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COMPUS

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Interventions for Optimizing Therapy in Patients with Diabetes Mellitus: A Literature Review

Supporting Informed Decisions

À l'appui des décisions éclairées

This report is prepared by the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), a service of the Canadian Agency for Drugs and Technologies in Health (CADTH).

It is a review of the existing public literature and information which was available to CADTH at the time this report was prepared. It has not been reviewed by peers.

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ABBREVIATIONS

BMI	body mass index
CI	confidence interval
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
HbA1c	glycosylated hemoglobin
SMBG	self-monitoring of blood glucose

GLOSSARY

Before-and-after study: a study design in which subjects are observed before and after a therapy or the introduction of an intervention.

Cluster randomized control trial: a randomized control trial in which the investigator randomly allocates units (such as clinics or physicians) to one or more intervention groups and a control group.

Controlled clinical trial: a prospective study designed to test the effectiveness of an intervention in which the investigator allocates subjects to one or more intervention groups and a control group using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier).

Randomized controlled trial: a prospective study designed to test the effectiveness of an intervention, in which the investigator randomly allocates subjects to one or more intervention groups and a control group.

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1 INTRODUCTION

In March 2004, the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) was launched by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) — now the Canadian Agency for Drugs and Technologies in Health (CADTH) — as a service to federal, provincial, and territorial jurisdictions, and other stakeholders. COMPUS is a nationally coordinated program, funded by Health Canada.

The goal of COMPUS is to optimize drug-related health outcomes and the cost-effective use of drugs by identifying and promoting optimal drug prescribing and use. Where possible, COMPUS builds on existing applicable Canadian and international initiatives and research. COMPUS achieves its goal through three main approaches:

- identifying evidence-based optimal therapy in the prescribing and use of specific drugs
- identifying gaps in clinical practice, then proposing evidence-based interventions to address these gaps
- supporting the implementation of these interventions.

Direction and advice are provided to COMPUS through various channels, including:

- COMPUS Advisory Committee (CAC): includes representatives from the federal, provincial, and territorial Health Ministries, and related health organizations.
- COMPUS Expert Review Committee (CERC): an advisory body that makes recommendations related to the identification, evaluation, and promotion of optimal drug prescribing and use in Canada.
- Stakeholder feedback.

1.1 CERC

CERC consists of eight Core Members appointed to serve for all topics under consideration during their term of office, and three or more Specialist Experts appointed to provide their expertise in recommending optimal therapy for one or more specific topics. For the insulin analogues, four endocrinologists/diabetes specialists were appointed as Specialist Experts. Two of the Core Members are Public Members who bring a lay perspective. The remaining six Core Members hold qualifications as physicians, pharmacists, health economists, or other relevant qualifications with expertise in one or more areas, such as, but not limited to: family practice, institutional or community clinical pharmacy, pharmacoeconomics, clinical epidemiology, drug utilization expertise, methodology, affecting behaviour change (through health professional and/or patient, and/or policy interventions), and critical appraisal. The Core Members, including Public Members, are appointed by the CADTH Board of Directors.

The mandate of CERC is advisory in nature; it is to provide recommendations and advice to the COMPUS Directorate at CADTH on assigned topics that relate to the identification, evaluation, and promotion of best practices in the prescribing and use of drugs across Canada. The overall perspective used by CERC members in producing recommendations is that of public health care policy makers in pursuit of optimizing the health of Canadians within available health care system resources.

2 ISSUE

CAC has identified management of diabetes mellitus as being a priority area for optimal practice initiatives, based on the following criteria:

- large deviations from optimal utilization (over- or under-use)
- size of patient populations

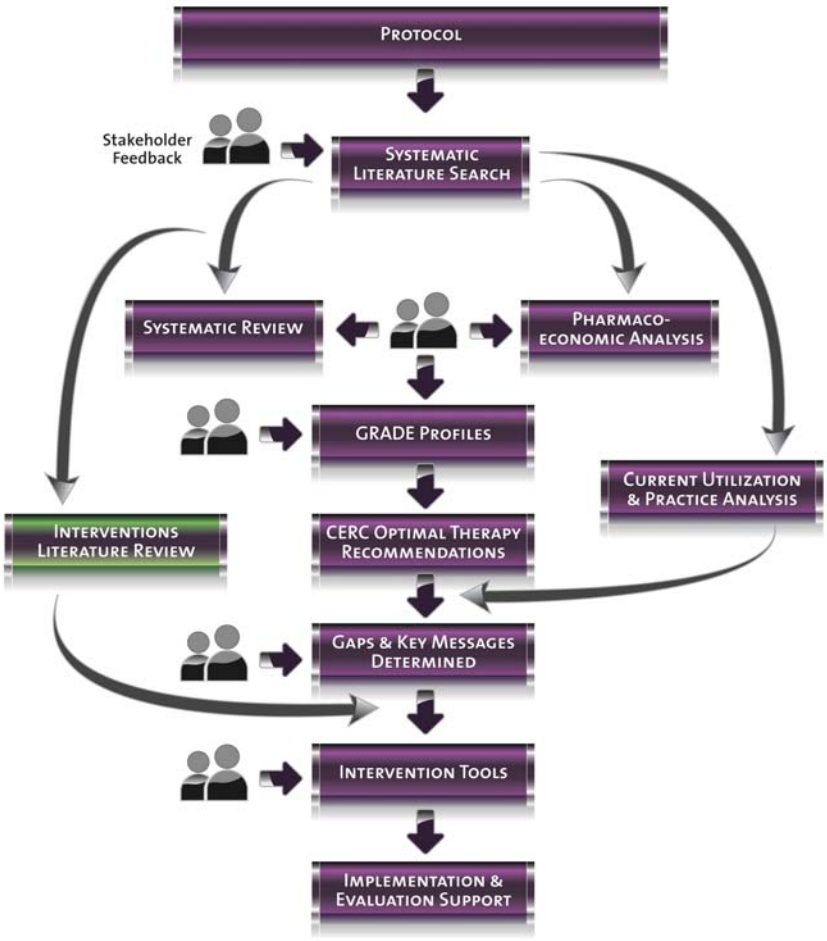
- impact on health outcomes and cost-effectiveness
- potential to effect change
- benefit to multiple jurisdictions
- measurable outcomes
- the extent that evidence is available.

3 OBJECTIVE

The objective of the Interventions Literature Review is to identify and review evidence-based intervention studies and intervention projects targeting diabetes management. The report consists of a selection of interventions aimed at influencing behaviour regarding diabetes management

4 PROJECT OVERVIEW

Once a topic is selected, COMPUS undertakes activities related to key areas in the COMPUS procedure. CAC provides advice and guidance throughout the process, from topic identification through to feedback and approval of recommendations and supporting interventions. CERC, as described in Section 1.1, provides expert advice and recommendations on the topic area relating to the identification, evaluation, and promotion of optimal prescribing and use of drugs. A broad range of stakeholders are invited to provide feedback at various stages in the COMPUS process.



To identify and promote the implementation of evidence-based and cost-effective optimal therapy in the prescribing and use of long- and rapid-acting insulin analogues, COMPUS follows the process outlined in the flow chart to the right.

This report represents the interventions literature review (purple box), a preliminary step in the selection of interventions.

5 RESEARCH FOCUS

For the purpose of this report, interventions have been classified into four main categories:

- Professional Interventions
- Disease Management Interventions
- Regulatory Interventions
- Patient Interventions.

5.1 Professional Interventions

Professional interventions are aimed at improving professional practice and the delivery of effective health services. These interventions include professional education, audit and feedback, and reminders.

Educational interventions are designed to change the providers' behaviours by increasing the understanding of existing clinical care principles or the awareness of specific practice recommendations.[1] Educational interventions include: the distribution of educational material (electronically published or printed recommendations for clinical care, including clinical practice guidelines and audio-visual materials); educational meetings (gatherings of health care professionals in face-to-face or virtual environments); a local consensus process (a debate and discussion between professionals and other concerned parties toward the establishment of a general consensus on the importance and management of specific clinical problems within a limited, local jurisdiction); educational outreach visits or academic detailing (face-to-face educational meetings between a trained facilitator and a health provider in his or her own setting); and local opinion leaders (use of providers nominated by their colleagues).[2]

Audit and feedback is a method that has been widely used to improve physician practice. Audit and feedback can be defined as any summary of clinical performance of health care over a period of time.[2] This summary may also include recommendations for clinical action. In some cases, health care professionals are passive recipients of feedback, while in other cases, professionals are actively involved and have specific and formal responsibilities for implementing change. The latter method of audit and feedback may have a larger impact on improving professional practice.[3]

Reminders are another strategy used to help clinicians remember information that they already know (or would be expected to know) by presenting the information in different, more accessible or relevant formats, or at a particularly appropriate time. Reminders can take the following forms:

- cue sheets containing general knowledge or advice, with no patient information or patient-specific advice, and not requiring a response
- checklists containing general knowledge or advice, with no patient information or patient-specific advice, but requiring response to specific questions
- patient profiles containing patient data and/or patient-specific knowledge or advice; these may also contain general knowledge or advice, but no response is required
- profile checklists containing patient data and/or patient-specific knowledge or advice; one or more of the statements or questions indicate that a response must be recorded.[4]

Reminders can be delivered manually (on paper) and electronically (on paper or on screen).[4]

5.2 Disease Management Interventions

Disease management programs are generally designed to improve the process of health care delivery and patient outcomes. Appropriate management of a particular chronic condition may lower the overall treatment costs by reducing emergency room visits, reducing hospitalizations, and providing a better choice of drugs.[5]

5.3 Regulatory Interventions

Regulatory interventions are often designed to target behavioural change based on guidelines that have been newly amended or implemented. The objective is to successfully implement recommendations from guidelines and policies through dissemination of the new information to health care professionals and individuals with diabetes. This is often accomplished by education, notices, and updated monitoring practices of disease management.

5.4 Patient Interventions

Patient interventions include patient education interventions and patient reminders. Patient education interventions are defined as those that include formal and structured instruction on the disease and on ways to manage symptoms.[6] Patient education interventions include self-management programs, counselling, leaflets, and small group meetings.

Patient reminders are used to improve patient adherence to medication, screening, or vaccination. They can be delivered through a variety of methods (e.g., telephone or mail) and with varying levels of intensity (e.g., single or multiple reminders).[7]

6 METHODOLOGY

6.1 Literature Search Strategy

In lieu of constructing and running a unique search, relevant material was identified in two subject-specific databases created and maintained by health technology agencies. The first is the Cochrane EPOC (Effective Practice and Organisation of Care Group) register. The EPOC register is a compilation of citations from an extensive and detailed search for interventions literature from MEDLINE, CINAHL, and EMBASE. For information on the register and the search strategies employed to identify its contents, see http://www.cochrane.org/consumers.homepage.htm . The second database is the CADTH *Rx for Change* database, which was searched for both consumer and professional interventions. For information on the CADTH *Rx for Change* database see: http://www.cadth.ca/index.php/en/compus/optimal-ther-resources/interventions/about and http://www.cadth.ca/index.php/en/compus/optimal-ther-resources/interventions/methods.

Both databases were searched for the terms *diabetes* or *diabetic* with no language or date restrictions. The search was run in February 2007.

6.2 Inclusion Criteria

Intervention studies were included if they attempted to influence appropriate prescribing and use of insulin products, oral anti-diabetes drugs, and monitoring devices. Studies were also included if they sought to bring about changes in therapeutic costs associated with diabetes management, patient compliance with drug and non-drug therapy, lifestyle modifications, as well as guideline implementation strategies for

diabetes management and prevention. Studies were included if they could be classified as randomized controlled trials, control only, randomized, or crossover studies.

Studies must have attempted to optimize the management of diabetes, but were also included if they focused on the primary prevention of diabetes in high-risk populations who were not yet diagnosed. Studies which were aimed at the secondary prevention of diabetes complications in individuals with diabetes were included as well.

6.3 Exclusion Criteria

Narrative reviews, editorials, and commentaries were not used for data extraction, but were identified as useful resources. Studies which primarily focused on blood pressure or lipid- lowering regimens, and those which only presented survey data, were not included. Studies which did not identify diabetes type or had included both types with blended results were excluded.

6.4 Classification

Studies were classified based on the aims or goals of the intervention, as identified by the author(s). We acknowledge that almost all studies in this report included some form of diabetes management, however, only when the primary goal was to improve diabetes control was that study classified as diabetes management. The categories are discussed under Research Focus.

While almost every study reported results in terms of patient outcomes, some studies also reported changes in professional behaviour. Because it was this change in professional behaviour which caused or intended to cause changes in patient outcomes, such studies were classified as professional interventions. If there was any discrepancy regarding whom the primary focus of the study was on, classification was based on the intention-to-treat population and on who the main results were about. For example, if results were reported for changes in professional behaviour (and if there was an intention-to-treat population that consisted of professionals), the study was classified as a professional intervention.

In some cases, studies used surrogate outcomes [e.g., glycosylated hemoglobin (HbA1c) levels in patients] to evaluate the effectiveness of professional interventions, meaning they did not report results in direct terms of changes in professional behaviour (e.g., checklist adherence, screening frequency changes). In such cases, these studies were classified as disease management or regulatory interventions instead of professional interventions. However, if the primary goal was to improve the process of delivery of care, the study was classified as disease management.

For studies which incorporated guidelines in the intervention, only those whose primary goal was dissemination and implementation/adherence to guidelines were classified as guideline interventions. This significantly underestimates the amount of studies which incorporated guidelines in their intervention, however, any studies which did use guidelines were identified in the summary table.

In order to specify the means through which each study affected behavioural change, studies were identified and categorized based on the primary mechanism which was intended to influence the participant. These categories include:

- Devices
- Education
- Registered nurse specialist
- Outpatient Care
- Guidelines
- Multi-disciplinary
- Pharmacist Availability
- Ongoing Care.

7 RESULTS

7.1 Combined Results

In total, 19 studies focusing on type 1 diabetes mellitus and 54 studies focusing on type 2 diabetes mellitus were included in this review, for a total of 73 studies. These studies were published between 1974 and 2007. Fifty-two of the 73 studies were randomized controlled trials, three were crossover studies, 12 were controlled, and the remaining studies were either randomized (2) or not-controlled (4). The sample size ranged from 12 to 3,437 participants. When possible, the results of diabetes-related outcomes (such as HbA1c) are reported in terms of the amount of change and level of significance. Note that a statistically significant difference does not necessarily indicate a clinical difference. Table 1 illustrates the breakdown of the included studies by intervention type and Table 2 presents these studies by the primary method used to illicit a change in behaviour. They are listed in order of most to least commonly occurring intervention in the literature review, and are separated by type.

Table 1: Breakdown of studies by intervention type

Category	Total	Type 1 diabetes	Type 2 diabetes
Professional interventions	6	0	6
Disease management interventions	18	8	10
Regulatory interventions	4	0	4
Patient interventions	45	11	34

Table 2: Breakdown of studies by type of diabetes and primary mechanism intended to elicit behaviour change

Category (Main Catalyst by which Study Influenced Change)	Total	Type 1 diabetes	Type 2 diabetes
Devices	22	8	14
Education	18	7	11
Registered nurse specialist	7	3	4
Outpatient care	7	1	6
Guidelines	6	0	6
Multi-disciplinary	5	1	6
Pharmacist availability	4	0	4
Ongoing care	3	0	3

7.2 Professional Interventions

There were six type 2 diabetes studies (and no type 1 diabetes studies) which aimed at improving professional practice and the delivery of effective health services. Three studies based their interventions on guidelines, using either education[8,9] or audit and feedback[10]as the primary means to change the behaviour of health care professionals. Varroud-Vial et al.[8] educated general practitioners in the French adaptation of the Staged Diabetes Management program and demonstrated improvements in glycemic control without significantly increasing health care costs. Harris et al.[9] improved diabetes care delivery by using teleconferences for the continuing education of physicians. Schectman et al.[10] provided doctors with audit and feedback about their level of care for patients with type 2 diabetes. Each participant completed

an "action checklist" for each patient, taking suggestions for improved care into consideration. This intervention proved both helpful and popular for improving rates of diabetes care guideline adherence.

Gruesser et al.[11] applied a structured treatment and teaching program, which resulted in a marked improvement in significantly decreased HbA1c ($p<0.0001$), and decreased medication prescriptions [from 1 to 0.7 tablets/patient/day ($p<0.0001$)].

Odegard[12] et al. applied a pharmacist-implemented care plan. No significant improvements were made in diabetes control [i.e., HbA1c ($p=0.61$)], however, pharmacist participation did allow for maintenance and reductions in HbA1c similar to those receiving usual care. At the end of this study, both groups decreased HbA1c ($p=0.001$), but the intervention group did so with fewer physician visits. Medication appropriateness was not significantly improved for diabetes medications in either group ($p=0.65$).

Olivarius et al.[13] applied a program that focused on a combination of feedback, education, and reinforcement of guidelines. Six-year mortality was assessed and results revealed that non-fatal outcomes and mortality were the same in both groups. However, the following risk factors were significantly reduced: post-prandial glucose, 7.9 mmol/L versus 8.7 mmol/L; HbA1c, 8.5% versus 9.0%; and systolic blood pressure, 145 mm Hg versus 150 mm Hg; $p=0.007$ for all outcomes.

7.3 Disease Management Interventions

7.3.1 Type 1 diabetes

A total of eight studies attempted to improve the process of health care delivery and patient outcomes in individuals with type 1 diabetes, with the use of devices. Devices assessed include a computer program to assist insulin dosage adjustment (n=4);[14-17] an electronic logbook to document data such as insulin dose, blood glucose, and exercise (n=1);[18] a mobile phone to transmit data such as insulin dose, food consumption, and blood glucose results (n=1);[19] and a modem/phone device for transmission of blood glucose results and data management (n=2).[20,21]

Interventions using devices generally led to similar or improved metabolic control (e.g., HbA1c) compared to standard care. Ryff-de Lèche et al.[18] demonstrated a decrease in HbA1c from 6.9 ± 0.2% to 6.7 ± 0.2 % ($p<0.005$) in all treated patients. The authors suggest that although the HbA1c values at baseline were already within the recommended values for individuals with diabetes, the concomitant decreases in hypoglycemia accompanied by this small reduction in HbA1c is still a positive outcome.

Schrezenmeir et al.[16] produced a large clinically and statistically significant decrease in HbA1c (i.e., from 10.2 ± 1.5% to 8.6 ± 0.8%) in the intervention group by using a pocket computer-assisting device. It was noted that a clinically meaningful change in HbA1c (i.e., from 9.8 ± 1.3% to 9.1 ± 1.0%) was observed in the control group. Peters et al.[14] produced clinically and statistically significant decreases in HbA1c ($p<0.001$) in both groups (i.e., from 9.8 ± 1.6% to 9.0 ± 1.2% in the experimental group versus from 9.9 ± 1.6% to 9.2 ± 1.2% in the control group). The proportion of hypoglycemia (i.e., blood glucose $\leq$ 3.3 mmol/L) was significantly decreased in both groups [i.e., from 3.3 to 1.7% ($p<0.05$) in the treatment group and from 3.7 to 2.3% (p=NS) in the control group]. The average daily insulin dose was significantly decreased in the treatment group (i.e., 0.63 ± 0.14 U/kg to 0.57 ± 0.15 U/kg $p<0.01$), while the dose remained unchanged in the control group (i.e., 0.65 ± 0.13 U/kg to 0.64 ± 0.20 U/kg).

Ryff-de Lèche et al.[18] demonstrated a reduction in the rate of hypoglycemia (i.e., 5.8 ± 0.9 % to 3.1± 0.5%, $p=0.08$) in patients using the Camit 1 (a computer program that facilitates the management of diabetes

data) versus patients using the traditional logbook. Although not statistically significant, the observed trend may be clinically important for increasing the quality of life for insulin-dependent patients.

Chase et al.[21] demonstrated a significant reduction in cost between the intervention group versus the control group (i.e., six months of modem use was $163.00 versus six months of usual care at $610.00; p<0.0001) despite no difference in HbA1c and rate of hypoglycemia. These conclusions demonstrate that transferring diabetes data with a modem device (followed by visits from a diabetes nurse) instead of visiting a clinic was as equally effective as traditional methods for achieving metabolic control, and resulted in significant cost savings. Follow-up visits by registered nurse specialists or other diabetes health care workers were vital elements to the success of the study. These connectors between doctor and patient often provided support for insulin dose changes, helped to resolve technical issues, and facilitated the making of recommendations regarding psychological services. Children in these studies demonstrated increased confidence and independence in decision making.

7.3.2 Type 2 diabetes

Of the ten type 2 diabetes studies classified as disease management, four used devices to elicit behavioural change. The devices included an electronic monitoring device to track pill-taking adherence,[22] an automated phone service to assess diabetes status,[23] an Internet-based blood glucose monitoring system,[24] and point-of-care HbA1c testing.[25]

Two of the ten studies followed guidelines to improve diabetes management by either changing the insulin titration method, in combination with measurement and provision of HbA1c levels at point of care,[26] or by instituting a program to improve the quality of care provided by health care professionals, through education, audits, and feedback.[27] One study[28] implemented a program designed to improve the process of care delivery between health care services via a local agreement on clinical protocols and structured communication across the primary-secondary care interface. One of the oldest studies in this report (i.e., 1974[29]) compared the type of supervision given to diabetes care groups; one by a doctor and the other by a registered nurse specialist.

The remaining three studies involved the active participation of a pharmacist in the management of diabetes. Education was the primary means by which behavioural change was intended to be influenced. Two of these studies used self-monitoring blood glucose (SMBG) as part of the intervention,[30,31] while the third used case management by a pharmacist.[32]

Most of these ten studies reported significant changes in HbA1c (from baseline) only for the intervention group; however, a few showed changes in both groups compared to baseline. Most often, the intervention group experienced a greater and more clinically meaningful improvement in metabolic control compared with the usual care group.

7.4 Regulatory Interventions

Four type 2 diabetes studies[33-36] (and no type 1 diabetes studies) were classified as regulatory interventions. These studies featured the dissemination of guidelines as their primary means for inducing behavioural change that would improve the quality of life of patients with diabetes. By training doctors and staff in the use of clinical practice guidelines, Benjamin et al.[33] was able to implement a problem-based learning technique to improve glycemic control in patients with type 2 diabetes. This intervention was based on Staged Diabetes Management guidelines.

The Medi-Cal group[34] used intensive diabetes case management with specific, population-directed strategies to improve glycemic control in patients with type 2 diabetes. HbA1c decreased substantially in both groups from an average of 9.54% to 7.66% (-1.88%) in the intervention group, and from 9.6%6 to 8.53% (-1.13%) in the control group. The reduction of HbA1c in the intervention group was significantly superior at each time point ($p<0.001$). Diabetes case management, added to primary care, substantially improved glycemic control compared with the usual primary care.

Franz et al.[35] used medical nutrition therapy, administered by dieticians according to practice guidelines for nutrition care, to improve glycemic control in people with type 2 diabetes. This intervention group received two follow-up sessions, whereas the control group received none. Practice guidelines for nutrition care resulted in significant improvements in fasting plasma glucose and HbA1c levels, and basic nutrition care resulted in significant improvements in HbA1c levels. The intervention group had a mean fasting plasma glucose level at endpoint that was 10.5% lower than at entry, and those in the basic nutrition care group had a 5.3% lower value. Among patients who had diabetes for longer than six months, those who received practice guidelines for nutrition care had a significantly better HbA1c level at three months versus the basic nutrition care group. The basic nutrition care group showed no improvement in glycemic control over the trial, while the intervention (practice guidelines for nutrition care) patients demonstrated significant improvements in cholesterol. Both groups had significant weight loss. Medical nutrition therapy provided by dieticians resulted in significant improvement in medical and clinical outcomes in both groups. Persons with a duration of diabetes longer than six months tended to do better with practice guidelines for nutrition care than with basic nutrition care. Because of the upward trend in glucose levels after three months, ongoing medical nutrition therapy by dieticians may be important for long-term metabolic control.

Meier et al.[36] instructed patients with type 2 diabetes to perform SMBG testing according to modified adapted Veterans Affairs guidelines. These researchers measured the difference in glucose test-strip use per day pre- and for two months post-implementation of guidelines. There were no significant changes in HbA1c at endpoint ($p=0.63$ versus baseline); however, the time lapse between pre- and post-measurements was only two months, which may not offer enough of a time lapse to measure a change in HbA1c. The frequency of SMBG decreased significantly in the intervention group (by 46%) versus baseline ($p<0.0001$). Similar findings were observed in sub-groups of patients who were either diet-treated or drug-treated (linear regression analysis showed no significant impact on HbA1c by reduction of strip use). Overall, average savings were $6.37 per patient, per month, in the intervention group over the control group. The program decreased the frequency of SMBG in people with type 2 diabetes, resulting in substantial cost-savings without affecting glucose control.

7.5 Patient Interventions

7.5.1 Type 1 diabetes

Eleven studies that provided patient education were identified.[26,37-46] Methods for educating participants included intensive teaching or training, structured care programs, and reminders. In three of these studies, the patient's family was also provided with an educational intervention.

Seven of the eleven studies provided patient education by an intensive and structured program format, utilizing a nurse specialist or a multidisciplinary team.[26,37-39,41,42,44] Improvements in HbA1c, episodes of hypoglycemia, reductions in hospital length of stay and re-admissions, improved adherence, family teamwork, and diabetic knowledge were demonstrated in both pediatric and adult populations. Three studies integrated home management into the patient care approach for pediatric and adolescent patients, [40,41,46] providing home visits by a health care worker. Each of these interventions proved to be effective strategies for improving diabetes control.

In the study by Couper et al.[41], HbA1c levels in the intervention group moved from 11.1 ± 1.3% to 9.7 ± 1.6% while non-significant changes were observed in the control group (from 10.5 ± 1.6% to 10.3 ± 2.2%). A similar trend was also observed in the Dougherty study,[46] however, the baseline HbA1c data was not suitable to compare changes from start to endpoint because patients were recruited at onset of the diabetes diagnosis. HbA1c at 24 months (endpoint) was 6.1 ± 1.3% in the home-based intervention group, and 6.8 ± 1.3% in the hospital-based control group ($p<0.02$). This difference was statistically significant, showing that these groups did indeed differ in long-term glycemic control. It is difficult to discern the level of clinical significance between these groups due to the lack of a change from baseline.

Two studies in pediatric and adolescent patients provided follow-up via weekly telephone contact.[42,45] Neither demonstrated an improvement in HbA1c, however, both did improve adherence to some degree in the intervention groups. In the study by Howe et al.,[42] an improved child adherence to safe behaviours and family teamwork regarding metabolic control was demonstrated in the group which received a combination of education and phone calls. In contrast, no significant improvement in any measures were identified in the groups that received education only, or in the control group.

In the study by Lawson et al.,[45] no significant changes in any outcome were observed until six months post-study. Post-hoc analysis revealed a clinically and statistically significant decrease in HbA1c levels (by at least 1%) in 29% of the patients in the intervention group and 0% in the control group. An increase in HbA1c levels was also reported in 19% and in 44% of patients in the intervention and control groups, respectively ($p=0.015$). The authors suggested that the skills and knowledge learned in the intervention may have been partially responsible for these results.

One study[43] investigated the effect of physician/patient knowledge of HbA1c results over a two- to three-year study period. There was a slight but significant increase in HbA1c during the blinded phases. HbA1c improved with knowledge of the test results in patients with baseline control that was poor (HbA1c > 12.7%). Results worsened slightly when intervention was withdrawn. Those with good control did not demonstrate a benefit.

Overall, patient education via structured counselling sessions, group information, homework or feedback, as well as home-based interventions and weekly telephone follow-up, provided similar or improved metabolic control as compared with usual care. A change in HbA1c was the most commonly reported outcome used to assess intervention effectiveness. Additional outcomes included improvement in cost-effectiveness, lipid profiles, blood pressure, quality of life, body weight, and increased number of screenings for foot ulcers, diabetic neuropathy, nephropathy, and cardiovascular disease. Statistically significant differences between study populations from baseline to end of study were used to identify changes in behaviour. No studies were directed specifically at influencing prescribing behaviour in prescribers (i.e., prescription of one drug over another).

7.5.2 Type 2 diabetes

A total of 34 studies focusing on patient interventions for type 2 diabetes were identified. Eleven studies used devices[47-57], seven studies[58-64] used education, one study[65] used guidelines, five studies[66-70] used a multi-disciplinary approach, three studies[71-73] used ongoing care, three studies[74-76] used outpatient care, one study[77] used a pharmacist, and three studies[78-80] used a registered nurse specialist as the primary means for influencing behavioural change.

7.5.3 Devices

Kirkman et al.[47] and Piette et al.[48] evaluated the impact of a telephone-delivered intervention where patients were phoned by a nurse or an automated system as a means to improve disease management. Calls emphasized some or all of the following: compliance with the medical regimen (diet, medications, and exercise), encouragement towards behavioural changes, and referrals to a dietician or a smoking cessation clinic.

Investigators of the Kirkman paper reported that more obese patients in the telephone-delivered intervention arm had seen a dietician (30 versus 7%, p=0.003), and that more patients with hyperlipidemia in the telephone-delivered intervention arm were receiving lipid-lowering medications (22 versus 9%, p=0.096) compared with those in the control group. Authors stated that telephone-delivered intervention improved self-reported adherence to regimens that might reduce coronary risk, but had little effect on objective measures of risk. In the Piette study, endpoint HbA1c was significantly better for patients with baseline HbA1c levels $\geq$ 8% following telephone-delivered intervention than the control group (8.7 versus 9.2%, p=0.04). Intervention patients also were more likely than control patients to have had a cholesterol test. At follow-up, intervention patients reported fewer symptoms of poor glycemic control than control patients, and greater satisfaction with their health care. Neither of these studies reported significant findings for all participants but, instead, presented findings for only high-risk patients (i.e., hyperlipidemia, poorly controlled obesity, HbA1c greater than 8%).

Authors of the Guerci study[49] sought to compare changes in metabolic control over six months in patients managed with usual recommendations alone or combined with SMBG. Physical activity, drugs, and diet were standardized. At endpoint, HbA1c was significantly lower in the intervention group (p=0.012). This trial demonstrates that SMBG is statistically associated with a slight but significant improvement of metabolic control. The benefit was greater in patients with higher initial HbA1c, lower body mass index (BMI), and shorter duration of diabetes.

Schwedes et al.[50] investigated the effect of meal-related SMBG on glycemic control and well-being in non-insulin-treated patients with type 2 diabetes. Patients in the intervention group had to perform SMBG, and record a diary of blood glucose values and dietary details while receiving standard counselling, whereas the control group received only usual care, and non-standardized counselling on diet and lifestyle. Incorporation of meal-related SMBG and standardized diet and exercise counselling significantly reduced HbA1c versus non-use and non-standardized counselling (p=0.0086).

Muchmore et al.[51] evaluated the impact of SMBG on diabetes control in patients who had been taught how to count and use carbohydrates. The amount of carbohydrates needed was determined by their SMBG results and metabolic requirements due to physical activity. Authors concluded that the addition of SMBG and dietary carbohydrate counting to pre-existing diabetes care programs resulted in improved HbA1c levels compared to the control group. The introduction of SMBG did not improve body weight for overweight patients. Additionally, this study failed to confirm the widely held belief that SMBG may improve patients' quality of life (by empowering them in their disease management). Participation in a comprehensive diabetes education program did, however, result in improvements in the life satisfaction index for both groups.

Fontbonne et al.[52] compared SMBG and self-monitoring of urine glucose with usual care in patients with type 2 diabetes who were not using insulin. Patients were instructed to perform either SMBG or self-monitoring of urine glucose two times per day, every other day. Results showed a decrease of HbA1c over the six-month period, however, the differences were not significant between any groups. The degree of compliance in the SMBG group (indicated by the number of strips used) was significantly correlated with

HbA1c at endpoint (r=-.36, p<0.02). The authors conclude that regular self-monitoring has no definite advantage over the usual management for improving metabolic control in non-insulin-treated patients with type 2 diabetes.

Allen et al.[53] compared the relative efficacy and cost of SMBG with routine self-monitoring of urine glucose testing in the management of patients with type 2 diabetes who were not taking insulin. Both groups were instructed in diet management by a dietician, based on patients' ideal body weights and activity levels. Both groups were required to conduct 36 tests each month. After six months, both groups showed similar improvements in fasting plasma glucose (p<0.03) and HbA1c (p<0.01) compared to baseline. A similar number of patients achieved normalized HbA1c levels (nine in the self-monitoring of urine glucose group versus eight in the SMBG group). Results indicate that SMBG is not more effective than self-monitoring of urine glucose at facilitating glycemic control in patients with type 2 diabetes who are not on insulin.

Menard et al.[54] evaluated the effect of an intensive multi-therapy on perceived quality of life, attitudes, knowledge, goals, and diabetes self-management in patients with poorly controlled type 2 diabetes. The intensive multi-therapy consisted of monthly visits, including clinical and biochemical assessment, education sessions on diet, physical exercise, medical management of diabetes, and associated diseases and adjustments in medication. Patients were given glucose monitors, a stationary bicycle, and phone calls were made twice a month. After one year, intervention patients had significantly improved their quality of life compared to controls (quality of life score: +13.2 ± 10.3 versus +5.6 ± 13.2). Knowledge and diabetes self-management improved. A higher proportion of intensive multi-therapy patients achieved established Canadian Diabetes Association goals for HbA1c, diastolic blood pressure, low-density lipoprotein and triglycerides than in the control group. No significant differences between groups were observed for attaining goals for fasting plasma glucose, systolic blood pressure, or total cholesterol: high-density lipoprotein ratio.

Sarkadi and Rosenqvist[55] investigated the long-term (24 weeks after baseline) effectiveness of an experience-based group educational program and pinpointed mediators for achieving desired metabolic outcomes. The intervention provided pharmacist-led group meetings and education through: a video entitled "How to Live Well with Diabetes"; a knowledge-based dice game; and a booklet/guide, "How to Manage Your Diabetes". The control group was wait-listed for two years before receiving the intervention. A mean decrease in HbA1c of 0.4% was achieved in the intervention group.

Glasgow et al.[56] compared the effects of a computer-assisted, generic, health risk appraisal service combined with usual care, to a tailored self-management regimen. Patients in both study arms received assessment of current health behaviour, feedback, tailored goal-setting, barrier/benefit identification, and problem-solving through action-planning, health counsellor interaction, and follow-up calls. A significant reduction in dietary fat intake and weight was observed in the tailored self-management group, compared to the usual care plus the computer program, at a two-month follow-up.

Simmons et al.[57] monitored medication adherence by distributing calendar blister packs to assess the impact on glycemia and blood pressure. Intervention patients received a special kit with their medications in a calendar blister pack, in a labelled box, with instructions on how to take the medications. The control group received the same packaging as the intervention group, but with medication contained in usual containers. At the end of the study, HbA1c was reduced by 0.95 ± 0.22% in the intervention group and 0.15 ± 0.25% in the control group (p=0.026). Diastolic blood pressure also decreased by 5.8 ± 1.5 mm Hg in the intervention group compared to an increase of 0.1 ± 1.9 mm Hg in the control group (p=0.0041). The authors suggest that calendar blister packs should be considered among diabetic patients with poor glycemic control who receive multiple medications.

7.5.4 Education

Litzelman et al.[58] evaluated the impact of providing education on appropriate foot care to patients with type 2 diabetes (not on insulin) and health care providers. Patients in the intervention group received foot-care education and entered into a behavioural contract, which was reinforced by phone and postcards. The health care providers in the intervention were given practice guidelines and informative flow-sheets on foot-related risk factors for amputation, and patient folders were flagged to prompt foot exams on each visit. Results indicated that patients receiving the intervention were less likely than control patients to have serious foot lesions [2.9%; odds ratio, 0.41(95%CI, 0.16 to 1.00); p=0.05] and other dermatologic abnormalities. Intervention patients were more likely to report appropriate foot-care behaviour, have foot exams during office visits (68 versus 28%; p<0.001), and receive foot-care education from health care providers (42 versus 18%; p<0.001). Physicians assigned to intervention patients were more likely than control physicians to examine patients' feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to the podiatry clinic (10.6 versus 5%; p=0.04). Overall, this study was successful in reducing the risk of lower extremity amputations in patients with diabetes.

O'Hare et al.[59] used a registered nurse specialist to implement enhanced care according to guidelines for tailored diabetes care in patients with type 2 diabetes. There was no significant change in HbA1c, and no differences between groups were observed. The authors suggest that improvement in glycemic control may require longer, and possibly different, strategies. Overall, this study was not successful at improving glycemic control.

Pieber et al.[60] educated Austrian patients with type 2 diabetes through the use of a modified Diabetes Teaching and Treatment Program originally developed for German-speaking patients. The intervention group received the Diabetes Teaching and Treatment Program (German version) for six months, accompanied by four teaching sessions (90 to 120 minutes in length), in groups of four to eight patients, and conducted by clinic staff and general practitioners. Patients were taught to practice SMBG, and to use simple dietary measures to improve glucose control and reduce body weight. They were also educated on the advantages of non-pharmacological therapy, taught about proper foot-care, and given guidelines for what to do in terms of physical activity, sick day rules, and late complications of diabetes. Results of SMBG were discussed in conjunction with dietary experiences, including the influence of simple carbohydrates on glucose control. At the end of the study, there were significant changes in the intervention group for: weight (1.57-3.67 lbs); BMI (0.69-1.37 points); HbA1c (0.09-0.83 %); systolic blood pressure (11.3-21.9 mm Hg); diastolic blood pressure (7.7-14.5 mm Hg); triglycerides (0.18-1.09 mmol/L); cholesterol (0.14-0.66 mmol/L); and diabetes-related knowledge (19-31 points). The control group only had a significant difference in systolic blood pressure (0.1-14.3 mm Hg) and diastolic blood pressure (1.3-9.5 mm Hg). Between the two groups, significant differences existed for body weight (p=0.01), BMI (p=0.01), HbA1c (p=0.01), diastolic blood pressure (p=0.05), triglycerides (p=0.01), and diabetes-related knowledge (0.001). The percentage of patients who were taking oral medications decreased significantly from 84% to 71% after the intervention (p<0.05), whereas the control group showed no significant change. Calculated care costs per patient over a year decreased in the intervention group and increased in the control group, mainly due to changes in prescription of oral hypoglycemic agents in both groups.

Mazzuca et al.[61] sought to determine the effects of patient and physician education on patient knowledge, skills, self-care behaviours, and relevant physiologic outcomes. Intervention patients were given seven modules of education, each containing didactic instruction (lecture, discussion, audio-visual presentation), skill exercises (demonstration, practice, feedback), and behavioural modification techniques (goal-setting, contracting, regular follow-up). At the end of the study, the intervention group had significantly greater reductions in fasting blood glucose (-27.5 versus -2.5 mg/dL, p<0.05) and HbA1c (-0.43 versus + 0.35%, p<0.05) as compared with controls. The changes in fasting blood glucose were clinically significant, while

the small changes in HbA1c were not large enough to suggest improved long-term glycemic control. The authors conclude that systematic education can have a demonstrable, prolonged effect on patient self-care skills, behaviours, intermediate indicators of glucose homeostasis, and chronic vascular complications.

Goudswaard et al.[62] provided an educational program to individuals with type 2 diabetes: the intervention patients were given an individual educational program by a diabetes nurse and the control patients were kept under usual care by their general practitioner. Six months after the intervention, HbA1c (adjusted for baseline) was 0.7% lower in the intervention group compared to the control group (95%CI 0.1, 1.4). Sixty per cent of patients who took part in the education program reached HbA1c levels below 7.0% compared with only 17% in the control group ($p<0.01$). Despite the early successes, follow-up at 18 months showed no significant differences for HbA1c, no differences in the number of patients with HbA1c < 7.0%, or in the number of patients treated with insulin. The reduced effect of the program after one year underscores the importance of incorporating regular reinforcement into any treatment program in order to maintain desired outcomes.

Rachmani et al.[63] used an intervention which incorporated patient participation and compared it to care received in a standard annual consultation. At the end of the study, mean HbA1c was 8.9% ± 1.2% and 8.2 ± 1.5% in the control and intervention groups, respectively ($p=0.04$). Mean low-density lipoprotein was 124 ± 8 mg/dl and 114 ± 6 mg/dl in the control and intervention groups, respectively ($p=0.01$).The average annual fall in estimated glomerular filtration rate was 3.5 mL/min/year in the control group versus 2.25 mL/min/year in the intervention group ($p<0.05$). At four years, blood pressure was 148/88 ± 6.1/1.7 mm Hg in the control group and 142/84 ± 5.8/1.8 mm Hg in the intervention group ($p=0.02$). Nephropathy (as indicated by albumin/creatinine ratio> 300 mg/g) developed in four patients in the control group and no patient in the intervention group. Overall, well-informed and motivated patients were more insistent to reach and maintain target values of the main risk factors of diabetic complications.

Kulzer et al.[64] compared the impact of three education programs targeting patients with type 2 diabetes. Treatment A consisted of didactic group sessions to gain knowledge, skills, and information about the correct treatment of diabetes, much like usual care for diabetes patients. Treatment B, consisting of group sessions based on self-management and empowerment, focused on emotional, cognitive, and motivational processes of behavioural change. Treatment C involved the same treatments as B, but six lessons were in a group session and six were individually completed. HbA1c remained unchanged for patients in group A; was significantly improved and sustained for 15 months in group B; and was significantly improved, however, not sustained, in group C. Overall, there was a significant treatment effect for HbA1c ($p=0.013$); HbA1c was significantly lower in intervention group B versus C, and group C was lower than the control group A at three months. At fifteen months, group C had higher HbA1c than group B. Results were significantly different among groups for BMI and fasting plasma glucose. Most psychological variables were influenced by the treatments. There were comparable improvements in urine, and SMBG and foot care, in all three groups. Patients in groups B and C performed exercise more regularly compared to control group A.

7.5.5 Guidelines

Rutten et al.[65] implemented a detailed therapeutic protocol which emphasized weight reduction and restricted prescription of oral anti-diabetic drugs in order to create diabetes checkups that would enhance everyday practice. The intervention groups were separated into smaller groups, as follows: SMBG (subgroup 1); unwilling or incapable of SMBG (subgroup 2); specialist care (subgroup 3). A therapeutic scheme was used with fixed targets for weight loss and all patients were required to have checkups. The control group experienced usual care by either a general practitioner (subgroup 4) or a specialist (subgroup 5). These groups had no fixed checkup appointments. In the end, there were no significant changes in weight.

However, after exposure to the intervention, patients decreased their HbA1c values by a statistically significant margin compared to the control group (from >10 to 8-10%). Furthermore, HbA1c actually increased significantly in the control group ($p<0.05$). The positive results can be attributed to a combination of greater participation of the patient, the consultation frequency determined per individual patient, and the prescription of oral hypoglycemic agents according to body weight changes.

7.5.6 Multi-disciplinary approach

Gary et al.[66] evaluated the impact of interventions, which were implemented by a nurse case manager, a community health worker, or both. Patients who received interventions by both professionals experienced significant improvements in triglycerides (-35.5 mg/dl; $p=0.041$) and diastolic blood pressure (-5.6 mm Hg: $p=0.042$) compared to the other groups. This study focused on improving diabetic control in urban African-Americans with type 2 diabetes.

Jiang et al.[67] implemented an intervention that included advanced diabetes education and training for patients, doctors, and health care providers, while the control group received only a basic diabetes education course. Authors state that both groups changed significantly from a statistical point of view, where the controls changed from 9.3 ± 1.4% to 9.0 ± 1.5%, ($p=0.008$), and the treatment group changed from 9.4 ± 1.2% to 8.7 ± 1.4%, ($p<0.001$). Fasting plasma glucose ($p<0.001$), total cholesterol ($p=0.009$), systolic blood pressure ($p<0.001$), weight ($p<0.001$), and waist-hip ratio ($p=0.021$) all decreased significantly in the intervention group, but not in the control group. The changes in metabolic control, which were significantly correlated with self-care total scores, included the change in HbA1c ($p<0.001$, $r= -0.224$), and the change in systolic blood pressure and diastolic blood pressure ($p=0.007$, $r = -0.186$ and 0.080, $r = -0.122$, respectively). The study confirms that a diabetic health care team equipped with endocrinologists, dieticians, nurse educators, and advanced education programs is effective in the management of diabetes mellitus and in improving metabolic control.

Maislos and Weisman[68] also evaluated the impact of a multi-faceted approach for patients with poorly controlled type 2 diabetes. The intervention included education through diabetes clinic visits, nurse and dietician visits, a session with a diabetes nurse educator, as well as follow-up visits, while the control group received usual care. There was 19% compliance in both the intervention and control groups, which was defined as an HbA1c decrease of 0.5%. At a six-month follow-up visit, the authors identified a significant improvement in plasma glucose (-1.5mmol/L, $p=0.003$) and HbA1c (-1.8%, $p=0.00001$) in the intervention group, but not in the control group. Compliance and response rates were 85% and 71% for the intervention group and 32% and 35% for the control groups, respectively.

Kim and Oh[69] applied an intervention that included continuing education and reinforcement of diet, exercise, and medication adjustment recommendations, as well as frequent self-monitoring of blood glucose levels (recording information in diaries, telephone calls two times per week for the first month and then weekly after that), whereas the control group received usual care. The authors reported significant changes in HbA1c from baseline in both groups. Patients in the intervention group displayed a mean decrease in HbA1c of 1.2% ($p<0.05$) and those in the control group displayed a mean increase in HbA1c of 0.6% ($p<0.05$). There was a significant correlation between diet ($p=0.006$) and SMBG adherence ($p=0.024$) between the groups. Adherence to diet ($p<0.05$) and blood glucose testing ($p<0.05$) improved in the intervention group compared with baseline. These findings indicate that a nurse telephone intervention can improve HbA1c and diet and blood glucose testing adherence.

Kronsbein et al.[70] applied a structured Diabetes Teaching and Treatment Program to assist patients with non-insulin-treated type 2 diabetes in achieving the recommended treatment goals by non-pharmacological means. The intervention group was introduced to the Diabetes Teaching and Treatment

Program in groups wherein the primary care physicians' staff incorporated guidelines and material with an education program, while the physicians themselves took a Diabetes Teaching and Treatment Program course. The control group remained under usual care. HbA1c remained unchanged in both groups. The percentage of patients on oral anti-diabetic drugs was reduced from 68% to 38% (mean difference: 30%, CI 16-44%), and weight was reduced by 2.7 kg (95 CI, 1.6-3.8kg) in the Diabetes Teaching and Treatment Program group. Triglycerides also decreased by 0.77 mmol/L (95% CI 0.35-1.19 mmol/L) in the Diabetes Teaching and Treatment Program group. No changes were observed for these indices in the control group, and 10% of patients started insulin, indicating a worsening health status due to the advancement of diabetes. The Diabetes Teaching and Treatment Program improved the overall quality of patient care in elderly non-insulin-dependent patients with type 2 diabetes when administered by general practitioners and their staff.

7.5.7 Ongoing care

Penfornis and Millot[71] used a group of health care professionals to provide ongoing inpatient care so that patients just starting insulin therapy were adequately supported in their efforts to maintain glycemic control and manage their diabetes. Evaluation of the safety and cost of both methods was a secondary objective. The intervention group was hospitalized for five to seven days, and provided with education about proper disease management from endocrinologists, nurses, and dieticians. Patients were taught how to effectively manage diet and insulin dosages, monitor blood glucose, take urine measurements which test for sugar levels, and were taught about the risks of hypoglycemia and sports. The control group was treated as outpatients. They received a summary of the same information as the inpatient group and returned home the same day. They returned to the hospital in one week to check insulin doses and blood sugar levels from SMBG records. Co-variance analysis demonstrated equivalent glycemic control at three months in both groups (equivalence hypothesis p=0.01). Hypoglycemic episode-frequency was low and similar in both groups. Clinical tests, paramedical care, and the cost of hospitalization itself resulted in a direct cost of initiating treatment that was more than four times higher for the inpatient group than the outpatient group (mean total cost: FF 15,231 and FF 3.296, respectively). Investigators concluded that insulin-requiring patients with type 2 diabetes can be efficiently and safely started on insulin as outpatients, and that this approach is cost-effective.

De Berardis et al.[72] sought to compare the effectiveness of care-giving methods between diabetes outpatient clinics and usual care by a general practitioner. Statistically significant differences in favour of patients attending clinics were demonstrated for HbA1c, high-density lipoprotein, creatinine, micro-albuminuria testing, as well as for foot and eye examinations. More clinic patients had satisfactory blood pressure and total cholesterol readings compared with usual care, and higher total low-density lipoprotein levels were observed in patients receiving usual care. Quality of care was higher in the patients who attended clinics, especially when patients were followed by the same physician. The level of quality of care was further enhanced if the overseeing physician had a specialty in diabetes, particularly regarding process measures. However, physicians' specialties were not independently related to patient outcomes.

Groeneveld et al.[73] evaluated the impact of having patients referred to a diabetes service by physicians on diabetes-related parameters in patients with type 2 diabetes. The diabetes service was comprised of nurses and diabetes educators who provided counselling and follow-up calls every three months, and performed physical examinations and laboratory testing. The control group consisted of patients who remained under usual care practices. HbA1c did not differ significantly between the intervention and control groups (7.1% versus 7.5%, p=0.06) at endpoint. Patients who were initially poorly controlled (fasting blood glucose >10 mmol/L) had a significantly lower final HbA1c if they were in the intervention group (p=0.001). Fewer patients in the intervention group were referred to hospital specialists (one versus 14), indicating adequate specialization within the diabetes service. Overall, diabetes service support did not significantly influence

HbA1c, however, the subgroup of initially poorly controlled patients developed a significantly lower HbA1c in intervention practices than in control practices.

7.5.8 Outpatient care

Rothman et al.[74] used a pharmacist-led, primary care-based disease management program to assess the ability to improve cardiovascular disease risk factors and HbA1c levels in patients with poorly controlled diabetes. The intervention patients received intensive management from clinical pharmacists and from a diabetes care coordinator who provided diabetes education, applied algorithms for managing glucose control and decreasing cardiovascular risk factors, and addressed barriers to care. The control patients received a one-time management session from a pharmacist, followed by usual care. At 12 months, patients in the intervention group reported significantly greater improvements in systolic blood pressure (reduced by a mean of 9 mm Hg; 95% CI -16 to -3 mm Hg) and HbA1c levels (-0.8%; 95% CI -1.7 to 0%). At 12 months, aspirin use was 91% in the intervention group compared to 58% among controls ($p<0.0001$), which indicates improved care and management in reducing cardiovascular risk factors. Diabetes knowledge and satisfaction improved to a greater extent in the intervention group than in the control group. Overall, the comprehensive disease management program reduced cardiovascular risk factors and HbA1c levels among patients with type 2 diabetes and poor glycemic control.

Hurwitz et al.[75] evaluated the impact of a computerized database against usual care for the management patients with type 2 diabetes. The intervention patients were prompted by a database which sent requests to patients asking them to provide blood and urine samples for random glucose, HbA1c, and albumin estimations. There was a significant difference in the number of patients who failed to receive a single review of diabetes status: 14 control group patients versus three in the intervention group ($p=0.013$). Follow-up for retinal screening was better in prompted patients than in those in the control group. The number of patients who defaulted from the study was far less in the intervention group: two versus 12 patients in the intervention and control groups, respectively ($p=0.008$). Continuity of care was better in the prompted group, resulting in 3.2 versus 2.2 ($p<0.001$). The authors concluded that computer prompting of non-insulin-treated diabetic patients for care by inner city general practitioners and by optometrists is effective and acceptable.

Skaer et al.[76] evaluted various pharmacy-based reminders and descriptions on proper taking of diabetes medications to improve compliance with sulfonylurea therapy and health service utilization. Four different groups received standard pharmaceutical care with each dispensing of glyburide. Three groups received an intervention, in addition to standard care. The control group (Group 1) received standard pharmaceutical care. Group 2 received medication-refill reminders 10 days before each sequential refill date; Group 3 was given unit-of-use packaging with each prescription-refill request; and Group 4 was given mail reminders and unit-of-use packaging. Patients in the intervention groups achieved a significant increase in the medication possession ratio for glyburide therapy relative to controls ($p\leq0.05$). A significant improvement in the medication possession ratio, relative to all other groups, was observed for patients in Group 4. There was no significant difference detected between Groups 2 and 3. Patients in Group 4 also experienced a significant ($p\leq0.05$) reduction in the use of physician, laboratory, and hospital services compared to patients in the control group.

7.5.9 Pharmacists

Jaber et al.[77] assessed the effectiveness of a pharmaceutical care model on the management of type 2 diabetes in urban African-American patients. The intervention patients were supported by a pharmacist-led care group, while the control group remained under usual care. There was a significant improvement in HbA1c ($p=0.003$) and fasting plasma glucose ($p=0.015$) in the intervention group, compared to baseline

values. No significant changes were observed in the control group. This created a significant difference between groups for HbA1c (p=0.003) and fasting plasma glucose (p=0.022), in favour of the intervention group.

7.5.10 Nurse specialists

Both Vetter et al.[78] and Krein et al.[79] employed a collaborative approach towards making the best use of the case management skills of a nurse specialist. The Vetter study targeted improving diabetes control among inner-city African-Americans. Patients received either nurse case management home visits from a community health worker or a combination of both (nurse case management-community health worker). HbA1c levels were decreased in the various intervention groups (i.e., -0.31% with nurse case management, -0.30% with community health worker, and -0.8% with nurse case management-community health worker).

The Krein study chose to examine changes in glycemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization in patients with poorly controlled type 2 diabetes. The intervention group received automated SMBG monitors with guidelines and a periodic study newsletter. Intervention patients were assigned to a case manager (i.e., nurse specialist) who monitored via telephone, collaborated with patients and physicians to set goals, and followed treatment algorithms. Patients in the control group received usual care. No significant differences in HbA1c were observed between the intervention and control groups. Significant differences were observed for other parameters (i.e., satisfaction with diabetes care 82% versus 64% for intervention and control groups, respectively; p=0.04).

Weinberger et al.[80] examined the impact of a nurse-coordinated intervention delivered to patients with type 2 diabetes between office visits. The intervention group patients received phone-calls from the nurse on a regular basis (minimally monthly). These phone calls served to provide education to the patients, with particular emphasis on healthy diabetes care regimens, including how to recognize significant signs and symptoms of hyperglycemia and hypoglycemia. Nurses also took this opportunity to reinforce compliance with regimens, monitor patient health status, facilitate resolution of identified problems, and facilitate access to primary care. The control group received usual care. Statistically significant differences for fasting blood glucose levels (174.1 versus 193.1 mg/dL, p=0.011) and HbA1c (10.5% versus 11.1%, p=0.046) were observed in favour of the intervention group. Statistically significant differences were not observed for either health-related quality of life or diabetes-related symptoms.

7.6 Gaps in Practice

Many of the studies reviewed indicated that individuals who do not complete study trials are more likely to have higher HbA1c, body mass index (BMI), and lipid values at baseline and exhibit an overall poorer state of health and willingness to change behaviour than those who complete the study protocol.

Numerous patients participated in these interventions on a volunteer basis. Of note, patients with poorly controlled diabetes were less likely to volunteer for such programs.

8 DISCUSSION AND CONCLUSIONS

The studies evaluated in this report involve patients with both type 1 and type 2 diabetes and the appropriate use of insulin, or appropriate lifestyle modifications, to achieve optimal metabolic control.

The most common finding among these studies was that patients responded positively for the duration of the intervention, but failed to maintain the benefits gained when the intervention was withdrawn. Studies

which included follow-up data reported that patients reverted to their pre-intervention lifestyle after six months or more following cessation of the intervention. This was a common occurrence despite adherence during the study period. Interventions which appeared to offer the greatest long-term benefit included follow-up phone calls, reminders for health care providers and patients, and continuing education or refresher courses on optimal diabetes care.

Compared to usual care, interventions demonstrated improvements in both biochemical and behavioural outcomes, with varying degrees of significance. Improvements were most clinically significant in patients who were poorly controlling their diabetes, indicating that there was little value in changing the routines that the well-controlled patients already follow.

Studies investigating devices appeared promising; however, baseline costs may prevent widespread implementation of such programs. The disease management process with improved delivery of health care via home-based strategies or patient education with programs and continued follow-up will likely provide improvement in diabetic control, knowledge, and adherence.

The importance of SMBG with a personal meter was often addressed, and adherence to appropriate checking standards was a primary outcome for 10 studies. Many studies sought to improve glycemic control (measured by recording results of SMBG and HbA1c values) in patients with type 2 diabetes, regardless of insulin consumption. All but seven studies used HbA1c as an outcome.

The cost-effectiveness and ability to improve glycemic control through SMBG in individuals with type 2 diabetes, particularly those not taking insulin, is not supported by many studies. There were few studies which intended to improve glycemic control using SMBG in individuals with type 1 diabetes.

The majority of the intervention studies reviewed were at least six months (85% of studies) or 12 months (58% of studies) in duration. These are adequate timeframes with which to identify significant changes in HbA1c. Many studies reported a statistically significant effect of the intervention by noting the disparity of differences between the control and experimental groups, between baseline and endpoint data. Despite initial benefits, these differences became insignificant between groups at follow-up (post-intervention), in most studies.

9 REFERENCES

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APPENDIX 1: STUDIES OF PROFESSIONAL INTERVENTIONS

Table 3: Summary of trial results for studies with patients with type 2 diabetes*

Details	Goal/ Intervention	Outcomes Measured	Results/Conclusions
Varroud-Vial, 2004[8] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 67(57) doctors, 364(340) patients Setting: Outpatient	Goal: To assess the impact of a French adaptation of the staged diabetes management program Intervention: General practitioners enrolled patients to be educated in the staged diabetes management program Control: Usual care	• HbA1c (adjusted due to use of different methods of assessment) • blood pressure • cost • blood lipids • QoL • medications • initiation and monitoring of SMBG	• HbA1c: decreased by 0.31% in the intervention group and increased by 0.56% in the control group, resulting in a difference of 0.87% (p=0.001) • no further significant differences (no significant difference of cost between groups) • greater prescription of SMBG in the intervention group (p<0.001) • greater use of metformin in the intervention group (77.4%) versus controls (62.5%), p<0.05 Educating general practitioners in the French adaptation of the staged diabetes management program improves glycemic control in a primary care setting without significantly increasing health care costs.
Gruesser, 1993[11] Design: Randomized – before/after (assessment was done 12 months after participation in the training course); see companion study[70] Duration: 12 months Population: Intention to treat (completed study): 139 doctors, 179 patients Setting: Outpatient	Goal: To evaluate the practicability and efficacy of a structured treatment and teaching program for non-insulin-treated patients with type 2 diabetes in routine primary health care Intervention: Doctors interviewed patients and reviewed patient data before and after a treatment program was implemented Control: Usual care	From doctors, changes in: • number of times they performed a structured treatment and patient education course in their practice • did they alter their practice to accommodate lessons learned from the education program? From patients, changes in: • HbA1c • weight • BMI • blood glucose levels	• 61% of physicians had performed at least 1 structured treatment and patient education course at re-evaluation • 54% of doctors had tuning forks before the seminar, 31% bought some afterwards, and15% still did not own one at re-evaluation • body weight was reduced by an average 2.8 kg (p<0.0001) • HbA1c decreased significantly, (p<0.0001) 8.11± 1.68 to 7.47± 1.64, in the intervention group • prescribed amount of oral anti-diabetic drug was ~50% lower after patients attended program (significant decrease

Table 3: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
		• frequency of SMBG • prescribed amount of oral anti-diabetic drug	from 1.41± 1.42 to 0.76± 1.11 tablets/patient/day, p<0.0001) • proportion of patients in intervention treated with oral anti-diabetic drugs decreased from 63% to 42% (p<0.0001) • SMBG and logbooks were introduced After the introduction of nationwide remuneration of outpatient education for patients with type 2 diabetes (given by office-based physicians), an improvement was observed in the quality of care.
Harris, 2005[9] Design: Cluster randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 90 (61) doctors, 660 (660) patients Setting: Outpatient, and doctor's practice clinic	Goal: To evaluate the effects of a tele-conferenced educational detailing-type of continuing education on glycemic control (in their patients) for physicians, and family physician adherence to national diabetes guidelines Intervention: Eight 1-hour, small-group educational sessions for doctors, each covering a module related to the management of type 2 diabetes, based on national guidelines. Participants received an educational manual with defined learning objectives for each module, guideline recommendations, detailed clinical cases, and pertinent research articles. Flow sheets were provided with medical charts to serve as reminders for clinical targets of the patients Control: Usual care	• HbA1c • medication management • physician adherence to clinical practice guideline complication screening recommendations	• intervention did not affect mean HbA1c levels, but did significantly (p=0.04) alter the distribution of patients by category of glycemic control, with fewer in the intervention group having inadequate control (15.8% versus 23.9%) • more patients took insulin (alone or with oral agents) in the intervention group (21.2% versus 12.0%, p=0.03) • more patients in the intervention group had documentation of body mass (p<0.02), eye exam (p=0.02), and treatment plan (p=0.01), and use of flow sheet (p<0.03) An intervention designed to reduce risk factors for lower extremity amputations positively affected patient self-foot care behavior, as well as the foot care given by health care providers, and reduced the prevalence of lower extremity clinical disease in patients with diabetes.

Table 3: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Design: Schectman, 2004[10] Design: Not controlled Duration: 12 months Population: Intention to treat(completed study): 83 (83) doctors, 789 (521) patients Setting: Doctor's office/outpatient	Goal: To evaluate whether or not physician feedback, accompanied by an action checklist, improved diabetes care process measures Intervention: Feedback report given to doctors, and educational session about feedback report and adherence information was provided. Doctors were asked to fill out a checklist after reviewing feedback report. Patients attended education session and, if control was inadequate, were recommended to nurse case management	• HbA1C • lipids • creatinine • retinal exams • checklist completion per guidelines	• the odds of ophthalmologic referral were 4.5 x higher if the last exam was more than 1 year earlier (p<0.0001) • no significant changes were noted in HbA1c or cholesterol • diabetes medication adherence below 80% was associated with a 2.7 x greater odds of referral for pharmacist adherence counselling (p<0.0001) A simple physician feedback tool with an action checklist can be both helpful and popular for improving rates of diabetes care guideline adherence – although more complex interventions are likely required to improve diabetes outcomes.
Reference: Odegard, 2005[12] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 77 Setting: Outpatient	Goal: To evaluate the effect of a pharmacist intervention on improving diabetes control, and to evaluate mediation appropriateness and self-reported adherence Intervention: Pharmacist intervention Control: Usual care	• HbA1c • care plan • medication appropriateness • self-reported adherence	• HbA1c did not differ between groups over the 12-month period (p=0.61) • a reduction in HbA1c was noted for both groups over time, compared with baseline (p=0.001) • medication appropriateness was not improved for diabetes medications (p=0.65) This pharmacist intervention did not significantly improve diabetes control, but did allow for similar HbA1c control with fewer physician visits. Medication appropriateness and self-reported adherence, compared with usual care in individuals with poorly controlled diabetes, were not changed.
Reference: Olivarius, 2001[13] Design: Randomized controlled trial	Goal: To assess the effect of a multi-faceted intervention directed at general practitioners on six-year	• HbA1c non-fasting blood glucose	• non-fatal outcomes and mortality were the same in both groups

Table 3: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Duration: 72 months (6 years) Population: Intention to treat (completed study): 474 doctors, 874 patients Setting: Outpatient	mortality and risk factors of patients with newly diagnosed type 2 diabetes Intervention: Structured care follow-up every 3 months and annual screening for diabetic complications and questionnaire to doctor • goal-setting with patient and feedback • doctors were given feedback, too, with guidelines and seminars Control: Usual care	• blood pressure • total cholesterol • fasting triglycerides • mortality • retinopathy • myocardial infarction • stroke • urinary albumin concentration	• the following risk-factor levels were lower for intervention patients than for control patients (median values): post-prandial glucose (7.9 versus 8.7 mmol/L, p=0.0007); HbA1c (8.5 versus 9.0%, p<0.0001); systolic blood pressure (145 versus150 mm Hg, p=0.0004); and cholesterol concentration (6.0 versus 6.1 mmol/L, p=0.029) • both groups lost weight (2.6 kg versus 2.0 kg) • metformin was the only drug used more frequently in the intervention group (24% versus 15%) • intervention doctors arranged more follow-up consultations, referred fewer patients to diabetes clinics, and set more optimistic goals In primary care, individualized goals with educational and surveillance support may – for at least 6 years – bring risk factors of patients with type 2 diabetes to a level that has been shown to reduce diabetic complications, but without weight gain.

BMI=body mass index; HbA1c=glycolsylated hemoglobin; QoL=quality of life; SMBG=self-monitoring of blood glucose
* There were no studies of professional interventions for patients with type 1 diabetes

APPENDIX 2: STUDIES OF DISEASE MANAGEMENT INTERVENTIONS

Table 4: Summary of trial results for studies with patients with type 1 diabetes

Details	Goal/ Intervention	Outcomes Measured	Results/Conclusions
Reference: Strack, 1985[17] Design: Crossover Duration: 2 months Population: 10 adults (intention to treat) for 8-day test phase, then 6 (intention to treat) outpatients for crossover study Setting: Inpatient (n=10) x 8 days for test phase, then outpatient (n=6) for 60-day study period	Goal: To improve on the regulation/use of computer system, insulin consumption, and metabolic control Intervention: Computer-assisted insulin dose adjustments Control: Conventional therapy	• change in HbA1c • change in insulin consumption • incidence of hypoglycemia	• improved HbA1C (no statistics presented) • insulin consumption increased moderately, but was stable (no statistics presented) • no change in frequency of hypoglycemia Computer-assisted therapy appears promising in aiding metabolic control, as demonstrated in this small number of patients.
Reference: Ryff-de Lèche, 1992[18] Design: Randomized crossover Duration: 6 months Population: Intention to treat (completed study): 20(19), adults Setting: Outpatient	Goal: To evaluate two computer-assisted data management programs for insulin compared to a conventional logbook Intervention: Computer (Camit S1) – electronic logbook (data input of blood glucose, carbohydrates, insulin administration, exercise, stress, hypoglycemic events) Control: Manual logbook	• HbA1c • frequency of hypoglycemia • targeted blood glucose values	• decreased HbA1c for all patients ($p<0.005$), however, this decrease was only from 6.9 ± 0.2 down to 6.7 ± 0.2 %, which is not a clinically significant decrease (NOTE: these values are already within the healthy recommended values, therefore, the concomitant stability and decreases in hypoglycemia accompanied by this small reduction in HbA1c is still a positive outcome) • decreased frequency of overall hypoglycemic blood glucose values (blood glucose<2.9 mmol/L) in all patients, from 5.8 ± 0.9 to 3.9 ± 1.0 % ($p=0.08$); this decrease is significant to improve the quality of life of people with type 1 diabetes

Table 4: Summary of trial results for studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			• increased percentage of blood glucose values in target range (4.0-10.0 mmol/L): from 52.7 ± 2.6% to 58.9 ± 2.9% (p<0.02) Computer-assisted data collection, as compared to a manual logbook, was much less strenuous when using the Camit electronic logbook. The use of the electronic data collection method also increased the amount of time spent during clinical visits discussing the patient's questions and problems.
Reference: Schrezenmeir, 1985[16] Design: Randomized controlled trial crossover Duration: 3 months Population: Intention to treat (completed study): 12 (12) adults Setting: Outpatient	Goal: To investigate the use of algorithms developed for a pocket computer to optimize meal-related insulin injections Intervention: Pocket computer-assisted meal-related insulin therapy (CAMIT). The insulin doses accounted for carbohydrates ingested, time of day, past, actual, and target BGs, and physical activity Control: Conventional therapy	• pre-meal blood glucose levels • change in HbA1C	• pre-meal blood glucose was reduced in both groups, with a greater reduction in the CAMIT group than in the CT group (p<0.05) • HbA1C was reduced in both groups, with a greater reduction in the CAMIT group than in the CT group (p<0.05) • the number of meals per day was 3 to 5 in the CAMIT group, and 6 to 7 in the CT group, and carbohydrate intake was variable in the CAMIT group and fixed in the CT group during the treatment • the average daily insulin requirements were reduced in the CAMIT group (p<0.05) Computer-assisted, meal-related dose adjustment was superior to conventional therapy by allowing more factors to be considered for each dose that is not normally considered in daily life.
Reference: Chase, 2003[21] Design: Randomized controlled trial Duration: 6 months	Goal: To determine whether or not modem technology allows for effective management of type 1 diabetes when used in lieu of a clinic visit	• HbA1C • hypoglycemic events • cost analysis	• HbA1C significantly decreased in both groups, but there was no difference between groups (p=0.96) • no difference in hypoglycemic events

Table 4: Summary of trial results for studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 63 adolescents n (15 to 20 yrs) Setting: Patients were recruited from a pediatric and young adult diabetes clinic; technology for home use	Intervention: Modem data transfer of blood glucose data every 2 weeks with review and follow-up by health care worker Control: Standard of care visits every 3 months	(The cost of a clinic visit was calculated by determining the cost to the patient/family or insurance company, plus additional costs like child care, parking, hotel stay, and meals. The cost of modem technology was based on the time for each transmission and telephone follow-up, health professional salaries, overhead, and the cost of the equipment amortized.)	• cost of care was significantly less in intervention group (p<0.0001) Use of modem data transfer in lieu of clinic visits provided similar metabolic results to standard of care.
Reference: Marrero, 1995[20] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 106 pediatrics (> 5 years) Setting: Outpatient	Goal: To evaluate the efficacy of using a telecommunications system to assist in the outpatient management of pediatric diabetic patients Intervention: Data transmission of blood glucose by modem every 2 weeks and phone follow-up by registered nurse to adjust regimen based on age-appropriate algorithms Control: Standard care with dosage adjustment by physician at diabetes clinic every 3 months	• HbA1C • hospitalizations/emergency room visits • psychosocial status • family functioning • perceived quality of life • parental/child responsibility • nursing time required (number of phone calls, duration of calls)	• no significant differences in most outcomes, except nursing duration of phone calls in intervention group was less, but the number of phone calls was more (p<0.001) This telecommunication system was reliable and was used dependably by patients and their families.
Reference: Farmer, 2005[19] Design: Randomized controlled trial Duration: 9 months Population: Intention to treat (completed study): 93 adults	Goal: To determine whether or not a system of telemedicine support can improve glycemic control in patients with type 1 diabetes. Real-time results transmitted via mobile phone (insulin dose, food, etc.) with past 24-hour blood glucose graphical feedback display	-median blood glucose -HbA1C	• the median blood glucose level was lower in the intervention group than in the control group over the trial (p<0.0001) • no difference in the change of HbA1C between groups, although both decreased significantly over study period

Table 4: Summary of trial results for studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Recruited from young adult clinic, but intervention intended for home use	Intervention: Immediate graphical feedback with analysis (intensive feedback to patient), nurse specialist counselling/clinical advice and personalized objectives supporting behavioural change, and web page access of data and summaries (intervention is also a patient intervention: education, audit/feedback) Control: Data transmission and past 24-hour results only (no analysis – minimal feedback), no nurse specialist, patient diary, only on web page		This is a feasible and acceptable system for patients; however, to significantly improve glycemic control, diet, exercise, and real time support for medication, dosing may be required.
Reference: Peters, 1991[14] Design: Randomized controlled trial Duration: 32 days Population: Intention to treat (completed study): 42 (42) adults Setting: Diabetic education centre (computer intended for home use)	Goal: To assess if a wallet-sized memory decision-support system to adjust insulin dose would provide similar results to conventional therapy. The system accepted variables such as actual blood glucose, hypoglycemic episodes, carbohydrate intake, and physical activity Intervention: Computerized insulin dose adjustment – wallet-sized memory decision support system: learning memory system Control: Dose adjustment supported by the education team with daily follow-up	• blood glucose result and frequency of reading • HbA1C • frequency of hypoglycemia • BMI	• HbA1C decreased significantly from a statistical ($p<0.001$) and clinical point of view in both groups: from 9.8 ± 1.6% to 9.0 ± 1.2% in the experimental group versus from 9.9 ± 1.6% to 9.2 ± 1.2% in the control group • proportion of hypoglycemia (blood glucose ≤ 3.3 mmol/L) decreased significantly in experimental group, from 3.3 to 1.7%, ($p<0.05$), whereas the control group's decrease from 3.7 to 2.3% was not significant compared to baseline. Any reductions in the frequency of hypoglycemic blood glucose values is a positive change, regardless of statistical significance

Table 4: Summary of trial results for studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			• decreased insulin dose from baseline in experimental group (0.63 ± 0.14 to 0.57 ± 0.15 U/kg p<0.01), but remained unchanged in controls (0.65 ± 0.13 to 0.64 ± 0.20 U/kg) Metabolic control and safety were comparable in both groups. Patients may benefit from such a system in adjusting their insulin dose at home where no support by diabetes educators is available.
Reference: Chiarelli, 1990[15] Design: Non-randomized, controlled, matched; crossover Duration: Three 8-week time periods. Period 1: Both groups followed manually adjusted insulin dosages via traditional care Period 2: Experimental group only received microprocessors which used algorithms to determine changes in insulin dosages Period 3: Same as period 1(basically their follow-up) Population: Intention to treat (completed study): 20 pediatrics (<12 years) well-controlled Setting: Not specified, but insulin dosage computer intended for home use	Goal: To assess if a wallet-sized memory decision support system to adjust insulin dose would provide similar results to conventional therapy. The system accepted variables such as actual blood glucose, hypoglycemic episodes, carbohydrate intake, and physical activity Intervention: Computerized insulin dose adjustment (insulin dosage computer) – wallet-sized memory and decision support system Control: Team dose adjustment with daily follow-up	• blood glucose result and frequency of reading • HbA1c • frequency of hypoglycemia • BMI	• HbA1c varied up and down non-significantly in the experimental group from 7.8.± 1.0 at baseline, to 8.1 ± 1.6 in period 1, 7.7 ± 2.1 in period 2, and 7.4 ± 1.8 in period 3 • HbA1c in the control group decreased non-significantly from 7.9± 1.3 at baseline to 7.9 ± 1.5 in period 1, 7.8 ± 1.9 in period 2, and 7.6 ± 1.5 in period 3 • there were no significant differences in HbA1c between the two groups during the three periods of the trial • significant decreases in insulin requirements for the experimental group between periods 1 and 2 (0.94±0.02 U/kg/day versus 0.82±0.02 U/kg/day, p<0.0001), but no further significant change in the third period (0.84 ± 0.05 U/kg/day) • in the control group, insulin requirements were similar in the first two periods (0.95±0.03 versus 0.96±0.07 U/kg/day), and slightly, but not significantly lower in the third period (0.91 ± 0.04 U.kg/day)

Table 4: Summary of trial results for studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			• hypoglycemic events for the intervention and control groups did not change between periods 1 and 2 (despite the implementation of the insulin dosage computer in the experimental group), but rose significantly in period 3 for both groups – this was after reverting to manual methods of insulin adjustment! (changes were significant compared to period 1 $p<0.005$): 1.2 versus 1.1 events/week in period 1; 1.2 versus 2.3 events/week in period 2; and 2.0 versus 3.4 events/week in period 3

BMI=body mass index; CT=conventional therapy; HbA1c=glycolsylated hemoglobin

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Matsuyama, 1993[22] Design: Randomized controlled trial – double-blind Duration: 2 months Population: Intention to treat (completed study): 47(32) Setting: Veterans Affairs Medical Center ambulatory care (outpatient) clinics	Goal: To compare adherence data from Micro-ElectroMechanical System – an electronic medication-event monitoring device – with pill counts in assisting pharmacists in making recommendations regarding diabetes therapy. Investigators made pharmacologic or educational recommendations to the patient's health care provider Intervention: Micro-ElectroMechanical System readings Control: Pill count	• HbA1c • fasting plasma glucose • quantities and types of recommendations regarding diabetes therapy made by pharmacists using adherence data from the two methods	• in the interventions group, 47% of the recommendations related to patient education instead of pharmacological changes (such as increased dosage), compared with 12 % in the control group (p=0.028) Micro-ElectroMechanical System data resulted in different numbers and types of recommendations than pill counts. Pharmacists then could make specific recommendations regarding patient education before resorting to pharmacologic manipulations.
Reference: Piette, 2000[23] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 280 (248) Setting: Outpatient	Goal: To evaluate the effect of automated telephone assessment and self-care education calls with nurse follow-up on the management of diabetes Intervention: Usual care and bi-weekly automated assessment and self-care education calls with telephone follow-up by a nurse educator Control: Usual care	• HbA1c • serum glucose levels • survey-reported self-care • perceived glycemic control • symptoms	• HbA1c levels were lower in intervention than controls (p=0.1) and more patients in the intervention group (about twice as many as control group) had HbA1c levels within the normal range (p=0.04) • serum glucose levels were significantly lower in the intervention group (by 41 mg/dL, p=0.002) • intervention patients reported better glycemic control (p=0.005) and fewer diabetic symptoms (p<0.0001) • intervention patients reported more frequent glucose monitoring, foot inspection, and weight monitoring, and fewer problems with medication adherence (better self-care) (all p≤ 0.03)

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			Automated calls with telephone nurse follow-up may be an effective strategy for improving self-care behaviour and glycemic control, and for decreasing symptoms among vulnerable patients with diabetes.
Reference: Kennedy, 2006[25] Design: Randomized controlled trial Duration: 6 months Population: Intention to treat (completed study): 7,893 (patients with type 2 diabetes taking insulin) Setting: Outpatient	Goal: To assess the impact of active versus usual monitoring of algorithmic insulin titration and point-of-care versus laboratory HbA1c measurement on glycemic control in primary care Intervention: Take insulin glargine with : Group 2: Usual titration and point-of-care and HbA1c testing Group 3: Active (weekly monitoring) titration and lab HbA1c testing Group 4: Active titration and point-of-care and HbA1c testing Control: Group 1: Usual insulin titration using a simple algorithm with lab HbA1c testing (no unsolicited contact between visits)	• HbA1c • SMBG/fasting blood glucose • % of patients with HbA1c < 7.0% • frequency of hypoglycemia	• significant HbA1c and SMBG reductions were observed in all arms (p<0.0001) • compared with usual insulin titration, active titration achieved greater HbA1c reduction (1.5 versus 1.3%; p< 0.0001), SMBG reduction, (88 versus 79 mg/dL; p<0.0001) • proportion of patients achieving HbA1c M 7.0% (38 versus 30%; p<0.0001) • among patients receiving active titration, point of care and HbA1c testing was associated with an increase in the proportion achieving an HbA1c < 7.0% (41% for point of care versus 36% for lab HbA1c) • hypoglycemia rates were low; 3.7 versus 6.0 confirmed episodes/patient-year in usual versus active groups (p<0.001); 0.09 versus 0.14 severe episodes/patient-year In a predominantly primary care setting, addition of insulin glargine using a simple algorithm achieved significant improvements in glycemic control in patients with type 2 diabetes in all four study arms. Active titration resulted in significant incremental improvements in glycemic control; and among patients receiving active titration, point-of-care and HbA1c testing resulted in a greater portion achieving HbA1c < 7.0%.

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Kwon, 2004[24] Design: Randomized controlled trial Duration: 3 months Population: Intention to treat (completed study): 110 (101) Setting: Outpatient	Goal: To investigate the effectiveness of an internet-based blood glucose monitoring system on controlling the changes in HbA1c levels Intervention: Internet-based blood glucose monitoring system; it served as an integration centre and primary point of contact between patient and health care team (doctors, registered nurses, endocrinologists, professors, dieticians); recommendations were continuously made when required Control: Usual care	• HbA1c	• HbA1c was significantly decreased in the intervention group (from 7.59 to 6.94%; p<0.001) and this was significantly lower than the control group at end point (7.62%; p<0.001) The internet-based blood glucose monitoring system resulted in a significant reduction of HbA1c during the study period.
Reference: Smith, 2004[28] Design: Randomized controlled trial Duration: 18 months Population: Intention to treat(completed study): 183 Setting: Outpatient	Goal: To assess the feasibility and effectiveness of a structured diabetes shared care service in a mixed health care system and to analyze the impact on total patient care Intervention: Shared diabetes care Control: Usual care	• HbA1c • blood pressure • BMI • smoking status • treatment satisfaction and well-being scores	• there were significant improvements in diabetes care delivery and in psycho-social outcomes, but no significant improvements in biomedical outcomes • there was a significant increase in diabetes care-related activity for participating patients, with an increase in structured annual reviews and fewer patients defaulting from care • there were also significant improvements in information exchange between primary and secondary care Structured diabetes shared care, in a mixed health care system, can produce significant improvements in diabetes care delivery and in psychosocial outcomes for patients, with improved information exchange across the primary-secondary care interface.

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Renders, 2001[27] Design: Controlled, non-randomized Duration: 42 months Population: Intention to treat (completed study): 389(312) Setting: Outpatient	Goal: To assess the long-term effectiveness of a quality improvement program on care provided and patient outcomes in patients with diabetes Intervention: A quality improvement program for doctors of patients who have type 2 diabetes; general practitioners received guidelines for the structure of diabetes care, targets for glycemic control, and cardiovascular disease factors in accordance with the Dutch College of General Practitioners and the European Non-Insulin-Dependent Diabetes Mellitus Policy Group; structured meetings for general practitioners to interact with peers and experts, and get feedback regarding patient outcomes and obstacles; general practitioners were given diabetes templates to achieve structured registration of the care provided; a central recall system for annual control visits of the patients was implemented so data could be sent to general practitioners Control: Usual care	• HbA1c • annual number of patient visits • blood pressure • blood lipid levels • urine albumin	• patients in the intervention group received care far more in accordance with the guidelines than patients in the control group • odds ratios ranged from 2.43 (95% CI 1.01-5.82) for the measurement of urine albumin to 12.08 (4.70-31.01) for the measurement of blood pressure • no beneficial effect was found on any patient outcome The quality improvement program improved the provision of diabetes care, but this was not accompanied by any effect on patient outcomes.
Reference: Choe, 2005[32] Design: Randomized controlled trial Duration: 12 months	Goal: To evaluate the effect of case management by a clinical pharmacist on glycemic control and preventive measures in patients with type 2 diabetes	• HbA1c • low-density lipoprotein • retinal exam	• the intervention group achieved greater reduction in HbA1c than control (2.1 versus 0.9%; p=0.03)

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 80 (65) Setting: Outpatients from a university-affiliated ambulatory care clinic	Intervention: Clinical pharmacist-assisted primary care providers in the management of patients with type 2 diabetes Control: Usual care	• urine microalbumin testing (or use of angiotensin-converting enzyme inhibitors) • monofilament screening for neuropathy	• 3/5 process measures (tests for diabetes complications and diabetes status) were conducted more frequently in the intervention group than the control group, including low-density lipoprotein measurement (100% versus 85.7%, p=0.02), retinal examination (97.3% versus 73.3%), and monofilament foot screening (92.3% versus 62.9%) Proactive diabetes case management by a pharmacist substantially improved glycemic control and diabetes process-of-care measures. This approach, integrated with and based in the primary care setting, was an effective and efficient method to improving care, especially for those with poor glycemic control at baseline.
Reference: Coast-Senior, 1998[30] Design: Not controlled Duration: 6 months Population: Intention to treat (completed study): 23 Setting: Outpatient	Goal: To determine the impact of clinical pharmacists involved in direct patient care on the glycemic control of patients with type 2 diabetes Study design: SMBG and education, medication counselling, monitoring, and insulin initiation and/or adjustments by the pharmacist	• HbA1c • fasting blood glucose • blood glucose • frequency of hypoglycemia • number of emergency room hospital visits	• HbA1c, fasting blood glucose, and random blood glucose concentrations significantly decreased from baseline by 2.2% (p=0.00004), 65 mg/dL (p<0.01), and 82 mg/dL (p=0.00001), respectively • symptomatic hypoglycemic episodes occurred in 35% of patients, but none of these episodes required physician intervention This study demonstrates that pharmacists working as members of interdisciplinary primary care teams can positively impact gylcemic control in patients with type 2 diabetes requiring insulin.
Reference: Clifford, 2005[31] Design: Randomized controlled trial Duration: 12 months	Goal: To examine the effect of a 12-month pharmaceutical care program on vascular risk in type 2 diabetes	• HbA1c • fasting blood glucose AND fasting plasma glucose • blood pressure • high-density lipoprotein	• mean reductions were greater in the pharmaceutical care group than in control subjects for HbA1c [-0.5 (95% CI) -0.7 to -0.3%] versus [0 (-0.2 to 0.2)]; the same held true for systolic blood pressure (-14 mm Hg

Table 5: Summary of trial results for studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 198 Setting: Outpatient	Intervention: pharmaceutical care; included face-to- face, goal-directed medication and lifestyle counselling at baseline, and at 6 and 12 months, and 6 weekly phone assessments, and were given other educational material. Clinical, biochemical, and medication-related data were sent regularly to each patient's doctor Control: Usual care	• low-density lipoprotein • existence and severity or risk of cardiovascular disease and stroke • statin therapy • smoking cessation status (if appropriate) • exercise • diet • compliance • SMBG • urinary albumin: creatinine ratio (indicator of nephropathy)	[-19 to -9] versus -7 [-11 to -2]) and diastolic blood pressure (-5 mm Hg [-8 to -3] versus -2 [-4 to 1]) • the median (IQ range) 10-year estimated risk of a first coronary heart disease event decreased in the pharmaceutical care group (25.1% [15.6-36.2] to 20.3 [14.6-30.2]; n= 42, p=0.002) but not in control subjects 26.1% [17.2-39.4] versus 26.4 [16.7-38]; n=52, p=0.17) A 12-month pharmaceutical care program in patients with type 2 diabetes reduced glycemia and blood pressure. Pharmacist involvement contributed to improvement in HbA1c independently of phamacotherapeutic changes. Pharmaceutical care could prove a valuable component of community-based multidisciplinary diabetes care.
Reference: Stein, 1974[29] Design: Control Duration: 6 months Population: Intention to treat (completed study): 23 Setting: Outpatients	Goal: To evaluate and analyze the clinical outcome data of a nurse practitioner-managed group of diabetic out-patients, compared with a physician-internist group of similar patients Intervention: Management of a group by nurses Control: Management of a group by doctors	• blood glucose • weight • knowledge	• no significant difference in patient mortality or morbidity between groups • significant improvement occurred in the patients' understanding of diabetes in the registered nurse group This study contributes to the viewpoint that the role of the registered nurse may be extended to encompass more comprehensive treatment programs in patients with chronic disease.

CI=confidence interval; HbA1c=glycolsylated hemoglobin; SMBG=self-monitoring of blood glucose

APPENDIX 3: STUDIES OF REGULATORY INTERVENTIONS

Table 6: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Benjamin, 1999[33] Design: Control Duration: 15 months Population: Intention to treat (completed study): 144 (not applicable) Setting: Outpatient	Goal: To study the effects of using a problem-based learning technique to implement a diabetes clinical practice guideline Intervention: Doctors and staff were trained in the use of a clinical practice guideline based on staged diabetes management; a problem-based learning educational program was instituted to reach consensus on a stepped intensification scheme for glycemic control, and to determine the standards of care used in the clinic Control: Usual care	• HbA1c	• the mean within-subject change in HbA1c of -0.62% in the intervention group was significant (p=0.006) Clinical practice guidelines are an effective way of improving processes and outcomes of care for patients with diabetes. Problem-based learning is a useful strategy to gain physician support for clinical practice guidelines. More intensive interventions are needed to maintain treatment gains.
Reference: The California Medi-Cal Type 2 Diabetes Study Group, 2004[34] Design: randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 362 (not applicable) Setting: Outpatient	Goal: To determine if intensive diabetes case management using specific, population-directed case management strategies could improve glycemic control in a southern California Medicaid population of patients with type 2 diabetes in which minorities are over-represented Intervention: Diabetes case management Control: Traditional primary (usual) care treatment	• HbA1c	• HbA1c decreased substantially in both groups from an average of 9.54 to 7.66% (-1.88%) in the intervention group, and from 9.66 to 8.53% (-1.13%) in the control group. The reduction of HbA1c in the intervention group was significantly greater at each time point (p<0.001) Diabetes case management, added to primary care, substantially improved glycemic control compared with the usual primary care. Diabetes case management can help reduce disparities in diabetes health status among low-income ethnic populations.

Table 6: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Franz, 1995[35] Design: Randomized controlled trial Duration: 6 months Population: Intention to treat (completed study): 247 (179) Setting: Outpatient	Goal: To assess the effect of medical nutrition therapy provided by dieticians on medical and clinical outcomes for adults with non-insulin-dependent diabetes mellitus and to compare medical nutrition therapy administered according to practice guidelines for nutrition care to medical nutrition therapy administered with basic nutrition care Intervention: Practice guidelines for nutrition care; patients received an initial session of 1 hour and 2 follow-up sessions of 30-45 minutes, with a dietician obtained from the referring physician, data related to diagnosis, current medical therapy, lab data, and medical clearance for exercise; dietician assumed responsibility for determining the appropriate nutrition, education, and medical prescriptions, especially as it related to medical nutrition therapy Control: Basic nutrition care; 1 visit for 1 hour with a dietician wherein the data from the patient and referring physician were used to develop a nutrition care plan; nutritional goals designed to improve glycemic control were introduced, and general principles of nutrition management were discussed	• HbA1c • fasting plasma glucose • total cholesterol • low-density lipoprotein • high-density lipoprotein • triglycerides	• practice guidelines for nutrition care resulted in significant improvements in blood glucose control as indicated by fasting plasma glucose and HbA1c levels, and basic nutrition care resulted in significant improvements in HbA1c level • practice guidelines for the nutrition care group had a mean fasting plasma glucose level at endpoint that was 10.5% lower than the level at entry, and those in the basic nutrition care group had a 5.3% lower value; among patients who had diabetes for longer than 6 months, those who received practice care guidelines had a significantly better HbA1c level at 3 months versus the basic nutrition care group • the basic nutrition care group showed no improvement in glycemic control over the trial • practice guidelines for nutrition care patients had significant improvements in cholesterol, while both groups had significantly weight loss Medical nutrition therapy provided by dieticians resulted in significant improvements in medical and clinical outcomes in both groups and is beneficial to persons with non-insulin-dependent diabetes mellitus. Persons with a duration of diabetes longer than 6 months tended to do better with practice guidelines for nutrition care than with basic nutrition care. Because of the upward trend in glucose levels after 3 months, ongoing medical nutrition therapy by dieticians is important for long-term metabolic control.

Table 6: Summary of trial results for studies with patients with type 2 diabetes*			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Meier, 2002[36] Design: Retrospective, not controlled (states that it's non-crossover – but it's not a true set of two separate samples) Duration: 6 months Population: Intention to treat (completed study): 2491 (1887) adult Setting: Unclear	Goal: To assess the impact of a modification of Veteran's Affairs guidelines on HbA1c and monitoring cost Intervention: Instructed patients with type 2 diabetes to perform SMBG- testing according to modified adapted Veterans Affairs guidelines. Control: Measured differences in glucose test-strip use/day before and 2 months post-implementation of guidelines	• HbA1c • frequency of SMBG (strips/patient/day) • cost	• no significant change in HbA1c (p=0.63 versus baseline) • frequency of SMBG decreased significantly (by 46%) versus baseline (p<0.0001) • similar findings were found for sub-groups of patients who were either diet-treated or drug-treated (linear regression analysis showed no significant impact on HbA1c by reduction of strip use) • average savings were $6.37/patient/month The program decreased the frequency of SMBG in people with type 2 diabetes, resulting in substantial cost-savings without affecting glucose control.

HbA1c=glycolsylated hemoglobin; S MBG=self-monitoring of blood glucose;

* No studies of regulatory interventions for type 1 diabetes

APPENDIX 4: STUDIES OF PATIENT INTERVENTIONS

Table 7: Summary of trial results of studies with patients with type 1 diabetes

Details	Goal/ Intervention	Outcomes Measured	Results/Conclusions
Reference: Cox, 2004[37] Design: Randomized before 6 months after 18 months Duration: 18 months Population: Intention to treat (completed study): 60 adults with recurrent hypoglycemia Setting: Recruited from clinics in 3 cities, outpatient visits, but intervention group also participated in sessions over 7 weeks	Goal: To assess a program teaching hypoglycemic awareness, and its effects on detection and treatment of low blood glucose, the frequency of low blood glucose, as well as metabolic control Intervention: Structured program to manage hypoglycemic episodes, readings, and group sessions with required reading and homework before SMBG measurements– HAATT Control: SMBG	• SMBG (patient diaries) • frequency hypoglycemia • HbA1c	• pre-post-treatment (data from monthly diaries of moderate and severe hypoglycemia for 6 months, and 4 daily diary entries of SMBG readings and participants' judgment for 1 month) • less extreme blood glucose fluctuations in HAATT group (p=0.01) • significantly less severe hypoglycemia (p<0.03), moderate hypoglycemia (p<0.001), and nocturnal hypoglycemia (p=0.055) in HAATT group relative to SMBG group • HbA1c was not different between groups • long-term follow-up (data from month 13 to month 18 post-treatment) • HAATT group had fewer episodes of severe hypoglycemia (p<0.023) and fewer episodes of moderate hypoglycemia (p<0.001) than SMBG group The program produced significant improvement in occurrence of hypoglycemia and detection/treatment of low blood glucose.
Reference: Sämann, 2006[44] Design: Before and after intervention Duration: 1 year Population: Intention to treat	Goal: To evaluate diabetes treatment and teaching programs in patients at high risk of hypoglycemia and diabetic ketoacidosis	• HbA1c • episodes of severe hypoglycemia • episodes of severe diabetic ketoacidosis • hospitalizations	• decrease in HbA1c (95% CI [difference]: -0.5 to –0.14, p<0.0006) • decrease in severe hypoglycemic events (95% CI [difference]: -5.4 to -4.0, p<0.0001) • decrease in severe diabetic ketoacidosis (95% CI [difference]: -3.3 to –2.1, p<0.0001) • decrease in days in hospital (95% CI [difference]: -12.9 to –3.2, p<0.00014)

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
(completed study): 341 adults with recurrent hypoglycemia Setting: Intervention given in diabetes centre, outpatient	Intervention: Structured program of diet, lifestyle, measurement blood glucose, understanding risks of hypoglycemia, and administration of insulin by special educator Control*:* Historical control (self)		Patients at high risk of hypoglycemia had fewer episodes after intervention and maintained metabolic control.
Reference: Wysocki, 2001[26] Design: Randomized controlled trial Duration: Intervention every 3 months Follow up every 12 months Population: Intention to treat (completed study): 119 adolescents 12 to 17 years and their families Setting: Centre for teaching and home	Goal: To report the effects of behavioural family systems therapy in adolescents with diabetes on relationship measures, adherence to regimen, and diabetic control Intervention: Group 2: group meetings with educator/social components Group 3: handouts, homework, problem solving, cognitive restructuring, communication skills, and functional family therapy based on specific patient needs identified by psychologist-behaviour family systems therapy Control: Group 1: Usual treatment	• questionnaires of specific behavioural variables (parent-adolescent relationships and teen adjustment) • adherence • metabolic control	• Group 3 improved, versus Group 1, for behavioural variables ($p<0.05$) and, depending on the time post-intervention, was either no different to or significantly better than Group 2 • adherence was significantly improved in Group 3, as compared to both other groups ($p<0.05$) • HbA1c was not different between groups Behavioural family systems therapy yielded lasting improvement in family relationships and delayed improvement in treatment adherence. However, it had no effect on adjustment to diabetes or metabolic control.
Reference: Howe, 2005[42] Design: Randomized controlled trial Duration: 6 months Population: Intention to treat: 164 (completed study): 75 pediatrics, aged 1 to 16 yrs, with suboptimal control	Goal: To compare three nursing interventions and their impact on glycemic control among children with type 1 diabetes (can also be classed as disease management intervention to improve delivery of health care)	• HbA1c • diabetes knowledge, parent/child teamwork • adherence	• there was no difference in HbA1c ($p=0.12$), although it decreased slightly in all groups • there was a significant improvement in teamwork scores in Group 3 ($p=0.0003$) (evaluated by clinicians to determine a child's ability to assume age-appropriate behaviours related to diabetes management and parents' abilities to provide age-appropriate supervision of their child's diabetes management)

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Home	Intervention: Group 2: taught skills, diet, problem management, given written information Group 3: same as Group 2 plus telephone management by nurse specialist for patient-specific blood glucose and insulin dose adjustment Control: Group 1: usual care		• family/child adherence (measured by an index which determines if family/child exhibits safe diabetes control behaviours) improved significantly from baseline to endpoint in Group 3 compared to the other two groups (p=0.0002) No difference in HbA1c, although increased knowledge/teamwork and adherence in the combination group.
Reference: Bacon, 1986[43] Design: Randomized controlled trial, double-blind, crossover Duration: 2-3 years Population: Intention to treat (completed study): 146 pediatrics and adolescents, 3 to 21 yrs Setting: Clinic	Goal: To determine if the results of the HbA1c, when made available to the physician and patient, is therapeutically beneficial (can also be classed as professional intervention) Intervention: Provision of HbA1c results to group's physicians and patients Control: No HbA1c results were provided. All other parameters were available	• HbA1c	• slight but significant change in HBA1c during blinded phases • there were no significant differences between groups at the conclusion of either phase • improvement was most pronounced in those who had baseline poor control (p<0.03) HbA1c improved with knowledge of the test results in patients with baseline control that was poor (HbA1c > 12.7%). Results worsened slightly when intervention was withdrawn. Those with good control did not demonstrate a benefit.
Reference: Laffel, 2003[39] Design: Randomized controlled trial Duration: 1 year	Goal: To evaluate an ambulatory family-focused intervention to optimize glycemic control, minimize family conflict, and maintain quality of life	• HbA1c • QoL • diabetes-related family conflict	• HbA1c was lower in the intervention group (p<0.05) • family involvement was significantly increased in the intervention group (p<0.05) without increasing family conflict or reducing QoL after one year

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 100 pediatrics/ adolescents, 8 to 17 years Setting: Outpatient with clinic visits	Intervention: Intensive education of both patient and family by team. Written materials were given to both groups, but reinforcement of materials and education on responsibility-sharing was provided in intervention group Control: Usual education		Intervention provided improved glycemic control with successful prevention of deterioration in control as seen with standard care.
Reference: Likitmaskul, 2002[38] Design: Non-randomized controlled Duration: Retrospective analysis of hospital length of stay Population: Intention to treat(completed study): 52 pediatrics, mean age 7.1 to 8.4 years; new diagnosis Setting: Hospital	Goal: To determine if young children newly diagnosed with diabetes who underwent an intensive multidisciplinary education program would have reduced hospitalization days and readmission rates for diabetic ketoacidosis Intervention: Intensive education of patients and parents (to develop patient/family management skills, strong motivation for self management) by multidisciplinary team (pediatric endocrinologist, clinical psychologist, diabetes nurses, dieticians) during first hospital admission Control: Historical	• length of stay • readmission rate for diabetic ketoacidosis • HbA1c	• average length of stay was reduced from 36.04 to 17.63 days (p=0.03) • readmission rate was reduced from about 18% to 4% (no statistics) • HbA1c levels were lower in the intervention group (9.19%) than in the control group (11.52%) (p=0.03) The education program resulted in a decrease in length of stay, and hospital readmissions, and better control of HbA1c.
Reference: Couper, 1999[41] Design: Non-randomized controlled Duration: Intervention lasted 6 months	Goal: To determine if a 6-month home intervention program in adolescents with poorly controlled diabetes would improve and then maintain metabolic control	• HbA1c • diabetes knowledge: assessed by means of the Diabetes Knowledge Assessment scale, which is a 15-item questionnaire designed to provide a reliable assessment	• HbA1c decreased significantly from baseline to endpoint (6 months) in the intervention group (11.1 ± 1.3 to 9.7 ± 1.6, p=0.0001), but not in the control group (10.5 ± 1.6 to 10.3 ± 2.2)

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Follow-up at 12 and 18 months Population: Intention to treat:73 (completed study): 69 adolescents, 12 to 17 years with poor control Setting: Home	Intervention: Structured program included guided goal setting, support for SMBG, and understanding target ranges, as well as usual care in diabetes clinic. Intervention group also had monthly home visit from a diabetes nurse educator, as well as weekly phone calls Control: Usual care; both groups had 24-hour access for acute problems and every 3months clinic visits	of the knowledge of patients about the management of type 1 diabetes	• mean knowledge scores increased in intervention group from baseline (11.6 ± 1.5) to every time point: 13.4 ± 1.3 at 6 months (p=0.0001), 12.8 ± 1.6 at 12 months (p=0.0009), and 13.2 ± 1.4 at 18 months (p=0.0001) • mean knowledge scores were increased significantly for the control group only at 12- and 18-month follow-ups; baseline mean score was 11.1 ± 2.4, which rose to • 12.3 ± 1.8 at 12 months (p=0.007) and 13.0 ± 1.3 at 18 months (p=0.007) • mean knowledge scores differed between groups significantly (p=0.001)at the 6-month checkpoint, where the intervention group had higher knowledge scores (13.4 ± 1.3) compared to controls (11.8 ± 2.1) This study improved HbA1c and knowledge during intervention, but HbA1c changes in the intervention group were not sustained at the 12-month follow-up (rose back up to 10.5 ± 1.8); yet the difference from baseline approached significance (p<0.06) at 18 months, dropping to 10.0 ± 1.5.
Reference: Dougherty, 1999[46] Design: Randomized controlled trial Duration: 24 months Population: Intention to treat (completed study): 63 pediatrics > 2 years; newly diagnosed	Goal: To determine if home-based management could provide superior or similar control at a reduced cost to traditional hospital and clinic-based care.	• HbA1c at 2 yrs • cost • hospital length of stay • advanced diabetic retinopathy • psychosocial outcomes (self-report instruments) • knowledge/adherence • family impact • child behaviour • life events	• HbA1c was significantly lower in the intervention group (home-based care) than the control group (hospital-based group) at each three-month checkup between 12 and 24 months (p<0.02) • HbA1c at 24 months was 6.1 ± 1.3% in the home-based intervention group and 6.8 ± 1.3% in the hospital-based control group p<0.02)

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Home versus hospital	Intervention*:* Home care – discharged from hospital once metabolic control achieved; outpatient training and insulin dose adjustments by nurse specialist Control: Traditional inpatient (hospital-based care); includes teaching		• at 36 months (post-intervention follow-up), differences between groups held the same amount of significance in their differences, although values changed slightly: these values rose to 6.4 ± 1.4% and 7.1 ± 1.3% ($p<0.02$) in the intervention versus controls, respectively • because patients were recruited at onset of diabetes diagnosis, no HbA1c data was used to compare changes from start to endpoint; authors purposely analyzed data after 12 months from diagnosis in order to allow for complete beta-cell deterioration and subsequent levelling off of insulin dose changes • higher mean insulin doses (no statistics given) • costs not different, as increased health services costs (e.g., hospital days) were offset by decreased parental costs • home-based care had lower mean hospital ward days (2.2 ± 1.6 nights, 70 total) than hospital-based care (4.7±1.6 nights, 147 total) • no significant differences were detected for psychosocial measures Home-based management resulted in decreased hospital length of stay; increased social cost offset by parental cost savings
Reference: Lawson, 2005[45] Design: Randomized controlled trial Duration: 6 months	Goal: To determine the effect of regular standardized telephone contact by a diabetes nurse educator on metabolic control, adherence, and quality of life	• HbA1c • blood glucose • QoL • adherence • family functioning • insulin dose	• no significant differences in HbA1c, quality of life, family functioning, or insulin dose at endpoint • slight increase in adherence

Table 7: Summary of trial results of studies with patients with type 1 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat: 49 (completed study): 46 adolescents; 13 to 17 years, poorly controlled Setting: Home	Intervention: Weekly telephone call with monitoring of blood glucose and insulin dose-adjustment Control: Usual care		• 6 months after the study ended, post-hoc analysis revealed a clinically and statistically significant decrease in HbA1c levels (by at least 1%) in 29% of the patients in the intervention group and 0% in the control group, as well as an increase in HbA1c levels in 19% of the intervention patients and 44% of the control patients (p=0.015) Telephone contact did not lead to immediate benefits, although delayed improvements are possible.
Reference: Lowes, 1997[40] Design: Controlled Duration: Data from prior 2 years Population: Intention to treat (completed study): 56 pediatrics with new diagnosis Setting: Home	Goal: To evaluate the impact of a pediatric nurse specialist on hospital length of stay in newly diagnosed children with diabetes (can also be classed as disease management intervention to improve delivery of health care) Intervention: Assessment by nurse specialist for home management and close follow-up Control: Historical • usual care (prior 2 years); both groups had 24-hour health care worker access	• hospital length of stay	• length of stay was significantly reduced from 5 to 1.5 days (p<0.0001) Pediatric diabetes specialist nurses can improve pediatric diabetes care by minimizing or avoiding hospitalization in newly diagnosed children.

CI=confidence interval; HAATT=Hypoglycemia Anticipation, Awareness and Treatment Training; HbA1c=glycolsylated hemoglobin; QoL=quality of life; SMBG=self-monitoring of blood glucose

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Kirkman, 1994[47] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 275 Setting: Outpatient	Goal: To examine whether or not a telephone-delivered intervention, designed to improve glycemic control in patients with non-insulin-dependent diabetes mellitus, is more effective than usual care Intervention: Patients were phoned at least monthly by a nurse • calls emphasized compliance with the medical regimen (diet, medications, and exercise), encouraged behavioral changes, and facilitated referrals to a dietician or smoking cessation clinic Control: Usual care	• lipid profiles • weight • smoking status (self-reported; cessation verified by measurement of exhaled carbon monoxide) • adherence to diet and exercise (self-reported) • appointments • medications (hospital computerized database)	• equal numbers of obese patients in the two groups reported adhering to a diabetic diet and exercising, although more obese telephone-delivered intervention patients had seen a dietician (30 versus 7%, p=0.003) • hyperlipidemic telephone-delivered intervention patients were more likely to see a dietician (31 versus6%, p=0.003) and receive lipid-lowering medications (22 versus 9%, p=0.096) The telephone-delivered intervention improved self-reported adherence to regimen that might reduce coronary risk, but had little effect on objective measures of risk.
Reference: Piette, 2001[48] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 272 Setting: Outpatient	Goal: To evaluate an automated telephone disease management system with telephone nurse follow-up as a strategy for improving diabetes treatment processes and outcomes in Department of Veterans Affairs clinics; also compared the results with those of a prior automated telephone disease management trial conducted in a county health care system	• HbA1c • serum glucose (SMBG) • telephone surveys were used to measure: o patients' self-care o symptoms o satisfaction with care	• among patients with baseline HbA1c levels • 8%, mean end-point values were lower among intervention than control patients (8.7 versus 9.2%, p=0.04) • intervention patients also were more likely than control patients to have had a cholesterol test • at follow-up, intervention patients reported fewer symptoms of poor glycemic control than control patients and greater satisfaction with their health care

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Intervention: Patients received bi-weekly automated telephone disease management health assessment and self-care education calls, and a nurse educator followed up with patients based on their automated telephone disease management assessment reports Control: Usual care		This intervention improved the quality of Veterans Affairs diabetes care. Intervention effects for most end-patients replicated findings from the prior county clinical trial, although intervention-control differences in the current study were smaller because of the relatively good self-care and health status among the current study's enrollees.
Reference: Guerci, 2003[49] Design: Randomized controlled trial Duration: 6 months Population: Intention to treat (completed study): 988 (689) adults Setting: Outpatient	Goal: To compare changes in metabolic control over 6 months in patients managed with usual recommendations alone or combined with SMBG Intervention: Conventional lab work-up and SMBG 6x/week Control: Conventional lab work-up (NOTE: all patients received a conventional lab work-up, based on measurements of HbA1c, every 12 weeks, according to recommendations of the Agence nationale d'accréditation et d'évaluation en Santé (ANAES); physical activity, drugs, and diet were standardized	• SMBG • HbA1c • weight • blood pressure	• at endpoint, HbA1c was significantly lower in the intervention group (p=0.012), although 57.1% of patients in the SMBG group and 46.8% of patients in the control group had an improvement in HbA1c (p=0.007) after 3 months • the change in HbA1c levels between baseline and endpoint was classified into two cases: improvement if a change of >0.5% occurred versus stability or worsening in case of a change ≤ 0.5%. • multivariate logistic regression identified predictive factors of: improvement in HbA1c at baseline, odds ratio=1.749 (p<0.001); SMBG group reference value, odds ratio=0.665 (p=0.015); duration of diabetes, odds ratio=0.953 (p=0.001); and BMI, odds ratio=0.969 *-/(p=0.039).mean change in weight and blood pressure between the inclusion and endpoint was not significantly different between groups, and no time-effect was found for these parameters

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			This trial demonstrates that SMBG is statistically associated with a slight but significant improvement of metabolic control. The benefit was greater in patients with higher initial HbA1c, lower BMI, and lower duration of diabetes.
Reference: Schwedes, 2002[50] Design: Randomized controlled trial Duration: 6 months intervention, 6 months follow-up Population: Intention to treat (completed study): 250(223) adults Setting: Outpatient setting in 21 locations in Germany and Austria, conducted by family practitioners and hospitals	Goal: To investigate the effect of meal-related SMBG on glycemic control and well-being in non-insulin- treated patients with type 2 diabetes Intervention: SMBG and diary of blood glucose, and dietary details and standard counselling Control: Non-standardized counselling on diet and lifestyle	• SMBG • HbA1c • lipids • microalbumin • well-being • treatment satisfaction	• use of a SMBG device significantly reduced HbA1c versus non-use (p=0.0086) • sub-group analysis showed 3 types of responders: body weight, total cholesterol, and microalbumin improved when using the device, but no significant difference between groups • treatment satisfaction increased in both groups, to a similar extent (p=0.9) • well-being increased in SMBG group, with significantly improvements in the sub-items of depression (p=0.032) and lack of well-being (p= 0.02) Meal-related self-monitoring of blood glucose with a structured counselling program improved glycemic control in the majority of non-insulin-treated patients with type 2 diabetes. The finding of 3 types of responders will be important for future planning of counselling and educational interventions.
Reference: Muchmore, 1994[51] Design: Randomized controlled trial (randomized after 8-week run-in program) Duration: 6.5 months (28 weeks)	Goal: To determine if the combined use of SMBG and dietary carbohydrate-counting – using the blood monitoring results to shape dietary carbohydrate quotas – is beneficial in managing type 2 diabetes	• weight loss • HbA1c • quality of life	• weight loss was identical in both groups at 12-month follow-up • HbA1c levels showed a progressive decline in the intervention group, whereas control showed no improvement

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 29 (23) adults Setting: Outpatient	Intervention: Behavioural weight control program, and SMBG and dietary carbohydrate counting – glucose testing 6x/day (pre- and 2 hours post-prandial) Control: Behavioural weight control program, only(NOTE: for the first 8 weeks, all patients received behavioural weight control programming, then patients were split in half)		• QoL results are identical for both control and intervention groups, and scales were stable over time ($p>0.03$), while there was improvement of the satisfaction scale between 0 to 24 weeks ($p<0.05$), but not between weeks 0-44 ($p>0.1$) The present study confirms that the addition of SMBG to a diabetes care program offers no benefit in achieving weight-loss goals for overweight patients with type 2 diabetes. Additionally, this study failed to confirm the widely-held belief that SMBG may improve the QoL by empowering patients in their disease management. Participation in a comprehensive diabetes education program did, however, result in improvements in the life satisfaction index for both groups.
Reference: Fontbonne, 1989[52] Design: Randomized comparative Duration: 6 months Population: Intention to treat (completed study): 208 (164) adults Setting: Patients from 3 clinics	Goal: To determine if self-monitoring of blood glucose SMBG or urinary capillary could help improve metabolic control through better compliance to diet and/or hypoglycemic agents in patients with non-insulin-treated type 2 diabetes compared to controls Intervention: Group B = self-monitoring of urine glucose twice every other day Group C = SMBG twice every other day Control: Group A = no self-monitoring, just regular HbA1c measurements	• HbA1c • weight • compliance	• there was a decrease of HbA1c over the 6-month period, however, the differences were not significant between groups • the degree of compliance (indicated by the number of strips used to monitor SMBG) in Group C was significantly correlated with HbA1c at endpoint ($r=-.36$, $p<0.02$) Regular self-monitoring has no definite advantage over the usual management for improving metabolic control in non-insulin-treated patients with type 2 diabetes, although it may possibly help patients ready to comply with its use.

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Allen, 1990[53] Design: Randomized controlled trial Duration: 6 months, 6 months follow-up Population: Intention to treat (completed study): 61 (54) Setting: Outpatient	Goal: To compare the relative efficacy and cost of SMBG with routine urine testing in the management of patients with type 2 diabetes (not those taking insulin) Intervention: SMBG Control: Urine-testing (NOTE: Both groups were instructed in diet management by a dietician based on their ideal body weight and activity level. Emphasis was placed on achieving increased fiber intake with a target goal of 30-40 g fiber/day – patients were given booklets with food suggestions. Both groups were required to conduct 36 tests per month)	• HbA1c • fasting plasma glucose • weight • compliance • cost of testing	• both groups showed similar improvement in glycemic control: there were significant improvements in fasting plasma glucose (p<0.03) and HbA1c, p<0.01) • 17/54 patients achieved normalized HbA1c levels (9 versus 8 in the urine and SMBG groups, respectively) SMBG is not more effective than urine testing at facilitating glycemic control in patients with type 2 diabetes who are not on insulin.
Reference: Menard, 2007[54] Design: Randomized controlled trial Duration: 12 months intervention, 6-month follow-up Population: Intention to treat (completed study): 72 (61) adults Setting: Outpatient, with lots of visits to clinic	Goal: To assess the impact of an intensive multi-therapy on perceived QoL, attitudes, knowledge, and diabetes self-management in patients with poorly controlled type 2 diabetes (Note: companion paper assessed impact of intervention on goal attainment)	• QoL • attitudes • knowledge • diabetes self-management • fasting plasma glucose • HbA1c • blood pressure • cholesterol	• after 1-year intervention, patients' QoL improved significantly in the intensive multi-therapy group versus controls (and13.2 ± 10.3 versus +5.6 ± 13.2), especially re satisfaction • QoL scores improved in intensive multi-therapy patients who began insulin therapy during the trial, and knowledge and diabetes self-management improved • QoL was not associated with hypoglycemic episodes or HbA1c

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Intervention: Intensive multi-therapy consisted of monthly visits, including clinical and biochemical assessment, education sessions on diet, physical exercise, medical management of diabetes, and associated diseases and adjustments in medication. Patients were given blood glucose monitors, a stationary bicycle, and phone calls 2x/month Control: Patients were under the care of their physicians		• by 12 months, a higher proportion of intensive multi-therapy patients achieved Canadian Diabetes Association goals for HbA1c, diastolic blood pressure, low-density lipoprotein, and triglycerides, whereas there were no significant differences between groups for attaining goals for fasting plasma glucose, systolic blood pressure, or total cholesterol/high-density lipoprotein ratio • by 18 months (6 months post-intervention), differences in goal attainment were no longer evident between the 2 groups, except for low-density lipoprotein• in poorly controlled patients, QoL improved significantly, despite the inherent constraints imposed by the intensive multi-therapy intervention Intensive multi-therapy for patients with poorly controlled type 2 diabetes is successful in helping patients meet most of the goals set by a national diabetes association, however, 6 months after therapy ceased and patients returned to usual care, benefits vanished.
Reference: Sarkadi, 2004[55] Design: Randomized controlled trial Duration: 1 year intervention, 1 year follow-up Population: Intention to treat (completed study): 77 (64)	Goal: To investigate the long-term (24 weeks after baseline) effectiveness of an experience-based group educational program and pinpoint mediators that might play a role in achieving desired metabolic outcomes	• HbA1c • questionnaire (control and understanding of blood glucose, depression, treatment satisfaction)	• group training sessions significantly decreased HbA1c by 0.4 % at 24 months after baseline • initial HbA1c, satisfaction with own diabetes-related knowledge, and treatment were found to be directly related to glycemic outcomes

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Undetermined	Intervention: Pharmacist-led group meetings and education through video "How to live well with diabetes"; a dice game with Q&A where answers had to be negotiated by players; a booklet/guide on "How to manage your diabetes" Control: No treatment, but were instead wait-listed for 2 years, then received the intervention		• intervention group exercised more in order to decrease blood glucose, and was more able to predict current blood-glucose levels before measuring them Experienced-based educational intervention produced significant decrease in HbA1c at 6- and 24-months follow-up.
Reference: Glasgow, 2006[56] Design: Randomized controlled trial Duration: 2 months Population: Intention to treat (completed study): 400 (301) adults Setting: Patients from fee-for-service and health maintenance organizations	Goal: To evaluate a computer-assisted intervention which was designed to be practical, efficient, and broad-reaching, evoking changes in lifestyle behaviours such as healthy eating and weight loss Intervention: Usual care and computer-assisted generic health risk appraisal Control: Tailored self-management (Note: Although unclear, it appears that both groups received assessment of current health behaviour, feedback, tailored goal-setting, barrier/benefit identification, and problem-solving through action-planning, health counsellor interaction, and follow-up calls.)	• dietary behaviour • HbA1c • lipids • weight • QoL • depression	• tailored self-management patients reduced dietary fat intake and weight significantly more than usual care at 2-month follow-up Intervention appealed to a large, generally representative sample of patients, was well implemented, and produced improvement in targeted behaviours.

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Simmons, 2000[57] Design: Randomized controlled trial Duration: 8 months Population: Intention to treat (completed study): 68 (64) Setting: Outpatient	Goal: To assess the impact of CBP use on glycemic and high blood pressure control Intervention: Received a special kit with medications in a CBP, in a labeled box, and instructions on how to take medications Control: Same packaging as intervention group but with medication contained in usual containers	• HbA1c • blood pressure	• HbA1c was reduced by 0.95 ± 0.22% in the intervention group and 0.15 ± 0.25% in the control group (p=0.026) • diastolic blood pressure decreased by 5.8 ± 1.5 mm Hg in the intervention group and increased by 0.1 ± 1.9 mm Hg in the control group (p=0.0041) CBPs should be considered among diabetic patients with poor glycemic control receiving multiple medications.
Reference: Litzelman, 1993[58] Design: Randomized controlled trial – double blind Duration: 12 months n=395 (352) Setting: Academic general medicine practice	Goal: To evaluate the effect of a patient intervention, health care provider intervention, and systems intervention on the prevalence of risk factors for lower extremity amputation in patients with non-insulin dependent diabetes mellitus Intervention: Patients received foot-care education and entered into a behavioural contract for desired self-foot-care – reinforced by phone and postcards; health care providers were given practice guidelines and informative flow-sheets on foot-related risk factors for amputation, and patient folders were flagged to prompt foot exams on each visit	• foot-care	• patients receiving the intervention were less likely than control patients to have serious foot lesions (2.9%; odds ratio, 0.41[95%CI, 0.16 to 1.00]; p=0.05) and other dermatologic abnormalities • intervention patients were more likely to report appropriate foot-care behaviours, have foot exams during office visits (68 versus 28%; p<0.001), and to receive foot-care education from health care providers (42 versus 18%; p<0.001) • physicians assigned to intervention patients were more likely than control physicians to examine patients' feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to the podiatry clinic (10.6 versus 5%; p=0.04)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Control: Usual care		An intervention designed to reduce risk factors for lower extremity amputations positively affected patient self-foot-care behavior, as well as the foot-care given by health care providers, and reduced the prevalence of lower extremity clinical disease in patients with diabetes.
Reference: O'Hare, 2004[59] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 361 (325) Setting: Outpatient	Goal: To determine if enhanced care for diabetes, tailored to the needs of one South Asian community with type 2 diabetes, would improve risk factors for diabetic vascular complications and ultimately reduce morbidity and mortality Intervention: Enhanced care (registered nurse specialist following guidelines) Control: Usual care	• HbA1c • blood pressure • lipid profile	• no significantly change in HbA1c and no difference between groups. • there was a significant difference in reduction of systolic blood pressure (4.6 mm Hg, p=0.035) and diastolic blood pressure (3.4 mm Hg, p=0.003), and total cholesterol (0.4 mmol/L, p=0.005) comparing intervention versus control groups; however, after adjusting for baseline measurements and age, only diastolic blood pressure remained significant Using the input of link workers (translators) and extra community diabetes specialist nurses, together with treatment protocols in primary care, might prove a useful strategy in working towards targets for diabetes management. Small reductions in blood pressure and lipids were achieved. Improvement in glycemic control may require longer and possibly different strategies.
Reference: Jiang, 1999[67] Design: Control Duration: 4 months	Goal: To assess the effect of diabetes education programs directed at populations with diabetes through a multi-centre study (by educating physicians and other health care practitioners first)	• HbA1c • fasting plasma glucose • total cholesterol • blood pressure • weight • waist-hip ratio • total questionnaire scores	• HbA1c decreased significantly in both groups, p=0.008 in controls (from 9.3 ± 1.4 to 9.0 ± 1.5) and p<0.001 in treatment group (from 9.4 ± 1.2 to 8.7 ± 1.4)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 208 Setting: Outpatient	Intervention: Advanced diabetes education course: basic knowledge and dietary control, blood-glucose monitoring, management of hypoglycemia, medication compliance, foot-care, and exercise Control: Basic diabetes education course		• fasting plasma glucose ($p<0.001$), total cholesterol ($p=0.009$), systolic blood pressure ($p<0.001$), weight ($p<0.001$), and waist-hip ratio ($p=0.021$) all decreased significantly in the intervention group, but not in the control • the changes in metabolic control (as measured by outcomes), which were significantly correlated with self-care total scores, included: the change in HbA1c ($p<0.001$, $R = -0.224$), and the change in systolic blood pressure and diastolic blood pressure ($p=0.007$, $r = -0.186$ and $p=0.080$, $R = -0.122$, respectively) The study indicates that a diabetic health care team equipped with endocrinologists, dieticians, nurse educators, and advanced education programs is effective in the management of diabetes and in improving metabolic control.
Reference: Pieber, 1995[60] Design: Control Duration: 6 months Population: Intention to treat (completed study): 108 Setting: Patients from general practitioners in rural southern Austria	Goal: Evaluation of a German model of the DTTP for type 2 diabetes in the Austrian health care system in a rural area of the Province of Styria Intervention: Diabetes treatment and teaching program for 6 months with 4 weekly teaching sessions (90 to120 minutes) in groups of 4 to 8 patients – conducted by staff and general practitioners. Participants were	• HbA1c • triglycerides • cholesterol • weight • BMI • blood pressure • diabetes knowledge • number of patients with callus formation and poor nail care on feet • number (%) of patients taking oral anti-hyperglycemic medications	• there were significant changes in the intervention group for weight, 95%CI (1.57-3.69); BMI (0.69-1.37); HbA1c (0.09-0.83); systolic blood pressure (11.3-21.9); diastolic blood pressure (7.7-14.5); triglycerides (0.18-1.09); cholesterol (0.14-0.66); and diabetes-related knowledge (19-31) • control group had significant differences in systolic blood pressure (0.1-14.3) and diastolic blood pressure (1.3-9.5), only

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	taught to practice SMBG, simple dietary measures, and weight reduction and advantages of non-pharmacological therapy. They were also taught about proper foot-care, physical activity, sick-day rules, and late complications of diabetes. Results of SMBG were discussed in conjunction with dietary experiences, including the influence of simple carbohydrates on glucose control Control: Usual care		• between groups, significant differences existed for all conditions except systolic blood pressure and cholesterol; thus, differences between body weight (p=0.01), BMI (p=0.01), HbA1c (p=0.01), diastolic blood pressure (p=0.05), triglycerides (p=0.01), and diabetes-related knowledge (0.001) • number of patients with callus formation and poor nail care decreased significantly after participating in the intervention teaching program (p< 0.001) • the percentage of patients with inter-digital cracks, inter-digital fissures, or mycosis decreased from 58% to 49% in the intervention group, and increased from 53% to 65% in the control group (p<0.05) Calculated care costs per patient and year decreased in the intervention group and increased in the control group, mainly due to changes in prescription of oral hypoglycemic agents in both groups. This program may be an efficient and helpful model to increase overall quality of diabetes care.
Reference: Mazzuca, 1986[61] Design: Randomized controlled trial Duration: 12 months	Goal: To determine the effects of patient and physician education on patient knowledge, skills, self-care behaviours, and relevant physiologic outcomes	• HbA1c • weight • blood pressure • serum creatinine • fasting blood glucose • understanding of diabetes	• intervention group had significantly greater reductions in fasting blood glucose (-27.5 versus -2.8 mg/dL, p<0.05) and HbA1c (-0.43 versus + 0.35%, p<0.05) as compared with controls

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 532 (275) Setting: Outpatient	Intervention: Patients were given 7 modules of education, each containing didactic instruction (lecture, discussion, audo-visual presentation), skill exercises (demonstration, practice, feedback), and behavioural modification techniques (goal-setting, contracting, regular follow-up) Control: Usual care	• acute complications (hyper/hypoglycemia) • diabetic and hypertensive medications • diet and activity • foot-care • urine care	Systematic education can have a demonstrable, prolonged effect on patient self-care skills and behaviours and on intermediate indicators of glucose homeostasis, and chronic vascular complications. Despite the requirement that patients demonstrate mastery of educational objectives for each module, post-intervention assessment 11 to 14 months after instruction showed only rare differences between experimental and control patients in diabetes knowledge. However, statistically significant group differences in self-care skills and compliance behaviours were relatively more numerous.
Reference: Goudswaard, 2004[62] Design: Randomized controlled trial Duration: 18 months Population: Intention to treat (completed study): 54 Setting: Outpatient	Goal: To study the efficacy, in the short- and long-term, of a 6-month educational program in patients with type 2 diabetes treated in primary care Intervention: Patients were given an individual educational program by a diabetes nurse group Control: Usual care by general practitioner (usual care group)	• HbA1c • weight	• 6 weeks after the intervention, HbA1c (adjusted for baseline) had improved 0.7% more in the diabetes nurse group than in the usual care group (95%CI 0.1, 1.4) • of the patients in the diabetes nurse group, 60% reached HbA1c <7.0% compared with 17% in usual care (p<0.01). • at 18 months, there were no significant differences In the number of patients with HbA1c < 7.0% or the number of patients treated with insulin Education was effective in improving glycemic control and in delaying the need for insulin therapy in patients treated with maximal oral hypoglycemic therapy. The reduced effect after 1 year was probably due to the discontinuation of the educational program. Short-term education should not be offered without regular reinforcements integrated into standard diabetes care.

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Rachmani, 2002[63] Design: Randomized controlled trial Duration: 48 months Population: Intention to treat (completed study): 165 (141) Setting: Outpatient	Goal: To examine whether or not sharing the therapeutic responsibility with the patients will improve the outcome Intervention: Patient participation program Control: Standard annual consultation	• HbA1c • blood pressure • low-density lipoprotein • BMI • glomerular filtration rate • albumin/creatinine ratio as an indicator of nephropathy	• mean HbA1c was 8.9% ± 1.2% and 8.2 ± 1.5% in standard annual consultation and patient participation groups, respectively (p=0.04) • mean low-density lipoprotein was 124 ± 8 (standard annual consultation) and 114 ± 6 mg/dl (p=0.01) • average annual fall in estimated glomerular filtration rate was 3.5 ml/min/year in the standard annual consultation group versus 2.25 in the patient participation group (p<0.05) • at 4 years endpoint, blood pressure was 148/88 ± 6.1/1.7 mm Hg in the standard annual consultation group versus 142/84 ± 5.8/1.8 in the patient participation group (p=0.02) • nephropathy (as indicated by albumin/creatinine ratio> 300 mg/g) developed in 4 standard annual consultation patients and in none of the patients in the participation group Well-informed and motivated patients were more insistent to reach and maintain target values of the main risk factors of diabetic complications.
Reference: Kulzer, 2007[64] Design: Randomized, semi-controlled Duration: 3 months intervention, 15 months follow-up Population: Intention to treat (completed study): 193 (181) adults	Goal: To test the efficacy of three education programs for patients with type 2 diabetes Intervention: Treatment B: group sessions based on self-management/ empowerment focusing on emotional, cognitive, and motivational processes of behaviour change;	• HbA1c • diabetes knowledge (psychosocial variables) • weight • self-care behaviour • fasting plasma glucose • BMI • cholesterol • triglycerides • urine or blood glucose self-test	• HbA1c did not change throughout treatment in the control group, but there was significant improvement in Group B at time-interval one (three months), which was sustained at time-interval two (15 months) • at time-interval one, group C had a significant decrease in HbA1c, but this was not sustained at time-interval two

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Various (see above)	Treatment C: same as B but 6 lessons were in group and 6 were individually completed Control: Treatment A: Didactic group sessions to gain knowledge, skills, and information about correct treatment of diabetes	• foot-care • exercise	• overall, there was a significant treatment effect for HbA1c (p=0.013); HbA1c was significantly lower in group B versus C, and group C was lower than group A at time-interval one, only; at time-interval two, group C had higher HbA1c than group B • results were significantly different among groups for BMI and fasting plasma glucose • most psychological variables were influenced by the treatments • there were comparable improvements in urine and blood glucose monitoring and foot-care in all three groups, however, regular exercise was significantly more stimulated among groups B and C patients versus A, where B had a greater effect on exercise than C Self-management training had a significantly higher medium-term efficacy than didactic diabetes education. Group sessions were more effective than a more individualized approach.
Reference: Rutten, 1990[65] Design: Control Duration: 12 months (NOTE: lack of randomization was biased towards participants' preference/ability for self-monitoring)	Goal: To evaluate a detailed therapeutic protocol which emphasized weight reduction and restricted prescription of oral anti-diabetic agents and aims at making diabetes checkups fit into everyday practice	• HbA1c • weight • fasting blood glucose • % of patients on hypoglycemic medications • % of patients on diabetogenic medications	• no significant changes in weight • after the intervention, more patients in the experimental group decreased their HbA1c values by a significant margin than the control group (from >10 to 8-10%); HbA1c actually increased significantly in the control group (p<0.05)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 149 Setting: Outpatient	Intervention: SMBG (subgroup 1); unwilling or incapable of SMBG (subgroup 2);specialist care (subgroup 3). Therapeutic scheme was used with fixed targets for weight regulation with emphasis on weight loss; required checkups Control group: Conventional general practitioner care (subgroup 4)or specialist care (subgroup 5). No fixed check-up appointments		Good results can be attributed to a combination of greater patient participation, the consultation frequency determined per individual patient, and the prescription of oral hypoglycemic agents according to body weight changes.
Reference: Gary, 2003[66] Design: Randomized controlled trial Duration: 24 months Population: Intention to treat (completed study): 186 (149) Setting: Outpatient	Goal: To determine whether multifaceted, culturally sensitive, primary care-based behavioral interventions implemented by a case management nurse and/or community health worker could improve HbA1c and other indicators of diabetic control in a sample of urban African-Americans with type 2 diabetes Intervention: Group 2: usual care and nurse case management; Group 3: usual care and community health worker; Group 4: usual care, and nurse case management and community health worker team Control: Usual care	• HbA1c • blood pressure • triglycerides	• the combo group showed significantly improvements in triglycerides (-35.5 mg/dl; p=0.041) and diastolic blood pressure (-5.6 mm Hg: p=0.042) compared to the control group Combined interventions may improve diabetic control in urban African-Americans with type 2 diabetes. Although results were clinically important, they did not reach statistical significance.
Reference: Maislos, 2004[68] Design: Randomized controlled trial Duration: 6 months	Goal: To • determine if the interdisciplinary approach offered by the Western Negev Mobile Clinic Diabetes	• HbA1c • compliance	• patients who had an HbA1c decrease of 0.5% and were compliant were said to have met the inclusion criteria/goals: 48/258 (19%) intervention and 34/179 (19%) controls

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Population: Intention to treat (completed study): 437 Setting: Outpatient	Program is of benefit in patients with poorly controlled type 2 diabetes • more fully characterize patients' refractory treatment Intervention: Education via clinics, nurse and dietician visits (for diabetes self-care counselling), session with diabetes nurse educator, follow-up visits Control: Usual care		• at 6-month follow-up, there was a significant improvement in plasma glucose (-1.5mmol/L, p=0.003) and HbA1c (-1.8, p=0.00001) in the intervention group, but not in the control group • compliance and response rates were 85% and 71% for intervention and 32% and 35% for the control groups, respectively
Reference: Kim, 2003[69] Design: Randomized controlled trial Duration: 3 months Population: Intention to treat (completed study): 50 (36) Setting: Outpatient	Goal: To investigate the effect of nurse telephone calls on HbA1c levels and adherence to diabetes control recommendations Interventions: Continued education and reinforcement of diet, exercise, medication adjustment recommendations, as well as frequent self-monitoring of blood glucose levels (recording information in diaries; telephone calls 2x/week for the first month and then weekly after that Control: Usual care	• HbA1c • adherence to diet, exercise, blood glucose testing, medication-taking, hypoglycemia management, and foot care	• both groups had significant changes from baseline for HbA1c; patients in the intervention group had a mean decrease of 1.2% (significantly from baseline; p<0.05) for HbA1c levels whereas those in the control group had an increase of 0.6% (significant from baseline; p<0.05) • there was a significant interaction between diet (p=0.006) and blood glucose testing adherence (p=0.024) between the groups and times • in the intervention group, diet (p<0.05) and blood glucose testing (p<0.05) adherence at post-test improved compared with the pretest These findings indicate that a nurse telephone intervention can improve HbA1c, and diet and blood glucose testing adherence.

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Reference: Kronsbein, 1988[70] Design: Control Duration: 12 months Population: Intention to treat (completed study): 127 (99) elderly adults Setting: Outpatient	Goal: • to evaluate the effects of a structured DTTP for non-insulin-treated/dependent patients with type 2 diabetes • to achieve patient treatment goals by non-pharmacological means via group teaching by the primary care physicians' staff Intervention: DTTP – doctors: course; patients: guidelines, education, materials Control: Usual care (DTTP was implemented post-study)	• HbA1c • weight • triglycerides • knowledge score • SMBG • % of patients on oral antidiabetic drugs • % of patients treated with insulin	DTTP group: • HbA1c remained unchanged • % of patients on oral antidiabetic drugs fell from 68% to 38% (mean difference 30%, CI 16-44%) • weight was reduced by 2.7 kg (95 CI, 1.6-3.8kg) • triglycerides decreased by 0.77 mmol/L (95% CI 0.35-1.19 mmol/L) Control group: • none of these indices changed, but 10% of patients started insulin The DTTP improved the overall quality of patient care in elderly non-insulin dependent patients with type 2 diabetes, when administered by general practitioners and their staff.
Reference: Penfornis, 1998[71] Design: Randomized controlled trial Duration: 3 months Population: Intention to treat (completed study): 114 Setting: Inpatient and outpatient	Goal: To compare glycemic control (as determined by HbA1c levels) in two groups of insulin-requiring patients with type 2 diabetes three months after initiation of insulin therapy, either on an inpatient group or outpatient group basis. Evaluation of the safety and cost of both methods was a secondary objective. Intervention: Patients initiated insulin therapy as inpatients (Group A) and outpatients (Group B).	• HbA1c • safety • cost • SMBG	• although HbA1c level at inclusion was slightly but significantly lower in group A than group B (10.17 ± 0.19% versus 10.87 ± 0.22%, respectively, p= 0.019), co-variance analysis showed equivalent glycemic control at 3 months in both groups (equivalence hypothesis p=0.01) • hypoglycemic episode frequency was low and similar in both groups • clinical tests, paramedical care, and the cost of hospitalization itself resulted in a direct cost of initiating treatment that was more than four times higher in group A than group B (mean total cost: FF 15,231 and FF 3,296, respectively)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Group A – Inpatients were hospitalized for 5 to 7 days and received appropriate education provided by endocrinologists, nurses, and dieticians concerning their disease and its management (especially diet and insulin, proper use, SMBG, urinary sugar measurements, hypoglycemia, and sports) Group B – Outpatients received a summary of the same information as the inpatient group and returned home the same day. They returned to the hospital in 1 week to check insulin doses and blood sugar levels from SMBG records		Insulin-requiring patients with type 2 diabetes can be efficiently and safely started on insulin as outpatients and this approach appears to be cost-effective.
Reference: De Berardis, 2004[72] Design: Non-randomized controlled trial Duration: 24 months Population: Intention to treat (completed study): 3437 Setting: Inpatient versus outpatient	Goal: To compare the care provided to patients with type 2 diabetes attending diabetes outpatient clinics or being treated by a general practitioner using appropriate statistical methods to adjust for patient case mix and physician-level clustering Intervention: Patients using diabetes outpatient clinic Control: Usual care	• HbA1c • cholesterol • lipids • microalbuminuria • creatinine • frequency of foot and eye examinations	• statistically significant differences in favour of patients treated by diabetes outpatient clinics were found for HbA1c, high-density lipoprotein, creatinine, microalbuminuria testing, as well as foot and eye examinations • more diabetes outpatient clinic patients showed satisfactory blood pressure and total cholesterol compared with those seen by general practitioners, whereas high total low-density lipoprotein levels were found more often among patients cared for by general practitioners • differences were marked for patients who were always treated by the same physician within a diabetes outpatient clinic, and if that physician had a specialty in endocrinology

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			• overall, patients attending diabetes outpatient clinics attained better total cholesterol, whereas no major differences emerged regarding metabolic control and blood pressure levels between diabetes outpatient clinics and general practitioners • physicians' specialties were not independently related to patient outcomes Being followed always by the same physician in a diabetes outpatient clinic, particularly if the physician had a specialty in diabetes, ensured better quality of care in process measures. In the short-term, care provided by diabetes outpatient clinics was also associated with better intermediate outcome measures, such as total cholesterol levels.
Reference: Groeneveld, 2001[73] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 246 Setting: Outpatient	Goal: To study differences in diabetes-related parameters in patients with type 2 diabetes treated with the support of a diabetes service compared to conventional general practice care Intervention: General practitioners tried to refer all patients to the diabetes service (nurses and diabetes educators provided counseling, and physical and lab exams were performed); follow-up calls every3 months	• HbA1c • fasting plasma glucose • lipids • blood pressure • weight	• HbA1c was not significantly different between intervention and control groups (7.1 versus 7.5%, p=0.06) at endpoint • patients who were initially poorly controlled (fasting blood glucose > 10 mmol/L) had a significantly lower final HbA1c if they were in the intervention group (p=0.001) • fewer patients in the intervention practices were referred to hospital specialists (1 versus 14)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Control: No patients were referred to the diabetes service but, instead, remained under usual care		Support by the Dutch Diabetes Service did not significantly influence HbA1c. The subgroup of initially poorly controlled patients developed a significantly lower HbA1c in intervention practices than in control practices.
Reference: Rothman, 2005[74] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 217 Setting: Outpatient	Goal: To assess the efficacy of a pharmacist-led, primary care-based disease management program to improve cardiovascular disease risk factors and HbA1c levels in patients with poorly controlled diabetes Intervention: Patients received intensive management from clinical pharmacists, and from a diabetes care coordinator who provided diabetes education, applied algorithms for managing glucose control and decreasing cardiovascular risk factors, and addressed barriers to care Control: Patients received a one-time management session from a pharmacist, followed by usual care	• HbA1c • blood pressure • cholesterol • acetylsalicylic acid use	• of the patients with 12-month data, the intervention group had significantly greater improvement than did the control group in systolic blood pressure (- 9 mm Hg; 95% CI, -16 to -3 mm Hg) and HbA1c level (-0.8; 95% CI, -1.7 to 0%). • at 12 months, acetylsalicylic acid use was 91% in the intervention group versus 58% among controls ($p<0.0001$) • diabetes knowledge and satisfaction improved more in the intervention group than in the control group Our comprehensive disease management program reduced cardiovascular risk factors and HbA1c levels among vulnerable patients with type 2 diabetes and poor glycemic control.
Reference: Skaer, 1993[76] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 258	Goal: To discern the effect of pharmacy-based, value-added utilities on prescription-refill compliance with sulfonylurea therapy and health service utilization	• medication possession ratio	• patients receiving mailed prescription-refill reminders, unit-of-use packaging, or the combo of both achieved a significant increase in the medication possession ratio for sulfonylurea therapy relative to controls ($p\leq0.05$)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
Setting: Outpatient	Intervention: Group 2: same as control and received medication-refill reminders 10 days before each sequential refill date Group 3: same as control and given unit-of-use packaging with each prescription-refill request Group 4: same as control and given mail reminders and unit-of-use packaging Control: Group 1: standard pharmaceutical care with each dispensing of glyburide		• combo group showed significant improvement in the medication possession ratio relative to all other groups, whereas there was no significant difference between groups 2 and 3 • patients in combo group also experienced significant ($p \leq 0.05$) reduction in the use of physician, lab, and hospital services relative to patients in the control group These results argue for an increased use of pharmacy-based, value-added utilities under both public and private health insurance programs.
Reference: Hurwitz, 1993[75] Design: Randomized controlled trial Duration: 24 months Population: Intention to treat (completed study): 181 Setting: Outpatient	Goal: To evaluate the effectiveness and acceptability of centrally organized prompting for coordinating community care of non-insulin- dependent diabetes mellitus patients Intervention: Patients received prompted care via a database which sends requests to patients asking them to provide blood and urine samples for random plasma glucose, HbA1c, and albumin estimations Control: Usual care	• HbA1c • random plasma glucose • albuminuria • number of diabetic reviews	• there was a significant difference in the number of patients who failed to receive a single review of diabetes status: 14 in the control group did not receive a review versus only 3 who did not receive a review in the intervention group ($p=0.013$) • follow-up for retinal screening was better in prompted patients than in controls; two prompted patients defaulted versus 12 controls ($p=0.008$) • measures per patient, yearly, were more frequent in prompted patients for albuminuria (3.0 versus 2.3, $p=0.03$), plasma glucose estimations (3.1 versus 2.3, $p=0.003$) and HbA1c (2.4 versus 0.9, $p<0.001$) • continuity of care and the number of diabetic reviews performed by each participating doctor was better in the prompted group (3.2 versus 2.2; $p<0.001$)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
			Six monthly promptings of non-insulin-treated diabetic patients for care by inner city general practitioners and by optometrists appears to be effective and acceptable.
Reference: Jaber, 1996[77] Design: Randomized controlled trial Duration: 4 months Population: Intention to treat (completed study): 45 (39) Setting: University-affiliated internal medicine outpatient clinic	Goal: To assess the effectiveness of a pharmaceutical care model on the management of type 2 diabetes in urban African-American patients Intervention: Pharmacist-led care group Control: Usual care	• fasting plasma glucose • HbA1c • blood pressure • serum creatinine • creatinine clearance • microalbumin: creatinine ratio • total cholesterol • triglycerides • high-density lipoprotein • low-density lipoprotein • QoL	• significant improvement in HbA1c (p=0.003) and fasting plasma glucose (p=0.015) in intervention group, but no changes in control group • significant difference existed between groups for HbA1c (p=0.003) and fasting plasma glucose (p=0.022) • there are no significant differences between or within groups for remaining outcomes Pharmaceutical care model has been shown to be effective in the reduction of hyperglycemia associated with type 2 diabetes in this group of African-American patients.
Reference: Vetter, 2004[78] Design: Randomized controlled trial Duration: 24 months Population: Intention to treat (completed study): 186 (149) Setting: Outpatient	Goal: To test the effect of nurse case management and community health worker interventions on diabetes control among inner city African- Americans Intervention: Nurse case management group: usual care and nurse case management Community health worker group: usual care and home visits from a community health worker Nurse case management and community health worker group: usual care and nurse case management and home visits from	• HbA1c • high-density lipoprotein • low-density lipoprotein • triglycerides • blood pressure • dietary practices • leisure time physical activity	• all intervention groups experienced improved diabetes control versus control group; although none of these were statistically significant, the authors suggest that there was still clinical importance in the reduction of HbA1c (nurse case management and community health worker decreased HbA1c 0.31 and 0.30, respectively, and the combination group decreased HbA1c by 0.8% • no further significant changes, although improvements were favoured in the intervention groups

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	the community health worker Control: Usual care		The greatest improvement was seen with combined nurse case management and community health worker visits.
Reference: Weinberger, 1995[80] Design: Randomized controlled trial Duration: 12 months Population: Intention to treat (completed study): 275 (251) Setting: Outpatient	Goal: To examine the impact of a nurse-coordinated intervention delivered to patients with non-insulin- dependent diabetes mellitus between office visits to primary care physicians Intervention: Nurse-initiated contacts were made by telephone, at least monthly, to provide patient education (with special emphasis on regimens and significant signs and symptoms of hyperglycemia and hypoglycemia), to reinforce compliance with regimens, monitor patients' health status, facilitate resolution of identified problems, and facilitate access to primary care Control: Usual care	• HbA1c • fasting blood glucose • health-related QoL	• between-group differences favoured intervention patients for fasting blood glucose (174.1 versus 193.1 mg/dL, p=0.011) and HbA1c (10.5 versus 11.1%, p=0.046) • statistically significant differences were not observed for either health-related QoL or diabetes-related symptoms The intervention – designed to be a pragmatic, low-intensity adjunct to care delivered by physicians – modestly improved glycemic control, but not health-related QoL or diabetes-related symptoms
Reference: Krein, 2004[79] Design: Randomized controlled trial Duration: 19 months Population: Intention to treat (completed study): 246(216) Setting: Outpatient	Goal: To evaluate the effects of a collaborative case management intervention for patients with poorly controlled type 2 diabetes on glycemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization	• HbA1c • satisfaction • cost • lipid profile • blood pressure	• small, non-significant difference between groups at endpoint • HbA1c was 9.3 versus 9.2%; difference=0.1%;95% CI:-0.4 to 0.7%; p=0.65) in intervention versus control respectively • intervention patients were significantly more satisfied with their diabetes care: 82% rating their providers as better than average compared with 64% of patients in the control group (p=0.04)

Table 8: Summary of trial results of studies with patients with type 2 diabetes			
Details	**Goal/ Intervention**	**Outcomes Measured**	**Results/Conclusions**
	Intervention: Patients were given an automated BP monitor with guidelines and a periodic study newsletter. Patients were assigned to a case manager (registered nurse specialist who monitored via telephone, and collaborated with patient/doctor to set goals, and followed treatment algorithms) Control: Usual care		An intervention of collaborative case management did not improve key physiologic outcomes for high-risk patients with type 2 diabetes. The type of patients targeted for intervention, organization factors, and program structure are likely critical determinants of the effectiveness of case management. Health systems must understand the potential limitations before expending substantial resources on case management, as the expected improvements in outcomes and downstream cost savings may not always be realized.

BMI=body mass index; BP=blood pressure; CBP=calendar blister pack; CI=confidence interval; DTTP=Diabetes Teaching and Treatment Program; HbA1c=glycolsylated hemoglobin; QoL=quality of life; SMBG=self-monitoring of blood glucose