines, and public and health-care professional education campaigns.

Evaluation

Number of health-care professionals and services performing screening, proportion of the population being screened, and detection rate of undiagnosed diabetes should be ascertained. Percentage of diagnosed people entering and continuing in care should be measured.

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Recommendations

■ Standard care

- CD1 Offer care to all people with diabetes, with sensitivity to cultural wishes and desires.
- CD2 Encourage a collaborative relationship, by actively involving the person with diabetes in the consultation, and creating opportunities for them to ask questions and express concerns. Ensure that issues important to the person with diabetes are addressed.
- CD3 Offer annual surveillance of all aspects of diabetes control and complications to all people with Type 2 diabetes (see *Table CD1*).
- CD4 Agree a care plan with each person with diabetes
 - review this annually or more often if appropriate
 - modify it according to changes in wishes, circumstances and medical findings.
- CD5 Use protocol-driven diabetes care to deliver the care plan between annual reviews, at booked routine reviews.
- CD6 Provide urgent access to diabetes health-care advice for unforeseen problems.
- CD7 Organize care around the person with diabetes.
- CD8 Use a multidisciplinary care team with specific diabetes expertise maintained by continuing professional education.
- CD9 Ensure that each person with diabetes is recorded on a list of people with diabetes, to facilitate recall for annual complications surveillance.
- CD10 Provide telephone contact between clinic visits.
- CD11 Consider how people with diabetes, acting as expert patients, and knowing their limitations, together with local/regional/national associations, might be involved in supporting the care delivery of their local health-care team.
- CD12 Use data gathered in routine care to support quality assurance and development activities.

■ Comprehensive care

CD_c1 In general this would be as *Standard care*.

CD_c2 The person with diabetes will have access to their own electronic medical record via secure technology from remote sites. They will be able to give permission for any health-care professional to access that record.

CD_c3 Decision support systems might be available to the health-care professional, and perhaps to the person with diabetes.

■ Minimal care

CD_M1 Offer annual surveillance, agree care plans, deliver protocol-driven care, and ensure that each person with diabetes is recorded on a local list of people with diabetes, as for *Standard care*.

CD_M2 Organize care around the person living with diabetes, using an appropriately trained health-care professional to deliver the diverse aspects of that care.

Table CD1

A summary of the assessments to be performed at Annual Review (or annually) for each person with Type 2 diabetes

Assessment topic	Guideline section
Self-care knowledge and beliefs	<i>Education</i>
Lifestyle adaptation and wishes (including nutrition, physical activity, smoking)	<i>Lifestyle management</i>
Psychological status	<i>Psychological care</i>
Self-monitoring skills and equipment	<i>Self-monitoring</i>
Body weight trends	<i>Lifestyle management</i>
Blood glucose control	<i>Glucose control; Clinical monitoring</i>
Blood pressure control	<i>Blood pressure control</i>
Blood lipid control	<i>Cardiovascular risk protection</i>
Cardiovascular risk	<i>Cardiovascular risk protection</i>
Erectile dysfunction, neuropathy	<i>Nerve damage</i>
Foot condition	<i>Foot care</i>
Eyes	<i>Eye screening</i>
Kidneys	<i>Kidney damage</i>
Pre-pregnancy advice (need for)	<i>Pregnancy</i>
Medication review	—

Rationale

The person diagnosed with Type 2 diabetes requires access to immediate and ongoing care. Who provides this care, and where and when, will depend on local circumstances, but it needs to be organized in a systematic way. General principles include: annual review of control and complications; an agreed and continually updated diabetes care plan; and involvement of the multidisciplinary team in delivering that plan, centred around the person with diabetes.

Evidence-base

Systems underlying structured organization of care for people with diabetes do not easily lend themselves to comparison by randomized controlled trials (RCTs). Much of the literature in this area is descriptive and interventions are often multifaceted. Some aspects of care organization that do not have a strong evidence-base have been adopted as good practice by a wide range of diabetes services across the world. Systematic review of the evidence was undertaken by the Canadian guideline [1] and the UK National Institute for Clinical Excellence (NICE) guideline on Type 1 diabetes [2].

Both guidelines found support for the multidisciplinary approach, with the Canadian guideline citing a systematic review by Renders et al [3]. Involvement of nurses with training in teaching skills and adult education in a number of aspects of diabetes education, and of formally trained dietitians and podiatrists within the specifically relevant areas of diabetes care, was highlighted [2]. Although there is no RCT evidence for annual review of control and complications, this has become the basis for many quality control structures for diabetes care [2,4]. Some of the rationale for annual surveillance in different areas of care is given in individual sections of the current guideline.

The Canadian guideline advocates organizational interventions that have been shown to improve health-care efficiencies, such as databases to provide patient and physician reminders and transfer of information [1,5], while NICE considers a database-driven recall system to be implicit in recommendations for annual surveillance [2]. Evidence for the usefulness of telemedicine (ranging from the telephone to technology for transmission of images) was reviewed by NICE, who recommended its use to improve process and outcomes [2,6], and drew attention to its potential in rural and remote situations.

Protocol-driven care is not specifically addressed by the guidelines, but Davidson has reviewed studies, including RCTs, in which nurses or pharmacists delivered diabetes

care following agreed protocols, and found they achieved improved process and outcomes compared with 'usual care' within the US health-care system [7,8].

The literature on care plans and patient-held/accessed records is as yet only descriptive, without useful analysis of patient-related outcomes, but the UK National Service Framework finds that these can help to empower people with diabetes [9].

Consideration

Given the diversity of health-care systems around the world, recommendations in this part of the guideline are presented in very general terms. Flexibility and adaptability would seem to be important principles. Redeployment of underused resources (such as leprosy clinics) may offer opportunities for improved care in some areas. Where databases are not feasible, lists of people with diabetes can be established in simple book form. Telemedicine can encompass anything from telephones allowing access to health-care professional advice to sophisticated data transfer, but any advance in communications technology, or access to it, may offer opportunities for improved organization of care. Empowering patients to find their way in the system through access to their own data and perhaps through use of decision-support tools would seem to be a logical development.

Implementation

Organization of care to deliver the above recommendations is largely concerned with:

- putting registration, recall and record systems in place to ensure care delivery occurs for all people with diabetes, and
- having the health-care professionals trained and available to provide the appropriate advice.

Simple communications technologies, and personnel support for those, need to be in place. More sophisticated telemedicine and other IT approaches require not just appropriate software and hardware, but again appropriately trained staff, and continuing maintenance.

Evaluation

Evaluation will show evidence of structured records being appropriately completed as part of recall and appointment systems driven from a list of people with diabetes. Evaluation of proportions of the managed population receiving defined components of care (such as glucose control, eye screening or blood pressure checks) within a 12-month

period should be made regularly. The staff providing the service should be identified, together with evidence of their continued professional training. The existence of appropriate communications equipment and protocols, and arrangements for their use, can be reviewed.

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Recommendations

■ Standard care

- ED1 Make structured patient education an integral part of the management of all people with Type 2 diabetes:
- from around the time of diagnosis
 - on an ongoing basis, based on annual assessment of need
 - on request.
- ED2 Use an appropriately trained multidisciplinary team to provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Where desired, include a family member or friend.
- ED3 Include in education teams a health-care professional with specialist training in diabetes and delivery of education for people with diabetes.
- ED4 Ensure that education is accessible to all people with diabetes, taking account of culture, ethnicity, psychosocial, and disability issues, perhaps delivering education in the community or at a local diabetes centre, and in different languages.
- ED5 Use techniques of active learning (engagement in the process of learning and with content related to personal experience), adapted to personal choices and learning styles.
- ED6 Use modern communications technologies to advance the methods of delivery of diabetes education.

■ Comprehensive care

- ED_c1 This would be as for *Standard care* but would also include the availability on demand of individual advice, through a named key contact.

■ Minimal care

- ED_M1 This would be as for *Standard care* but education would be provided by an appropriately skilled individual rather than a team.
- ED_M2 Consider how available technologies can best be used to deliver education.

Rationale

Education in the broadest sense underpins diabetes care, at every contact between the person with diabetes and the health-care team. This has made it difficult to isolate those aspects of education which best contribute to its effectiveness. Recognition that 95 % of diabetes care is provided by people with diabetes themselves, and their families, is reflected in the current terminology of 'diabetes self-management education' (DSME) programmes. With the understanding that knowledge itself is not enough to enable people to change behaviour and improve outcomes [1,2], new approaches emphasizing active learning have been introduced and continue to be developed.

Evidence-base

Systematic reviews of the evidence are generally critical of the quality of reporting and methodology in many of the studies in this field, and point out the need for further research, and possible strategies for this [3-7]. In the technology report informing its guidance on the use of patient-education models, NICE provided a review, rather than formal meta-analysis, due to differences in design, duration, outcome measures and reporting of studies [4].

NICE excluded foot self-care education but otherwise reviewed the evidence on both general and focused self-management education in Type 2 diabetes. The evidence from eight trials (6 RCTs, 2 CCTs) suggested that general self-management education has a limited impact on clinical outcomes, although few long-term data were available. The evidence from eight trials (7 RCTs, 1 CCT) of focused self-management education (focused on one or two aspects of self-management) suggested that this may have some effect in reducing or maintaining HbA_{1c} levels, although there was little evidence of impact on other clinical outcomes, partly because of short study durations. Also reviewed were four trials (3 RCTs, 1 CCT) that included people with Type 1 or Type 2 diabetes, where there was some evidence that education may improve glycaemic control and quality of life, but little evidence about the longer-term benefits of education. The other reviews painted a similar picture of educational interventions producing modest improvements in glycaemic control [5-7]. The NICE review commented that generally those studies reporting significant results used group interventions [4].

NICE found that costs depended on the type of programme offered, starting with a diabetes centre-based teaching programme spread over three afternoons. Although there is very little evidence regarding the cost-effectiveness of

patient education in general, it was concluded that, given the relatively small costs associated with educational programmes, only small improvements in terms of morbidity or health-related quality of life were needed to make educational interventions cost effective [4].

Consideration

Despite the patchy evidence, certain common principles emerge and are reflected in the recommendations. Assessment of needs is fundamental to tailoring education to the perspective of the person with diabetes, while identified needs of the population served will determine the curriculum. Delivery of advice on nutrition (see *Lifestyle management*) or foot-care (see *Foot care*) or any other aspect of diabetes care would apply the same underlying educational principles outlined in these recommendations. It is noted that diabetes education was an integral part of intensification of care in the DCCT (in Type 1 diabetes), and that nutritional advice made a significant impact in the UKPDS cohort prior to randomization. Accordingly diabetes education is taken as an essential part of diabetes care.

Implementation

Major components of implementing these recommendations are the recruitment of personnel and their training in the principles of both diabetes education and behaviour change strategies. These staff then need to develop structured education programmes for people with diabetes, supported by suitable education materials matched to the culture of the community served. Attention needs to be given to provision of space in an accessible location, and access to communication tools such as telephones. Levels of literacy and understanding need to be considered.

Evaluation

NICE suggests measures that could be used, for instance, to audit education for people newly diagnosed with diabetes [4]. These will include the presence of the multidisciplinary team, space and education resources, together with a local curriculum. There will be an entry within individual records of the offering and provision of education around the time of diagnosis, of annual assessment of educational need subsequently, and of provision of such education when the need is identified.

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Other useful resources

Diabetes patient education is a large topic, and many health-care professionals are unfamiliar with modern educational principles. The following documents are chosen as helpful resources for those wishing to develop materials (curriculum) and skills in this area.

- *IDF Consultative Section on Diabetes Education. International Curriculum for Diabetes Health Professional Education. Brussels: IDF, 2002. www.idf.org*

This comprehensive document deals with education of the diabetes health-care professionals, and is directed towards (though not solely applicable to) the diabetes educator.

- *European Diabetes Policy Group 1999. A Desktop Guide to Type 2 Diabetes Mellitus. Diabet Med* 1999; 16: 716-30. www.staff.ncl.ac.uk/philip.home/guidelines

This formal consensus guideline succinctly covers in three pages the appropriate approach to the education of someone with diabetes (initial and ongoing), and some of the content and issues which need to be addressed.

- *Diabetes Education Study Group of the European Association for the Study of Diabetes. Basic Curriculum for Health Professionals on Diabetes Therapeutic Education. 2001. www.desg.org*

This approachable booklet sets out step by step to address the issues and skills which need to be understood and acquired by anyone seeking to deploy educational techniques in helping people with diabetes.

- *WHO Working Group Report. Therapeutic Patient Education: Continuing education programmes for healthcare providers in the field of prevention of chronic diseases. Copenhagen: WHO Regional Office for Europe, 1998.*

This document again addresses the competencies needed by those delivering 'therapeutic patient education', and in so doing addresses to some extent the detail of areas to be covered in delivering a comprehensive education programme.

Recommendations

■ Standard care

PS1 In communicating with a person with diabetes, adopt a whole-person approach and respect that person's central role in their care (see also *Education, Lifestyle management*).

Communicate non-judgementally and independently of attitudes and beliefs.

PS2 Explore the social situation, attitudes, beliefs and worries related to diabetes and self-care issues.

Assess well-being and psychological status (including cognitive dysfunction), periodically, by questioning or validated measures (e.g. WHO-5 [1]).

Discuss the outcomes and clinical implications with the person with diabetes, and communicate findings to other team members where appropriate.

PS3 Counsel the person with diabetes in the context of ongoing diabetes education and care.

PS4 Refer to a mental health-care professional with a knowledge of diabetes when indicated. Indications may include: adjustment disorder, major depression, anxiety disorder, personality disorder, addiction, cognitive dysfunction.

■ Comprehensive care

PS_c1 Principles of communication will be as for *Standard care*.

PS_c2 A mental health specialist (psychologist) would be included in the multidisciplinary diabetes care team.

PS_c3 Periodic assessment and subsequent discussion would be as for *Standard care*, but could use additional measures [2-4] and computer-based automated scoring systems. The mental health specialist in the team would be able to provide a more comprehensive (neuro)psychological assessment, if indicated.

PS_c4 Counselling would be as for *Standard care*, but the mental health specialist in the team would be available to offer psychological counselling, to participate in team meetings, and to advise other team members regarding behavioural issues.

■ Minimal care

PS_M1 Principles of communication will be as for *Standard care*.

PS_M2 Be alert to signs of cognitive, emotional, behavioural and social problems which may be complicating self-care, particularly where diabetes outcomes are sub-optimal.

PS_M3 Refer for mental health specialist advice according to local availability of such professionals.

Rationale

Psychological well-being is itself an important goal of medical care, and psychosocial factors are relevant to nearly all aspects of diabetes management. Being diagnosed with diabetes imposes a life-long psychological burden on the person and his/her family. Having diabetes can be seen as an additional risk factor for developing psychological problems, and the prevalence of mental health problems in individuals with diabetes is therefore likely to exceed that found in the general population. Poor psychological functioning causes suffering, can seriously interfere with daily diabetes self-management, and is associated with poor medical outcomes and high costs [5-7]. More serious psychological disorders need to be identified, and referral to a mental health specialist for diagnosis and treatment considered.

Ways in which health-care professionals can directly or indirectly help resolve behavioural and psychological issues, with the aim to protect and promote emotional well-being (quality of life) can be considered in terms of: 1. communication with the patient; 2. assessment or monitoring; and 3. counselling.

Evidence-base

Psychosocial aspects of diabetes care are included (to varying extents) in the guidelines from the CDA [8], SIGN [9], NICE (Type 1) [10] and ICSI [11] and, for the first time in 2005, in the ADA standards of care [12]. NICE examined evidence from studies including people with Type 2 diabetes, particularly in the area of depression, which is the only topic addressed by ICSI and (for adults) by SIGN. Depression has been found to be twice as prevalent in people with diabetes compared with the general population [13] and is often under-detected [14].

Evidence-based guidelines for psychosocial care in adults with diabetes have been published under the auspices of the German Diabetes Association (DDG), indicating the

level of evidence for psychological interventions in different problem areas [15].

There is RCT support for efficacy of antidepressant treatment (in a mixed group of Type 1 and Type 2 diabetes with major depressive disorder), and for cognitive behaviour therapy (in Type 2 diabetes with major depression) [8,14]. There is growing evidence that psychological counselling can contribute to improved adherence and psychological outcomes in people with diabetes [16]. A systematic review and meta-analysis has shown that, overall, psychological interventions are effective in improving glycaemic control in Type 2 diabetes [17].

Consideration

People coping with diabetes are more likely to be affected by mental health problems, and self-management is likely to be more difficult in the presence of such disorders. Detection of emotional problems in relatively brief consultations with diabetes professionals is likely to be problematic without a formal or structured approach. Lastly there is a clear need for some basic training for diabetes professionals in management issues in this area, and for appropriate referral pathways to mental health specialists with a knowledge of diabetes for people more seriously affected.

If followed by adequate treatment or referral, screening for mental health problems as part of routine diabetes care can help to improve patient satisfaction and psychological outcomes.

Implementation

Agreement on the importance of psychological factors, and the underpinning philosophy of empowerment of people with diabetes, implies agreement within the care team on the relevance of psychological issues in diabetes. There is then a need for training of diabetes care team members in communication/interview skills, motivational techniques

and counselling. Training of health-care professionals in the recognition of psychological problems will also be needed. Where resources allow, psychological assessment tools should be made available to diabetes teams, and health-care professionals should be trained in applying assessment/monitoring procedures. Collaboration with mental health specialists who already have an interest in diabetes can help to extend the education/training of other mental health specialists in relation to diabetes.

Evaluation

Evaluate by number of psychological assessments in a given time-period, level of well-being and satisfaction in the managed population over a period of time (overall and by subgroups), and by number of referrals to mental health specialists, indications and outcomes. The training, and continuing education, of diabetes health-care team members can also be evaluated.

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Recommendations

■ Standard care

- LS1 Advise people with Type 2 diabetes that lifestyle modification, by changing patterns of eating and physical activity, can be effective in controlling many of the adverse risk factors found in the condition.
- LS2 Provide access to a dietitian (nutritionist) or other health-care professional trained in the principles of nutrition, at or around the time of diagnosis, offering one initial consultation with two or three follow-up sessions, individually or in groups.
- LS3 Provide ongoing counselling and assessment yearly as a routine, or more often as required or requested, and when changes in medication are made.
- LS4 Individualize advice on food/meals to match needs, preferences, and culture.
- LS5 Advise control of foods with high amounts of sugars, fats or alcohol.
- LS6 Integrate drug therapy, where needed, into the individual's chosen lifestyle.
- LS7 For people choosing to use fixed insulin regimens, advise consistent carbohydrate intake at meals. For these people, as well as those on flexible meal-time + basal insulin regimens, offer education on assessment of carbohydrate content of different types of foods.
- LS8 Provide advice on the use of foods in the prevention and management of hypoglycaemia where appropriate.
- LS9 Introduce physical activity gradually, based on the individual's willingness and ability, and setting individualized and specific goals.
- LS10 Encourage increased duration and frequency of physical activity (where needed), up to 30-45 minutes on 3-5 days per week, or an accumulation of 150 minutes of physical activity per week.
- LS11 Provide guidelines for adjusting medications (insulin) and/or adding carbohydrate for physical activity.

- LS12 Both nutrition therapy and physical activity training should be incorporated into more broadly based diabetes self-management training programmes (see *Education*).
- LS13 For weight reduction in people with Type 2 diabetes who are obese, it may sometimes be appropriate to consider weight loss medications as adjunct therapy.

■ Comprehensive care

- LS_c1 Advice on lifestyle management will in general be as for *Standard care*.
- LS_c2 Education might also be provided as a routine for special topics such as label reading, restaurant eating, special occasions.
- LS_c3 Intensive personal counselling might be offered on a regular basis with a health-care professional specifically trained in the principles of nutrition, to facilitate maintenance of lifestyle modifications and support weight loss or weight maintenance.
- LS_c4 Exercise testing could be available for those considering programmes of physical activity.
- LS_c5 Aerobic and resistance training sessions might be available, with individualized testing and education by exercise specialists, and continued support from them.

■ Minimal care

- LS_M1 The principles of lifestyle management are as for *Standard care*.
- LS_M2 Offer basic nutrition guidelines (healthy food choices) for improved glycaemic control.
- LS_M3 Advise on ways to reduce energy intake (carbohydrate, fat, alcohol as appropriate).
- LS_M4 Provide nutritional counselling from someone with training in nutrition therapy, around the time of diagnosis, then as assessed as being necessary, or more often as required or requested.
- LS_M5 Advise and encourage participation in regular physical activity.

Rationale

People with Type 2 diabetes often have lifestyles (eating and physical activity) which contribute to their problem. It is essential they receive help soon after diagnosis to consider how they may modify lifestyle in ways which enable them to take control of their blood glucose, blood lipid and blood pressure abnormalities, even if they also require drug therapy in the short or longer term (see *Glucose control: therapy*).

Evidence-base

Evidence supports the effectiveness of nutrition therapy and physical activity in the prevention and management of Type 2 diabetes [1-4]. This is reflected in the current ADA standards of medical care [5] (which draw on a detailed evidence-based technical review on nutrition [6] and a more recent review on physical activity [2]) and in the Canadian guideline [7]. An earlier UK guideline [8] pointed out that

involvement in a lifestyle study, even in the control group, can be beneficial, but that lifestyle modification can be difficult to achieve and maintain. That guideline expressed some concern over methodological problems in trials of complex and multifactorial interventions. Most studies have been short-term (a problem currently being addressed in a US trial), and we do not yet know the ongoing contribution of lifestyle measures once medication has been introduced, or what kind of support is required on a continuing basis. It may be noted that in the UKPDS initial dietary education was very effective in lowering blood glucose after diagnosis, and that some people were then able to maintain target glucose control for many years by diet modification alone [9,10].

Randomized controlled trials and outcome studies of medical nutrition therapy (MNT) in the management of Type 2 diabetes have reported improved glycaemic outcomes (HbA_{1c} decreases of 1.0-2.0 %, depending on the duration of diabetes). MNT in these studies was provided by dietitians (nutritionists) as MNT only or as MNT in combination with diabetes self-management training. Interventions included reduced energy intake and/or reduced carbohydrate/fat intake, and basic nutrition and healthy food choices for improved glycaemic control. Outcomes of the interventions were measurable by 3 months [6,7,11-15].

In a meta-analysis of non-diabetic people, MNT restricting saturated fats to 7-10 % of daily energy and dietary cholesterol to 200-300 mg daily resulted in a 10-13 % decrease in total cholesterol, 12-16 % decrease in LDL cholesterol and 8 % decrease in triglycerides [16]. An expert committee of the American Heart Association documented that MNT typically reduced LDL cholesterol 0.40-0.65 mmol/l (15-25 mg/dl) [17]. Pharmacological therapy should be considered if goals are not achieved between 3 and 6 months after initiating MNT.

A meta-analysis of studies of non-diabetic people reported that reductions in sodium intake to ≤ 2.4 g/day decreased blood pressure by 5/2 mmHg in hypertensive subjects. Meta-analyses, clinical trials and expert committees support the role of reduced sodium intake, modest weight loss (4.5 kg), increased physical activity, a low-fat diet that includes fruits, vegetables and low-fat dairy products, and moderate alcohol intake, in reducing blood pressure [18].

A meta-analysis of exercise (aerobic and resistance training) reported an HbA_{1c} reduction of 0.66 %, independent of changes in body weight, in people with Type 2 diabetes [19]. In long-term prospective cohort studies of people with Type 2 diabetes, higher physical activity levels predicted lower long-term morbidity and mortality and increases in insulin sensitivity. Interventions included both aerobic exercise (such as walking) and resistance exercise (such as weight-lifting) [2,20,21].

The Canadian guideline has a section on the management of obesity in Type 2 diabetes, which addresses lifestyle measures and also drug and surgical options [7].

Consideration

It is noted that in general costs of educational initiatives to change lifestyle are low, because unlike drug therapy they are provided on an intermittent rather than continuing basis. From a health-provider perspective many of the costs fall outside their budget, healthier foods and exercise programmes and equipment generally being a cost met directly by the person with diabetes. For these reasons, and because, for glucose control, the gain from lifestyle modification is greater than that from any individual therapy, lifestyle measures are heavily promoted. Lifestyle modification is, however, sometimes difficult for the individual to maintain in the long term, or to develop further after early changes have been made. Where professional nutritionists are unavailable, it was noted that other health-care professionals should be trained in basic nutritional and other lifestyle education.

Implementation

Recognition of the importance and cost-effectiveness of lifestyle interventions should drive allocation of resources required for care and self-management training. Implementation demands knowledgeable and competent personnel, and dietitians/nutritionists and other health-care professionals may require training to be effective providers of lifestyle interventions. Consistency of approach to lifestyle issues across the diabetes care team is an important principle here. A process is needed to enable people to gain access to services as required.

Self-management counselling in nutrition (for individuals or groups) has four components: 1. assessment; 2. identification of the nutrition problem; 3. intervention that integrates nutrition therapy into overall diabetes management and implementation of self-management training; and 4. nutrition monitoring and evaluation of outcomes. A similar approach needs to be taken for physical activity. Development of educational materials, or adaptation of them from elsewhere, is needed.

Evaluation

Services should be able to show the availability of appropriately trained personnel, and records that individuals with diabetes have contact with them around the time of diagnosis and at regular intervals thereafter. Educational

support materials should also be demonstrable. Outcomes can be assessed in terms of improvement in appropriate food choices and amounts, and responses to questioning about physical activity levels and, where appropriate, alcohol consumption. Metabolic measures are, however, likely to be confounded by changes in drug therapies.

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Recommendations

■ Standard care

- TT1 Advise people with diabetes that maintaining a DCCT-aligned HbA_{1c} below 6.5 % should minimize their risk of developing complications.
- TT2 Provide lifestyle and education support, and titrate therapies, to enable people with diabetes to achieve a DCCT-aligned HbA_{1c} below 6.5 % (where feasible and desired), or lower if easily attained.
- TT3 Advise those in whom target HbA_{1c} levels cannot be reached that any improvement is beneficial.
- TT4 Sometimes raise targets for people on insulin or sulfonylurea therapy in whom attainment of tighter targets may increase the risk of hypoglycaemic episodes, which may present particular problems for people with other physical or mental impairment.
- TT5 Equivalent target levels for capillary plasma glucose levels are <6.0 mmol/l (<110 mg/dl) before meals, and <8.0 mmol/l (<145 mg/dl) 1-2 h after meals.

■ Comprehensive care

- TT_C1 The intervention levels are as for *Standard care*, but it may be possible to devote more resources to achieving lower target levels without adverse impact on health.

■ Minimal care

- TT_M1 The intervention levels are as for *Standard care*, but may need to be based on measurement of plasma glucose levels alone.

Plasma glucose is the preferred measure of most modern laboratories. Whole blood gives lower readings due to the volume occupied by haemoglobin. Capillary blood glucose strips measure the glucose in the plasma of the capillary blood sample, but may be calibrated to give results either as plasma or whole blood glucose (check meter instructions).

Rationale

The UKPDS established the importance of glucose control in prevention of vascular complications in people with Type 2 diabetes. The issue then arises as to the desirable level of glucose control to be achieved. In an ideal world this would be 'normal', but if the available lifestyle and pharmaceutical therapies are less than optimal in terms of efficacy and adverse effects on quality of life, or if these therapies are expensive, then some compromise (varying between individuals and health-care systems) will be needed. The chosen measures of glucose control (HbA_{1c} and self-monitoring) are discussed elsewhere (see *Clinical monitoring, Self-monitoring*) – this section deals with target levels.

The concept of targets is open to criticism – they may be unattainable, they may limit what could be attained, and they may be uneconomic to attain. However, without some form of targeted control of an asymptomatic condition it becomes difficult to promote care at all. Targets are often better thought of as 'assessment levels' and 'intervention levels'.

Evidence-base

The evidence for a target level of control is rarely the subject of an RCT. However, the epidemiological analyses of the UKPDS [1] can be informative in setting targets. Other evidence will usually come from cohort and cross-sectional epidemiological studies [2,3]. While target levels have been set by a number of organizations (including the ADA [4,5] and IDF (Europe) [6]) and in the NICE Type 2 diabetes [7] and Canadian guidelines [8], they are rarely supported by any kind of formal discussion of literature. There is however a high degree of conformity of the recommendations. The NICE Type 1 diabetes guideline does attempt to derive its recommendations with more rigour, and while this is largely directed to microvascular prevention, the argument relating to prevention of arterial disease in people with Type 1 diabetes can be usefully extrapolated to people with Type 2 diabetes in general [9].

The UKPDS shows that good glucose control is attainable at least in the early years; this is consistent with many other intervention studies of different therapies. The issue of whether a microvascular control threshold might or might not exist for glucose control seems not to be relevant to most people with Type 2 diabetes, as the targets for glucose control for prevention of arterial disease are lower when set separately (by NICE [9] and the European Policy Group [6]); thus the issue is primarily that of arterial risk prevention.

Epidemiological evidence shows a relationship between HbA_{1c} and development of cardiovascular disease even within the normal range of HbA_{1c} [10]. This suggests that normal or even low normal is to be preferred, if attainable at reasonable cost and effort. However, this is virtually never attained in clinical studies of therapies. What is clear is that arterial risk in a population with diabetes (UKPDS) decreases down to a DCCT-aligned HbA_{1c} of 5.5 % (compared with normal range of <6.1 %), the lowest level achieved over time for a significant group of people in that study. Use of glucose-lowering therapies was highly cost-effective in UKPDS [11], and accordingly 6.5 % is the target/intervention level recommended in the NICE Type 1 [9] and Type 2 guidelines [7].

Translation of this into self-monitored capillary (whole blood or plasma calibrated) levels is not simple. The upper level of fasting plasma glucose is usually taken as 5.5 mmol/l (100 mg/dl), which might then equate with a DCCT-aligned HbA_{1c} of 6.1 %. Studies with newer insulins achieving pre-breakfast glucose levels of ~6.0 mmol/l (~110 mg/dl) typically return DCCT-aligned HbA_{1c} results of ~7.0 % [12], but glucose profiles in these studies show rising glucose levels through the day, explaining the inconsistency. Regression equations between capillary measured whole blood glucose or plasma glucose and HbA_{1c} referable to the DCCT assay have been published for Type 1 diabetes [13,14], but these combine pre-prandial and post-prandial tests through the day, and reflect the different profiles of glucose control seen in that type of diabetes.

The case for targeting post-prandial blood glucose control can be made on many grounds, none of them RCT-based. Overall the case is compelling, not least by the simple logical observation that the outcome trials have established the utility of lowering blood glucose levels overall, while the highest levels of the day are generally after meals. That post-prandial levels may be particularly pathophysiological for the endothelium is generally based around arguments surrounding 2-h OGTT post-challenge glucose concentrations rather than post-prandial levels. As post-challenge levels seem closely related to the features of the metabolic syndrome the argument for a special relationship to vascular damage is still limited, and the approach adopted in this document is simply to use the average relationship to basal glucose levels in people in good blood glucose control.

Consideration

The intervention level/assessment level has been taken as a DCCT-aligned HbA_{1c} of 6.5 %, with a target level less than that if easily achieved. This is taken as translating to basal self-

monitored plasma glucose levels <6.0 mmol/l (<110 mg/dl), with post-prandial target levels of <8.0 mmol/l (<145 mg/dl).

Implementation

These targets should be incorporated in local protocols and guidelines detailing methods for evaluating and advising on lifestyle and pharmaceutical therapies as the natural history of the condition evolves.

Evaluation

Glucose targets (as given above) should be present in local guidelines and protocols. Audit is of attained glucose control on different types of therapy.

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Recommendations

■ Standard care

- MO1 Monitor blood glucose control by high-precision methods of HbA_{1c} performed every 2 to 6 months depending on level and stability of blood glucose control, and change in therapy.
- MO2 Report all HbA_{1c} results DCCT-aligned, pending internationally concerted policy changes.
- MO3 Provide site-of-care measurement of HbA_{1c} or laboratory measurement before clinical consultation.
- MO4 Communicate the HbA_{1c} result to the person with diabetes. The term 'A1c' may be useful in some populations.
- MO5 Use appropriate alternative measures where HbA_{1c} methods are invalidated by haemoglobinopathy or abnormal haemoglobin turnover.
- MO6 Do not use fructosamine as a routine substitute for HbA_{1c} measurement; it may be useful where HbA_{1c} is not valid.
- MO7 Site-of-care capillary plasma glucose monitoring at random times of day is not generally recommended.

■ Comprehensive care

- MO_c1 This would be as for *Standard care*, but continuous glucose monitoring is an additional option in the assessment of glucose profiles in people with consistent glucose control problems, or with problems of HbA_{1c} estimation.
- MO_c2 HbA_{1c} estimation would be available at each visit, and provided in electronic or paper diary form to the person with diabetes.

■ Minimal care

MO_M1 Fasting plasma glucose measurement could be used for monitoring.

MO_M2 Site-of-care capillary blood glucose meters should be quality controlled by reference to laboratory methods.

MO_M3 Visually read glucose test strips have a role in emergency and remote situations where maintenance of functional meters is not feasible.

Rationale

Type 2 diabetes shows progression of hyperglycaemia with time, and causes organ damage through controllable hyperglycaemia. Accordingly hyperglycaemia has to be monitored. Some of this will be performed by the person with diabetes, some by site-of-care tests, and some by laboratory methods which can be referenced to studies of control and complications.

Evidence-base

In general the major national guidelines do not address this area in detail. An exception is the 2004 NICE guideline for Type 1 diabetes [1]. This can be seen as applicable in terms of the methods proposed for clinic and office monitoring, and in particular for people using insulin therapy. Other guidelines and the ADA standards [2] do also centre on the HbA_{1c} assay for clinic/office monitoring of glucose control, while laboratory guidelines address available methods and their quality implementation [3].

The central role for the HbA_{1c} assay largely derives from its position in the reports of the major outcomes studies (the DCCT [4] and the UKPDS [5]). These provide the main method by which clinicians can relate individual blood glucose control to risk of complication development [6], and make HbA_{1c} mandatory where affordable/available. The laboratory and site-of-care assays are precise and accurate if appropriately controlled and aligned with international standards. However, a number of issues still surround the results reported, including problems affecting haemoglobin itself (turnover or structural abnormalities [7]) and the absolute assay standard used. These issues in turn affect the recommendation to use HPLC-based assays where feasible,

in order to detect haemoglobin variants. Additionally there are recommendations in the published guidelines on site-of-care testing, and on communication of the result to the person with diabetes.

Random clinic plasma glucose testing is not seen as having a role in quality diabetes care. Where HbA_{1c} is unavailable, timed glucose levels are often recommended as a substitute (see also *Self-monitoring*). Recommendations are then made over the quality control of devices used to make such site-of-care tests. Continuous ambulatory blood glucose monitoring has become available in recent years. There is still no good evidence-base for its use, particularly in people with Type 2 diabetes.

Consideration

The central role for site-of-care quality-controlled DCCT-aligned HbA_{1c} testing was found to be solid. Blood glucose testing per se, using quality controlled methods, was noted to have a role in certain circumstances. The role of continuous monitoring remains to be established.

Implementation

There should be access to a laboratory or site-of-care test that participates in a certified quality assurance scheme for measurement of HbA_{1c}. People for whom HbA_{1c} measurement is inappropriate must be identified; HPLC can detect haemoglobinopathies. Organization to allow site-of-care or prior-to-visit sampling is also needed. Provision of capillary blood glucose meters and strips needs to be assured (if used). It is essential to establish whether meters report values for plasma or blood and to ensure that schemes for monitoring the quality of their output are in place.

Evaluation

This is of the presence of records of HbA_{1c} results in patient records, and documented evidence of the quality of performance of the assay system.

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Recommendations

■ Standard care

- SM1 Self-monitoring of blood glucose (SMBG) should be available for all newly diagnosed people with Type 2 diabetes, as an integral part of self-management education.
- SM2 SMBG (using meter and strips) on an ongoing basis should be available to those on insulin treatment.
- SM3 SMBG should be considered on an ongoing basis for people using oral agents, but not insulin, where it is used:
- to provide information on hypoglycaemia
 - to assess glucose excursions due to medications and lifestyle changes
 - to monitor changes during intercurrent illness.
- SM4 SMBG should be considered on an intermittent basis for people not using insulin or oral agents, where it is used:
- to assess glucose excursions due to lifestyle changes
 - to monitor changes during intercurrent illness.
- SM5 Structured assessment of self-monitoring skills, the quality and use made of the results obtained, and of the equipment used, should be made annually.

■ Comprehensive care

- SM_C1 This would be as *Standard care*, but SMBG (using meter and strips) on an ongoing basis could be offered to all people with Type 2 diabetes on insulin or oral agents.

■ Minimal care

- SM_M1 SMBG using meters with strips, or visually read blood glucose strips, should be considered for those on insulin therapy.

Rationale

Self-monitoring of glucose is widely used in the care plans of many people with Type 2 diabetes. It is often used to complement HbA_{1c} measurement to assess blood glucose control and, in the case of self-monitoring of blood glucose (SMBG), provides real-time feedback of blood glucose levels. Its use can be considered in relation to:

- outcomes (a decrease in HbA_{1c} with the ultimate aim of decreasing risk of complications)
- safety (identifying hypoglycaemia)
- process (education, self-empowerment, changes in therapy).

Self-monitoring should only be considered when the person with diabetes is prepared to learn the skill, record the findings, understand the data, and act appropriately on the data.

Urine glucose testing is cheap but has limitations. Urine free of glucose is an indication that the blood glucose level is below the renal threshold, which usually corresponds to a blood glucose level of about 10.0 mmol/l (180 mg/dl). Positive results do not distinguish between moderately and grossly elevated levels, and a negative result does not distinguish between normoglycaemia and hypoglycaemia.

Evidence-base

The rather unsatisfactory evidence-base surrounding self-monitoring is addressed by guidelines from NICE [1,2] and the CDA [3]. Most of the evidence has focused on self-monitoring in relation to outcomes. Studies on self-monitoring in Type 2 diabetes were found to have been limited by small numbers, short duration, inconsistencies in monitoring and in the training of patients in technique or use of data, and failure to stratify by treatment type. A meta-analysis in 2000 found eight randomized trials, but no evidence for clinical effectiveness of this component of care [4]. A large observational study subsequently found evidence for improved glycaemic control with more frequent self-monitoring, regardless of therapy, but there was no stratification of new and ongoing users [5], and the NICE working group drew attention to the problem of separating out the effects of motivation in observational studies [1].

It is generally accepted that SMBG is useful in insulin-treated Type 2 diabetes [1,3,5]. Two recent meta-analyses of RCTs have examined its effect in people with Type 2 diabetes not treated with insulin [6,7]. Both showed that SMBG achieved a statistically significant reduction of 0.4 % in HbA_{1c}. However, it was acknowledged that the quality of

the studies was limited and that a well designed RCT was needed to resolve this issue. Two accompanying point-of-view papers reached opposite conclusions about the value of SMBG [8,9].

There are many unresolved questions about SMBG, including frequency and timing of testing, its value in new users and ongoing users, and if and how users act on the results.

There are limited data on the impact of SMBG on quality of life and treatment satisfaction. From the two studies which reported on this [10,11], there was no difference compared with people who were not performing SMBG.

Also there are few data on self-monitoring using urine glucose testing. The meta-analysis by Welschen et al. [7] included two studies which compared SMBG and self-monitoring of urine glucose and reported a non-significant reduction in HbA_{1c} of 0.17 % in favour of SMBG.

Two large cohort studies of self-monitoring of blood glucose in people with Type 2 diabetes, and including people not using insulin, have been submitted for publication at the time of writing (one presented at an ACE meeting in January 2005, and one presented as late-breaking data at the 2005 ADA Scientific Sessions). The data of these studies support the recommendations given above. However, a very recent publication addressing the same issue could not find such supportive evidence [12].

Consideration

Self-monitoring of blood glucose is accepted as an integral part of self-management of people on insulin therapy. However, the data are less clear for people who are not being treated with insulin, and therefore the decision as to whether to recommend SMBG for this group will largely be determined by cost and individual and health-care system resources. Priority lists may be needed to decide which individuals should be offered SMBG on an ongoing basis. These might include people recently diagnosed with diabetes, with more erratic lifestyles, people having problems of hypoglycaemia, and those particularly keen to tighten their blood glucose control.

There is little evidence to support the use of urine testing. However, it should be noted that a recent IDF position statement has drawn attention to the fact that urine strips are cheap and that urine testing, although grossly inaccurate as a measure of blood glucose control, was used prior to the 1970s as the only means of self-monitoring, and could still be useful if its limitations are clearly understood [13].

Implementation

Provision should be made for the supply of glucose strips on a continuing basis. When providing meters, education in their use and in interpretation of results from them should be given. Review of technique, data interpretation, and meter function should be a part of Annual Review (see *Care delivery*).

Evaluation

Provision of self-monitoring education and equipment should be assessed, and protocols and a record of review as part of Annual Review should be available. There should be evidence of the results being made use of by the person with diabetes and in other clinical consultations with health-care professionals.

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Recommendations

■ Standard care

OA1 Begin oral glucose-lowering drugs when lifestyle interventions alone are unable to maintain blood glucose control at target levels (see *Glucose control levels*).

Maintain support for lifestyle measures throughout the periods of use of these drugs.

Consider each initiation or dose increase of an oral glucose-lowering drug as a trial, monitoring the response in 2-6 months.

OA2 Begin with metformin unless evidence or risk of renal impairment, titrating the dose over early weeks to minimize discontinuation due to gastro-intestinal intolerance.

Monitor renal function and risk of significant renal impairment (eGFR <60 ml/min/1.73 m²) in people taking metformin.

OA3 Use sulfonylureas when metformin fails to control glucose concentrations to target levels, or as a first-line option in the person who is not overweight.

Choose a drug of low cost, but exercise caution if hypoglycaemia may be a problem to the individual, including through renal impairment.

Provide education and, if appropriate, self-monitoring (see *Self-monitoring*) to guard against the consequences of hypoglycaemia.

Once-daily sulfonylureas should be an available option where drug concordance is problematic.

Rapid-acting insulin secretagogues may be useful as an alternative to sulfonylureas in some insulin-sensitive people with flexible lifestyles.

OA4 Use a PPAR- γ agonist (thiazolidinedione) when glucose concentrations are not controlled to target levels, adding it:

- to metformin as an alternative to a sulfonylurea, or
- to a sulfonylurea where metformin is not tolerated, or
- to the combination of metformin and a sulfonylurea.

Be alert to the contra-indication of cardiac failure, and warn the person with diabetes of the possibility of development of significant oedema.

- OA5 Use α -glucosidase inhibitors as a further option. They may also have a role in some people intolerant of other therapies.
- OA6 Step up doses, and add other oral glucose-lowering drugs, at frequent intervals until blood glucose control is at target levels. Consider whether the rate of deterioration suggests insulin therapy will be needed early despite such measures.

■ Comprehensive care

- OA_c1 The principles of use of oral glucose-lowering drugs are as for *Standard care*. Metformin remains the drug of choice for first-line therapy.

■ Minimal care

- OA_M1 Metformin and a generic sulfonylurea should be the basis of oral glucose-lowering therapy. Where the costs of thiazolidinedione therapy are lower than those of basic insulin therapy, use of these drugs may be considered before transfer to insulin.
- OA_M2 Where renal function tests are not routinely available for people on metformin, such tests are nevertheless required where the likelihood of renal impairment is high.

Rationale

The evidence that elevated blood glucose levels can result in various forms of vascular damage is discussed elsewhere in this guideline (see *Glucose control levels*). Lifestyle modification (see *Lifestyle management*) by itself can only provide control of blood glucose concentrations to safe target levels in a minority of people with diabetes, and then usually only for a limited period after diagnosis. Accordingly, supplementary pharmaceutical measures are needed, and these can be oral glucose-lowering drugs and insulin injection therapy, separately or in combination.

Evidence-base

A number of systematic evidence-based reviews addressing oral glucose-lowering drugs have been published in recent years [1-4]. These nearly always use the UKPDS as the basis of a conclusion that glucose lowering with oral drugs is effective in protection against vascular complications [5]. They also conclude that the evidence on better prevention

of arterial outcomes when using metformin in the overweight sub-study of UKPDS [6] supports the primary use of that drug in all overweight people with Type 2 diabetes, and indeed probably in all people with Type 2 diabetes.

The reviews note that UKPDS in particular confirms that hyperglycaemia in people with diabetes is a progressive condition due to progressive islet B-cell failure, and thus requires continued monitoring and stepping up of therapies to maintain glucose control targets. The NICE guideline [2] notes the problem of concordance with multiple therapies (particularly as people will often be on blood-pressure-lowering, lipid-lowering, and cardiovascular medications), and suggests once-daily drugs may have advantage in many circumstances.

Review of effectiveness of glucose lowering concludes that the drugs from different classes are generally similar, except that α -glucosidase inhibitors may be less efficacious than sulfonylureas [1,2,7]. Other evidence suggests that nateglinide, a rapid-acting insulin secretagogue, is also less efficacious in this regard.

The two available PPAR- γ agonists (thiazolidinediones), while as effective as metformin and sulfonylurea in lowering glucose levels, are found to have other positive effects on risk factors associated with cardiovascular disease, but mixed effects on lipoproteins [8-10]. The former include improvements in vascular inflammation, albumin excretion rate, blood pressure, endothelial and clotting factors, and insulin insensitivity. At the time of review, no studies have confirmed that these effects give beneficial health outcomes, but some of the effects are qualitatively similar in nature, but quantitatively greater, than are found with metformin. Systematic reviews of the α -glucosidase inhibitors have not found reason to recommend them over less expensive and better tolerated drugs [1,2,7].

Lactic acidosis is a rare complication (often fatal) of metformin therapy in people with renal impairment. Gastro-intestinal intolerance of this drug is very common, particularly at higher dose levels and with fast upward dose titration. Some sulfonylureas, notably glyburide, are known to be associated with severe hypoglycaemia and rarely death from this, again usually in association with renal impairment. Thiazolidinediones can cause fluid retention and are contra-indicated in the presence of higher grades of heart failure [11].

Generic metformin and sulfonylureas are available at very low cost. Proprietary oral glucose-lowering drugs are considerably more expensive, with limited evidence of extra benefit. Thiazolidinediones are relatively new drugs and are also usually expensive.

Consideration

The outcome-based evidence from the UKPDS for the use of metformin in overweight people with Type 2 diabetes, exceeding that for any other drug, leads to its recommendation for first-line use, although the sulfonylureas also protected against vascular damage in that study. Cheap generic versions of these drugs are available, and their glucose-lowering capacity is not surpassed by any newer drug, at least on a population basis. However, tolerance and safety issues are of concern with metformin, the latter particularly if renal impairment is present. Concern over hypoglycaemia with some of the sulfonylureas is also felt to be of significance, especially with renal impairment. The evidence on the thiazolidinediones, effective in glucose-lowering and in having positive effects on some cardiovascular risk markers, would now seem to justify an early role for these drugs in combination oral agent therapy. However, they remain relatively expensive in most health-care markets.

Combination of oral glucose-lowering drugs with insulin therapy is discussed below (see *Insulin therapy*).

Implementation

Contracts should be in place for uninterrupted availability of at least one sulfonylurea, metformin and (for standard/comprehensive care) at least one thiazolidinedione. Availability is needed of an HbA_{1c} assay and visits to health-care professionals at a frequency (sometimes 3-monthly) sufficient to titrate therapy where glucose control is deteriorating. Lifestyle measures, self-monitoring where appropriate, and education, as discussed elsewhere in this guideline, are integral parts of maintaining glucose control to target, and will enhance the effectiveness of oral drugs. The recommendations should be a basis of local clinical protocols and structured records.

Evaluation

Evaluation of achieved blood glucose control should be by reference to the documented use of oral therapies and insulin in different combinations to identify appropriately early use of these drugs, and in the appropriate order. Reference to measures of renal and cardiac failure may be used to identify use where contra-indications apply. Local protocols should be identifiable.

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Recommendations

■ Standard care

- IN1 Begin insulin therapy when optimized oral glucose-lowering drugs and lifestyle interventions are unable to maintain blood glucose control at target levels (see *Glucose control levels*).
- Maintain support for lifestyle measures after introduction of insulin.
- Consider every initiation or dose increase of insulin as a trial, monitoring the response.
- IN2 Explain to the person with diabetes from the time of diagnosis that insulin is one of the options available to aid management of their diabetes, and that it may turn out to be the best, and eventually necessary, way of maintaining blood glucose control, especially in the longer term.
- IN3 Provide education, including on continuing lifestyle management (see *Education, Lifestyle management*), and appropriate self-monitoring (see *Self-monitoring*).
- Explain that starting doses of insulin are low, for safety reasons, but that eventual dose requirement is expected to be 50-100 units/day.
- Initiate insulin therapy before poor glucose control develops, generally when DCCT-aligned HbA_{1c} has deteriorated to >7.5 % (confirmed) on maximal oral agents.
- Continue metformin. Additionally continue sulfonylureas when starting basal insulin therapy. α -Glucosidase inhibitors may also be continued.
- IN4 Use:
- a basal insulin once daily such as insulin detemir, insulin glargine, or NPH insulin (risk of hypoglycaemia is higher with the last), or
 - twice daily premix insulin (biphasic insulin) particularly with higher HbA_{1c}, or
 - multiple daily injections (meal-time and basal insulin) where blood glucose control is sub-optimal on other regimens, or meal-time flexibility is desired.
- IN5 Initiate insulin using a self-titration regimen (dose increases of 2 units every 3 days) or by weekly or more frequent contact with a health-care professional (using a scaled algorithm).

Aim for pre-breakfast and pre-main-evening-meal glucose levels of <6.0 mmol/l (<110 mg/dl); where these seem not to be achievable use monitoring at other times to identify the profile of poor glucose control.

- IN6 Continue health-care professional support by telephone until target levels (see *Glucose control levels*) are achieved.
- IN7 Use pen-injectors (prefilled or re-usable) or syringes/vials according to choice of the person using them.
- IN8 Encourage subcutaneous insulin injection into the abdominal area (most rapid absorption) or thigh (slowest), with the gluteal area (or the arm) as other possible injection sites. Bear in mind that reluctance to use the abdominal region may relate to cultural background.

■ Comprehensive care

- IN_c1 The principles of insulin use are as for *Standard care*.
- IN_c2 Insulin analogues would generally be used.
- IN_c3 Where permitted and appropriate, combination use of insulin and a PPAR- γ agonist is an option, with cautions over cardiac failure.
- IN_c4 Insulin pump therapy may be an additional option.

■ Minimal care

- IN_m1 The principles of insulin use, including professional support, are as for *Standard care*. Self-monitoring may be limited to pre-breakfast and pre-evening-meal.
- IN_m2 Use a combination of an oral glucose-lowering drug (usually metformin) with NPH insulin twice daily (or once daily if initiated early), or twice-daily insulin mixes.
- IN_m3 The supplied insulin should be of assured and consistent quality and type.
- IN_m4 Use insulin syringes and vials.

Rationale

The rationale for the use of glucose-lowering therapy titrated to blood glucose targets is given in the section on oral agents. The natural history of Type 2 diabetes is of progression of islet B-cell failure – insulin remains the only glucose-lowering therapy which can maintain blood glucose control despite such progression.

Evidence-base

The evidence-based guidelines addressing insulin use in Type 2 diabetes [1-3] draw on the evidence from UKPDS that insulin was among the glucose-lowering therapies which, considered together, reduced vascular complications compared with 'conventional' therapy [4]. The options for insulin therapy (preparations, delivery) have expanded

considerably since the UKPDS. The NICE evidence review found that studies on older preparations tended to be less highly rated for quality, while evidence for the newer insulin analogues was still emerging [1]. The more recent Canadian guidelines found indications for use of analogues in relation to postprandial glucose excursions, risk of hypoglycaemia, and weight gain [2]. A recent meta-analysis found good evidence of less hypoglycaemia with insulin glargine compared with NPH insulin [5]. Insulin glargine was the subject of specific guidance from NICE [6] including a recommendation for use where once-daily injections would suffice or NPH insulin gave troublesome hypoglycaemia. Other studies with insulin analogues or comparing basal analogues and analogue premixes have since appeared [7,8]. These suggest that basal analogues have advantage over NPH insulin for combined endpoints (HbA_{1c} + hypoglycaemia), while there is a balance of advantage between biphasic analogues and basal analogues when HbA_{1c}, hypoglycaemia and weight gain are considered together. Risk, and hence fear, of hypoglycaemia is greater with insulin than with any of the insulin secretagogues.

There is supporting evidence for insulin use in combination with metformin, insulin secretagogues (sulfonylureas), metformin plus sulfonylurea (no meta-analysis), α -glucosidase inhibitors, thiazolidinediones [2,9]. The NICE review found that for people on insulin therapy, glucose control was improved and body weight and hypoglycaemia risk reduced when metformin was used in combination; the evidence that blood glucose control was improved when sulfonylureas were taken concomitantly with insulin was not conclusive [1]. Uncontrolled observations since that review support the hypothesis, notably in combination with basal insulin therapy [10]. Major outcome studies are not yet available for the combination of insulin with rapid-acting insulin secretagogues or thiazolidinediones.

A 2005 Cochrane review including 45 RCTs with 2156 participants found no differences in metabolic control or hypoglycaemic episodes between human insulin and animal insulin [11], although patient-oriented outcomes like quality of life, diabetes complications and mortality were not suitably addressed by high-quality RCTs. Although cost-effectiveness currently favours non-human insulin, this situation is changing.

Rapid-acting insulin analogues were the subject of a recent Cochrane review, which had some methodological weaknesses [12]. Modest benefits were found for the analogues, which might be considered for patients using rather more intensified regimens or with more advanced insulin deficiency.

Intensified insulin therapy in Type 2 diabetes has been shown to improve metabolic control, improve clinical

outcomes [13], and increase flexibility. Evidence on pump therapy in Type 2 diabetes is still insufficient to support a recommendation for use in general, although it is a potential option in highly selected patients or in very individual settings [14].

Consideration

The evidence shows that a DCCT-aligned HbA_{1c} level of around 7.0 % (population mean) is achievable with insulin therapy in combination with oral glucose-lowering drugs, provided insulin deficiency has not progressed too far. This suggests it is worthwhile starting when control has deteriorated to >7.5 %. Active titration of dosage by self-monitoring and continued educational support is needed to achieve this. It is well recognized that personal preferences have a major role to play in the use of insulin. Long-acting analogue studies show less hypoglycaemia compared with NPH insulin. However, the evidence suggests that active use of combination oral agents is necessary in many people to maintain glucose control throughout the day, and that meal-time insulin (as biphasic preparations or with meal-time supplements) becomes necessary with time.

Insulin analogues can be expensive. Where this is an issue, NPH insulin and human insulin mixes are still very useful alternatives. However, consistency of supply (quality, availability, insulin type) requires careful organization.

Implementation

Contracts should be in place for uninterrupted availability of insulin and supporting materials (including for self-monitoring and education).

Availability of an HbA_{1c} assay (except in *Minimal care*), and of health-care professionals for education and advice at high intensity when titrating doses, needs to be assured.

Avoiding delay in starting insulin therapy has been problematic in nearly all diabetes services. Structured guidelines and protocols and audit of glucose control of people on oral drugs appear to be an integral part of dealing with this problem.

Evaluation

Evaluation should be of achieved blood glucose control of people on oral drugs and those started on insulin therapy, with reference to the documented use of those therapies once insulin has been started. Local protocols and resources should be identifiable.

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Recommendations

■ Standard care

- BP1 Measure blood pressure annually, and at every routine clinic visit if found to be above target levels (see below), or if on treatment:
- use a mercury sphygmomanometer or validated meter in good working order and an appropriately sized cuff (large or normal depending on arm size)
 - measure after sitting for at least 5 min, with arm at heart level, using first and fifth phases of Korotkoff sounds
 - record all values in a record card held by the person with diabetes
 - use 24-hour ambulatory monitoring (ABPM) if 'white coat' hypertension suspected, but adjust targets down by 10/5 mmHg.
- BP2 Consider secondary causes of raised blood pressure if there is evidence of renal disease, electrolyte disturbance or other features.
- BP3 Aim to maintain blood pressure below 130/80 mmHg (for people with raised albumin excretion rate see *Kidney damage*).
- Add further drugs if targets are not reached on maximal doses of current drugs, reviewing the preferences and beliefs of the individual concerned, and likely adherence problems as tablet numbers increase.
- Accept that even 140/80 mmHg may not be achievable with 3 to 5 anti-hypertensive drugs in some people.
- Revise individual targets upwards if there is significant risk of postural hypotension and falls.
- BP4 Initiate a trial of lifestyle modification alone with appropriate education for 3 months (see *Lifestyle management*), aiming to reduce calorie intake, salt intake, alcohol intake, and inactivity.
- BP5 Initiate medication for lowering blood pressure in diabetes not complicated by raised albumin excretion rate, using any agent except for α -adrenergic blockers, with consideration of costs, and actively titrating dose according to response:
- ACE-inhibitors and A2RBs may offer some advantages over other agents in some situations (see *Kidney damage, Cardiovascular risk protection*), but are less effective in people of African extraction
 - start with β -adrenergic blockers in people with angina, β -adrenergic blockers or ACE-inhibitors in people with previous myocardial infarction, ACE-inhibitors or diuretics in those with heart failure
 - care should be taken with combined thiazide and β -adrenergic blockers because of risk of deterioration in metabolic control.

■ Comprehensive care

BP_C1 This will in general be as for *Standard care*, but with the additional option of self-monitoring of blood pressure on validated semi-automatic devices to provide additional information and educational feedback.

■ Minimal care

BP_M1 Measurement and targets will be as for *Standard care*.

BP_M2 Initiate a trial of lifestyle modification (as *Standard care*) with appropriate education (see *Lifestyle management*).

BP_M3 Initiate medication for lowering blood pressure in diabetes not complicated by proteinuria, using generic diuretics, β -adrenergic blockers, calcium channel blockers, or ACE-inhibitors as available, increasing the number of preparations used according to drug availability locally.

Rationale

Blood pressure is elevated in many people with Type 2 diabetes. Increasing blood pressure levels are associated with a spectrum of later health problems in people with diabetes, notably cardiovascular disease (especially stroke), eye damage and kidney damage.

Evidence-base

Review of the evidence-base on this topic is spread among guidelines primarily addressing diabetes [1-4] or hypertension [5,6], often embedded in consideration of cardiovascular disease [7] or kidney disease (see *Kidney damage*). The evidence may derive from trials involving primarily people with diabetes [8] or people with hypertension [9].

Recommendations on thresholds for intervention and targets of therapy vary narrowly across the guidelines. Some of this variation reflects concern at setting targets that are difficult to achieve in some people, and may appear unduly daunting, especially when many drugs are required. In the UKPDS, beneficial effects on complications, in particular stroke and retinopathy, were achieved at 144/82 mmHg in the tighter control group [8], consistent with results from the HOT study [9]. However, epidemiological analysis of UKPDS suggested benefits well below this level, supported by achievement of blood pressure down to 128/75 mmHg in other studies [1]. The recommended target of <130/80 mmHg for people with Type 2 diabetes uncomplicated by nephropathy is in line with the more recent guidelines [1-3,5,6].

Evidence on methods for measuring blood pressure was reviewed by the Australian guideline [1]. A meta-analysis of use of self-monitoring of blood pressure found it resulted in a small but statistically significant reduction [10]. Lifestyle modification (including weight reduction, reducing salt intake, increasing physical activity, reducing alcohol intake) can reduce systolic blood pressure by 4-10 mmHg (see *Lifestyle management*).

Many randomized trials have shown that blood-pressure-lowering therapy reduces cardiovascular disease morbidity and mortality in people with diabetes. Many agents (ACE-inhibitors, β -adrenergic blockers and low-dose thiazide diuretics) have proved effective. Choice of agent for a person with diabetes may be influenced by a number of factors including their risk profile (cardiovascular, renal, end-organ damage), preferences, and previous experience of therapy, as well as costs. Thiazide diuretics may adversely affect glucose, lipid and potassium levels, and β -adrenergic blockers may adversely affect glucose and lipid levels, but no RCTs have shown these drugs to increase cardiovascular mortality in Type 2 diabetes [1]. Avoidance of α -adrenergic blockers as first-line therapy is based on evidence from ALLHAT [2].

Cost issues, and particularly the data from UKPDS [11], were considered in the Australian guideline [1], which concluded that controlling blood pressure in people with Type 2 diabetes is cost-effective.

Achieving effective control of blood pressure, and consequent therapeutic benefits, is reported to depend

on adherence to therapy. Cultural health beliefs, complex therapeutic regimens, adverse effects, tablet number burden, and poor social support are reported predictors of poor concordance with therapy. These issues need to be discussed with the person concerned, where response to drugs is poor.

Consideration

Blood pressure management appears to be among the most cost-effective methods of prevention of vascular complications in people with Type 2 diabetes. Lifestyle measures are generally preferred as a trial before therapeutic intervention, but alone are generally insufficient. Because individual therapies are not particularly effective even in full dosage, the experience of the need for multiple therapies found in UKPDS is reflected in the guideline recommendations. However, this also implies the need for frequent monitoring and dose titration until targets, or the limits of therapeutic effect, are reached.

Implementation

There is need for equipment for measurement of blood pressure, maintenance of that equipment, and training of personnel in its use. Protocols using locally available drugs should be drawn up and followed to ensure drug prescription, and dose titration to target. Lifestyle education is described elsewhere (see *Lifestyle management*).

Evaluation

A record of measurement of blood pressure within clinical records in the last 12 months should be found. Where that is elevated there should be evidence of action to lower it. The percentage of people in whom blood pressure achieves the target level 130/80 mmHg can be ascertained, and the percentage of those with blood pressure above target who are receiving treatment involving lifestyle modification and drug therapy. Availability of sphygmomanometers in working order, and appropriate cuffs can be ascertained, as can training and proficiency of staff measuring blood pressure.

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Cardiovascular risk protection

Cardiovascular risk protection through blood glucose control, blood pressure control, and lifestyle interventions is dealt with elsewhere in this guideline (see *Glucose control*, *Blood pressure control*, *Lifestyle management*). This section deals with cardiovascular risk assessment, lipid modifying therapy, and anti-platelet therapy.

Recommendations

■ Standard care

CV1 Assess cardiovascular risk at diagnosis and at least annually thereafter:

- current or previous cardiovascular disease (CVD)
- age and BMI (abdominal adiposity)
- conventional cardiovascular (CV) risk factors including smoking and serum lipids, and family history of premature CVD
- other features of the metabolic syndrome and renal damage (including low HDL cholesterol, high triglycerides, raised albumin excretion rate)
- atrial fibrillation (for stroke).

Do not use risk equations developed for non-diabetic populations. The UKPDS risk engine may be used for assessment and communication of risk.

CV2 Ensure optimal management through lifestyle measures (see *Lifestyle management*), and measures directed at good blood glucose and blood pressure control (see *Glucose control*, *Blood pressure control*).

CV3 Arrange smoking cessation advice in smokers contemplative of reducing or stopping tobacco consumption.

CV4 Provide aspirin 75-100 mg daily (unless aspirin intolerant or blood pressure uncontrolled) in people with evidence of CVD or at high risk.

CV5 Provide active management of the blood lipid profile:

- a statin at standard dose for all >40 yr old (or all with declared CVD)
- a statin at standard dose for all >20 yr old with microalbuminuria or assessed as being at particularly high risk
- in addition to statin, fenofibrate where serum triglycerides are >2.3 mmol/l (>200 mg/dl), once LDL cholesterol is as optimally controlled as possible
- consideration of other lipid-lowering drugs (ezetimibe, sustained release nicotinic acid, concentrated omega 3 fatty acids) in those failing to reach lipid-lowering targets or intolerant of conventional drugs.

Reassess at all routine clinical contacts to review achievement of lipid targets: LDL cholesterol <2.5 mmol/l (<95 mg/dl), triglyceride <2.3 mmol/l (<200 mg/dl), and HDL cholesterol >1.0 mmol/l (>39 mg/dl).

CV6 Refer early for further investigation and consideration of revascularization those with problematic or symptomatic peripheral arterial disease, those with problems from coronary artery disease, and those with evidence of carotid disease.

■ Comprehensive care

CV_c1 Assessment will be as for *Standard care*, but with more aggressive investigation of asymptomatic peripheral arterial disease, coronary artery disease, and carotid disease. Lipid profiles may be investigated more extensively to give better direct assessments of LDL cholesterol and apolipoproteins. A specialist lipidologist may be consulted.

CV_c2 Interventions will be as for *Standard care* but with aggressive lipid lowering for all, using multiple therapies and more expensive/efficacious statins except where LDL cholesterol, triglycerides and HDL cholesterol are all within target ranges.

CV_c3 Antiplatelet agents to consider might include clopidogrel substituted for aspirin, in particular for those with multiple CVD events/problems, peripheral arterial disease, or previous coronary bypass grafting.

CV_c4 Renin-angiotensin system blockers are an option for added CV risk protection.

■ Minimal care

CV_m1 Assessment will be as for *Standard care*, with lipid profile measures if available.

CV_m2 Management will be as for *Standard care*, but using statins or fibrates only where these are available at reasonable cost from generics' manufacturers, and in particular for those with known CVD. Statins may be used even if the serum lipid profile cannot be measured.

CV_m3 Revascularization procedures will generally not be available, but where possible those limited by symptoms should be so referred.

Rationale

Cardiovascular disease is the major cause of mortality and morbidity in people with Type 2 diabetes. Indeed some studies have suggested a risk similar to that of people without diabetes but with declared CVD. While others 'merely' show markedly increased risk, some cohorts with particular risk factors have shown extreme risk. Assessment,

but more particularly aggressive management, of CV risk factors in Type 2 diabetes is then seen as a core part of care. Some of the risk relates to blood pressure control and blood glucose control and is addressed elsewhere in this guideline, as are the lifestyle interventions which generally benefit the whole spectrum of CV risk factors.

Evidence-base

The epidemiological evidence that cardiovascular disease is the major cause of mortality in people with Type 2 diabetes is extensive, as is the evidence that the risk is considerably elevated above that of the background population, even where that population is itself prone to high levels of vascular disease. More controversy surrounds the extent of the increased risk. A much quoted paper by Haffner et al. [1] suggested that people with Type 2 diabetes have a CV risk equivalent to non-diabetic people with previous CVD, but this has not in general been supported by other data [2]. The evidence that people with Type 2 diabetes have an abnormal, atherogenic, lipid profile (high triglycerides, low HDL cholesterol, small dense LDL) is generally accepted, and leads all the major guidelines which have addressed the area to recommend assessment of a full serum lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol (derived), triglycerides) as a guide to therapy [3-7].

Since people with Type 2 diabetes may or may not have a high LDL cholesterol (as in the general population), and may have triglyceride/HDL levels anywhere from normal to highly abnormal, decision paths to therapy are uncertain and do vary between evidence-based recommendations. A further problem is assessment of risk. The HPS study (of simvastatin) recruited people with diabetes even if they had no history of cardiovascular risk, and the results showed strong benefit [8]. CARDS similarly studied people with diabetes who had no overt evidence of CVD, and showed marked benefit with atorvastatin [9]. These studies suggest statin treatment for all people with Type 2 diabetes without assessment of risk, if over 40 yr of age. This view is not universally accepted.

The situation is complicated by the difficulty of assessing CV risk in people with diabetes, due to a two-to-three-fold underestimation of risk from tables, charts and engines derived from the Framingham study. This led the NICE group to suggest risk estimation based on a lower threshold than used generally in the UK at that time [6], but the advent of the validated risk engine based on the UKPDS study does now allow CV risk to be appropriately calculated [10]. Nevertheless, since the calculation almost inevitably suggests high risk in people with other risk factors, the universal application of statins in the middle-aged and older groups may be justified. The Canadian guideline states that there is a strong evidence-base for considering nearly everyone with Type 2 diabetes as high risk [5]. However, little evidence is available on people with younger-onset Type 2 diabetes, or their CV risk, although this would seem likely to be high relative to their peers.

Cost-effectiveness of statins is not generally addressed by the evidence-based guidelines, but rather is assumed. Lately simvastatin prices have collapsed in many parts of the world with expiry of patents. This is likely to make them cost-effective in most parts of the world.

The guidelines also address the issue of management of serum triglyceride and HDL cholesterol levels, an area where the evidence-base is softer, but all conclude that management with fibrates is indicated if serum triglyceride levels are raised (triglycerides and HDL cholesterol being inversely correlated). However, there is no easy consensus on the levels at which fibrates should be introduced, or on how they should be introduced in combination with statins. The results of the FIELD trial may help to resolve this in late 2005.

While there are safety concerns with lipid-lowering drugs, and notably even rare life-threatening problems related to muscle necrosis, the drugs are life-saving to a degree many times exceeding the safety risk (with appropriate therapeutic cautions), even when fibrates (except gemfibrozil) are used in combination with statins in people with higher risk.

The evidence-base for other lipid-lowering drugs (extended-acting nicotinic acid, concentrated omega 3 fatty acids, ezetimibe) is weaker – indeed these are barely addressed by published evidence-based guidelines, except the Australian lipid control document [4]. These drugs are also expensive for the degree of lipid-lowering gained and, as noted in the Australian guideline, some may lead to minor deterioration of blood glucose control. It would seem, therefore, that their use should be reserved for uncontrolled hyperlipidaemia on the first-line agents, or intolerance of these.

The use of anti-platelet agents is also addressed by some of the major guidelines (most extensively by the Australian macrovascular prevention guideline and the NICE lipid-lowering guideline [3,6]), with a general recommendation of endorsement for the widespread use of low-dose aspirin, the most specific evidence coming from within the ETDRS and HOT studies [11,12], and the most complete review that of Eccles and colleagues [13]. The Canadian guideline [5] notes a more recent meta-analysis of anti-platelet therapy showing a significant $22 \pm 2\%$ (\pm SE) reduction in vascular events among all high-risk patients in 195 trials but only a non-significant $7 \pm 8\%$ reduction in people with diabetes (9 trials) [14]. Nevertheless, efficacy is accepted, although the risk of bleeding results in advice in the NICE [6] and SIGN guidelines [7] restricting use to people at calculated risk (which would, however, be most people with

Type 2 diabetes) and with some caution over uncontrolled hypertension. The use of clopidogrel (at least as effective but much more expensive), where considered, is only recommended for people with aspirin intolerance.

Most other aspects of CV risk protection, notably blood glucose and blood pressure control, physical activity, and body weight control, are addressed elsewhere in this and other guidelines. However, there is also an evidence-base for integrated multiple risk factor intervention in particularly high-risk people (with microalbuminuria), showing very powerful absolute and relative risk reductions [15]. Evidence on smoking and CVD is not generally addressed, the advice given simply being in line with general medical practice, based on consideration of evidence for the general population.

Consideration

Cardiovascular risk protection for people with Type 2 diabetes is an area which is found to be of high need, but with good and often strong evidence of ability to meet that need. One obvious problem is the need to extrapolate evidence in some areas from groups of people who do not have diabetes, for example as regards aspirin therapy. However, because event rates are much higher in people with diabetes (particularly with regard to 'primary' prevention) the gains and cost-effectiveness are also potentially much better, so that the risks of extrapolation of evidence are relatively low. This is especially true because the processes of arterial damage in people with Type 2 diabetes are similar pathologically to those occurring in the general population, though usually present (as in the case of platelet abnormalities) to a more abnormal degree.

Accordingly, the recommendations are for very active management. Statins and aspirin use are given prominence, as best founded in evidence, but the associations of hypertriglyceridaemia and low HDL cholesterol with poor outcomes, together with the limited trial evidence, lead also to strong recommendations over use of fibrates. In these circumstances assessment of risk has a relatively minor role, but is found useful educationally, and clearly can only be done formally using a risk engine properly validated for cohorts of people with diabetes in continuing care.

Implementation

The recommendations require access to measurement of a full lipid profile and supporting biochemistry, and to aspirin and statins and fibrate drugs as a minimum. Structured annual assessment and record-keeping should be instituted.

Evaluation

Evaluation is by achieved lipid levels, especially LDL cholesterol and triglycerides, and numbers of people treated (and in particular with elevated levels or existing cardiovascular disease) with statins, fibrates, and aspirin. In general, cardiovascular outcome rates are difficult to assess except in very large populations.

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These guidelines are concerned with preventative *diabetes* care. No advice is given on the further investigation of retinopathy by an ophthalmic specialist, or the subsequent use of laser or other retinal therapy, of vitrectomy, or other tertiary care. It is noted that a substantial evidence-base does exist for these techniques in the prevention of visual loss.

Recommendations

■ Standard care

- ES1 Ensure that examination of the eyes of people with Type 2 diabetes is performed around the time of diagnosis and then annually as part of a formal recall process:
- measure and document visual acuity, corrected with glasses or pinhole
 - assess retinopathy:
 - using retinal photography through dilated pupils, performed by an appropriately trained health-care professional, or
 - by examination by an ophthalmic specialist.
- ES2 Discuss the reasons for eye examination with the person with diabetes.
- ES3 Use tropicamide to dilate pupils, unless contra-indicated, after discussing the implications and obtaining agreement of the person with diabetes.
- ES4 Classify the findings of eye examination as requiring: routine annual review, earlier review, or referral to an ophthalmologist (if not making the examination).
- The following frequency of screening is suggested:
- 12 months if no or minimal unchanged retinopathy
 - 3 to 6 months if worsening since last examination
 - more often during pregnancy.
- ES5 The following situations require specialist referral:
- the same day:
 - sudden loss of vision
 - evidence of retinal detachment
 - within 1 week:
 - evidence of pre-retinal and/or vitreous haemorrhage
 - new vessel formation or rubeosis iridis

- within 1-2 months:
 - advanced retinal lesions
 - unexplained deterioration of visual acuity
 - macular oedema
 - unexplained retinal findings
 - cataract
 - inability to visualize fundus.

ES6 Advise that good control of blood glucose, blood pressure, and blood lipids (see relevant sections of this guideline) can help to reduce the risk of eye damage developing or worsening.

ES7 Advise that diabetic retinopathy is not a contra-indication for use of aspirin if this is indicated for prevention of cardiovascular disease.

ES8 Advise that tests of intra-ocular pressure should be made periodically.

■ Comprehensive care

ES_C1 Retinal screening will be as for *Standard care* in most respects, but could use seven-field stereoscopic colour fundus photography interpreted by a trained reader (where a retinal ophthalmological specialist is not anyway performing the eye check).

■ Minimal care

ES_M1 Use direct fundoscopy through dilated pupils, performed by a member of the health-care team who is properly trained and has appropriate experience to assess retinopathy.

ES_M2 Check visual acuity.

ES_M3 Repeat review, referral, and preventative therapy are as for *Standard care*.

Rationale

Diabetic retinopathy is the most common complication of diabetes and a major cause of visual loss. Damage (maculopathy) to the area of the retina used for fine and central vision (the macular area around the fovea) is the largest problem in people with Type 2 diabetes, though classical retinopathy with new vessels and consequent problems is also important. Measures to control blood glucose and blood pressure (discussed elsewhere) can help to prevent onset and delay worsening of retinopathy, but most people with retinopathy will be asymptomatic until the damage is far advanced. Early detection by regular surveillance is thus essential if people with sight-threatening retinopathy are to be identified in time to offer them the laser treatment which can prevent visual loss.

Evidence-base

General diabetes guidelines which address the subject of eye screening [1-4] draw on an evidence-base going back to the 1970s, including the findings of the American studies WESDR, DRS and ETDRS which provide the framework for retinal screening and laser treatment [5-7]. The 'gold standard' screening test of seven-standard field stereoscopic colour fundus photography and associated grading scheme were established by these studies. In recent years technological developments in digital photography have offered expanding opportunities for recording and transmitting images, with potential for automated grading, reviewed in the NICE Type 1 diabetes guideline [8].

The importance of screening people with Type 2 diabetes at diagnosis relates to the finding that between 21 and 39 % of them already have some retinopathy (which may already be sight-threatening) by this time [3]. In the WESDR 1.6 % of people with Type 2 diabetes were legally blind [5]. For people who have no retinopathy at diagnosis of Type 2 diabetes, the chance of developing sight-threatening retinopathy within 2 years is less than 1 % [1]. Although there is some argument as to whether such people need to receive screening as often as annually, and the Canadian guideline recommends every 1 to 2 years [3], the other three favoured annual systematic review [1,2,4] pending further information identifying sub-groups which might safely have longer review periods [2]. Cataract is another important cause of visual loss in people with diabetes, being twice as common as in people without diabetes [1].

Support for optimized glucose control and tighter blood pressure control (see elsewhere) derives from the reduction in risk of microvascular complications found in the UKPDS [9,10]. The effects of aspirin were investigated in the ETDRS (reported in reference 3). High levels of LDL cholesterol were associated with hard exudates in the ETDRS [11].

Recent review of screening methods found that digital photography best met the needs of appropriate sensitivity/selectivity, feasibility and opportunities for quality assurance [8]. SIGN found that direct ophthalmoscopy only rarely achieved 80 % sensitivity even when carried out by properly trained operators [1]. Where cost issues were considered [2], attention was drawn to the dependence of cost-effectiveness on features such as sensitivity and specificity of screening tests, attendance and prevalence.

Consideration

The core issue is how to provide regular structured review using either ophthalmological expertise or camera technologies. With regard to the latter, use of digital cameras with eyes dilated to reduce the incidence of screen failures is found to be desirable and cost-effective. However, camera technologies cannot detect macular oedema, so visual acuity testing must accompany photography. Where neither camera technologies nor ophthalmologists can be made available, ophthalmoscopy by a trained observer can detect many problems (though with significantly poorer sensitivity) and is thus recommended in these circumstances.

The availability of laser therapy is currently limited in many parts of the world due to cost and lack of trained expertise. It is noted that raising awareness of eye problems by examination and recording of detected problems can both

help individual preventative care (blood glucose and blood pressure control) and provide the necessary evidence for establishment of a laser service.

Implementation

Staff requirements are sufficient numbers of experienced ophthalmologists, optometrists and other health-care professionals to perform the screening, and sufficient ophthalmologists to perform laser therapy, and training of such staff. Equipment for screening and treatment will be required, as will a structured recall system and record. All screening modalities require quality assurance checks; for retinal photography it has been suggested this should happen for around 1 % of photographs [1].

A national or regional advisory group, including representation of ophthalmologists, optometrists, internists and people with diabetes, can work with health funders to define such issues as: criteria for screening and treatment; training and education programmes; provision of accessible facilities; awareness programmes; strategies for programme implementation and guideline dissemination; information systems (for monitoring diabetic eye disease, follow-up and recall, collection of baseline and annual data); annual reports based on defined indicators.

Evaluation

The percentage of records containing the results of eye examination within a 12-month period is easily evaluated. Where such records are of sight-threatening retinopathy or decrease of visual acuity, evidence of review by (or referral to) an ophthalmological specialist should be present. Eye screening services can be checked for appropriately trained personnel, and facilities sufficient to ensure diabetes population coverage. Evidence of quality checks should be assessed. Evidence of control of rates of visual loss is more difficult to gather unless the records of ophthalmological services can be linked to those of diabetes services.

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These guidelines are concerned with preventative *diabetes* care. No advice is given on further investigation of kidney disease by a renal specialist, or subsequent tertiary care.

Recommendations

■ Standard care

KD1 Check annually for proteinuria in an early morning urine sample (or a random sample otherwise) using a dipstick.

- if dipstick test positive,
 - check for urinary tract infection
 - obtain a laboratory urine protein:creatinine ratio (PCR)
- if dipstick test negative, check urine albumin using:
 - laboratory or site-of-care urine albumin:creatinine ratio (ACR), or
 - a semi-quantitative reagent strip if ACR test is unavailable.

Measure serum creatinine annually, and calculate GFR ('eGFR').

KD2 If PCR or ACR is raised (microalbuminuria ACR >2.5 mg/mmol in men, >3.5 mg/mmol in women; or 30 mg/g), repeat twice over the following 4 months.

- confirm as positive if proteinuria or raised urine albumin on two of three occasions
- if both repeat tests are not raised, check again annually.

KD3 Manage those with raised urine albumin or proteinuria or reduced eGFR (<90 ml/min/1.73 m² and falling) as follows:

- use ACE-inhibitor or A2RB titrated to maximum tolerated dose
- intensify management of blood pressure (actively target <130/80 mmHg) using drugs and dietary modification (low salt intake)
- intensify management of blood glucose (target DCCT-aligned HbA_{1c} <6.5 %)
- monitor progression by ACR or PCR, serum creatinine and potassium; calculate eGFR; discuss results
- advise limiting protein intake to 0.8 g/kg daily if proteinuric
- intensify other renal and cardiovascular protection measures (not smoking, aspirin therapy, lipid-lowering therapy).

KD4 Measure Hb/ferritin every 6 months if eGFR <90 ml/min/1.73 m², give iron or other haematinics if indicated, and refer to nephrologist if still anaemic despite supplements (Hb <11 g/dl in pre-menopausal women, <12 g/dl in others).

KD5 Refer to a nephrologist when eGFR <60 ml/min/1.73 m², or earlier if symptomatic or biochemical or fluid retention problems occur.

■ Comprehensive care

- KD_c1** This is in general as for *Standard care*, but assessment of albuminuria would always be by a laboratory quantitative method (ACR).
- KD_c2** Investigations to exclude other possible causes of renal disease for all with raised ACR or PCR might include auto-antibodies, ultrasound, biopsy.

■ Minimal care

- KD_M1** Check annually for proteinuria in an early morning urine sample (or a random sample otherwise) using dipstick or sulfosalicylic acid method.
- if test positive,
 - exclude urinary tract infection by microscopy (and culture if possible)
 - if possible, obtain a laboratory protein:creatinine ratio (PCR) and repeat on two occasions over the following 6 months (proteinuria confirmed if positive on two of three occasions)
 - if test negative, check again annually.
- If available measure serum creatinine (or urea) annually.
- KD_M2** Manage those with proteinuria as follows:
- advise to avoid risk factors (analgesic use, alcohol consumption, illicit drug use), to limit protein intake (to 0.8 g/kg daily), and not to smoke
 - aim for blood pressure <130/80 mmHg using any anti-hypertensive drug and control of salt intake
 - consider use of ACE-inhibitors if available
 - aim to achieve targets for blood glucose control
 - aim to improve lipid profile using available drugs
 - check proteinuric status/progression annually
 - measure serum creatinine or urea every 6 months.

Rationale

Diabetic renal disease has only received less attention in people with Type 2 diabetes in the past because their life expectancy was limited by cardiovascular disease. However, because of the higher incidence of Type 2 than Type 1 diabetes, renal failure in the former group has always been a significant cause of morbidity and mortality. With increasing numbers of people with Type 2 diabetes, younger age of onset, and better cardiovascular protection measures, the health impact of renal impairment in this population and in individuals is growing. While the major effort of management must go to primary prevention (good blood glucose and blood pressure control from early diagnosis), the success of interventions at a later stage (see below) suggests that detection of developing kidney damage would be useful.

Evidence-base

The evidence-based diabetes guidelines which address the subject of nephropathy describe the early stages of kidney damage in terms of albumin excretion rate (AER) increasing through 'microalbuminuria' to 'macroalbuminuria' (at which point it equates with proteinuria, 'overt nephropathy') [1-6]. There is general agreement on annual screening, and on the albumin:creatinine ratio (which corrects for urine concentration) as the preferred method of detection, but cut-off values differ somewhat, microalbuminuria being defined as 30 mg/g in the USA [1], 2.0/2.8 mg/mmol (men/women) in Canada [2], and 2.5/3.5 mg/mmol in Europe [3-6], and macroalbuminuria as 300 mg/g, 20/28 mg/mmol, and 30 mg/mmol respectively. Issues surrounding screening tests are reviewed in detail by the NICE Type 2 guideline [4],

with attention drawn to the day-to-day variation in albumin excretion which underlines the need for confirmatory testing. Monitoring of changes in glomerular filtration rate (which are not necessarily in line with changes in albumin excretion) is emphasized in all the guidelines, which recommend serum creatinine measurement, and more recently emphasize the need for calculation of estimated GFR [1,2].

UKPDS provided clear evidence for the benefits of blood glucose control and blood pressure control in delaying the development of kidney disease [7,8]. Other evidence for the importance of blood pressure control in prevention comes from trials of various anti-hypertensive drugs, and evidence continues to emerge in this area (although there will be no more placebo-controlled trials). Choice of agent stems from evidence on the additional benefits of agents which target the renin-angiotensin system in offering renal and cardiovascular (see *Cardiovascular risk protection*) protection, over and above the blood pressure-lowering effect. Both ACE-inhibitors and the newer A2RBs delay progression from micro- to macro-albuminuria in people with Type 2 diabetes and hypertension [1,2,9]. A2RBs have been shown to delay progression of nephropathy in those who have macroalbuminuria and renal insufficiency (serum creatinine >1.5 mg/dl (>130 µmol/l)) [1]. Of the other anti-hypertensive agents which might be used, the ADA cites evidence that dihydropyridine CCBs do not slow progression of nephropathy so should not be used as first-line therapy in nephropathy [1].

Targets for blood pressure have been tightening in diabetes care generally and the advice to treat to tighter targets for those with albuminuria, 130/75 mmHg as against 140/80 mmHg in people with Type 2 diabetes [4], is perhaps now a minority view, with general advice converging towards 130/80 mmHg for all irrespective of AER [1,2,5]. NICE found that reduction of blood pressure to less than 135/75 mmHg reduced the rate of progression of renal disease, with lowest achieved mean blood pressure being 134/75 mmHg in studies showing benefit in people with Type 2 diabetes and albuminuria [4].

The recommendation on treatment of anaemia once GFR starts to decline is supported by the finding in the RENAAL study that mild anaemia is associated with risk of renal disease progression [10].

Cardiovascular risk is increased in people with microalbuminuria, and further increased in those with proteinuria and/or reduced GFR. The issue of cardiovascular risk is addressed elsewhere in this guideline (see *Cardiovascular risk protection*).

Consideration

Although it is possible to treat kidney failure by dialysis or transplantation, availability of these very expensive treatments is severely limited in a global context. This makes efforts at prevention all the more important. It has been estimated that, once a dipstick test is positive, time to kidney failure is about 9 years, but that this time-interval can be doubled through appropriate treatment of blood pressure. The issue of targets can be a particular problem in people with Type 2 diabetes who are often more elderly, and in whom attainment of 140/80 mmHg or less can seem impossible even with multiple drugs and reasonable lifestyle intervention. Nevertheless control around this level has been achieved in a number of studies, implying that around half the population can get to (and thus benefit from) lower levels.

Implementation

Management of blood pressure overlaps with the advice given in *Blood pressure control*. Recurrent measurement and drug dose titration need good access for people with evidence of renal damage, where repeated measurements of potassium and creatinine are particularly important. Additionally the current section requires access to laboratory microalbumin estimation (or availability of semi-quantitative reagent strips), and availability of multiple blood-pressure-lowering drugs and in particular renin-angiotensin system blockers.

Evaluation

The percentage of people with appropriate urine albumin and serum creatinine measurements should be ascertained. Where abnormalities are detected, evidence of action to ensure tight blood pressure control is required, together with achieved blood pressure. Level of eGFR at which referral to nephrologists occurred may also be determined.

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Recommendations

■ Standard care

- FT1 Assess feet of people with diabetes as part of an annual review:
1. history of previous foot ulceration or amputation, symptoms of peripheral arterial disease, physical or visual difficulty in self-foot-care
 2. foot deformity (hammer or clawed toes, bone prominences) and footwear; visual evidence of neuropathy (dry skin, callus, dilated veins) or incipient ischaemia; nail deformity or damage
 3. detection of neuropathy by 10-g monofilament (or 128-Hz tuning fork); a biothesiometer is an option for quantitative assessment (cut-off point for ulcer risk >25 volts); non-traumatic pin-prick
 4. palpation of foot pulses (dorsalis pedis and posterior tibial) and capillary return time; Doppler ankle:brachial pressure ratio (<0.9 for occlusive vascular disease) may be used where pulses are diminished to quantify the abnormality.
- FT2 Discuss the reasons for foot review with each person with diabetes as part of the foot-care educational process.
- FT3 Agree a foot-care plan based on the findings of annual foot review with each person with diabetes.
- Assess and provide necessary foot-care education according to individual need and risks of ulcer and amputation.
- FT4 Classify according to findings:
- No added risk:** if no loss of sensation, no signs of peripheral arterial disease, and no other risk factor.
- At risk:** if neuropathy or other single risk factor.
- High risk:**
- diminished sensation plus foot deformities or evidence of peripheral arterial disease
 - previous ulceration or amputation (very high risk).
- Foot ulceration or infection:** foot ulcer present.

FT5 Manage according to classification level:

No added risk: agree a management plan including foot-care education with each person.

At risk: arrange regular review, approximately 6-monthly, by foot-care team.

At each review:

1. inspect both feet – ensure provision of local management as indicated
2. evaluate footwear – provide appropriate advice
3. enhance foot-care education.

High risk: arrange frequent review every 3-6 months by foot-care team.

At each review:

1. inspect both feet – ensure provision of local management as indicated
2. evaluate footwear – provide advice and specialist insoles and shoes if indicated
3. consider need for vascular assessment or referral
4. evaluate and ensure the appropriate provision of intensified foot-care education.

Foot ulceration or infection (including foot-care emergencies): refer to multidisciplinary foot-care team within 24 hours for:

1. appropriate wound management, dressings and debridement as indicated
2. consideration of systemic antibiotic therapy (often longer term) for cellulitis or bone infection as indicated; generic penicillins, macrolides, clindamycin, and/or metronidazole as indicated as first-line, with ciprofloxacin or co-amoxiclav as examples of second-line drugs
3. optimal pressure distribution (casting if indicated and not contra-indicated), investigation and treatment (referral) for vascular insufficiency
4. probing to bone, radiology and scans, MRI imaging, and biopsy where indicated for suspected osteomyelitis
5. optimal blood glucose control
6. specialist footwear and orthotic care (e.g. insoles), and individualized discussion of prevention of recurrence, when ulcer has healed.

FT6 Do not amputate unless:

1. a detailed vascular evaluation has been performed by the vascular staff
2. ischaemic rest pain cannot be managed by analgesia or revascularization
3. a life-threatening foot infection cannot be treated by other measures
4. a non-healing ulcer is accompanied by a higher burden of disease than would result from amputation.

A specialist foot-care team will include doctors with a special interest in diabetes foot care, people with educational skills, and people with formal training in foot care (usually podiatrists or trained nurses).

■ Comprehensive care

- FT_c1 In general this will be as *Standard care*, but the multidisciplinary foot-care team can be enhanced by on-site inclusion of vascular surgeons, orthopaedic surgeons, orthotists, social workers, and psychologists.
- FT_c2 Foot pressure distribution measurements might be made. Sophisticated vascular scanning and angiography could be available to the foot-care team.

■ Minimal care

- FT_M1 Sensory assessment would be by 10-g monofilament or tuning fork, with or without non-traumatic disposable pin-prick only.
- FT_M2 Antibiotic therapy would be with generic penicillins, macrolides, and/or metronidazole, intravenously for deep tissue infections, and adjusted by response or culture results.
- FT_M3 Vascular assessment would be by peripheral pulses and capillary return times only.
- FT_M4 Vascular referral would be according to findings and local revascularization facilities.

Rationale

Foot ulceration and limb amputation are among the major drivers of impaired health and of health-care costs in diabetes care. While primary prevention of the underlying damage to nerves and vessels is addressed elsewhere in this guideline, secondary intervention in those developing such risk factors can reduce this burden and cost on both the person with diabetes and society.

Evidence-base

Because of the potential for improvement of health and reduction of health-care costs, the evidence surrounding diabetes foot-care has been extensively and formally reviewed many times in recent years [1-10].

The output from these documents is very consistent in suggesting that formal regular review to detect people at risk, more regular review of those found to be at risk, and intensive management of those developing foot ulceration and infection can produce major returns in avoiding the health and monetary costs of amputation. Providing foot-care education for all patients, with increased intensity for those at higher

risk [11], and vascular interventions where critical ischaemia is identified (or is contributing to ulceration), are also common recommendations arising from the evidence-base.

Consideration

There is little controversy over the system and needs of diabetes foot-care provision. Most of the recommendations of formal evidence-based guidelines can be implemented with little modification in situations where minimal health-care funding resources are available, as simply removing shoes and examining feet can usefully save people from becoming disabled and unproductive members of their communities.

Implementation

Appropriate protocols, structured records, and recall systems need to be supported by appropriate training for professionals providing screening and management services. In particular the training and provision of non-medically qualified foot-care assistants (podiatrists or people fulfilling that role) need to be assured. Liaison needs to be established with orthotists and footwear suppliers, and cast

technicians. Facilities for vascular scanning and vascular interventions will be by agreement with vascular surgical staff. Policymakers should be approached to consider the socio-economic burden of diabetes foot problems and assure structural and financial support for preventative strategies.

Evaluation

Evaluation is by annual incidence of foot ulceration, foot hospitalization, foot ulceration healing rates within defined time-periods, and amputation rates at different levels of the limb.

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Recommendations

■ Standard care

- NU1 Diagnose sensorimotor nerve damage by history and examination (monofilament with or without temperature, non-traumatic pin-prick, vibration (tuning fork), ankle reflexes), and/or simple quantitative testing (e.g. vibration perception).
- Use serum B₁₂, thyroid function tests, creatinine/urea, and drug history to exclude other causes.
- NU2 Diagnose symptomatic (painful) diabetic neuropathy by excluding other possible causes of the symptoms.
- Manage by stabilizing blood glucose control, and treatment with tricyclic drugs if simple analgesia is not successful.
- Further treatment options include pregabalin/gabapentin and valproate, then tramadol, duloxetine, and oxycodone. Further management normally requires referral to a pain control team.
- Be aware of the psychological impact of continuing symptoms, particularly if sleep is disturbed.
- NU3 Diagnose erectile dysfunction by history (including drug history), exclusion of endocrine conditions (measure prolactin and testosterone), and a trial of a PDE5 inhibitor (where not contra-indicated by nitrate therapy).
- Consider other approaches such as intra-urethral or intracavernosal drugs and sexual and relationship counselling, where PDE5 inhibitors fail or cannot be used.
- NU4 Diagnose gastroparesis by history, trial of a prokinetic drug (metoclopramide, domperidone), and if troublesome by gastric emptying studies.
- NU5 Diagnose cardiovascular autonomic neuropathy by resting heart rate and heart rate response to provocation tests (lying-standing, Valsalva, deep breathing), and by lying and standing blood pressure.
- Advise anaesthetists when relevant where this is present.

■ Comprehensive care

NU_C1 This would be as for *Standard care*, but screening and diagnostic testing could also include a programme of quantitative sensory testing (vibration and temperature), electrophysiology, and autonomic function tests.

■ Minimal care

NU_M1 Screen and diagnose sensorimotor nerve damage by history of symptoms, and sensory assessment by 10-g monofilament or tuning fork with/without non-traumatic disposable pin-prick (as *Foot care*), and ankle reflexes.

NU_M2 Manage symptomatic (painful) diabetic neuropathy by excluding other causes, stabilizing glycaemic control, and treatment with tricyclic drugs if simple analgesia is not successful. Opiate analgesia may be necessary as locally available.

NU_M3 Assess erectile dysfunction by history and examination, to consider possible contributions of other medication or disease.

Rationale

Neuropathy (nerve damage) is a common late complication of Type 2 diabetes. It contributes not only to foot problems (see *Foot care*) but also to a range of troublesome symptoms including pain/paraesthesiae and (where the autonomic nervous system is involved) gastro-intestinal, bladder and sexual problems. New therapeutic options have emerged in recent years.

Evidence-base

Aspects of neuropathy which do not relate directly to foot care have received less attention in evidence-based guidelines [1-4], and some divergence in recommendations can be accounted for by recently emerging evidence on treatment options for painful neuropathy [5,6]. There is general agreement that stabilizing glycaemic control is important in the medium and longer term, and that tricyclic drugs should be used as first-line therapy for painful neuropathy, although side-effects are common.

Exclusion of non-diabetic causes of neuropathy is important because these may account for 10 % of cases of neuropathy in people with diabetes [7]. The range of tests available in clinical and research settings is detailed in two technical reviews [8,9].

Erectile dysfunction is addressed by three of the guidelines, which draw on evidence from Type 1 as well as Type 2

diabetes [1-3]. They conclude that the condition is rarely of simple causation, that it is important to consider the possible contribution of other medications and medical conditions, but that the expensive PDE5 inhibitors are worth a trial.

The evidence-base on some of the rarer aspects of autonomic neuropathy is weak, including that for gastroparesis, and cardiovascular parasympathetic autonomic neuropathy. In general, other guidelines have relied on conventional wisdom in making recommendations over the management of gastroparesis, orthostatic hypotension, bladder dysfunction, and nocturnal diarrhoea.

Consideration

The costs of newer therapies were felt to argue against their use in situations where resources could be better directed to prevention by measures aimed at improving and stabilizing glycaemic control. A limited number of tests were felt to be appropriate in the clinical setting, but the practice generally recommended in this area simply follows established medical lines.

Implementation

Appropriate protocols should be developed for sensory testing. Recommended drugs should be available according to level of resources. Medical teams need to remain trained in the diverse manifestations of autonomic neuropathy.

Evaluation

Evidence should be available of records of regular surveillance for neuropathic symptoms, usually as part of direct questioning in programmed annual review. Where appropriate, record should also be available of direct questioning for erectile dysfunction. The availability of simple equipment for surveillance, and of drug supplies, can be evaluated.

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Whenever pregnancy is complicated by diabetes, close liaison between health-care professionals involved in diabetes, obstetric and neonatal care will help to achieve the desired outcome of a healthy mother and baby.

This guideline only addresses areas of pregnancy care commonly affected by the co-existence of diabetes, and not routine obstetric care such as fetal scanning and monitoring.

Recommendations

■ Standard care

Pre-pregnancy counselling

- PR1 Identify possibility of pregnancy annually by direct questioning in all fertile women of child-bearing age with diabetes. Provide contraceptive advice where appropriate.
- PR2 Offer pre-pregnancy advice to all women so identified, including as appropriate:
- education on the management of pregnancy with diabetes
 - optimization of blood glucose control (pre-conception target DCCT-aligned $\text{HbA}_{1c} < 6.1\%$)
 - stopping oral glucose-lowering drugs (metformin may still be indicated), and starting insulin where appropriate
 - optimization of blood pressure control (to $< 130/80$ mmHg)
 - stopping ACE-inhibitors and A2RBs (use methyldopa, nifedipine MR, labetalol)
 - stopping statins and fibrates
 - assessment of eye and kidney damage (see *Eye screening, Kidney damage*); discuss and manage identified problems
 - assessment of thyroid function
 - advice on alcohol and smoking
 - folic acid therapy.

Screening for undiagnosed or new (gestational) diabetes in pregnancy

- PR3 In women at high risk of diabetes (previous gestational diabetes, obesity – especially abdominal obesity, population with high prevalence of diabetes) provide healthy lifestyle advice (nutrition and physical activity) from first pre-natal visit; check for hyperglycaemia at first pre-natal visit; perform 75-g OGTT [1] if indicated.
- PR4 In all women, measure plasma glucose at first visit after week 20 (24-28 weeks in low risk women); perform 75-g OGTT if abnormal.

- PR5 Manage as diabetes if fasting plasma glucose ≥ 7.0 mmol/l (>125 mg/dl) and/or 2-h plasma glucose ≥ 7.8 mmol/l (≥ 140 mg/dl).

Management during pregnancy

- PR6 Review understanding of management of diabetes in pregnancy, current drug therapy (see PR2), blood glucose control, diabetes complications, and presence of other medical conditions. Advise as appropriate.
- PR7 Examine eyes at first pre-natal visit and each trimester.
- PR8 Offer medical nutrition therapy and education. If overweight, advise a diet suitable for someone of optimal weight. Encourage moderate exercise such as walking.
- PR9 Review frequently, depending on achievement of blood glucose control targets, and management of other diabetes-associated and obstetric problems.
- PR10 Aim for DCCT-aligned HbA_{1c} < 6.0 %, or lower if safely achievable, using self-monitoring of blood glucose to 3.3-6.7 mmol/l (60-120 mg/dl), four times daily (pre-breakfast and 1-2 h after each meal), and insulin therapy if indicated.
- PR11 Manage insulin therapy through careful and intensive self-monitoring and dose adjustment, expecting a rise in insulin requirements as pregnancy proceeds. Insulin requirements may be further disturbed by hyperemesis or use of steroid therapy, and in-patient care may be needed.
- PR12 Monitor weight gain and blood pressure and advise/treat accordingly. Blood pressure should be $< 130/80$ mmHg, avoiding the use of renin-angiotensin system blocking drugs.

Labour and delivery

- PR13 Use intravenous insulin (if on insulin or if needed) during labour.
- PR14 Anticipate changed insulin requirements, and thus need for more frequent glucose monitoring, if continuing insulin postpartum and during lactation.
- PR15 Provide appropriate care and facilities for the newborn.
- PR16 At 45 to 60 days after pregnancy, check for diabetes in women who had developed new diabetes in pregnancy. If then non-diabetic, advise on the high risk of future diabetes, and preventative lifestyle measures. Advise check for diabetes annually.

■ Comprehensive care

- PR_C1 This would be as *Standard care* for screening, except that screening for new diabetes after week 20 might go direct to OGTT in situations with high prevalence and where health facilities are available.
- PR_C2 Specialist ophthalmological review can be offered throughout pregnancy.
- PR_C3 Personal dietetic support and fitness training can be offered throughout pregnancy.
- PR_C4 Self-monitoring of capillary blood glucose during pregnancy would be performed more frequently, at times of likely peak and trough plasma glucose concentrations. Continuous glucose monitoring would be a further possibility.
- PR_C5 HbA_{1c} will be performed at each clinical contact.
- PR_C6 Insulin delivery might be optimized by the use of continuous subcutaneous insulin infusion.

■ Minimal care

- PR_M1 Most of the procedures under *Standard care* can be offered by a specially trained health-care worker.
- PR_M2 If laboratory glucose testing is not easily available, capillary blood glucose measurement for fasting and 2-h OGTT estimation can be substituted, using a trained operator and a regularly validated meter system.
- PR_M3 Where resources allow only very limited access to self-monitoring of blood glucose, use in pregnant women should be a priority.
- PR_M4 If insulin availability is problematic, consider oral glucose-lowering drugs (not PPAR- γ agonists), with the proviso that safety in pregnancy is not fully established.

Rationale

With increasing numbers of women around the world developing Type 2 diabetes, and doing so at a younger age, and with women in many cultures tending to delay starting a family, the issue of diabetes complicating pregnancy has become increasingly important. These guidelines do not address prevention of Type 2 diabetes, so the increased risk of later development of diabetes in those who experience gestational diabetes (GDM) is not our principal concern here. We focus rather on the care of women with new diabetes in pregnancy, as well as the care of those who already have Type 2 diabetes. Although management of diabetes in pregnancy has been improving, women and their infants remain at higher risk for a number of complications

compared with non-diabetic pregnancy. The frequency of congenital anomalies is still high among infants of women with diabetes.

Evidence-base

The evidence-base for much diabetes pregnancy management is poor, and relies on some cohort studies, an occasional RCT, some retrospective analysis, and considerable clinical experience. Much of the data pertaining to Type 2 diabetes derives from people with Type 1 diabetes or studies of mixed populations. The only guideline formally addressing the area (Type 2 diabetes) is the Canadian guideline (in which most of the recommendations are consensus) [2], though consensus guidelines based on non-formal evidence review were also

prepared by IDF (Europe) [3]. The SIGN guideline [4] includes pregnancy, focusing on Type 1 diabetes, while ADA standards of care include pre-conception care and screening for diabetes in pregnancy [5].

Screening for GDM (defined as glucose intolerance of variable severity with onset or first recognition during pregnancy – which will include undiagnosed Type 2 diabetes) is a controversial issue (and the ongoing HAPO study may help here) [2]. Whether or not, and whom, to screen is likely to depend on prevalence of Type 2 diabetes in women of child-bearing age in the population under consideration; it is difficult therefore to develop universally appropriate recommendations. GDM is an asymptomatic condition most of the time, and there has been no RCT to test the effectiveness of its detection. Diagnostic and management levels remain uncertain. Cohort studies have shown increased risk of adverse outcomes according to levels of plasma glucose, independently of age, obesity and other risk factors. RCTs have shown that treatment of hyperglycaemia in pregnancy reduces macrosomia. The Canadian guideline recommends all pregnant women be screened for GDM between weeks 24 and 28 [2], while different strategies are outlined in other guidelines which address this [4,5,6]. A recent paper has supported the utility of detecting and managing GDM [7].

The guidelines present a confusing picture as regards screening tests for GDM. The use of a 4.7 mmol/l (85 mg/dl) cut-off for fasting plasma glucose is suggested from two analyses [8,9], but other studies have suggested higher cut-offs. Fasting glucose may not be the most appropriate measure, however, and the 75-g OGTT (fasting and 2-h values) advocated by WHO [1] is increasingly used internationally, as noted in a Brazilian study [10].

The Canadian and IDF (Europe) guidelines note the importance of blood glucose control in the first trimester for avoidance of fetal malformation, and the adverse effects of hyperglycaemia throughout pregnancy. Insulin is regarded as the natural means of improving blood glucose control in pregnancy where lifestyle measures fail, although metformin is increasingly regarded as safe. Frequent self-monitoring of blood glucose is a normal part of insulin therapy, in particular where insulin requirements are changing as in pregnancy, and where stricter targets may lead to increased risk of serious hypoglycaemia [2]. Special considerations surrounding labour and delivery have been reviewed recently [11].

Experience with rapid-acting insulin analogues has been reassuring for insulin lispro although no formal trials are available [12]. Experience with long-acting insulin analogues

is still very thin [2], and unless other clear advantage is apparent (previous major gain in blood glucose control over NPH insulin-based regimens) they are not generally used in pregnancy. Use of oral glucose-lowering drugs is still controversial, and mostly derives from experience of widespread use in some developing countries and in polycystic ovarian syndrome (see Canadian guideline [2]), but this mostly applies to glyburide and to metformin. Newer drugs are therefore assumed to be contra-indicated.

Consideration

Despite the poor evidence-base, it is clear that the consequences of poor management of diabetes in pregnancy (high risk of maternal and neonatal complications, dead and deformed babies) are such that this is a prime area where investment of health-care resources is appropriate. Furthermore, considerable consensus exists over the need for continued monitoring of complications for acceleration of diabetes-induced damage, and the early use of insulin therapy to tight targets backed by self-monitoring. While the issue of methods and schedules for screening for new-onset diabetes in pregnancy is diverse and confused, the need for detection is not in dispute, and again there is clear consensus that the OGTT in some form has an important role, and that tight blood glucose management in those testing positive is indicated. Some other areas of care, such as the need for folic acid supplementation, and the high risk of future diabetes in those remitting from diabetes after delivery, also seem secure. A particularly difficult issue relates to the use of oral glucose-lowering drugs during pregnancy in places where insulin supply is tenuous, and Type 2 diabetes in pregnancy common. However, while it is nearly impossible to exclude a low incidence of adverse effects (<1 in 100), the potential gain – if this (glyburide/metformin) is the only means of improving glucose control – would seem to be higher.

Implementation

Liaison with obstetric colleagues is a first step in implementation of these recommendations, such that joint protocols can be devised for screening for diabetes, and for pregnancy and post-pregnancy management. Health-care professionals need to be trained on pregnancy-specific lifestyle adaptation, insulin use, and complications screening. Availability of such staff needs to be assured. Where resources are scarce, the availability of insulin and self-monitoring equipment may need to be prioritized to this area, and supplies assured. Laboratory resources for clinical monitoring of glucose control and assessment of renal damage should be provided. Pre-pregnancy services may need to be organized separately.

Evaluation

Monitoring of outcome of diabetic pregnancy (healthy and unhealthy neonates) may seem logical, but because of small number problems is not a powerful tool of quality assurance. Investigation of each neonatal death may be more useful. Delivery weight of the infant and achieved maternal HbA_{1c} in each trimester are useful surrogate outcomes. Structural review should be of the existence of joint management protocols addressing the above recommendations, and appropriate availability of staff.

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Recommendations

■ Standard care

CH1 Diagnose symptomatic children using plasma glucose and WHO 1999 criteria [1].

CH2 Attempt to assign type of diabetes, using history and physical examination, including weight, BMI, urine ketones, pH, electrolytes.

When the diabetes appears to be Type 2 diabetes, remain alert to the possibility and associated risks of Type 1 diabetes or MODY.

Where differentiation is uncertain, islet-cell related antibodies and C-peptide estimation may add further information.

CH3 Provide initial care appropriate to age and developmental stage, including lifestyle counselling, diabetes education with the family, blood glucose monitoring, management with insulin or oral agents (metformin) according to clinical features, and psychological assessment.

CH4 Provide continuing care and support including:

- lifestyle measures in the context of the family
- self-monitoring of blood glucose, with attention to continuity from the management team, and to ensure care for diabetes at school
- HbA_{1c} every 2-6 months (see *Clinical monitoring*).

CH5 Arrange annual surveillance including weight and height, BMI, blood pressure, urine protein and albumin, eye review.

■ Comprehensive care

CH_c1 Screening might also be extended to asymptomatic children who are at high risk in the particular population (criteria might include BMI, family history, age, race/ethnicity, insulin resistance as evidenced by acanthosis nigricans).

CH_c2 Attempts to assign the type of diabetes after diagnosis could also include more routine testing for islet-cell related antibodies and C-peptide, and HNF and glucokinase genotyping.

CH_c3 Initial care will be as for *Standard care*, while continuing care may also include routine psychosocial support; ongoing surveillance may include lipid profile.

■ Minimal care

CH_M1 Diagnose symptomatic children by urine glucose or capillary plasma glucose.

CH_M2 Attempt to assign type of diabetes by history and physical examination assessing weight, BMI, blood pressure, and urine ketones.

CH_M3 Initial care should include lifestyle information, diabetes education with the family, monitoring of blood glucose, and management with insulin and/or metformin according to clinical features.

CH_M4 Provide continuing care including:

- lifestyle measures in the context of the family
- advice to the school on dealing with emergencies and avoiding discrimination.

CH_M5 Surveillance will include weight, height, BMI, blood pressure, urine protein, and eye review.

Rationale

Type 2 diabetes in children is increasing in many populations around the world. Affected children may have a positive family history of Type 2 diabetes, and in most cases the BMI is above the 85th percentile for gender and age, defined as overweight. However, this is not universal, notably in some Asian and Oriental populations. Overweight in childhood is associated with poverty in relatively developed areas but with affluence in developing areas of the world. Type 2 diabetes in children is a severe disease with very poor outcomes over 10-20 years. It is associated with significant islet B-cell failure as well as insulin resistance, and is at least as demanding to manage as Type 1 diabetes in children. Children with Type 2 diabetes are more at risk of hypertension, dyslipidaemia and polycystic ovarian syndrome than those with Type 1 diabetes.

Evidence-base

It is only relatively recently that the emergence of Type 2 diabetes in children has been recognized. In European populations Type 1 diabetes remains the predominant form in children, but in Japanese populations 80 % of childhood diabetes is Type 2 diabetes, and the condition is increasing in incidence and prevalence in many parts of the world. It is usually diagnosed after the age of 10 yr, in mid- to late-puberty, with the reduced insulin sensitivity of puberty

apparently playing a role [2]. The evidence-base remains limited, and only the Canadian guideline deals specifically with the condition [3]. There is a NICE guideline on Type 1 diabetes in children, and this refers briefly to the need to distinguish children with Type 2 diabetes [4]. Many of the global issues, and the paucity of evidence, were considered at an IDF meeting in 2003 [5], while the topic has been addressed in a number of US publications [6-10].

Use of adult diagnostic criteria [1] reflects lack of other evidence and the problems of staging and normative values in the 10- to 13-year age group. The Canadian guideline states that insulin is required when there is severe metabolic decompensation at diagnosis (ketoacidosis, HbA_{1c} ≥9.0 %, symptoms of severe hyperglycaemia); otherwise the recommended initial treatment is intensive lifestyle intervention, adding metformin as first-line therapy if glycaemic targets are not achieved [3]. An algorithm devised by Silverstein and Rosenbloom in a review of North American practice [6] suggests that in those started on insulin (plus lifestyle) achievement of a DCCT-aligned HbA_{1c} <7.0 % allows tapering of insulin dose with addition of metformin, and attempts to 'wean off' insulin. However, the evidence-base for treatment is very limited, with data on insulin use mainly from Type 1 diabetes. The Canadian guideline cites evidence for efficacy and safety of metformin (over 16 weeks) in adolescents with Type 2 diabetes, and draws attention to the contra-indications in the case of kidney or liver disease [3].

The gastro-intestinal side-effects of metformin are poorly tolerated by children and adolescents, yet other oral glucose-lowering options have barely been explored.

Recommendations on surveillance for complications reflect evidence on microvascular complications in Pima Indian and Japanese populations, cited in the Canadian guideline [3]. The risks of pregnancy in this age-group need to be borne in mind in relation to drug therapy.

Consideration

Health-care professionals dealing with children need to be alert to the possibility of Type 2 diabetes, and aware of the seriousness of the condition. Most of these children are overweight at diagnosis, and most are in families with others who are overweight and at risk of Type 2 diabetes, so advice on lifestyle modification can usefully involve the whole family.

Implementation

A continuing integrated package of care should be offered by a multidisciplinary paediatric diabetes team, trained in the difficult area of distinguishing Type 2 diabetes in children, outlining the pathways of care, and dealing with the possibility of multiple medication. Structured records and recall systems are essential, as is the need to address the transition to adult diabetes care services.

Evaluation

Systematic evaluation of an emerging epidemic will include, at all levels, numbers of patients, medications given, and complications at diagnosis. Standard care should also include documentation of BMI, glycaemic control, and complications on follow-up, while comprehensive care should additionally evaluate efficacy of treatment, cost, and criteria used for diagnosis.

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Recommendations

■ Standard care

In-patient care organization

- HO1 Designate a diabetes-trained health-care professional to:
- manage and co-ordinate systems of care related to diabetes management of in-patients
 - co-ordinate training of hospital staff in awareness of the needs of people with diabetes
 - implement strategies to prevent disempowerment of those who could self-manage their diabetes
 - plan for discharge and follow-up.
- HO2 Provide access for people with diabetes and hospital staff to a multidisciplinary diabetes team.
- HO3 Ensure laboratory/service support for:
- assays including plasma glucose, HbA_{1c}, basic haematology and biochemistry, lipid profile and hormone assays
 - microbiological investigation
 - radiology and other imaging.

General ward care

- HO4 Encourage self-management of diabetes (food choice, self-monitoring, insulin dose adjustment where appropriate) integrated into usual ward care.

Management during in-patient procedures

- HO5 Evaluate blood glucose control, and metabolic and vascular complications (in particular renal and cardiac status) prior to planned procedures; provide advice on the management of diabetes on the day or days prior to the procedure.
- HO6 Ensure the provision and use of an agreed protocol for in-patient procedures and surgical operations.
- HO7 Aim to maintain near-normoglycaemia without hypoglycaemia by regular quality-assured blood glucose testing and intravenous insulin delivery where needed, generally using a glucose/insulin/potassium infusion.

- HO8 Ensure awareness of special risks to people with diabetes during hospital procedures, including risks from:
- neuropathy (heel ulceration, cardiac arrest)
 - intra-ocular bleeding from new vessels (vascular and other surgery requiring anticoagulation)
 - drug therapy (risks of acute renal failure causing lactic acidosis in people on metformin, for example with radiological contrast media).

Critical care situations

- HO9 Provide access to intensive care units (ICU) for life-threatening illness, ensuring that strict blood glucose control, usually with intravenous insulin therapy, is a routine part of system support for anyone with hyperglycaemia.
- HO10 Provide protocol-driven care to ensure detection and immediate control of hyperglycaemia for anyone with a presumed acute coronary event or stroke, normally using intravenous insulin therapy with transfer to subcutaneous insulin therapy once stable and eating.

Comprehensive care

- HO_c1 General principles are as for *Standard care*, but would include repeated review by a diabetes specialist where general health state is changing or glucose control is problematic.
- HO_c2 Use telematic review of blood glucose control to a specialist's office for people in critical situations.
- HO_c3 Maintain staff trained in aspects of diabetes management on any ward or procedure area with a significant throughput of people with diabetes.

Minimal care

- HO_m1 General principles are as for *Standard care*, but hospitals should designate an individual in charge of matters relating to in-patient diabetes, to co-ordinate training in awareness of the needs of, and provision of in-patient care to, people with diabetes, and the provision and use of guidelines and protocols.
- HO_m2 Laboratory assays should include plasma glucose and basic biochemistry; basic radiology should be available.
- HO_m3 Management of plasma glucose levels during in-patient procedures will generally be as for *Standard care*. Where this is impossible or carries special risk, frequent intramuscular insulin with frequent monitoring may be useful in emergency situations, or frequently monitored subcutaneous insulin therapy (e.g. with NPH insulin) for minor procedures or more stable health states.

Rationale

Hyperglycaemia is found, and requires management, in hospital settings not only in people with known diabetes but also in people with previously unrecognized diabetes and in people with hospital-related hyperglycaemia which reverts to normal after discharge. Prevalence of diabetes in hospitalized adult patients is 12-25 % or more [1]. Hospital care for people with diabetes may be required for metabolic emergencies, in-patient stabilization of diabetes, diabetes-related complications, intercurrent illnesses, surgical procedures, and labour and delivery (see *Pregnancy*).

Evidence-base

Recent growth in the literature on hospital hyperglycaemia is reflected in the inclusion of sections on in-patient management in diabetes guidelines. The 2005 ADA standards have added a section on diabetes care in the hospital [1], drawing on a technical review [2] and the position statement of the American College of Endocrinology (ACE) [3]. The Canadian guidelines include separate sections on peri-operative and peri-acute coronary syndrome glycaemic control [4]. NICE reviewed evidence from people with Type 2 diabetes when developing recommendations for in-patient care in Type 1 diabetes [5].

The recent ACE position statement was based on a review of the literature on in-hospital hyperglycaemia [3]. They found multiple studies confirming that hospitalized patients with hyperglycaemia suffer significant excess mortality and morbidity, prolonged length of stay, unfavourable post-discharge outcomes, and significant excess health-care costs. They found RCTs as well as prospective observational and retrospective studies demonstrating improved outcomes (mortality, infection, intubation time, length of hospital stay) resulting from more aggressive treatment of hyperglycaemia. They strongly support the need for early detection of hyperglycaemia in the hospital and an aggressive management approach to improve outcomes.

ACE propose upper limits for blood glucose targets (ICU 6.1 mmol/l (110 mg/dl); non-ICU 6.1 mmol/l pre-prandial, 10.0 mmol/l (180 mg/dl) maximum), with the proviso that those for non-intensive care patients are less well supported by the evidence. They list indications for intravenous insulin infusion therapy (critical illness, prolonged nil-by-mouth status in insulin-deficient patients, peri-operative period, post transplantation, total parenteral nutrition therapy, elevated glucose exacerbated by high-dose glucocorticoid therapy, stroke, dose-finding prior to subcutaneous (SC) insulin injections, other illnesses requiring

prompt glucose control). For SC insulin they discourage the use of sliding scales. They found some evidence for a diabetes team approach (reduced length of stay, fewer re-admissions).

The Canadian guidelines also make recommendations on blood glucose levels, emphasizing tight control (4.5-6.0 mmol/l, 80-110 mg/dl) for post-operative ICU patients if random plasma glucose >6.1 mmol/l (>110 mg/dl) [4]. They found strong evidence for recommending that all patients with acute MI and blood glucose >12.0 mmol/l (>215 mg/dl) should receive insulin-glucose infusion therapy to maintain blood glucose between 7.0 and 10.0 mmol/l (125-180 mg/dl) for at least 24 h, followed by multi-dose SC insulin for at least 3 months.

Neither ACE nor the Canadian guideline addresses the issue of oral glucose-lowering drugs in the hospital setting, but the ADA [1] draws attention to limitations for in-patient use (especially with regard to flexibility) of the major classes. For metformin, the fact that many specific contra-indications (related to risks of renal impairment) to its use are found in the hospital setting was seen as limiting its use. For thiazolidinediones haemodynamic changes were felt to be an issue, and for sulfonylureas risk of hypoglycaemia.

One cost study, cited by ACE, found cost per QALY for intravenous insulin therapy in patients with acute myocardial infarction to be comparable to that for other well-accepted medical interventions.

NICE additionally notes the utility and importance of a holistic approach, using the skills and knowledge of a person with diabetes developed over years or decades [5].

Consideration

It was considered important that hospitals should designate a 'diabetes lead' individual, who would be in charge of matters relating to diabetes, and could co-ordinate training of staff in awareness of the needs of those with diabetes, and develop strategies to prevent disempowerment of those who could self-manage their diabetes. Major considerations were that diabetes should not complicate the management of whatever condition resulted in admission to hospital, and that a person's diabetes should not emerge from hospital worse than when they were admitted. While the evidence over use of protocol-driven intravenous insulin regimens is not conclusive, the widespread and general adoption of these regimens globally appears telling (for more detail of methods see references 6, 7).

Implementation

Systems of care and protocols need to be put in place and staff trained to ensure their effectiveness. Standardized protocols, developed by multidisciplinary teams, should specify insulin dose, include guidelines for identifying patients at risk for hypoglycaemia, and actions to be taken to prevent and treat hypoglycaemia. Bedside glucose monitoring requires defined administrative responsibility, a procedure manual, training, policies regarding frequency (hourly to twice-daily) and procedures for alert values, quality control, and regular maintenance of equipment.

Evaluation

Evaluation should consider evidence of the availability of trained staff (and training courses) and of protocols as above. Audit can be made of ward blood glucose control, and blood glucose control during surgery, after myocardial infarction and in intensive care. Admissions to coronary care can be reviewed to ensure measurement of blood glucose is occurring, and appropriate actions are then taken while in the unit and during follow-up.

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Acronyms and abbreviations

A2RB	angiotensin-II receptor blocker
ACE	American College of Endocrinology
ACE-inhibitor	angiotensin converting enzyme inhibitor
ACR	albumin:creatinine ratio
ADA	American Diabetes Association
AER	albumin excretion rate
BMI	body mass index
BP	blood pressure
CCB	calcium-channel blocker
CCT	controlled clinical trial
CDA	Canadian Diabetes Association
CV	cardiovascular
CVD	cardiovascular disease
DCCT	Diabetes Control and Complications Trial
DSME	diabetes self-management education
eGFR	estimated glomerular filtration rate
FPG	fasting plasma glucose
GDM	gestational diabetes
Hb	haemoglobin
HDL	high density lipoprotein
HNF	hepatocyte nuclear factor
HPLC	high-performance liquid chromatography
ICSI	Institute for Clinical Systems Improvement
ICU	intensive care unit
LDL	low density lipoprotein
MI	myocardial infarction
MNT	medical nutrition therapy
MODY	maturity-onset diabetes of the young
MRI	magnetic resonance imaging
NICE	National Institute for Clinical Excellence (England and Wales)
NPH	neutral protamine Hagedorn
OGTT	oral glucose tolerance test
PCR	protein:creatinine ratio
PDE5	phosphodiesterase type-5
QALY	quality-adjusted life year
RCT	randomized controlled trial
SC	subcutaneous
SIGN	Scottish Intercollegiate Guidelines Network
SMBG	self-monitoring of blood glucose
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization

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Revised SEMDSA Guidelines for diagnosis and management of type 2 diabetes mellitus for primary health care in 2002.

CRITERIA FOR THE DIAGNOSIS OF DIABETES MELLITUS

Symptoms of diabetes **plus**:
 casual plasma glucose concentration ≥ 11.1 mmol/l. ¹
OR
 Fasting plasma glucose ≥ 7.0 mmol/l.²
OR
 2-h PG ≥ 11.1 mmol/l during an OGTT.³

1. Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia and unexplained weight loss.
2. Fasting is defined as no caloric intake for at least 8 hours.
3. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

Note: In the absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria **should be confirmed by repeat testing** on a different day. The oral glucose tolerance test (OGTT) is not recommended for routine clinical use but as many as 30% of people with diabetes will not be diagnosed if only fasting measurements are done. Different criteria are used to diagnose gestational diabetes in pregnant women.

RECOMMENDATIONS FOR GLYCAEMIC CONTROL*

Biochemical Index	Optimal	Acceptable	Additional Action Suggested ¹
Capillary blood glucose values (finger-prick)²			
Fasting (mmol/l)	4-6	6-8	> 8
2-hour post-prandial (mmol/l)	4-8	8-10	> 10
Glycated hemoglobin (HbA_{1c}) (%)	< 7	7-8	> 8
Weight			
BMI (kg/m ²)	< 25		> 27 ³
Waist circumference (cm): Male	< 94		>102
Female	< 82		>88

*These values are for nonpregnant adults.

1. "Additional action suggested" depends on individual patient circumstances. Such actions may include enhanced diabetes self-management education, co-management with a diabetes team, referral to an endocrinologist/diabetologist, change in pharmacological therapy, initiation or increased self-monitoring of blood glucose, or more frequent contact with the patient. HbA_{1c} is referenced to a nondiabetic range of 4.0 – 6.0%. Note that often action should ideally be instituted before these levels are reached.
2. Preferably assessed over several visits.
3. In the presence of diabetes mellitus (DM) this level is 27 and not 30.

LIPID AND BLOOD PRESSURE GOALS (For nonpregnant adults)	
Blood Pressure (mmHg)	Lipids (mmol/l)
Systolic < 130 Diastolic < 80	Total-cholesterol < 5.0 LDL-cholesterol \leq 3.0 ¹ HDL-cholesterol > 1.2 Triglycerides < 1.5
<u>If persistent dipstick proteinuria (macroalbuminuria)</u>	
Systolic < 120 Diastolic < 70	

1. American National Cholesterol Education Program (NCEP) III recommends a level of < 2.6 mmol/l, especially in the presence of existing vascular disease (stroke, peripheral vascular disease, and ischaemic heart disease).

KEY TESTS / EXAMS (all initially)	
Test / Exam	Frequency
Glycated hemoglobin	<ul style="list-style-type: none"> Quarterly if treatment changes or not meeting goals At least 2 times/year if stable
Dilated eye exam	Yearly
Comprehensive foot exam	At least yearly (more often in patients with high-risk foot conditions)
Lipid profile	Yearly (less frequently if normal)
Serum creatinine level	Yearly
Microalbumin measurement	Yearly if no persistent dipstick proteinuria (macroalbuminuria)
Blood pressure	Each regular diabetes visit
BMI (body mass index) & waist circumference	Initially and weigh at each regular diabetes visit
ECG	Yearly if possible

Patient education and nutritional counseling

This is the cornerstone of effective diabetes care and sufficient time and resources should be made available in order to do this effectively. As obesity virtually always accompanies type 2 diabetes it should be targeted in its own right. A weight loss of 5-10% should be the initial aim and as such has been shown to improve insulin resistance and all its associated parameters. Evidence demonstrates that structured, intensive lifestyle programs involving participant education, individualized counseling, reduced dietary fat and energy intake, regular physical activity and frequent participant contact are necessary to produce long-term weight loss of >5% of starting weight.

Glucose Treatment Recommendations for type 2 DM.

1. Always provide or refer for dietary and lifestyle advice at diagnosis and regularly (as often as possible, at least annually) thereafter.
2. If random glucose values > 15 mmol/L consider starting oral agents together with lifestyle modification from the start.
3. If overweight (BMI > 25) consider metformin unless contra-indicated.
4. If postprandial glucose values constitute the major abnormality or sulphonylureas contra-indicated (e.g. renal failure) acarbose or meglitinides may be considered.
5. If insulin resistance is the major abnormality (abdominal obesity [see waist circumference above], lowered HDL, raised triglycerides, hypertension) metformin should be considered as first line or add on therapy. If metformin contra-indicated or poorly tolerated (e.g. raised serum creatinine or major cardio-pulmonary) then thiazolidinediones may be used.
6. Always start with monotherapy and titrate dosage to maximum over 1-3 months.
7. If goals still not reached then add second agent (lowest dose, titrate when necessary).
8. If goals still not attained despite good compliance and absence of major stressors such as infection consider insulin therapy.
9. In such cases insulin therapy may be initiated as intermediate or long acting insulin at bedtime (titrate against pre-breakfast reading) with or without oral agents. If possible self glucose monitoring should be done in all patients on insulin.
10. Initial insulin dose is 0.2-0.3 U/kg.
11. If more than 30 U per day are required or clinical judgment indicates, use twice daily biphasic insulin (2/3 intermediate, 1/3 short acting). Consider referral.

Blood pressure treatment recommendations.

1. If possible and affordable therapy should be angiotensin converting enzyme (ACE) inhibitor based.
2. Low dose diuretics (eg. hydrochlorothiazide (HCTZ) 12.5mg or Indapamide 1.25 -2.5 mg/day) may be appropriate first line agents in black patients and second line agents in others.
3. Many, if not most, patients will require at least 2 agents to control blood pressure.
4. In the presence of micro- or macroalbuminuria ACE inhibitors or angiotensin II receptor antagonists are of proven benefit.
5. In patients over age 55 yrs with hypertension (HT), or without HT but with another cardiovascular risk factor (history of coronary vascular disease, dyslipidaemia, microalbuminuria, smoking) an ACE inhibitor (if not contra-indicated) should be considered to reduce the risk of cardiovascular events.

Aspirin recommendations.

Use aspirin therapy as a secondary prevention strategy in individuals who have evidence of large vessel disease (a history of myocardial infarction, vascular bypass procedure, stroke or transient ischaemic attack, peripheral vascular disease, claudication, and/or angina).

In addition to treating the primary cardiovascular risk factor(s) identified, consider aspirin therapy as a primary prevention strategy in high-risk men and women with type 1 or type 2 diabetes. This includes diabetic subjects with the following: a family history of coronary heart disease, cigarette smoking, hypertension, obesity, albuminuria (micro or macro), age >30 years or dyslipidaemia.

Use of aspirin has not been studied in diabetic individuals under the age of 30 years.

1. Use 150-300 mg aspirin per day (enteric coated if possible).
2. People with aspirin allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy.
3. Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population.

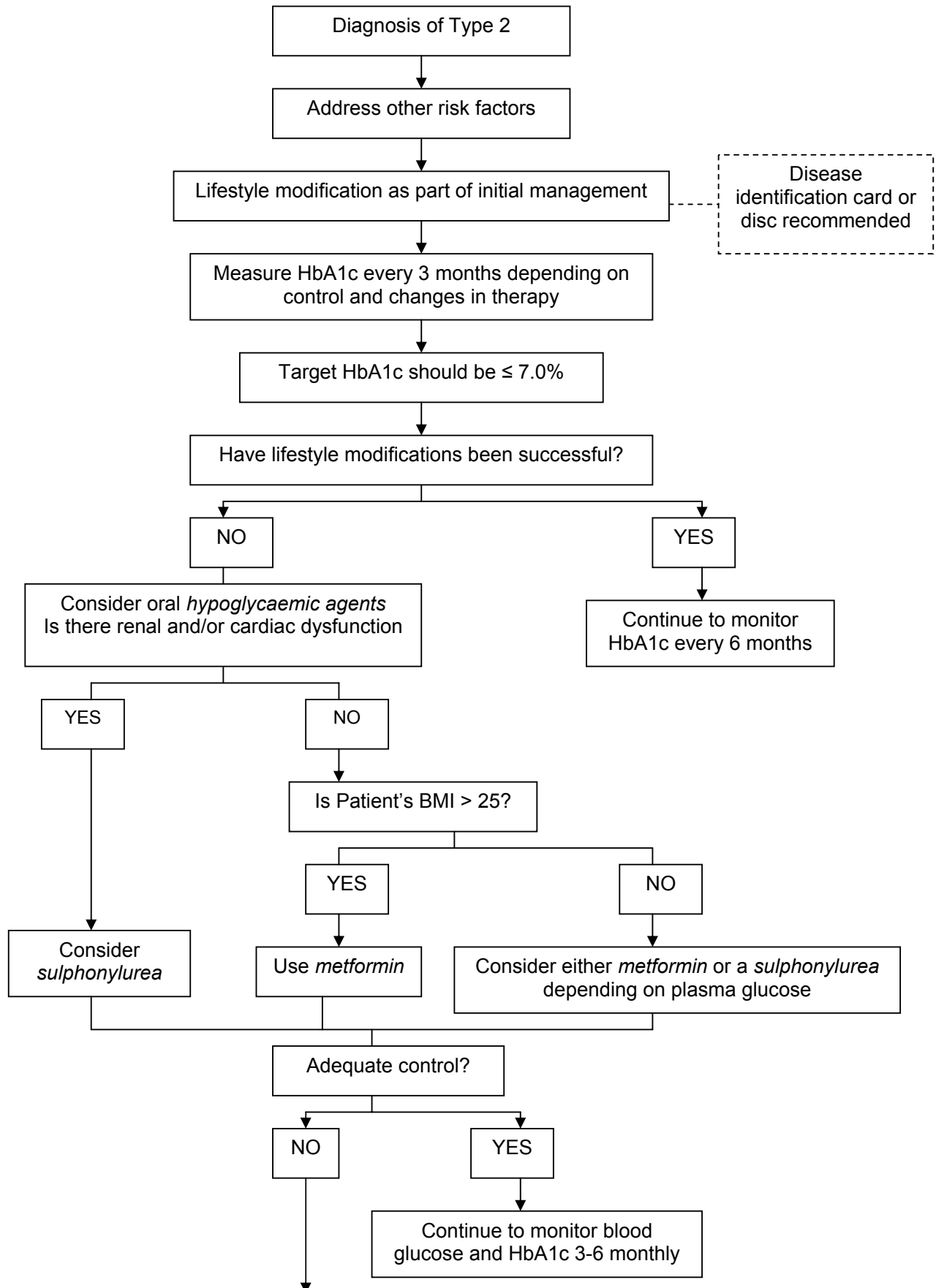
Lipid treatment recommendations.

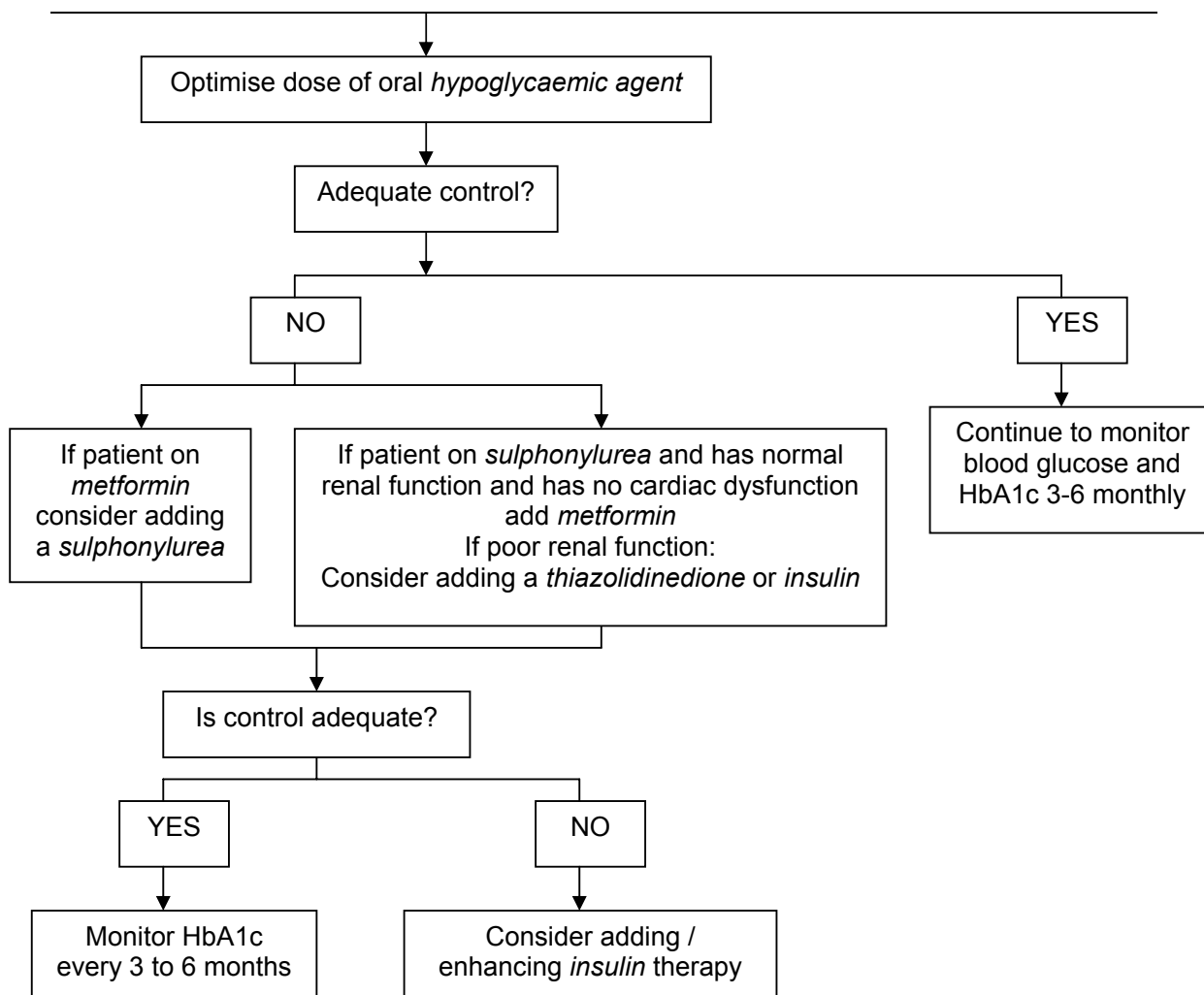
1. If LDL-cholesterol persists above 3 mmol/l refer for dietary advice. If despite adequate glycaemic control and dietary advice, LDL-cholesterol remains above 3 mmol/l consider a statin as therapy.
2. If triglycerides are above 1.5 mmol/l check for secondary causes such as poor glucose control, alcohol, thyroid disease etc. and if negative refer for dietary advice. If remains persistently high (> 4mmol/l) consider using a fibrate (especially if the HDL-cholesterol is < 0.9 mmol/l).
3. If both the LDL-cholesterol and triglycerides remain elevated following dietary advice initiate therapy with a statin. Consider adding a fibrate if raised triglycerides persist despite statin therapy but beware of drug induced rhabdomyolysis.
4. Fibrates should be used with extreme caution in patients with impaired renal function. In these patients if statins are used they should be started at low doses and doses subsequently titrated as needed. Hyperlipidemia in this setting should preferably not be managed at a primary care level.

Reference:

ADA Clinical Practice Recommendations 2002. Diabetes Care 2002; vol 25: nr 1: supplement1

DIABETES MELLITUS TYPE 2





Glossary:

- HbA1c – Glycosylated hemoglobin
- BMI – Body mass index

Applicable ICD 10 Coding:

- E11 Non-insulin-dependent diabetes mellitus
 - E11.0 Non-insulin-dependent diabetes mellitus with coma
 - E11.1 Non-insulin-dependent diabetes mellitus with ketoacidosis
 - E11.2 Non-insulin-dependent diabetes mellitus with renal complications
 - E11.3 Non-insulin-dependent diabetes mellitus with ophthalmic complications
 - E11.4 Non-insulin-dependent diabetes mellitus with neurological complications
 - E11.5 Non-insulin-dependent diabetes mellitus with peripheral circulatory complications
 - E11.6 Non-insulin-dependent diabetes mellitus with other specified complications
 - E11.7 Non-insulin-dependent diabetes mellitus with multiple complications
 - E11.8 Non-insulin-dependent diabetes mellitus with unspecified complications
 - E11.9 Non-insulin-dependent diabetes mellitus without complications

Applicable ICD 10 Coding: (continued)

- E12 Malnutrition-related diabetes mellitus
 - E12.0 Malnutrition-related diabetes mellitus with coma
 - E12.1 Malnutrition-related diabetes mellitus with ketoacidosis
 - E12.2 Malnutrition-related diabetes mellitus with renal complications
 - E12.3 Malnutrition-related diabetes mellitus with ophthalmic complications
 - E12.4 Malnutrition-related diabetes mellitus with neurological complications
 - E12.5 Malnutrition-related diabetes mellitus with peripheral circulatory complications
 - E12.6 Malnutrition-related diabetes mellitus with other specified complications
 - E12.7 Malnutrition-related diabetes mellitus with multiple complications
 - E12.8 Malnutrition-related diabetes mellitus with unspecified complications
 - E12.9 Malnutrition-related diabetes mellitus without complications

- O24 Diabetes mellitus in pregnancy
 - O24.1 Pre-existing diabetes mellitus, non-insulin-dependent
 - O24.2 Pre-existing malnutrition-related diabetes mellitus
 - O24.3 Pre-existing diabetes mellitus, unspecified

Note:

- 1. Medical management reasonably necessary for the delivery of treatment described in this algorithm is included within this benefit, subject to the application of managed health care interventions by the relevant medical scheme.**

- 2. To the extent that a medical scheme applies managed health care interventions in respect of this benefit, for example clinical protocols for diagnostic procedures or medical management, such interventions must –**
 - a. not be inconsistent with this algorithm;**
 - b. be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability; and**
 - c. comply with all other applicable regulations made in terms of the Medical Schemes Act, 131 of 1998**

- 3. This algorithm may not necessarily always be clinically appropriate for the treatment of children. If this is the case, alternative paediatric clinical management is included within this benefit if it is supported by evidence-based medicine, taking into account considerations of cost-effectiveness and affordability.**

In Brief

Improved health outcomes for individuals with diabetes depend on integrating self-management into daily life. A wide variety of educational, behavioral, and affective interventions are available that individually produce modest improvements in patient adherence to treatment recommendations in diabetes and related chronic illnesses and that work somewhat better when used in combination. A summary of selected successful interventions is presented.

Improving Adherence to Diabetes Self-Management Recommendations

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Diabetes is one of the chronic illnesses for which self-management plays a central role in care. In this regard, it is similar to hypertension or congestive heart failure but quite different from some other chronic illnesses such as breast cancer.

To optimize their health, individuals with diabetes may be advised regarding diet and exercise, frequent medical examinations, annual specialized examinations of their eyes and feet, and, for many, prescribed multiple oral or injected medications every day. Until there is a cure for diabetes, these behaviors must be sustained for a lifetime.

Matters are made more complicated by the high prevalence of comorbidity among adults with diabetes: they are at increased risk of hypertension and lipid disorders. These conditions may require still more medical management, which must be integrated with the treatment of diabetes itself. For those unfortunate enough to develop the vascular complications of diabetes, still more demands of self-management are imposed.

Managing one's diabetes is a complex task that touches nearly every important aspect of daily life, and we providers might marvel that any individual manages to do it at all. Success requires an alliance between patients and their health care providers, one or more from a team including physi-

cians, nurses, dietitians, diabetes educators, pharmacists, and other specialized health professionals. In the current organization of health care, it falls to primary care providers to monitor patients' biological progress and prescribe an appropriately tailored treatment plan. Much of the difficult work of supporting and facilitating patients' implementation of these complex plans (i.e., self-management education, behavior change choices) is delegated to other members of the team or not done at all.

It is worth noting, of course, that discrepancies between treatment recommendations and patient self-management are not the only cause of poor diabetes outcomes: providers' prescriptions and the advice of other health professionals do not always draw on the full base of knowledge about treating diabetes. Whereas guidelines for treatment of hypertension¹ have been set out in algorithmic detail, the more fluid evidence-based guidelines for treatment of diabetes may contribute to provider deviations from best practices. In addition, the multiple variables to be considered in diabetes management increase the complexity of the task. Health care systems may place additional barriers in the way of bringing what we know about diabetes to bear on the care of their patients. But systems design and provider adherence to guidelines are

topics worthy of extensive separate treatment and are not dealt with here.

We focus instead on what can be done to ensure that patients are given the opportunity to consider, adopt, and maintain the central tasks of diabetes self-management: practicing healthy lifestyle behaviors related to nutrition and exercise, taking medications as prescribed, self-monitoring glucose, and seeking medical care as appropriate. The goal of this article is to provide a useful summary for practitioners: we will refer to methodological issues only to the extent that they organize and clarify the presentation. We make recommendations for practice, but not for the research agenda. We will not emphasize logistical interventions such as providing transportation or mobile services, which are often not feasible in usual clinical settings.

Our review will touch on several areas: who is not likely to adopt self-management recommendations, how adherence can be assessed in clinical settings, and what steps have been demonstrated effective at improving adherence. It is interesting to note that this literature does not generally report whether subjects have made informed choices regarding the behaviors in question.

Although we appreciate the origin of Haynes² definition of “compliance” as the extent to which a patient’s actual behavior conforms to the advice dispensed by the health care provider, we also subscribe to the philosophy that individuals should be given the opportunity to make informed choices about their lifestyle and health care.³ We try to use the term “patient adherence” in the context of patients’ choice to adopt and maintain health behaviors, although the research literature for adherence/compliance does not often share this context.

The body of research in this area is manageable. For example, a Medline search for clinical trials of interventions specifically to enhance or promote adherence to prescribed medications among patients with diabetes turns up only a few hundred studies. Much of what we know about improving adherence is, in fact, borrowed from closely related areas facing similar behavioral issues, namely hypertension and coronary artery disease.

Despite its modest size, the adherence literature can be confusing.

Studies appear to contradict each other, or findings appear to change with only minor differences in the described intervention or the population studied. Fortunately, two excellent meta-analyses^{4,5} and two excellent reviews^{6,7} have been carried out, from which a few simple conclusions have been drawn: 1) nearly any intervention that makes sense will be of some benefit, 2) the effects of any particular intervention are typically small, and 3) application of multiple interventions of different types is more effective than any single intervention.

How Do We Recognize the Need for Intervention?

The breadth of the gap between providers’ recommendations and those behaviors patients choose to adopt, observed in either research or clinical practice, depends in large part on how it is assessed; estimates range widely as a result. The most common clinical practice is probably to ask patients to estimate their own level of adherence with diet and medications. These self-reports typically provide overestimates of adherence for several reasons. First, they may rely on patients’ own interpretation or memory of what advice was given and, if accepted, how closely it has been followed. Second, patients may tend to report higher levels of adherence in order to please health care providers or avoid embarrassment. In addition, recall is often disproportionately influenced by the most recent events, whereas it has been shown that adherence increases in proximity to a health care appointment.⁸

Lower estimates of adherence are typically found when recall-independent behavioral measures are used, such as pill counts, food diaries completed contemporaneously with eating, and review of monitoring logs. Of course, it is possible that patients choose to discard pills or engage in other misleading behaviors when these methods are used, so there is still room for error. The accuracy of pill counts, for example, may be enhanced (with a better picture of adherence behaviors) when pill counts are carried out on an unannounced basis during the course of a home visit. But this method of appraising adherence would generally be too intrusive and too labor-consuming for clinical settings, besides perhaps jeopardizing the trust relationship between providers and

patients, unless specifically requested by patients.

Indirect measurement of adherence can sometimes be accomplished through biological measurements: drug or metabolite levels in body tissues, weight gain or loss, assays for inert tracers incorporated into compounded medications, or nutrient components of foods. It should be remembered, though, that there is substantial biological variability among people in the drug levels that will be achieved with the same level of medication ingestion or the amount of weight that will be lost with a given degree of dietary restraint. And, like recall-based reports, the results of these measurements are typically most influenced by recent behaviors, thereby missing the greater degree of gaps in adherence that occur in days more remote from health care appointments. Their cost and discomfort also relegate these methods largely to research settings.

More recently, electronic devices to measure medication adherence have become available. These have not attained a significant role in the management of adherence in clinical settings at this time, and we do not discuss them here.

In short, there are serious methodological problems with the most common methods of measuring adherence. It is not surprising that published estimates of adherence range from very low to very high. It is probably best to consider all such estimates suspect and to remain agnostic about the extent of the challenges to adherence in various self-management behaviors for diabetes.

One area in which research is quite clear, however, is that there are very few characteristics that identify patients at high risk for gaps in adherence to recommendations.⁶ Neither sociodemographic characteristics nor aspects of personality predict treatment adherence. With the exception of relatively uncommon states such as mental illness (particularly paranoid thinking)² and transient periods of social instability^{9,10} (e.g., recent divorce, loss of job), no useful risk factors have been identified. Dunbar-Jacob et al.⁶ juxtaposing the results of Morrell et al.¹¹ and Park et al.¹², have suggested that older age improves adherence, and cognitive impairment is associated with lesser adherence. But in practice, cognitive impairment increases with advancing age so that

these two effects tend to cancel each other out, making each of little use in identifying patients at risk. Indeed, the conclusion of the literature is quite the opposite: the risk of adherence issues/gaps is essentially the same in all types of patients.

If attempts to identify people at risk for low adherence to recommendations have been largely fruitless, other approaches to targeting efforts at improving adherence may be useful. Adherence has been found to occur at very low rates early in the course of new treatments. Dropout rates from treatment for hypertension, cardiac rehabilitation, and smoking cessation are all high initially and then decline.¹³⁻¹⁵ Furthermore, early adherence is a good predictor of sustained adherence later on.¹⁶ Common sense then suggests that concentrating on identifying and improving adherence at the start of a regimen has greater potential for benefit than targeting old and new patients equally, although to our knowledge, this approach has not been tested in a clinical trial. Similarly, adherence is diminished by factors such as complexity of the treatment regimen, occurrence of side effects, and high treatment cost. While direct action to improve these aspects of a regimen is arguably the best approach, when circumstances do not permit this, these characteristics of the regimen can also be used to target efforts at adherence improvement to individuals at greatest risk.

If adherence is difficult to measure and high-risk subgroups are difficult to identify, how can we best target our efforts to improve adherence to those most in need of them? Haynes² has suggested three criteria to alert providers to a potential adherence problem:

1. Patients with a poor record of appointment-keeping are likely to have issues with other aspects of self-management as well. Fortunately, adherence with appointment-keeping is relatively simple to assess in most clinical settings.
2. Patients who do not respond to treatment, particularly to increasing intensity of treatment, in all probability are not adhering to treatment recommendations. Although nonresponse to increasing the dose of a drug might indicate that the particular drug is ineffective for the patient, when adding additional drugs or switching to new drugs of a different class does not bring about

improvement, an adherence issue is a likely cause.

3. The patients themselves may tell you if you ask them. Although patient self-reports of the extent of adherence are likely to be overestimates, Haynes asserts that a nonthreatening inquiry about self-management behaviors will yield answers with a sensitivity of 55% and a specificity of 87%. That is, 55% of patients who are not adhering will volunteer this information, and 87% of patients who are adhering will accurately affirm their status.

What Approaches to Improving Adherence Seem to Work?

In reviewing approaches to adherence, it is helpful to consider separately the aspects of adherence being improved and the type of intervention being considered. Haynes² and Roter et al.⁴ classify interventions into three similar categories (although they use slightly different labels for them): educational, behavioral, and affective.

Educational interventions seek to improve adherence by providing information and/or skills. The information may concern the nature of the disease, the array of diabetes self-management behaviors, and the positive and negative consequences of not adopting health recommendations. But at least as important is information about what to do if a dose of medication has been missed or if intercurrent illness or other problems arise or if you are traveling across many time zones.

Education may take the form of individual instruction or group classes. It might be provided in writing or through a visual medium such as videotape, multimedia computer software, or access to special Internet sites. In any event, a key element of successful educational strategies is providing simple, clear messages, hopefully tailored to the needs of the individual, and verifying that the messages have been understood.

Behavioral approaches have their roots in cognitive-behavioral psychology and use techniques such as reminders, memory aids, synchronizing therapeutic activities with routine life events (e.g., taking pills before you shower), goal-setting, self-monitoring, contracting, skill-building, and rewards. As with educational approaches, some of these approaches, such as skill building, may be pro-

vided individually or in groups and through a variety of media. For example, reminders may be mailed, e-mailed, or telephoned. What is important is that the behavior in question has been negotiated with and accepted by individual patients so that adoption of the behavior has a chance of succeeding in the long term.

Affective interventions seek to enhance adherence by providing emotional support and encouragement; recent diet and exercise intervention studies¹⁷ have used lifestyle "coaches" to help people adhere to the behavioral changes to which they have committed. Examples include rapport building through frequent telephone contact, home visits when feasible, family-based approaches (including family contracting), and interventions to enhance coping skills and self-efficacy.

The classification of interventions is important because, as Haynes says, "It is important to bear in mind that no single intervention has been shown to maintain long-term adherence; one must combine strategies from two or more of these three categories to achieve success."² Roter et al.,⁴ in their more recent review of this area, draw a similar, if less boldly asserted, conclusion. What seems clear from a systematic review of studies of self-management training in type 2 diabetes¹⁸ is that it takes varying degrees of all three categories of intervention to have a positive impact on health or behavioral outcomes in diabetes; this possibly reflects the complex psychological landscape of self-management in a chronic disease such as diabetes.

In the remainder of this section, we identify specific interventions that appear to be effective in enhancing adherence with specific aspects of self-management. Because the effects of any particular intervention are usually small and because of methodological differences across studies, interventions listed here have not necessarily been found consistently effective. Nor is our list restricted to approaches that have been shown effective specifically in the management of diabetes. We include interventions, rather, when they have been found effective at least once and when they belong to a class of interventions that have been identified in a meta-analysis as having a significant effect on an adequate measure of adherence for treatment of chronic diseases.

Adherence with medications is affected by many things. It is generally agreed that simpler regimens such as once-a-day dosing are associated with better adherence than more complicated ones. Nevertheless, even with the simplest regimens, adherence can be poor.¹⁹ Numerous approaches have been used to improve adherence to prescribed medication regimens.

Table 1 presents selected interventions that have been found workable. What is striking is the diversity of personnel who can implement interventions successfully and the variety of technologies that can be used. It should also be noted that studies of interventions to improve medication adherence, both included and beyond those shown in the table, have focused on both prescription-filling and self-administration of the medication.

Physical activity plays a vital role in the self-management of type 2 diabetes. Exercise is the best predictor of maintaining weight loss, and, independent of weight loss, it decreases insulin resistance. Unfortunately, it is in the area of efforts to improve adherence with exercise recommendations that we have, perhaps, the smallest body of research. There are relatively few studies, and they tend to be small and brief. The most noteworthy findings are reviewed here.

Carlson et al.²⁰ sought not so much to increase adherence to exercise therapy among cardiovascular rehabilitation patients as to see whether it could be sustained using a less expensive program that de-emphasized electrocardiographic monitoring and allowed some of the sessions to be carried out

at home. They found, however, that the less expensive approach, perhaps because of its increased simplicity and lower cost, was associated with enhanced adherence.

In a study of exercise as a weight-loss treatment, Jakicic et al.²¹ found that women randomized to have access to home exercise equipment for short bouts of exercise were more adherent and lost more weight than those without access to exercise equipment. Mahler, Kulik, and Tarazi²² randomized patients being discharged after coronary artery bypass surgery to standard discharge information or to viewing of one of two educational videotapes. Both videotape recipient groups exhibited greater adherence with exercise recommendations, and those who viewed the tape portraying the post-discharge course as characterized by ups and downs were more adherent than the group whose tape portrayed it as steady progress. Annesi²³ found that a computerized feedback system that tracked progress, provided feedback, and set goals reduced dropout rates and delayed dropout from a prescribed exercise program carried out in a fitness center.

King et al.²⁴ studied the use of semi-weekly staff-initiated telephone contact as a supplement to baseline education to sustain participation in a home-based exercise program. They found the telephone intervention to result in both greater participation and improved fitness among those initiating the program and better maintenance of the behavior among long-term participants who had already

demonstrated improved fitness before randomization. In the maintenance phase of the study, they also found that daily self-monitoring was superior to weekly self-monitoring.

Jeffery et al.²⁵ found that obese men and women randomized to receive a personal trainer or financial incentives for participation in the exercise component of a behavioral weight-loss program achieved higher attendance levels than those randomized to usual treatment or usual treatment plus supervised walks. Notwithstanding this success, the increased attendance did not translate into increased energy consumption or greater weight loss.

The types of interventions used in these trials are similar to those used for improving adherence to other types of treatment. It is therefore reasonable to assume that similar generalizations about the increased effectiveness of multiple interventions, as established for other types of adherence behavior, will apply to exercise adherence as well.

Adherence to dietary recommendations to lower cholesterol and lose weight has been studied extensively in patients with or at risk for coronary heart disease. Dietary recommendations for these people are similar to those for patients with type 2 diabetes, so that similar interventions to improve adherence may be applicable.

Metz et al.²⁶ randomized 560 people with hypertension, diabetes, or lipid disorders to receive detailed dietary plans or prepared meals. They found that the group receiving prepared meals had better dietary adherence as measured by 3-day food diaries. While providing patients with meals is not a feasible intervention in most clinical settings, this study and others (e.g., the DASH trial²⁷) suggest that a market for meal provision for medical nutrition therapy might be developed. They also reinforce the notion that dietary adherence is very strongly influenced by the ready availability of healthy food choices and the unavailability of unhealthy ones.

From a more practical perspective, McCulloch et al.²⁸ found that practical lunch time demonstrations or videotape education were superior to conventional diet-sheet instruction among adults with poorly controlled type 2 diabetes (average pretreatment hemoglobin A_{1c} [A1C] 13%). The patients in the demonstration and videotape groups showed improved dietary knowledge, better adherence

Table 1. Selected Interventions to Improve Medication Adherence

Intervention	Ref.
Educational	
Teaching by nurse and psychologist supplemented with audiotapes	36
Affective	
Home visit to increase family support, group sessions to increase patient confidence and skills	37
Behavioral	
Frequent follow-up by nurse at worksite clinic until treatment goals achieved	38
Feedback through patient record of medications and blood pressure response	39
Combination of medication chart and pill organizer	40
Mailed prescription refill reminder and special packaging	41
Nurse counseling plus reminder chart, structured counseling by pharmacist	42
At end of hospitalization, phasing in patient responsibility for medication administration	43
Telephone reminders and monitoring using computerized telephone system	44
Educational videotape or picture book (note: subjects were asthmatic children)	45

on 7-day food diaries, and substantial improvements in A1C (to 10.6 and 9.6%, respectively, versus no change in the conventional diet-sheet group).

Although the Multiple Risk Factor Intervention Trial (MRFIT) did not achieve its primary goal of reducing mortality from coronary heart disease,²⁹ it was highly successful at reducing the prevalence of risk factors for coronary disease in its special intervention group. MRFIT may be the longest, largest-scale success in improving adherence to cardiovascular dietary recommendations.³⁰ In that study, intensive and sustained counseling of middle-aged men with multiple risk factors for cardiovascular disease was provided by nutrition counselors. Most remarkable is that dietary adherence as measured by 3-day dietary records and improvements in serum lipid levels was largely sustained during 6 years of follow-up.

The use of videotapes by Mahler et al.²² cited earlier in connection with exercise adherence was also successful in reducing dietary fat intake after coronary artery bypass surgery, and, again, the tape presenting the post-operative period as a series of ups and downs generated greater success than the other tape.

Compared to usual care and printed information, dietary advice provided by nurses to healthy patients at risk for coronary heart disease, along with sustained follow-up by these nurses, was associated with slightly greater weight loss, lower intake of total fat and saturated fat, and lower serum cholesterol levels. Roderick et al.³¹ pointed out, however, that the modest gains achieved would be proportionate to the effort and resources required only in patients at the highest risk levels.

What is most striking about interventions to improve dietary adherence is the key role played by health care professionals such as dietitians and nurses. In successful interventions, the physicians' role, if there is any at all, is one of providing approval and initial encouragement. The actual intervention is implemented by nurses or dietitians. It is a matter of speculation whether this reflects greater interest, training in counseling skills, better patient rapport, or more time to devote to dietary matters. We were unable to find any successful interventions that relied primarily on physicians to improve dietary adherence.

Appointment-making and -keeping

is another aspect of chronic disease self-management. For diabetes, this can involve both regular appointments for monitoring and care (typically several times a year) and annual appointments for dilated fundus examinations and comprehensive foot examinations. As with interventions to promote adherence, the track record of any single approach is mixed, but when the literature is viewed as a whole, mail and telephone reminders produce improvements in appointment-keeping.

It has been harder to demonstrate that these same interventions also result in improved glycemic control or reduced hospitalization. For example, Feder et al.³² used mailed prompts to both coronary heart disease patients and their providers to attempt to boost patient clinic attendance and adherence by physicians to treatment guidelines. While their intervention did increase attendance and also increased rates of referral to cardiologists for evaluation, they found no improvement in other markers of quality of care nor any change in lifestyle modifications to reduce risk of recurrent coronary events.

Similarly, in Smith, Weinberger, and Katz' trial³³ of mailed information, appointment reminders, and intense follow-up of missed appointments, the intervention group kept significantly more appointments than the control group, but this improved adherence to outpatient care did not reduce hospitalizations. Of course, management of diabetes was less effective in 1987, and the intervention in this trial did not attempt to improve the quality of care delivered at the visits. Thus, this result is less surprising than that of Feder et al.

Basch et al.³⁴ doubled the rate of retinopathy screening among African Americans with diabetes who had not had an eye exam in the preceding 14 months using a multicomponent educational intervention. Their approach relied heavily on telephone-based problem-solving phone calls to overcome barriers to screening.

Summary and Conclusions

Our glass is half full. A wide variety of methods to improve all aspects of patient adherence to treatment recommendations for diabetes have been studied. Even though many interventions used have been applied broadly to populations without tailoring to individual patients' stage of change,³⁵

a modicum of success is often attained.

Although meta-analyses have shown that broad categories of interventions are, in aggregate, successful, their effects are small. Simultaneously applying several approaches drawn from different modalities (educational, behavioral, affective) tends to produce better results than any single modality. Practitioners seeking to enhance adherence among patients will find no "silver bullet." Rather, we have a collection of reasonably useful tools at our disposal, which we are challenged to use as effectively as we can.

Our efforts are likely to bring the most benefit if temporally targeted to the patients at highest risk of adherence problems and issues: patients being newly introduced to a treatment or patients with previous problems with adherence or adoption of behaviors. If we respect the autonomy of people who live with diabetes while providing them with the educational, behavioral, and emotional support to manage their disease, we have probably fulfilled our health care professional role in promoting adherence.

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Pharmacist copy

Type 2 Diabetes Mellitus Research Project Knowledge Questionnaire*

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1. The diabetes diet is:
 - a) the way most South Africans eat
 - b) a healthy diet for most people**
 - c) too high in carbohydrate for most people
 - d) too high in protein for most people

2. Which of the following is highest in carbohydrate?
 - a) Baked chicken
 - b) Swiss Cheese
 - c) Baked potato**
 - d) Peanut butter

3. Which of the following is highest in fat?
 - a) Low fat milk**
 - b) Orange juice
 - c) Maize
 - d) Honey

4. Which of the following is a “free food”?
 - a) Any unsweetened food
 - b) Any dietetic food
 - c) Any food that says “sugar free” on the label
 - d) Any food that has less than 80 kilojoules per serving**

5. Glycosylated haemoglobin (HbA_{1c}) is a test that is a measure of your average blood glucose level for the past:
 - a) day
 - b) week
 - c) 6-10 weeks**
 - d) 6 months

6. Which is the best method for testing blood glucose?
- a) Urine testing
 - b) Blood testing**
 - c) Both are equally good
7. What effect does unsweetened fruit juice have on blood glucose?
- a) Lowers it
 - b) Raises it**
 - c) Has no effect
8. Which should not be used to treat low blood glucose?
- a) 3 hard sweets
 - b) Half a cup of orange juice
 - c) One cup of diet soft drink**
 - d) One cup of skim milk
9. For a person in good control, what effect does exercise have on blood glucose?
- a) Lowers it**
 - b) Raises it
 - c) Has no effect
10. Infection is likely to cause:
- a) an increase in blood glucose**
 - b) a decrease in blood glucose
 - c) no change in blood glucose
11. The best way to take care of your feet is to:
- a) look at them and wash them each day**
 - b) massage them with alcohol each day
 - c) soak them for one hour each day
 - d) buy shoes a size larger than usual
12. Eating foods lower in fat decreases your risk for;
- a) nerve disease
 - b) kidney disease
 - c) heart disease**

d) eye disease

13. Numbness and tingling may be symptoms of:

a) kidney disease

b) nerve disease

c) eye disease

d) liver disease

14. Which of the following is usually not associated with diabetes:

a) vision problems

b) kidney problems

c) nerve problems

d) lung problems



Pharmacist copy

Type 2 Diabetes Mellitus Research Project Questionnaire*

* Reproduced with the permission of the University of Michigan Diabetes Research and Training Center

Your research identity number: _____

Please tick one box only per question answered

Q1*	Do you test your blood sugar?	Yes	No
-----	-------------------------------	-----	----

If **Yes** please continue with the questionnaire

Q2*	How many days a week do you test your blood sugar?	Days per week						
		1	2	3	4	5	6	7

Q3*	On the days that you test, how many times do you test your blood sugar?	Times per day			
		1	2	3	4

Q4*	Do you keep a record of your blood sugar results?	Yes	No
-----	---	-----	----

Q5	Do you use your blood sugar test results to assist you in the management of your diabetes?	Yes	No	Sometimes
----	--	-----	----	-----------

Q6	Does your medical practitioner use your blood sugar test results in prescribing your diabetes therapy?	Yes	No	Sometimes
----	--	-----	----	-----------

Q7	Does your pharmacist use your blood sugar test results to suggest adjustments to your medication therapy?	Yes	No	Sometimes
----	---	-----	----	-----------

Thank you for completing the questionnaire



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Diabetes Empowerment(DES-SF) Questionnaire*

* Reproduced with the permission of the University of Michigan Diabetes Research and Training Center

Below are some statements about diabetes. Each numbered statement finishes the sentence, "In general, I believe that.." For each of the statements, please tick the box that is closest to your opinion .

	In general I believe that I:	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree
1	...know what part(s) of taking care of my diabetes that I am dissatisfied with	5	4	3	2	1
2	...am able to turn my diabetes goals into a workable plan	5	4	3	2	1
3	...can try out different ways of overcoming barriers to my diabetes goals	5	4	3	2	1
4	...can find ways to feel better about having diabetes	5	4	3	2	1
5	...know the positive ways I cope with diabetes-related stress	5	4	3	2	1
6	...can ask for support for having and caring for my diabetes when I need it	5	4	3	2	1
7	...know what helps me stay motivated to care for my diabetes	5	4	3	2	1
8	...know enough about myself as a person to make diabetes care choices that are right for me.	5	4	3	2	1



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Understanding Self-care Practices Questionnaire*

* Reproduced with the permission of the University of Michigan Diabetes Research and Training Center

Please tick one box only per question answered

Q3. Have you ever received diabetes education? ¹ No ² Yes

Q4	How do you rate your understanding of:	Poor	Good	Excellent
a	diet and blood sugar control?	1	2	3
b	weight management?	1	2	3
c	exercise?	1	2	3
d	use of medication (tablets and or insulin)?	1	2	3
e	sugar testing?	1	2	3
f	foot care?	1	2	3
g	complications of diabetes?	1	2	3
h	eye care?	1	2	3
i	combining diabetes medication with other medication?	1	2	3
j	alcohol use and diabetes?	1	2	3



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Medicines Adherence Report Questionnaire*

* Reproduced with the permission of Professor Robert Horne

Questions about using your medicines

Many people find a way of using their medicines which suits them and this may differ from the instructions on the label or from what the doctor has said. We would like to ask you a few questions about how you use your medicines

Here are some ways in which people have said that they use their medicines. For each of the statements, please tick the box that best applies to you

	Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
1	I forget to take them	1	2	3	4	5
2	I alter the dose	1	2	3	4	5
3	I stop taking them for a while	1	2	3	4	5
4	I decide to miss out a dose	1	2	3	4	5
5	I take less than instructed	1	2	3	4	5



Major (ICD-10) Depression Inventory

The following questions ask about how you have been feeling over the last two weeks. Please put a tick in the box which is closest to how you have been feeling.

	How much of the time ...						
		All the time	Most of the time	Slightly more than half the time	Slightly less than half the time	Some of the time	At no time
1	Have you felt low in spirits or sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Have you lost interest in your daily activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Have you felt lacking in energy and strength?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Have you felt less self-confident?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Have you had a bad conscience or feelings of guilt?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Have you felt that life wasn't worth living?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Have you had difficulty in concentrating, e.g. when reading the newspaper or watching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8a	Have you felt very restless?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8b	Have you felt subdued or slowed down?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Have you had trouble sleeping at night?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10a	Have you suffered from reduced appetite?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10b	Have you suffered from increased appetite?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name: _____

Date: _____

Major Depression Inventory (MDI): Scoring Key

At the top, the diagnostic demarcation line is indicated and at the bottom, the total scores of the 10 items are summed up.

How much of the time ...		Diagnostic demarcation line						
		All the time	Most of the time	Slightly more than half the time	Slightly less than half the time	Some of the time	At no time	
Highest score for DSM-IV major depression	1	Have you felt low in spirits or sad?	5	4	3	2	1	0
	2	Have you lost interest in your daily activities?	5	4	3	2	1	0
	3	Have you felt lacking in energy and strength?	5	4	3	2	1	0
	4	Have you felt less self-confident?	5	4	3	2	1	0
	5	Have you had a bad conscience or feelings of guilt?	5	4	3	2	1	0
	6	Have you felt that life wasn't worth living?	5	4	3	2	1	0
	7	Have you had difficulty in concentrating, e.g. when reading the newspaper or watching television?	5	4	3	2	1	0
Highest score	8a	Have you felt very restless?	5	4	3	2	1	0
	8b	Have you felt subdued or slowed down?	5	4	3	2	1	0
	9	Have you had trouble sleeping at night?	5	4	3	2	1	0
Highest score	10a	Have you suffered from reduced appetite?	5	4	3	2	1	0
	10b	Have you suffered from increased appetite?	5	4	3	2	1	0

Total Score (item 1 - 10) : = _____ + _____ + _____ + _____ + _____ =

DSM-IV diagnosis _____

Major Depression Inventory (MDI):

Scoring Instruction

A: As a diagnostic instrument for DSM-IV major depression

The diagnostic demarcation line indicates at which point a symptom is severe enough to be used in the DSM-IV algorithm of major depression. Thus, the first three symptoms should have been present at least "most of the time" during the past two weeks, while the other symptoms should have been present "more than half" of the period. For symptoms 4 and 5, only the highest score should be used, as the DSM-IV contains only 9 of the 10 MDI symptoms and as symptoms 4 and 5 belong to the same category in DSM-IV. For symptoms 8 and 10, only the one of the two alternatives (a or b) with the highest score is considered.

Major depression is diagnosed if 5 or more of the 9 symptoms (items 4 and 5 combined) have been present in the past two weeks and if symptom 1 or symptom 2 are included in these 5 symptoms.

Reference:

Bech P, Rasmussen N-A, Olsen LR, Noerholm V, Abildgaard W. The sensitivity and specificity of the Major Depression Inventory, using the Present State Examination as the index of diagnostic validity. *J Affect Disord* 2001; 66: 159-164

B: As a depression rating scale

As a severity measure, the MDI score ranges from 0 to 50, since each of the 10 items can be scored from 0 (at no time) to 5 (all the time). Again, for items 8 and 10, alternative a or b with the highest score is considered.

Mild depression	MDI total score of 20 to 24
Moderate depression	MDI total score of 25 to 29
Severe depression	MDI total score of 30 or more

Reference:

Olsen LR, Jensen DV, Noerholm V, Martiny K, Bech P. The internal and external validity of the Major Depression Inventory in measuring severity of depressive states. *Psychol Med* 2003; 33, 351-356



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Pharmacy Practice Research
Patient Adherence to Self-Care Recommendations in Type 2 Diabetes Mellitus

Dear *name of pharmacist*,

I refer to my fax to you of 31 March 2007, in which I advised you of the names and contact details of your patients who remain participants in the research, and who need to present at your pharmacy for the final set of clinical data. Attached please find:

- Ampath forms for the Lipogram, HbA1c and Creatinine
- Post-baseline Clinical Data forms

Ampath forms

You will note that these forms have been coded as "Type 2 diabetes adherence research 41676" by Ampath in order for the data to be directly communicated to me.

Post-baseline Clinical Data Form

You need not complete the Result & Date fields for tests 1, 2 and 3 as these will be sent directly to me by Ampath. I will forward your patients tests results for your records as soon as I receive them from Ampath. Tests 4, 5, 6 & 7 should be done in the pharmacy. A random urine sample will suffice for the dip-stick test for Proteinuria.

Please fax the data forms to me at 046 6243575 by 31 May 2007.

Kind regards and many thanks for your continued support

Peter Hill

Tel/fax 046 6243575

Annexure 6.8

Faculty of Pharmacy

PW Hill
PO Box 275
Port Alfred
6170
Tel: 046 6243575
Mobile: 0829285020
E-mail: peterhill@intekom.co.za



27 April 2007

Dear *name of pharmacist*

I would appreciate it if you would be so kind and have your patients complete the attached questionnaires as soon as possible. Please return the completed to me using the enclosed self-addressed postage paid envelopes.

Best wishes and thanks once again for staying the course

Peter Hill



Type 2 Diabetes Research: Prescribed Medication & Refill Questionnaire

Name of patient:

Please ✓ boxes below that correspond with your answers.

Q1. Please review the patient's prescription medication refill records ("repeats") for the 6 month period 1 December 2006 to 31 May 2007 and indicate how many refills for each medicine were dispensed during this period.

*Please PRINT name of medication clearly	6 refills	5 refills	4 refills	3 refills	< 3 refills
Oral hypoglycaemic medication					
1.					
2.					
3.					
Blood lipid lowering medication					
4.					
5.					
6.					
Anti-hypertensive medication					
7.					
8.					
9.					

Q2. Has the patient's hyperglycaemia-related pharmacotherapy been changed during the past 12 months (May 2006-April 2007)?

	Yes	No
10. Oral hypoglycaemic agent (OHA) dosage increased		
11. Alternative OHA prescribed		
12. Additional OHA added to existing regimen		
13. Insulin added to or substituted for OHA		

Please fax (046 6243575) or email (peterhill@intekom.co.za) the completed form as soon as possible. Thank you.