Diabetes Mellitus Revisited: A Narrative Review

Sami Saqf el Hait [1], Iman A. Basheti [2]*

[1]Department of Quality Assurance, SANOFI, Jeddah, Saudi Arabia.
[2]Department of Clinical Pharmacy and Therapeutics, Faculty of Pharmacy,
Applied Science Private University, Amman, Jordan

ABSTRACT

To explore the management of diabetes from a pharmacy perspective and engaging patients in self-management. Methods: A search was made of international peer-reviewed literature in PubMed, Medline, Cochrane Library and the grey literature. This document provides a review of a relevant literature including a general overview of diabetes mellitus, therapeutic goals, pharmacologic and lifestyle treatment. The epidemiology of diabetes was explored, and an overview of new approaches for treatment and management of diabetes mellitus collated. Results: The search yielded studies and information that met the inclusion criteria. Pharmacological and lifestyle management, diabetes education and knowledge, and the prevalence of diabetes were also documented. Conclusion: Research examining the role of healthcare providers as diabetes educators and exploring the needs of patients with diabetes is of importance to optimize health outcomes and minimize costs related to treatment and complications.

Keywords: Management, Education, Type 2 diabetes, Medicines, Nutrition.

INTRODUCTION

Diabetes Mellitus is a group of metabolic disorders characterized by hyperglycaemia which is associated with chronic complications including microvascular, macrovascular, and neuropathic disorders. Hyperglycaemia can result from defects in insulin secretion, insulin action or both[1,2]. Chronic hyperglycaemia in diabetes is associated with damage to or failure of the eyes, kidneys, nervous system, heart, and blood vessels [2, 3]. Diabetes mellitus is a common chronic disease which, as a result of increase in obesity, changing lifestyles, and an ageing population, is growing globally[4]. In 2013, it has been estimated that 347 million people have diabetes worldwide[5]. The high prevalence of obesity, has led to new cases of diabetes Type 2 early in life, which is becoming common in children as well as teenagers [6]. The less common type of the disease is Type

1 diabetes and is an autoimmune disease. In more than 90% of those affected it is characterized by beta-cell destruction that usually leads to absolute insulin deficiency, and the rest is idiopathic [3, 7].

Diabetes is associated with substantial morbidity and mortality, and has significant impact on individuals and their families[3,8]. The onset of macrovascular and microvascular complications lowers quality of life with an increased burden of illness and the costs of managing the specified complications of diabetes over time [2, 3].

Review of the Literature

Search Strategy

A literature search was performed, from 2013 to 2014 in Australia, to retrieve information on evidenced-based diabetes care. Search terms used included type 2 diabetes mellitus, education, patients, needs, counselling, adults, knowledge, nutrition, and exercise. The information included in this review was extracted from the PubMed, Medline and Cochrane Library databases and the grey

literature which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers[9], including evidence based guidelines, unpublished theses and reports from the University of Sydney.

Patients' Perception and Knowledge of Diabetes Mellitus

The assessment of diabetes-related knowledge in people with diabetes is an essential first step to individualise diabetes education programs and make evaluations of their effectiveness[10]. When examining patient knowledge and perception about diabetes mellitus before and after applying the Diabetes Education Program, a knowledge enhancement was observed, as the percentage of correct answers for each topic including questions about diabetes increased[11]. The research by Otero *et al* [11] found that patients should be followed for a certain period in an attempt to collaborate with their health care providers in terms of the many circumstances imposed by the disease. When people with low health literacy and Type 2 diabetes were enrolled in a diabetes education program in a hospital diabetes clinic in the USA, the participants achieved notable improvement in self-management, diabetes knowledge, and glycaemic control [12].

Patients' Knowledge and Perception of Diabetes Questionnaires

Diabetes Knowledge Questionnaire (DKQ-24) is a validated 24 item scale, developed by Garcia *et al* [10] designed to assess general diabetes knowledge. Patients respond to the questionnaire by either answering *yes, no,* or *do not know*[10]. Improved knowledge was demonstrated with the use of the DKQ-24, when people with Type 2 diabetes were enrolled in a three months education program[10].

Diabetes Management

Management relies on a number of factors including healthy lifestyle, nutrition, medicines, and behavioural strategies[13].

Non-pharmacological (Lifestyle) Management

Non-pharmacological management involves nutritional therapy and exercise. Significant research has been done that confirmed the correlation between weight reduction and improved insulin sensitivity that would result in improved glycaemic control which would result in better patients' disease outcomes and improved quality of life [8, 14].
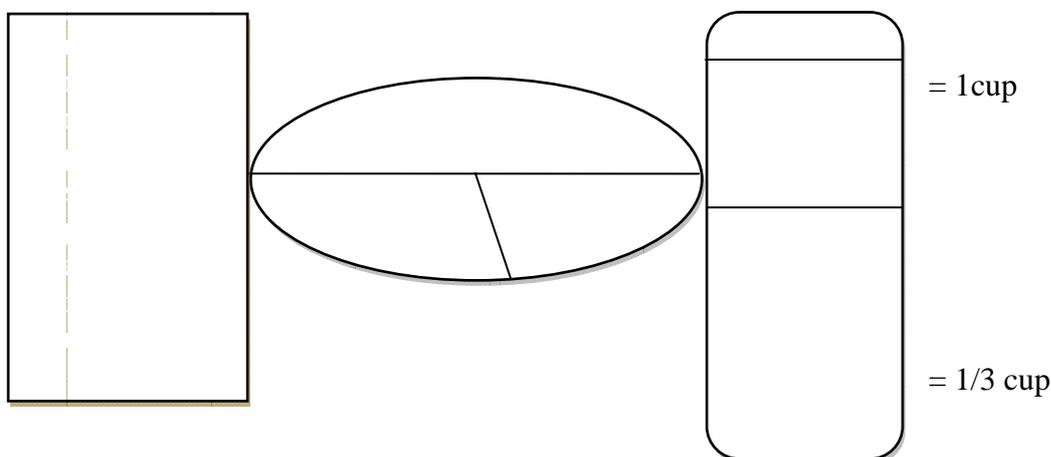

$= 1\text{cup}$

$= 1/3 \text{ cup}$

Figure 1: Meal Planning Schematic (adapted from the Idaho Plate Method Lunch and Dinner for Diabetes home page, http://platemethod.com)

Blood glucose control is essential to ensure optimal outcomes are achieved in people with diabetes[15]. Diabetes education represents an important strategy to address patients who find meal planning difficult[16]. A study by Raidl *et al*[16] provided information to participants on diabetes signs and symptoms and introduction of the Idaho Plate Method (Figure 1) for meal planning were covered. This included information about the five food groups (vegetables, starches, meats and other types of proteins, dairy, and fruits)[16]. The intervention in this study consisted of meal planning education in three different settings that are at home, supermarket, and restaurant settings[16]. Participants were also trained to know how to make a healthy meals which consisted of the specified allowed amount of each of the five components for each meal during the day[16]. As a result, there were significant increases in daily fruit (*p*=0.02) and vegetable consumption (*p*=0.01)[16].

Diabetic patients are advised to combine the best choices from both food habits of Mediterranean and Western food in which a well-organized meal plan will consist mainly of high fibre carbohydrates (e.g. whole grain breads and cereals), vegetables and fruits, being low in fat and provide adequate amount of needed protein for healthy lifestyle pattern[15]. Overweight patients (with body mass index greater than 25 kg/m^2) should reduce their total calorie intake to aid in weight reduction[17]. A healthy diabetic diet should typically include less than 10 % of its energy in the form of saturated fat (less than 8% if hyperlipidaemic), less than one third from all fats, and 50 to 60% carbohydrate which is mostly complex high fibre[17]. Moreover, sugar intake should be limited to about 25 g/day and sodium content to be less than 6 g/day for diabetic patients who are not hypertensive and to lower than 3 g/day if the patient has hypertension[17]. Protein intake should be between 11-35 g/day for health diabetic nutrition [8].

Regular physical activity has been shown to significantly improve the health outcomes for people with diabetes[18,19]. Physically active patients with diabetes have been shown to have lower rates of mortality and cardiovascular heart disease[19, 20]. Regular exercise supports in maintaining good blood glucose control which in turn helps in decreasing the risks of developing diabetes complications (e.g. neuropathy and nephropathy)[18]. Exercise can also enhance quality of life and reduce stress, anxiety and depression[18,21]. Encouraging people to exercise should be considered one of the essential components of diabetes care. Although researchers have demonstrated the importance of exercise as a component of diabetes management, it remains underused [19].

Regular aerobic exercise has been shown to improve blood lipid profiles, blood pressure and resting heart rates, body composition and glycaemic control in addition to reducing serum cholesterol[18,19]. Aerobic exercise aids in weight reduction[18]. Guidelines recommend that aerobic activity should be performed for at least 30 minutes at a moderate intensity on most, if not all days of the week with no more than 72 hours between exercise sessions[19]. If weight loss is a desired outcome, then one hour of exercise or more is recommended [18, 19]. It is often hard for the majority of people to begin at this level; thus the recommended exercise regimen should firstly begin at a level the patient could manage, with the aim of gradually increasing exercise duration and intensity as the patient progresses [19]. Exercise could include activities such as walking, swimming or cycling[19]. However, the type of exercise will depend on the patient's safety.

The importance of suitable foot care and comfortable, well-fitting footwear during physical activity needs to be stressed, especially if the patient has neuropathy, vascular disease, abnormal foot structure, and/or is present with a history of previous foot ulcer(s)[18, 21].

Healthy life style would include, in addition to diet and exercise, self-measurement of blood glucose concentrations at home, and recognizing, preventing and managing hypoglycaemia [15]. Looking after the feet to aid in managing skin breakage, and self-managing during illness or infection, as well as knowing when to go to the doctor are also important issues to consider in maintaining healthy life style [15,17]. Tests the doctor should perform include blood pressure, foot examination, HbA$_{1C}$

to be repeated every 3 months if trying to improve diabetes management in the patient or in a duration of 6-12 months if stability of disease is achieved, cholesterol and triglycerides test to be repeated every 12 months, kidney tests which would be repeated every 12 months and eye examination every 12 months[15,17]. Insulin

injection devices and the correct process of injection, and timing, frequency, how and cautions of taking oral hypoglycaemic agents are important part of patient education that will aid in improving the clinical, biologic and quality of life outcomes in diabetic persons [8, 14, 17].
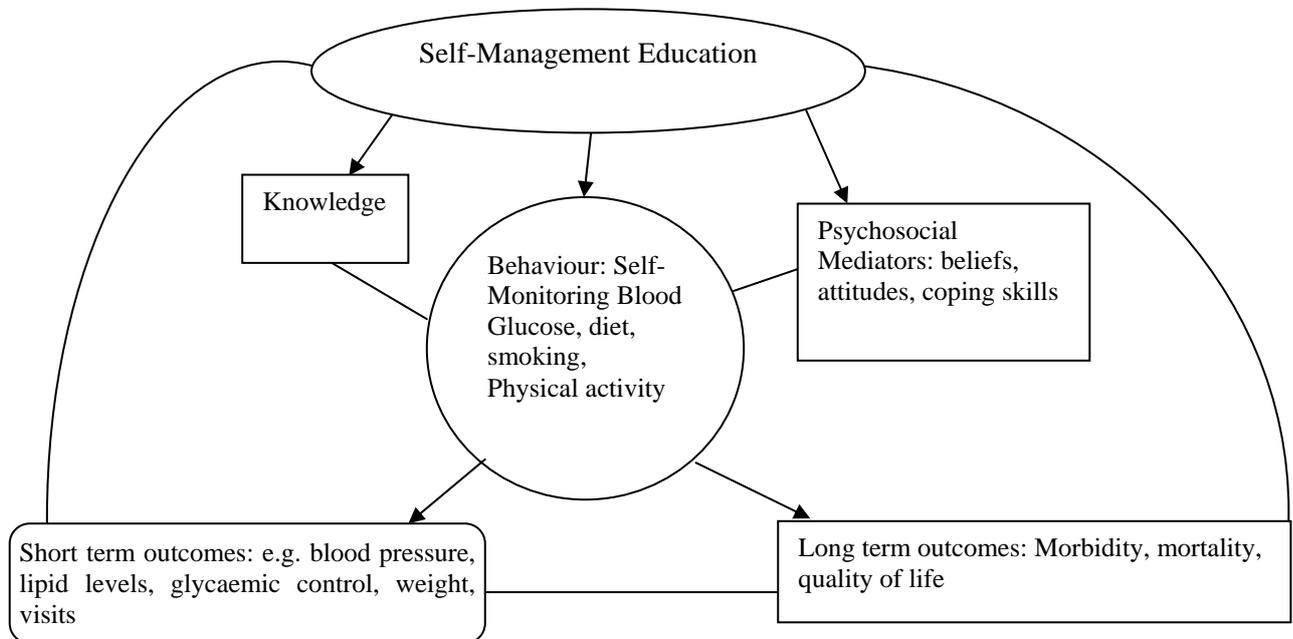

Figure 2: Impact of Self-Management Education Intervention (adapted from http://www.thecommunityguide.org/diabetes/dm-AJPM-evrev-incr-DSME-comm.pdf)

Pharmacological Management

Currently eight different classes of oral hypoglycaemic agents (Table 1) are present in addition to insulin (Table 2) that are approved for the treatment of diabetes[3,17, 18]. An additional goup of oral hypoglycaemic agents, called sodium glucose cotransport inhibitors (SGLT2 inhibitors, e.g. dapagliflozin, remogliflozin and serligliflozin) are in clinical trials[22].

Metformin is the first choice in people with diabetes[3,18]. Metformin decreases hepatic glucose output, and reduces insulin resistance[18]. Metformin acts by significantly reducing the risk of diabetes-related morbidity and mortality in overweight patients [18]. Significant renal impairment is the only absolute

contraindication to metformin[3,8]. Metformin is contraindicated in people with an estimated glomerular filtration rate (GFR) <30 ml/min/1.73 m^2, and should be used with caution in people with a GFR of 30-45 ml/min/1.73 m [23]. CKD (Chronic Kidney Disease) affects approximately 40% of patients with diabetes [3, 23]. The presence of kidney disease worsens cardiovascular risk and limits the number of hypoglycaemic medication options available [3, 23]. Further, the availability of over-the-counter nephrotoxic medications (e.g. NSAIDs, Nonsteroidal Anti-inflammatory Drugs)) can easily exacerbate disease, and the combined effect of ACEI (Angiotensin Converting Enzyme Inhibitors), diuretics, and NSAIDs may go unrecognised without specific

questioning[23]. The onset of renal disease can be insidious[3, 24]. Therefore, NSAIDs can lead to a sudden drop in Glomerular Filtration Rate (GFR). Cyclooxygenase 2 (COX-2) inhibitors are similar to other NSAIDs in their potential for renal toxicity [24]. Daily low-dosage aspirin is safe in patients with diabetes, and the cardiac benefits greatly outweigh risks of nephrotoxicity[24]. Nevertheless, prescribing aspirin at higher dosages and other NSAIDs should be avoided if possible in diabetes[24].

Table 1. Pharmacotherapeutic Effectiveness of the Pharmacologic Antihyperglycaemic agents on HbA$_{1C}$ levels (adapted from Fonseca *et al*, 2010; Turner and Wass, 2010 and List *et al* 2009)

Pharmacologic Category	Approximate reductions in HbA$_{1C}$ (%) in (Example) patients with Type 2 Diabetes
Biguanides (metformin)	0.9-2.5
Sulfonylureas (glipizide, glimperide, gliclazide etc)	1.1-3.0
Glinides (repaglinide, nateglinide)	1.0-1.5
Alpha-Glucosidase inhibitors (acarbose, miglitol)	0.6-1.3
DDP-4 inhibitors (e.g. Sitagliptin)	0.8
GLP-1 analogs (e.g. exenatide)	0.8-0.9
Amylin Analogs (Pramlinitide)	0.4-0.6
Thiazolidinediones (Pioglitazone, Rosiglitazone)	1.5-1.6
SGLT-2 Inhibitors (e.g. Dapagliflozin)	0.55-0.9

Metformin should be used with caution in people with hepatic or cardiac disease and in patients with a heavy alcohol intake and stopped if the patient develops acute illness, due to the risk of lactic acidosis[17, 18]. When used alone, metformin rarely causes hypoglycaemia[8,18]. However, when insulin sensitizers (metformin or thiazolidinediones) are used with insulin secretagogues, the dose of the secretagogue should be reduced to minimize the risk of hypoglycaemia [3].

Sulfonylureas increase insulin secretion by binding to a high affinity receptor on the surface of islet beta cells of the pancreas [3], and the Royal Australian College of General Practitioners and Diabetes Australia [18] recommend the use of sulfonylureas if a trial of healthy lifestyle and metformin failed to accomplish the required goals. The most significant adverse effect of sulfonylureas is hypoglycaemia[18]. Long acting sulfonylureas such as glibenclamide and glimperide have the potential to prolong hypoglycaemia in geriatric patients and in patients with renal impairment[25].

Therefore, glibizide and gliclazide, which are converted to inactive metabolites by the liver, are the sulfonylureas of choice in these patients[25]. The American Diabetes Association [13] recommends the early initiation of insulin therapy if an intervention of lifestyle changes in combination with metformin does not allow the person to achieve the target of HbA$_{1C}$<7%.

Acarbose is used when blood glucose concentrations remain high after meals despite dietary modification [18]. Acarbose acts by inhibiting the digestion of carbohydrate thus slow the rate of glucose delivery into the circulation[18]. Acarbose is to be taken at the start of the meal and introduced slowly to avoid the impact of the side effects of flatulence and abdominal discomfort [3, 18].

If hypoglycaemia occurs in people taking acarbose, because of concurrent sulfonylurea or insulin treatment, glucose rather than other carbohydrates is required[8]. Care is necessary in people with renal impairment or gastrointestinal disease, and liver disease [18].

Repaglinide, not included in the Pharmaceutical

Benefits Scheme, causes a rapid increase in pancreatic insulin secretion[18]. Repaglinide can be used as mono-therapy or as dual therapy with metformin to control postprandial hyperglycaemia [18]. Diabetes Australia [18] recommends that repaglinide should not be used in combination with sulfonylureas. Glitinides as well as sulfonylureas can lead to weight gain so discussion of lifestyle management (exercise and food intake) is of benefit to minimize the adverse effect.

The thiazolidinediones are another class of oral hypoglycaemic medicines and include pioglitazone and rosiglitazone[8,17]. These medicines are effective in lowering blood glucose concentration by reducing insulin resistance with their action as selective agonists for peroxisome profilator-activated receptor gamma. Both of these drugs can be used as dual therapy with metformin or sulfonylureas[18]. Pioglitazone could also be used in triple therapy with metformin and a sulfonylurea or in combination with insulin[18]. Contraindications to pioglitazone include moderate to severe cardiac failure[17]. Rosiglitazone is not approved in triple therapy with metformin and a sulfonylurea or in combination with insulin[18]. Pioglitazone is contraindicated in patients with moderate to severe heart failure and rosiglitazone is contraindicated in all classes of heart failure[17]. Rosiglitazone is not recommended in patients with known ischaemic heart disease, particularly in people taking nitrates[18]. These recommendations were approved after many years of studying the cardiovascular safety of rosiglitazone[26].

Two groups of hypoglycaemic agents target the glucagon-like peptide (GLP-1) actions[3,17]. GLP-1 enhances insulin secretion and inhibits glucagon secretion in a glucose dependent approach[8]. Fasting and postprandial glucose concentrations are reduced [3]. The GLP-1 'mimetics' are injected subcutaneously and bind to the GLP-1 receptor (e.g. exenatide, and liraglutide)[18].

The GLP-1 enhancers, DPP4 inhibitors, are oral medications that slow the catabolism of endogenous GLP-1 [17]. Sitagliptin, saxagliptin, and vildagliptin, are available in Australia [18]. The GLP-1 mimetics also aid weight loss and the DPP-4 inhibitors are generally weight neutral and improve post prandial control [18].

Sodium glucose co-transport (SGLT2) inhibitors (dapagliflozin, sergliflozin, and remogliflozin) increase glucose urinary excretion and lower plasma glucose concentrations in an insulin-independent mechanism[27]. The most frequently reported adverse effects in phase II and III trials are gastrointestinal (constipation, diarrhea, nausea, urinary frequency), urinary tract infections (UTIs) and vulvovaginal infections [27]. In a recent phase III clinical trial, urinary tract infections and genital infections were more frequently detected in the dapagliflozin group compared to the placebo group [27].

When used as mono-therapy, metformin, acarbose, glitazones, GLP-1 mimetics and DPP-4 inhibitors will not cause hypoglycaemia[3, 17].

All sulfonylureas could cause hypoglycaemia[8]. Guidelines recommend starting with a small dose and increase weekly or fortnightly until control is established[18].

Anti-diabetic medications available are metformin, glipizide, gliclazide, glimperide, glibenclamide, acarbose, pioglitazone, rosiglitazone, vildagliptin, exenatide, sitagliptin, metformin ER (extended release), and a combination of metformin/glibenclamide, metformin/rosiglitazone, and metformin/sitagliptin [18].

The American Diabetes Association[13] recommends early initiation of insulin if an intervention of lifestyle management and metformin did not help in achieving HbA_{1C} goals. Diabetes Australia and Royal Australian College of General Practitioners[18] recommends the initiation of insulin therapy if adequate control was not achieved with the use of the maximum doses of oral hypoglycaemic medications. The guideline states that insulin maybe needed early in therapy where treatment is being started (primary failure of oral hypoglycaemic medicines suggesting Type 1 diabetes) or when the patient has become refractory to oral antihyperglycaemic agents (secondary failure with progression of Type 2 diabetes mellitus)[18]. Insulin types and brands available in are listed in Table 2.

Other Aspects of Management

Adverse effects may contribute to poor adherence [3].

This confirms the importance of the patient's health beliefs in effective disease management [3]. For the management of Type 2 diabetes, the rate of adherence among patients to insulin administration was about 20%[28]. More than 20 studies published in the past few years found that compliance with oral hypoglycaemic medicines ranged from 65% to 85% [28].

Table 2. Insulins Preparations (adapted from Diabetes Management in General Practice: Guidelines for Type 2 Diabetes 2011-12 by Diabetes Australia and Royal Australian College of General Practitioners)

Type	Brand Name	Manufacturer	Nature
Ultra Short Acting (peak at 1hr, last 3.5-4.5 hrs)			
Insulin lispro	Humalog	Eli Lilly	Analogue
Insulin aspart	NovoRapid	Novo Norodisk	Analogue
Insulin glulisine	Apidra	Sanofi-Aventis	Analogue
Short Acting (peak at 2-5 h, last 6-8 hrs)			
Neutral	Actrapid	Novo Norodisk	Human
	Humulin R	Eli Lilly	Human
	Hypurin Neutral	Aspen	Bovine
Intermediate Acting (12-24 h)			
Isophane	Humulin NPH	Eli Lilly	Human
	Protophane	Novo Norodisk	Human
	Hypurin Isophane	Aspen	Bovine
Long Acting			
Insluin detemir (up to 24 hrs)	Levemir	Novo Norodisk	Analogue
Insulin glargine (24 hrs)	Lantus	Sanofi-Aventis	Analogue
Premixed Insulins			
Lispro 25%, Lispro protamine 75%	Humalog Mix 25%	Eli Lilly	Analogue
Lispro 50%, Lispro protamine 50%	Humalog Mix 50%	Eli Lilly	Analogue
Insulin aspart 30%, Insluin aspart protamine 70%	Novomix 30%	Novo Norodisk	Analogue
Neutral 30%, Isophane 70%	Humulin 30/70	Eli Lilly	Human
	Mixtard 30/70	Novo Norodisk	Human
Neutral 50%, Isophane 50%	Mixtard 50%	Novo Norodisk	Human

Optimal diabetes care can be achieved if clinicians collaborate with patients in diabetes management, if healthcare systems support systematic patient response monitoring, and enhance treatment titration to achieve positive diabetes outcomes with minimal complications[29]. The first step in achieving optimal diabetes outcomes is by knowing that not taking medications as directed is common in patients with diabetes mellitus [29]. Useful clinical approaches include a nonjudgmental assessment of medication-taking, clear explanations about how to use medications, simplified regimens, and scheduled follow-up visits to monitor progress and adjust treatment [29]. Such approaches can be used by health care providers and patients in a busy primary care setting [29].

Diabetes self-management education (DSME) is considered to be an important part in improving patients' clinical outcomes[2,8,13]. Specific self-management addresses the following issues: self-monitoring of blood glucose (SMBG), hypoglycaemia, insulin injection devices, sick day rules, pre-pregnancy counselling, medications, meal planning, and exercise [8].

The American Diabetes Association developed the National Standards for Diabetes Self-Management Education which are updated and published every year to define standards for the DSME[8]. Topics required in DSME are: diabetes disease process and treatment options, nutritional management, exercise, therapeutic effectiveness of medicines, monitoring of blood glucose, preventing, detecting and treating acute and chronic complications, goal setting to promote health and resolve problems, psychological and social adjustment, and preconception care for patients with diabetes during pregnancy[8,13].

It was found that diabetes mellitus costs the Australian Government around AUS\$680 million per year which is considered a negative influence from the economic perspective as well as from the health wellbeing of the community population[30]. The National Diabetes Services Scheme (NDSS), which is an initiative of the Australian Government administered by Diabetes Australia, financially supports patients with diabetes-related products and provides information and support services to people with diabetes[21]. Registration is free and open to all diabetic Australian patients [21].

Behaviour change, lifestyle modification, and self-management are crucial elements to the cost-effective management of diabetes mellitus[31]. Krass *et al*[32] found a greater reduction in HbA_{1c} when community pharmacists in Australia provided diabetes education, self-monitoring of blood glucose, and adherence support measurements[32]. Participants (n=289) in the intervention group achieved 0.97% reduction in HbA_{1c} compared to 0.27% in the control group[32]. Based on evidence from this study, the extent of improvement in diabetes control achieved by the participation of the pharmacist in diabetes management will translate into future cost savings to the health care system in delaying and reducing diabetes related complications[32]. Some limitations are associated with this study. Whilst the intervention and control groups were well matched on most clinical measurements, mean HbA_{1c} levels were higher at baseline in the intervention group (8.9%) compared with the control group (8.3%)[32]. To address this issue of uncertainty, the researchers used appropriate statistical methods to control the difference in baseline measurements[32]. There were also difficulties in retrieving final clinical data from general practitioners for some patients; however, the proportion of patients for whom final clinical data were missing was similar for the intervention and control groups (20% and 24%) respectively [32]. The duration of the study was only six months [32]. Further research is needed to clarify the sustainability of changes in disease control over time and the type and intensity of interventions which are most suitable clinically and are cost-effective [32].

An approach to DSME is shown in the analytic framework (Figure 2), which shows the relationships between the intervention, intermediate outcomes (knowledge, psychosocial mediators, and behaviours), and short- and long-term health and quality of life outcomes [33]. In the figure, ovals indicate interventions, rectangles with rounded corners represent short-term outcomes, and rectangles with squared corners refer to long-term outcomes [33]. Self-management education and education interventions can improve knowledge and clinical outcomes[33].

CONCLUSION

This review of the literature has highlighted the importance of diabetes as a global health issue, as well as discussed therapeutic goals, pharmacologic treatment, and the impact of treatment on quality of life. Future studies should examine the adherence of prescribers to evidence based medicine at the pharmacological and lifestyle levels. Assessment of patients' knowledge about diabetes and their quality of life should also be incorporated into daily practice. Healthcare providers

should also engage patients in self-management education to facilitate behaviour change, achieve better

clinical and quality of life outcomes, and minimize costs related to treatment and complications.

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مرض السكري: مراجعة علمية للإصابة وطرق المعالجة

سامي سقف الحيط [1]، ايمان ا. بشيتي [2]

[1] قسم ضمان الجودة، سانوفي، جدة، المملكة العربية السعودية.

[2] قسم الصيدلة السريرية والعلاجات، كلية الصيدلة، جامعة العلوم التطبيقية الخاصة، عمان، الأردن.

ملخص

الهدف: استكشاف علاج مرض السكري من منظور صيدلاني وإشراك المرضى في العلاج الذاتي.

المنهجية: تم إجراء بحث صيدلاني علمي في قواعد البيانات الطبية العالمية مثل: ميدلاين، مكتبة كوكرين وPubMed على جميع الأصعدة (الحكومة، الصناعة، الجامعات، الأعمال).

تقدم هذه الوثيقة لمحة عامة عن مرض السكري، أهداف المعالجة، والعلاج بتعديل نمط الحياة، وبالأدوية.

وقد تم البحث في نسب الإصابة بمرض السكري، وطرق المعالجة الحديثة له.

النتائج: بناء على معايير مبينة على الأدلة والبراهين العلمية، تم توثيق نسب الإصابة بمرض السكري والطرق الحديثة لمعالجته المتضمنة تثقيف المريض ومشاركته في المعالجة من خلال نمط نمط حياته بالإضافة إلى المعالجة الدوائية.

الاستنتاج: إن دور مقدمي الرعاية الصحية في تثقيف مرضى السكري ومعرفة حاجاتهم مهم لتحسين النتائج العلاجية وتقليل الكلفة الناتجة عن المضاعفات المرضية.

الكلمات الدالة: العلاج، التثقيف، مرض السكري نوع 2، الأدوية، التغذية.