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Canadian Journal of Diabetesjournal homepage:
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CANADA****2018 Clinical Practice Guidelines****Introduction**

Diabetes Canada Clinical Practice Guidelines Expert Committee

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Welcome to the *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada*. Updated every five years, these comprehensive, evidence-based guidelines represent the sixth set since their introduction in 1992; and the first under the new name of Diabetes Canada. In 2017, the name of the Canadian Diabetes Association was changed to Diabetes Canada to reflect the seriousness of diabetes, and to increase perception of the organization as being committed to helping all Canadians with diabetes, as well as to ending the disease.



The Diabetes Canada Clinical Practice Guidelines are intended to guide practice; inform general patterns of care; enhance diabetes prevention efforts in Canada; and reduce the burden of diabetes complications. The intended users are all health-care professionals that are involved in the management of people with diabetes and those at risk of developing diabetes, with a particular focus on primary care or “usual care” providers. The guidelines are also intended for people living with diabetes. In this version, key messages directed at people living with this chronic disease have been added to each chapter.

For these 2018 Clinical Practice Guidelines, volunteer members of the Clinical Practice Guidelines Expert Committee have assessed the relevant peer reviewed evidence published since the last guidelines in 2013 through a rigorous systematic review process. They have then incorporated the evidence into revised diagnostic, prognostic and therapeutic recommendations for the care of Canadians living with diabetes, as well as recommendations to delay the onset of diabetes for at risk populations. The grading of all recommendations has been stringently reviewed by an Independent Methods Committee (see Methods chapter, p. S6).

The guidelines are meant to improve the quality of care and healthcare outcomes of Canadians living with diabetes. A primary purpose is to address clinical care gaps that exist, i.e. discrepancies between evidence-based knowledge and day-to-day clinical practice. The guidelines also summarize key research findings and make clinical decisions more transparent. They are meant to reduce

inappropriate variation in practice, promote efficient use of health-care resources, empower people living with diabetes, identify gaps in knowledge, prioritize research activities, inform public policy, and support quality control activities, including audits of practice (1).

The guidelines represent a summary of material and do not provide in-depth background clinical knowledge which is typically covered more comprehensively in medical textbooks and review articles. They are not meant to provide a “menu-driven” or “cook-book” approach to diabetes care where the clinician has no discretion. In addition, they are unable to provide guidance in all circumstances and for all people with diabetes. People with diabetes are a diverse and heterogeneous group; treatment decisions must be individualized. Guidelines are meant to aid in decision making by providing recommendations that are informed by the best available evidence; however, therapeutic decisions are made at the level of the relationship between the health-care provider and the individual with diabetes. That relationship, along with the importance of clinical judgement, can never be replaced by guideline recommendations. Evidence-based guidelines try to weigh the benefit and harm of various treatments; however, patient preferences are not always included in clinical research and, as a result, patient values and preferences must be incorporated into clinical decision making (2). For some clinical decisions, strong evidence is available to inform these decisions, and these are reflected in the recommendations within these guidelines. However, there are many clinical situations where strong evidence is not currently available, or may never become available due to feasibility issues. In those situations, the consensus of expert opinions, informed by whatever evidence is available, is provided to help guide clinical decisions that need to be made at the level of the individual with diabetes. It is also important to note that clinical practice guidelines are not intended to be a legal resource in malpractice cases as their more general nature renders them insensitive to the particular circumstances of individual cases (1).

Key Changes

A number of changes have occurred with the development of the 2018 Clinical Practice Guidelines, including:

- Expansion of the Expert Committee to include 135 health-care professional volunteers from across Canada with broader representation from more allied health/interprofessional stakeholder groups. Expert Committee members bring expertise from

Conflict of interest statements can be found on page S5.

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diverse practice settings across the country and include professionals from family medicine, endocrinology, internal medicine, cardiology, neurology, nephrology, infectious disease, urology, psychiatry, psychology, obstetrics, ophthalmology, pediatrics, nursing, dietetics, pharmacy, chiropractics, exercise physiology and others.

- Inclusion and active participation of informed people with diabetes on the Expert Committee to ensure that their views and preferences inform the guideline development process and the recommendations, as well as development of key messages using lay terms directed at people living with diabetes.
- Increased recognition of ethnocultural diversity in Canada and its relationship with diabetes care.
- Increased involvement of Indigenous authors, organizations and health-care providers working with Indigenous populations and communities in the development of recommendations related to type 2 diabetes in Indigenous peoples. In addition, acknowledgment of the legacy of colonization and residential schools and their ongoing effects on Indigenous health, as well as the call to action of the 2015 Truth and Reconciliation Commission (3).
- Addition of new material on diabetes and driving, and post-transplant diabetes.
- More rigorous systematic review of literature with the assistance of the McMaster Evidence Review and Synthesis Centre; a former Evidence-based Practice Centre (EPC) designated by the U.S. Agency for Healthcare Research and Quality (AHRQ) under the auspices of their Evidence-based Practice Program which has completed high quality reviews for the Canadian Task Force on Preventive Health Care and the Public Health Agency of Canada.
- More rigorous review of the grading of recommendations by an Independent Methods Review (IMR) Committee. In the event of a discordance between author-assigned grade and IMR-assigned grade, the recommendation was arbitrated by an IMR co-chair.
- Wider external review by specialists, community primary care providers, academic Departments of Family Medicine across Canada, and specialty and disease support organizations.
- Additional efforts to manage and minimize conflict of interest among all Expert and Steering Committee members.
- Expanded harmonization of recommendations through collaboration with other organizations, including the Canadian Cardiovascular Society (CCS), Hypertension Canada, and the Canadian Cardiovascular Harmonization of National Guidelines Endeavour (C-CHANGE).
- Expanded dissemination and implementation strategies to support all recommendations with increased use of web-based technology.

A key message throughout the guidelines remains the importance of individualizing therapy for the person with diabetes. It is hoped that primary care providers and other health-care professionals who care for people with diabetes or those at risk of diabetes will continue to find the guidelines an indispensable resource. If properly applied, the guidelines should lead to improved quality of care, reduced morbidity and mortality from diabetes and its complications, and a better quality of life for Canadians living with this chronic disease.

The Challenge of Diabetes

The International Diabetes Federation (IDF) has identified diabetes as one of the largest global health emergencies of the 21st century (4). Each year, more and more people worldwide are

diagnosed with this serious chronic condition with potentially devastating complications that affects all age groups. The World Health Organization estimates that, globally, high blood glucose is the third highest risk factor for premature mortality, after high blood pressure and tobacco use (5). In 2015, the IDF estimated that 415 million adults currently had diabetes and 318 million adults had impaired glucose tolerance, putting them at high risk of developing the disease in the future (4,6). Canada has also seen rising rates of diabetes. In 2015, the estimated prevalence of diabetes was 3.4 million or 9.3% of the population, and is predicted to rise to 5 million or 12.1% of the population by 2025, representing a 44% increase from 2015 to 2025 (6). The estimated prevalence of prediabetes in adults in Canada in 2015 was 5.7 million or 22.1% of the population (6).

Diabetes is the leading cause of blindness, end stage renal disease (ESRD) and non-traumatic amputation in Canadian adults (see Retinopathy chapter, p. S210; Neuropathy chapter, p. S217; Foot Care chapter, p. S222). Cardiovascular disease (CVD) remains the leading cause of death in individuals with diabetes and occurs two- to four-fold more often than in people without diabetes (see Cardiovascular Protection in People with Diabetes chapter, p. S162; Screening for the Presence of Cardiovascular Disease chapter, p. S170). People with diabetes are over 3 times more likely to be hospitalized with CVD, 12 times more likely to be hospitalized with ESRD and over 20 times more likely to be hospitalized for a non-traumatic lower limb amputation compared to the general population (7). Diabetes complications are also associated with premature death and it is estimated that 1 of 10 deaths in Canadian adults was attributable to diabetes in 2008/09 (7). Thirty per cent of people with diabetes have clinically relevant depressive symptoms (8); and individuals with depression have an approximately 60% increased risk of developing type 2 diabetes (9) (see Diabetes and Mental Health chapter, p. S130).

Diabetes and its complications increase costs and service pressures on Canada's publicly funded health-care system. This is because of an increased use of health services, loss of productivity and the long-term support needed to manage diabetes-related complications. Among adults aged 20 to 49 years, those with diabetes were 2 times more likely to see a family physician and 2 to 3 times more likely to see a specialist (3). Also, people with diabetes were 3 times more likely to require hospital admission in the preceding year with longer lengths of stay (2) (see In-Hospital Management of Diabetes chapter, p. S115). Canada has been identified as the country with the seventh highest spending on diabetes-related health expenditure, totaling 17 billion US dollars in 2015 (4). With the aging of Canada's population, the total direct health-care costs associated with diabetes are expected to continue to increase (10).

Prevention of Diabetes

Prevention of type 1 diabetes has not yet been successful, but remains an active area of research (see Reducing the Risk of Developing Diabetes chapter, p. S20). However, there is good evidence that the onset of type 2 diabetes can be delayed or prevented through a number of strategies, including healthy behaviour interventions (physical activity, weight loss), certain dietary patterns and pharmacotherapy (see Reducing the Risk of Developing Diabetes chapter, p. S20). An obesity epidemic is currently paralleling the diabetes epidemic worldwide (see Weight Management in Diabetes chapter, p. S124) with over 60% of Canadian adults and close to one-third (31.5%) of children and adolescents having overweight or obesity (11,12). There is an urgent need for governments to develop and evaluate strategies to prevent and treat rising rates of obesity and promote physical activity and reduction of sedentary time (see Physical Activity and Diabetes chapter, p. S54). In addition, Canada's diverse population, with some ethnic groups disproportionately

affected by diabetes, requires that health promotion and disease prevention and management strategies be culturally appropriate and tailored to specific populations (see Self-Management Education and Support chapter, p. S36; Organization of Care chapter, p. S27).

It is becoming increasingly apparent that social determinants of health play an important role in risk of diabetes and its complications. Two large public health surveys, the Canadian Community Health Survey (CCHS) (13) and the National Population Health Survey (14) have found that lower-income people are significantly more likely to develop diabetes. In the CCHS, the prevalence of type 2 diabetes in the lowest income group was 4.14 times higher than in the highest income group (13); and, in the National Population Health Survey, being in the low income group was associated with a 77% higher risk of developing type 2 diabetes (hazard ratio 1.77, 95% confidence interval 1.48–2.12) (14). The primary goals of public health interventions to prevent type 2 diabetes include the maintenance of a healthy body weight, physical activity and healthy eating (see Nutrition Therapy chapter, p. S64; Physical Activity and Diabetes chapter, p. S54); however, an individual's ability to adopt these healthy behaviours is influenced by many factors, including the social, environmental, cultural and economic conditions in which the individual lives (the "determinants of health"). These include income, education and literacy; employment and working conditions; food security; environment and housing; early childhood development; social support and connectedness; and access to health care (15) (see Type 1 Diabetes in Children and Adolescents chapter, p. S234). There is a need for governments to develop policies aimed at addressing poverty and other systemic barriers to health care (16).

Ethnocultural Diversity

Canada is a country rich in ethnocultural diversity. Canada boasts the highest percentage of foreign-born citizens than any other G8 country. More than 200 ethnic origins were reported in Canada in the 2011 census, with the most common ethnic origins with populations in excess of 1 million from highest to lowest, including Canadian, English, French, Scottish, Irish, German, Italian, Chinese, Indigenous, Ukrainian, East Indian, Dutch and Polish. The largest visible minority groups in 2011—South Asians, Chinese and Blacks (accounting for 61.3% of the total visible minority population)—are populations identified as being at high risk for diabetes; and were followed by Filipinos, Latin Americans, Arabs, Southeast Asians, West Asians, Koreans and Japanese (17). Studies have shown that culturally appropriate diabetes education (incorporating cultural or faith traditions, values and beliefs, delivery in the person's preferred language, adapted cultural dietary advice, the person's needs, and/or involving family members) results in improvements in diabetes-related knowledge, self-management behaviours and clinical outcomes (18,19) (see Self-Management Education and Support chapter, p. S36; see Nutrition Therapy chapter, p. S64). Given our diversity, Canada has much to teach the world of the importance of incorporating cultural traditions and health-care beliefs in diabetes care with many innovative models of diabetes health-care delivery. As Canada's Prime Minister Justin Trudeau has aptly stated "Diversity is Canada's strength" (20).

Diabetes rates are 3 to 5 times higher in Indigenous populations in Canada (7), a situation compounded by barriers to care for many Indigenous peoples. Indeed, the vastness of Canada poses challenges in providing comprehensive and uniform diabetes care throughout the country. Indigenous people are generally diagnosed at a younger age than non-Indigenous people (21), and Indigenous women experience higher rates of gestational diabetes than non-Indigenous women (22). Complications of diabetes are also more frequently seen among the Indigenous population than in the non-Indigenous population (23). The chapter on type 2 diabetes and

Indigenous peoples in these guidelines (see Type 2 Diabetes and Indigenous Peoples chapter, p. S296) provides an important lens for recognizing the diabetes epidemic and challenges in providing diabetes care in these populations, and acknowledges the legacy of colonization and residential schools and their ongoing effects on Indigenous health, as well as the call to action of the 2015 Truth and Reconciliation Commission (3).

Optimal Care of Diabetes

Effective diabetes care should be delivered within the framework of the Chronic Care Model and centred around the individual who is practicing, and supported in, self-management (see Organization of Care chapter, p. S27). To achieve this, an interprofessional team with the appropriate expertise is required, and the system needs to support and allow for sharing and collaboration between primary care and specialist care, as needed. A multifactorial approach utilizing an interprofessional team addressing healthy behaviours, glycemic control, blood pressure control, lipid management and cardiovascular protection measures has been shown to effectively and dramatically lower the risk of development and progression of serious complications for individuals with diabetes (24–27) (see Cardiovascular Protection in People with Diabetes chapter, p. S162; Dyslipidemia chapter, p. S178; Treatment of Hypertension chapter, p. S186; Nutrition Therapy chapter, p. S64; Physical Activity and Diabetes chapter, p. S54; Pharmacologic Glycemic Management of Type 2 Diabetes, p. S88; Targets for Glycemic Control chapter, p. S42). In addition, individuals with diabetes must be supported in the skills of self-management since their involvement in disease management is absolutely necessary for success (see Self-Management Education and Support chapter, p. S36). People with diabetes require training in goal setting, problem solving and health monitoring, all of which are critical components of self-management. They also need access to a broad range of tools, including medications, devices and supplies to help them achieve the recommended blood glucose, lipid and blood pressure targets. Health outcomes depend on managing the disease effectively, and, without access to the necessary tools and strategies, Canadians living with diabetes will not be able to achieve optimal results. All levels of government should commit to investing in chronic care management and support the tools needed for successful self-management to ensure that optimal care can be delivered.

The Diabetes Charter

The Diabetes Charter for Canada clearly outlines the support Canadians with diabetes need to live to their full potential. It defines the right of people with diabetes to information, education and care that take into account a person's culture and language (see Appendix 1. Diabetes Charter, p. S307). The Charter also puts forth the right of people with diabetes to high quality care regardless of where they live. The Charter notes that governments have a responsibility to address the unique needs and disparities in care and outcomes of vulnerable populations who experience higher rates of diabetes and complications and/or significant barriers to diabetes care and support. These supports will help Canadians with diabetes manage their disease and related complications.

Other Topics

Each set of Diabetes Canada Clinical Practice Guidelines has become increasingly longer. This set of guidelines has seen the addition of material on diabetes and driving, post-transplant diabetes

and many other topics. However, it is recognized that several topics are still not covered. Oral health is one such topic. Gingivitis, an inflammatory condition of the gums surrounding the teeth, and periodontitis, the destruction of the ligament, bone and soft tissues that support the teeth, are two of the most serious dental conditions identified in individuals with both type 1 and type 2 diabetes (28). One study found that adults with poorly controlled diabetes had a significantly higher prevalence of severe periodontitis than those without diabetes (odds ratio 2.90, 95% confidence interval 1.40–6.03) (29). The pain, discomfort and eventual tooth loss associated with these conditions can lead to poor diet, nutritional deficiencies, psychosocial problems and an overall decline in quality of life. Periodontal disease may also increase the risk of developing type 2 diabetes because the body's inflammatory response to the periodontal bacteria may contribute to insulin resistance (30). In addition to gingivitis and periodontitis, individuals with diabetes have higher rates of dental caries and salivary dysfunction. The IDF has prepared guidelines on oral health for people with diabetes (31). The recommendations include: people with diabetes should see a dental professional regularly for oral health check-ups; health-care providers should enquire at least annually for symptoms of gum disease (including bleeding when brushing teeth, and gums which are swollen or red); and people with diabetes should be reminded that daily dental care is a normal part of diabetes self-management.

The relationship between diabetes and cancer is another topic not reviewed in this set of guidelines. Diabetes has been consistently associated with increased risk of several of the more common cancers (32); however, it remains unclear whether the association is direct (e.g. due to hyperglycemia), whether diabetes is a marker of underlying biologic factors that alter cancer risk (e.g. insulin resistance and hyperinsulinemia), or whether the cancer-diabetes association is indirect and due to common risk factors, such as obesity (33). It is also not known whether diabetes treatments influence risk of cancer or cancer prognosis. Pending further research, people with diabetes should be encouraged to undergo appropriate cancer screenings as recommended for all people in their age group and sex (33).

Conflict of Interest

The *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* have been developed by a multidisciplinary panel of volunteer experts and informed individuals living with diabetes based on a rigorous systematic review that rates the quality of evidence and strength of recommendations (see Methods chapter, p. S6). The need to incorporate patient preferences is also discussed throughout the document. Any discussion regarding off-label use of drugs includes the caveat that the use is off-label.

An explicit and transparent process has been used to minimize biases. Experts have not received honoraria or stipends. In addition, a policy defining manageable or disqualifying conflict of interest is strictly adhered to and available on request. Detailed conflict of interest statements using the International Committee of Medical Journal Editors (ICJME) disclosure form (<http://www.icmje.org/>) (with the addition of government funding sources) for all members of the Expert, Steering and Executive Committees, as well as the Independent Methods Review Committee, are posted publically on the guidelines website and updated annually for each year of the guideline development process (<http://guidelines.diabetes.ca>).

Research

Since Banting and Best's discovery of insulin in Toronto in 1921, the scope of diabetes research in Canada has been vast and the

numerous studies both varied and unique. There have been huge strides and key advances in mapping and understanding the physiology, biochemistry and genetics of diabetes, as well as developments in the prevention, treatment and management of the disease. Key goals remain a desire to improve the quality of life of people living with diabetes and to find a cure.

Regulatory agencies should not apply these guidelines in a rigid way with regard to clinical research in diabetes. It is suggested that study protocols may include guideline recommendations, but individual decisions belong in the domain of the patient-physician relationship. The merits of each research study must be assessed individually so as to not block or restrict the pursuit of new information. Diabetes Canada welcomes the opportunity to work with regulatory agencies to enhance research in Canada and, ultimately, to improve the care of people with diabetes.

Cost Considerations

These clinical practice guidelines, like those published before, have purposefully not taken into account cost effectiveness in the evaluation of the evidence surrounding best practice for a variety of reasons, including the paucity of cost-effectiveness analyses using Canadian data; the difficulty in truly accounting for all relevant diabetes-related costs; as well as lack of expertise and resources to perform the appropriate cost-effectiveness analyses needed for all the clinical questions within the clinical practice guidelines. In addition, it is often difficult to philosophically judge which is of greater importance: clinical benefit for the person living with diabetes or cost to the health-care system, as well as, at what level of cost effectiveness should one consider a therapy worth recommending? Based on issues of feasibility and philosophical considerations of our role as recommendation developers, it was decided that cost would not be included in the recommendations to ensure that they reflect the best available clinical evidence for the individual with diabetes.

Dissemination and Implementation

Dissemination & Implementation Committee co-chairs and volunteer members were appointed at the beginning of the guidelines process. On an ongoing basis, the committee develops strategies to increase health-care practitioner implementation of the recommendations with the goal of improving health care for the person with diabetes. A major activity of the committee has been the development and maintenance of a guidelines website (<http://guidelines.diabetes.ca/>) which hosts the full guidelines; interim updates; a quick reference guide; key messages; health-care provider tools, slide kits, videos and webinars; as well as resources for people with diabetes and their support systems in a variety of languages. Both iOS and Android apps have also been developed.

Conclusions

Diabetes is a common condition with significant implications for quality of life, as well as mental health and physical conditions. Although there have been a number of advances in prevention and treatment, many individuals with diabetes have less than optimal glycemic control and are at risk for or have complications. Given the large number of people at risk for or currently living with diabetes, as well as predictions for dramatic increases in these numbers in the future, there is a need to improve prevention and treatment strategies, particularly for vulnerable and high

risk populations. Diabetes is also a complicated disease with a constantly expanding literature on new therapies and technologies that makes it challenging for health-care providers who care for people with or at risk for diabetes to remain up to date. These guidelines are a celebration of the work, contributions and creativity of health-care providers and people living with diabetes across Canada and contain evidence-based recommendations that provide a useful reference tool to help health-care providers translate the best available evidence into clinical practice as well as for people with diabetes and at risk of diabetes to make informed choices. It is hoped that these guidelines will also continue to provide all levels of government with the evidence they need when rationalizing access to health care so that the potentially beneficial health outcomes are maximized for people living with diabetes. Finally, Canada has much to teach the globe about optimal diabetes care through our world class research and innovative models of health-care delivery to Canada's rich ethnoculturally diverse population. We truly have much to celebrate.

Relevant Appendix

Appendix 1. Diabetes Canada Diabetes Charter

Author Disclosures

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