

The House of Representatives,
Standing Committee on Health, Aged Care and Sport,
PO Box 6021,
Canberra ACT 2600

30 July 2023.

To the Hon. Members of the Committee,

Thank you for the opportunity to provide our submission to the Parliamentary Inquiry into Diabetes in Australia.

I am submitting this document on behalf of:

- Hayden Dikeman, Type-1 Diabetes advocate and researcher.
- Dr Gary Fettke, Orthopedic Surgeon, metabolic health expert and advocate, and
- I, Jane MacDonald, living with Type-1 Diabetes, advocate for Type-1 Diabetes

We note the Terms of Reference, and we are responding to:

- New evidence-based advances in the prevention, diagnosis, and management of diabetes in Australia and internationally.
- The effectiveness of current Australian government policies and programs to prevent, diagnose and manage diabetes.

We thank you in advance for considering Low Carbohydrate Nutritional Therapy and the insulin dosing regimen we have outlined below to become the standard of care for people living with Type 1 Diabetes to achieve Normoglycemia.

Yours faithfully,

Jane MacDonald

Low Carb Nutritional Therapy and Normoglycemia for People with Type 1 Diabetes.

Hayden Dikeman
Jane MacDonald
Dr. Gary Fettke

A summary assessment of the evidence for a low-carb nutritional therapy for people with Type 1 diabetes is presented.

First, a review of the current dietary protocol and corresponding adverse outcomes is discussed.

Next, a review of research demonstrating normoglycemia and ‘unprecedented’ glyceimic control for people with Type 1 diabetes who follow a low carbohydrate diet is detailed.

Finally, recommendations are given to balance the current diabetes management protocol with the implementation of a low-carb management protocol so that people with Type 1 diabetes are ensured access to quality information and choice.

Executive Summary

This document summarizes current flaws in Type 1 diabetes nutritional therapies and outcomes. We propose the systemization of unfettered access and support to comprehensive low-carb nutritional therapy as an option for people with Type 1 diabetes of all ages upon diagnosis.

Background Information

Type 1 diabetes is an autoimmune condition with no known cure and is characterized by the inability to produce insulin. Approximately 134,000 Australians (0.5%) live with Type 1 diabetes, and diagnosis rates are rising [1]. The management of Type 1 diabetes is characterized by the difficult minute-to-minute job of controlling one's blood glucose sugar via a careful balance of diet and injected insulin. The fundamental task of the person with Type 1 diabetes is to manage blood glucose in a way that realizes blood glucose levels at healthy nondiabetic levels. This process requires a constant, rigorous 24/7 cycle of testing blood glucose and subsequent treatment of any detected hypoglycemia or hyperglycemia. Failure to correctly perform this process results in hypoglycemia induced discomfort and even seizure, or hyperglycemia, if too high, too often, which generates long-term complications, loss of quality of life, and a shortened lifespan.

Current Nutritional Standard Therapy and Outcomes

Critical to the success of a person with Type 1 diabetes is the implementation of a successful nutritional therapy and insulin dosing plan. The results of the current protocols can best be characterized as 1) emphasizing carbohydrate nutrition, and 2) resulting in chronic hyperglycemia and blood glucose unpredictability. Indeed, according to the 2021 Australian National Diabetes Audit, the median HbA1c for people with Type 1 diabetes was 66.0 mmol/mol (8.2%) [2], corresponding to an average blood glucose roughly *triple* that of a healthy nondiabetic. Such high blood glucose damages every organ in the body and cause more than a decade of lost life. Moreover, currently, 37.1% of Australians with Type 1 diabetes are classified as obese, a condition known as 'double diabetes' [3]. Quality of life metrics for people with Type 1 diabetes in Australia are also tragic, and it has been found that 41% of adults experience diabetes-related depression [3]. Such psychological issues and diminished quality of life have been linked with suboptimal glycemic control and diabetes complications. Given these outcomes, examining the de rigueur nutritional therapy makes sense. Surprisingly, despite carbohydrates being the most potent determiner of elevated postprandial blood glucose, carbohydrates in the form of grains, starch, and glucose are *emphasized and encouraged* as an essential component in the diet for people with Type 1 diabetes.

Low-Carb Nutritional Therapy for People with Type 1 Diabetes Conclusion

Low carbohydrate diets for people with Type 1 diabetes have recently gathered major media attention. A seminal study, "Management of Type 1 Diabetes with a Very Low-Carbohydrate Diet," was published in the American Academy of Pediatrics journal, PEDIATRICS, which demonstrated "unprecedented glycemic control" for people with Type 1 diabetes who follow a low-carb diet [4]. The results were detailed in a New York Times article which became the most shared article for June 2018. Regarding the PEDIATRICS article, the study's lead author, Dr. Belinda Lennerz of Harvard Medical School, noted: "Their blood sugar control seemed almost too good to be true; it was nothing like what we see in clinic." Indeed, not only was average blood glucose in the nondiabetic range but several other important cardiometabolic and quality-of-life factors were also improved demonstrated.

Recommendation

The current standard of practice for people with Type 1 diabetes is best characterized as a high carbohydrate and large insulin dosing protocol that results in essentially mathematically guaranteed outcomes of high and unpredictable blood glucose and, therefore, diabetic complications. It is recommended that a low-carb program is put in place so that people with Type 1 are empowered with accurate information and access to

the low-carb option to attain normoglycemia and avoid the consequences of elevated blood glucose upon diagnosis.

I. Introduction

Type 1 Diabetes Mellitus is an autoimmune disease that affects roughly 15 per 100,000 globally and has no known cure. The condition involves a complex, 24/7, manual management of blood glucose via an attempt to balance injected insulin, food, activity, and many other factors. Despite modest technological increases with newer insulin pumps and continuous glucose monitors, HbA1c values remain little changed and very high in people with Type 1.

Upon diagnosis of Type 1 diabetes, a patient is placed on a blood glucose management plan centered on two essential features:

1. A diet that strongly emphasizes the importance of carbohydrates.
2. An insulin management technique that involves ‘counting’ carbohydrates and covering them with injected insulin.

Results attained by the carbohydrate-emphasized nutritional therapy are characterized by chronic hyperglycemia, with the average person with Type 1 diabetes achieving an HbA1c of 66 mmol/mol (8.2%), which is roughly triple a normal blood glucose level [2] with even more dire results within ethnic minority groups. The consequences of such high blood glucose levels are grave, resulting in diabetic complications, shortened lifespan, and a diminished quality of life punctuated with daily agony of high and ‘rollercoaster’ blood glucose levels.

Given these consistently poor results and the somewhat obvious physiologic fact that carbohydrate is essentially a polymer of simple sugars that can break down almost instantly into glucose molecules via the salivary amylase reaction in the mouth, it is a paradox why the professional diabetes associations advocate such dietary guidelines. Such a discussion is outside the scope of this document; however, it is evident that the current protocol is now highly dependent on institutional inertia, and no sound basis for the approach exists in the research. Below, we further discuss the consequences of the standard high carbohydrate approach, which results in chronic hyperglycemia, followed by evidence for the alternative low carbohydrate approach for people with Type 1 diabetes.

II. Current nutritional therapy and blood glucose management outcomes

Historically, starting from roughly the 1980s, a low-fat diet containing up to 60% of energy from carbohydrates became the standard of care for people with Type 1 diabetes. Although recently, the American Diabetes Association (ADA) and Diabetes Australia (DA) have begun mentioning the individualization of diet, emphasis on carbohydrates is still the norm. For example, in the NEMO Nutrition Guide for Children with Type 1 Diabetes published by Queensland Health, [5] breads, rice, pasta, noodles, polenta, couscous, and oats are emphasized with a total amount of carbohydrates for Type 1 children targeted at the 40 to 60% level, see Figure 1. Consider the representative case of a 14-year-old child who typically might require 2000 calories of food per day. Figure 1 shows that such a child is recommended to eat 250 – 300 grams of carbohydrates, roughly 50% carb, which is technically considered a high carbohydrate diet. Similar qualitative guidelines are given by Diabetes Australia [6].

Carbohydrate Recommendations				
Age	Main meals (maximum)		Snacks (maximum)	
	Portions	Grams	Portions	Grams
2-3 years	3 carb portions	45g carbohydrate	½ carb portion	7g carbohydrates
4-8 years	4 carb portions	60g carbohydrate	1 carb portion	15g carbohydrate
9-13years	5 carb portions	75g carbohydrate	1-2 carb portions	15-30g carbohydrate
14 years & older	6 carb portions	90g carbohydrate	2-3 carb portions	30-45g carbohydrate

This is a consensus document from Dietitian/ Nutritionists from the Nutrition Education Materials Online, "NEMO", team.
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Figure 1. Type 1 children are currently recommended a high-carb diet.

The poor results of the standard carbohydrate counting approach have been appreciated for a considerable time. For example, in a study in 2014, [7] a University of Sydney team published results from six randomized controlled trials investigating standard 'carb counting' strategies that showed an overall change in hemoglobin HbA1c levels of just 0.3% points (about a 0.5 mM improvement). For reference, the difference between healthy blood glucose and the blood glucose average attained by a Type 1 child following the standard protocol is 6 to 8 mM, so a 0.5 mM improvement is nearly insignificant. The result underscores a main feature of diabetes management with injected insulin: it is impossible to consistently match the action of rapid-acting carbohydrate foods like grains, starches, and sugars with rapid-acting injected insulin [8].

Further problems in standard management:

It is worthwhile to examine the industry's response to the long-standing failure in attaining normoglycemia in people with Type 1 diabetes. Despite published research and copious, well-known success in social media of the efficacy of a change in nutritional therapy to a low-carb approach, a main response instead has been in a redefinition of blood glucose targets. Roughly ten years ago, the American Diabetes Association began to popularize Time in Range or 'TIR' as a new guideline for people with Type 1. TIR encourages people with diabetes to target blood glucose levels of 4 mM to 10 mM (double normal) 70% of the time (thus allowing blood sugars *higher* than 10 mM 30% of the time). These levels are nowhere near healthy normoglycemia which ranges from 4 to 6 mM, and as seen below, such high blood glucose targets are well within the level where diabetic complications can occur. In response, the diabetes industry is now seeing pushback, and the time in range concept is coming under fire. For example, at a recent international diabetes conference, Professor Thomas Danne introduced a new 'Time in Tight Range' concept because he "no longer wanted to lie to his patients" [8]. Indeed, we strongly believe that people with diabetes – Type 1 and Type 2 – are entitled to normoglycemia and access to accurate information on achieving normoglycemia.

Time in Tight Range: The New Standard?

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What is the clinical relevance of TIR/TAR 70-140 mg/dl for T1D and T2D ?

Prof. Dr. Thomas Danne
Diabetes Center "AUF DER BULT", Hannover, Germany

Professor **Thomas Danne** introduced a concept of a Time in Tight Range (TITR) which reduces the range to 70-140 mg/dL (3.9-7.8 mmol/L). Why a new range? Because Professor Danne literally said "I don't want to lie any longer".

Figure 2. Time in Tight Range

Outcomes of the standard approach

The dominant cause of long-term diabetic complications is elevated blood glucose. We know that such complications start when blood glucose rises from normal levels. Elevated blood glucose is a continuous risk factor for micro- and macrovascular diabetic complications starting from near normoglycemia [11]. This section provides a rapid review of the etiology and recent literature on diabetic complications. The data presented below show that the probability of diabetic complications rises at non-normal HbA1c levels in the mid-5 % range (38 mmol/mol) and continues rising as HbA1c rises. The summary of diabetic complications demonstrates that the current standard of care is doing great harm. The research makes clear the following facts: complications occur well within the current industry standard 'target range' of 4 to 10 mM, elevated blood glucose causes complications to occur in virtually every organ in the body, and complications not only cause disease and a shortened lifespan but also dramatically reduce the quality of life of people with Type 1. In summary, strong evidence exists that the current high carbohydrate nutritional therapy of diabetes management leads to chronic, damaging levels of hyperglycemia and diabetic complications and should be abandoned as a singular therapy.

Elevated blood glucose was long suspected of causing the complications of Type 1 diabetes. However, it was not until 2005 that the precise physiology was well understood – an achievement that resulted in the award of the prestigious Banting Prize to Michael Brownlee for his “The Pathobiology of Diabetic Complications: A Unifying Mechanism” [9]. We now know that there are over 100 diabetic complications in total, and it is important to note that children are not spared [10]. Below, we list recently published research that emphasizes the grave nature of current outcomes:

- [1] Diabetic complications already appear at the high end of nondiabetic levels. A 2020 study in the American Diabetes Association journal "Diabetes Care" sheds light on this critical question, showing that both micro and macrovascular complications begin as soon as blood sugars rise from normal levels, *even within the nondiabetic range* [11].

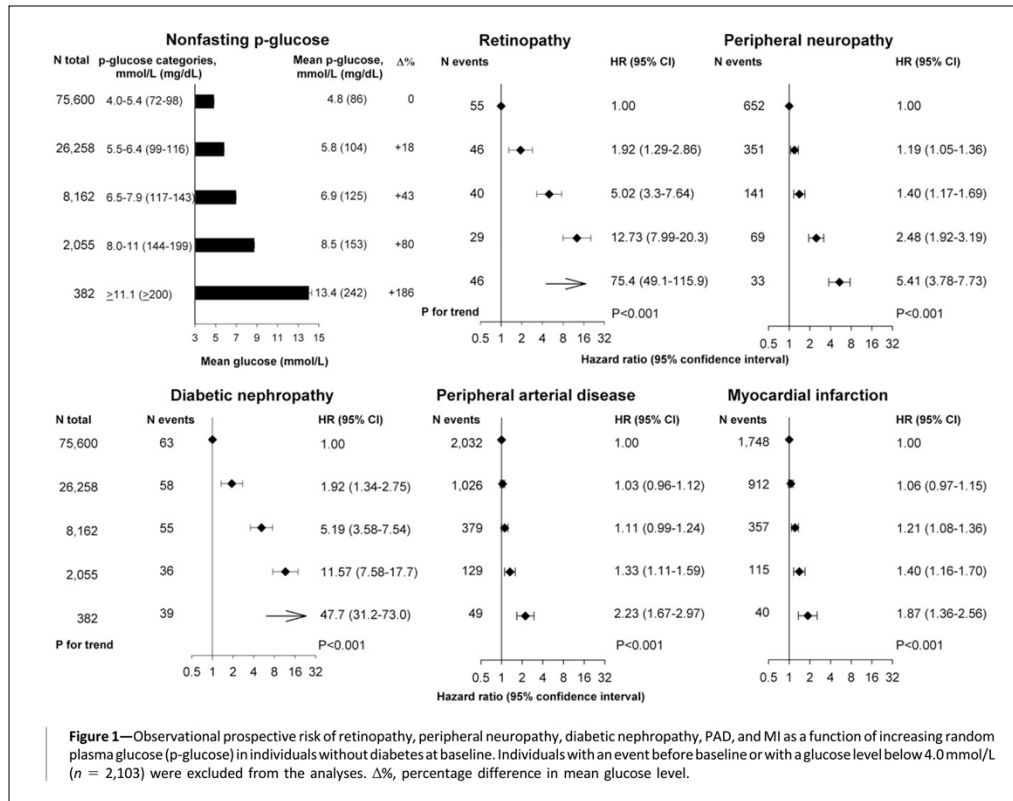


Figure 3. Micro and Macrovascular complication rates rise as blood glucose levels rise from normal.

- [2] Loss of nearly two decades of life for people with Type 1 diabetes. A 2018 study in the prestigious journal, The Lancet shows that women who developed type 1 diabetes before the age of ten die an average of nearly 18 years earlier than women who do not have diabetes. Men in the corresponding situation lose almost 14 years of life [12].
- [3] Cardiovascular disease is up to 10x the rate of nondiabetics. The single largest risk factor for cardiovascular disease in people with Type 1 diabetes is elevated blood glucose. Recent data from Sweden shows up to a tenfold elevated risk of cardiovascular mortality in T1DM according to glycemic control, and up to an eightfold increase in risk at various ages, Recent data from Sweden show up to a tenfold elevated risk of cardiovascular mortality in T1DM according to glycemic control and up to an eightfold increase in risk at various ages [13].
- [4] Microvascular complications include damage to the eyes, brain, kidneys, and nervous system damage.
 - A. Retinopathy: A 2012 European study showed the prevalence of retinopathy in Type 1 children was already at the 20% level within ten years of diagnosis [14].
 - B. Child microvascular complications. A 2006 paper on “Early diabetic complications in a population of young patients with type 1 diabetes” studied eighty children and adolescents with DM1, age 7-22 years and DM1 duration >3 years; the prevalence of neuropathy was 59%, of

retinopathy 27% and of nephropathy 5% after 13 years DM1 duration. The mean long-term HbA1c was 8.4%, equivalent to the Australian average [15].

- C. Damage to the developing brain. High-resolution MRIs show the immediate impact of high blood sugars on the Type 1 child's brain: "These results demonstrate that early-onset type 1 diabetes has widespread effects on the growth of gray and white matter in children whose blood glucose levels are well within the current treatment guidelines for the management of diabetes." [16].
- D. Growth stunting. In a 2012 study of a large set of Type 1 children, growth remains sub-optimal in this population and likely reflects ongoing metabolic derangement linked with classic microvascular diabetic complications [17].

[5] Quality of life and depression. While strictly speaking, not a direct physiologic complication, it has long been known that Type 1 diabetes is associated with depression [18]. Notably, a study on blood glucose normalization via low-carb diets showed high quality of life metrics and reduced depression levels [Bernstein Israel].

III. Low Carb Nutritional Therapy for Type 1 Diabetes: Approach and Evidence

The primary goal of nutrition therapy for diabetes management is to achieve optimal blood glucose levels in the normal range to reduce the risk of micro- and macrovascular complications. As summarized above, there is increasing recognition that chronic hyperglycemia is the most potent risk factor for long-term diabetes complications.

It is now known that therapeutic carbohydrate reduction can decrease postprandial glycemia and insulin requirements more effectively than any other dietary intervention, with additional benefits for reducing cardiometabolic risk factors (ADA). The low-carb approach to normalizing blood sugars has been introduced previously. Before the advent of insulin (circa 1923), it was the de facto standard in attempting to increase lifespan as much as possible. Later in the 1980s, a detailed approach to a very low-carb management protocol, including insulin dosing, was invented by Dr. R. Bernstein. While the low carb concept is easy and intuitive to grasp initially, the method in all its detail is explained exhaustively in Bernstein's "Diabetes Solution" [20]. The protocol is comprised of the following features:

1. Adopting a low-carb, high-protein diet that removes all rapid-acting carbohydrate foods – breads, crackers, sugars, etc. All grains, starches, simple sugars, and modern high-sugar fruit like bananas and oranges are removed. These foods rapidly spike blood glucose too high. Non-diabetic levels are virtually impossible to match with injected insulin consistently.
2. Developing a meal and basal-bolus insulin plan that allows for nearly flat, stable blood sugars from 4 to 6 mM. This meal plan consists chiefly of healthy protein foods and fibrous veggies; see Figure 4 below.



Figure 4. The low-carb food pyramid emphasizes protein foods and fibrous vegetables.

3. Modulation of protein amounts to account for the individual – less protein for weight loss, more (much more) for children and athletes. As occurs physiologically in people without diabetes, protein foods are covered with small doses of intermediate-acting insulins.
4. It is important to note that such an approach can also accommodate a vegetarian and vegan lifestyle, and indeed a co-author of the seminal low-carb paper [4] follows such an approach.

Evidence is now growing that with such an approach, Type 1 Diabetes is a disease that can be controlled. Normoglycemia *can* be attained, and complications can be avoided, and at the very least, delayed.

Evidence for the efficacy of low-carb nutritional therapy in Type 1 Diabetes:

Evidence for low-carb nutritional therapy for people with diabetes is growing. Here, we focus on results from the seminal study published by a Harvard-led team in the American Academy of Pediatrics journal PEDIATRICS [4]. Highlights from the paper are:

- ✓ Most participants were from the United States, Canada, Europe, or **Australia**.
- ✓ Carbohydrate intake was 20 to 50g per day.
- ✓ Exceptional glycemic control of Type 1 with low rates of adverse events was reported by a community of children and adults who consume a very low-carbohydrate diet.
- ✓ Normal BMI and low total daily insulin doses were reported.
- ✓ Important measures of Type 2 diabetes (double diabetes is now common in people with Type 1) were measured, including low triglycerides and high HDL.
- ✓ 97% of participants achieved glycemic goals as established by the diabetes advisory groups and industry.
- ✓ Reported mean HbA1c was 5.57% per medical records.
- ✓ Low rates of adverse effects, including hypoglycemia.
- ✓ Patients did not use traditional carb counting techniques and instead used a protocol first implemented by Dr. Richard Bernstein. This protocol details the use of injected insulin in the low-carb context, including how to cover protein foods with insulin as is required physiologically [20].

- ✓ Participants reported high overall health and satisfaction with diabetes management but not with their traditional, ‘professional’, diabetes care.

Personal Accounts

The popularity of low-carb diets has been growing steadily since 2014 via non-industry pathways. For example, testimonies to the power of a low-carb therapy appeared in Australian social media via professional physicians with Type 1 diabetes, e.g., Dr. Troy Stapleton as well as parents of children with Type 1, e.g., Lisa Scherger [19]. In agreement with these results, an exhaustive set of testimonials from a diverse set of people with Type 1 Diabetes who have achieved normoglycemia have been collected [20]. In [21], a detailed account of daily experiences is given by a Type 1 teen, including positive social-emotional experiences, the ability to perform at a high athletic and academic level, and overall positive satisfaction brought by a low-carb approach. Such personal accounts are now critical as myths perpetuate [22], for example, the myth that the low-carb approach that generates normoglycemia approach is ‘unsustainable’.

A common theme runs through these testimonials: a new lease on life has been achieved as the ability to achieve normoglycemia is transformative and empowering: “I realized that I was not doomed to share the fate of others who died prematurely after years of painful diabetic complications. With the ability to control my blood sugar came the ability to prevent the consequence of high blood sugar, and I became the captain of my ship.”

IV. Conclusions and recommendations:

The current high-carb nutritional therapy that professional diabetes associations advocate results in chronic hyperglycemia and adverse outcomes, including diabetic complications and a shortened lifespan. With the growing evidence of the efficacy of a low-carb nutritional therapy for people with Type 1, it will be important to invoke systematic change in implementing low-carb nutritional therapies from the top down. Such an approach should include:

- Unfettered access to information on low-carb nutritional therapies for *all* people with Type 1 diabetes upon diagnosis.
- Detailed education materials, and support, on the implementation of low-carb nutritional therapies.
- Education on the use of insulin in the low-carb context.

A natural pushback on any change of current dogma to include low-carb nutritional therapy, likely due to the institutional inertia within the diabetes industry, should be countered with a close consideration of the acute, and chronic, negative clinical outcomes seen with the current approach. The research shows that the consequences of the current guidelines in Type 1 children (for example, high-resolution MRI showing impaired brain differentiation shortly after diagnosis) occur rapidly and with a permanent loss of quality of life. We believe *all* people with Type 1 diabetes should be empowered with unfettered access to information regarding the low-carb option upon diagnosis. Those that wish to pursue this path should be supported, rather than undermined, as is the current paradigm.

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