

Provincial Day of Action 2019:

Research Primer

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Memorial University Faculty of Medicine



FACULTY OF MEDICINE

What is Type 1 Diabetes?

Type 1 diabetes mellitus (T1DM) is a disorder in which the pancreas cannot produce insulin. Given the role of insulin in maintaining blood sugar, external sources of insulin, or insulin therapy, must be taken to avoid elevated sugar levels and adverse outcomes [1].



What is Insulin Therapy?

Insulin therapy, which generally consists of either human insulin or an analog, supplements the inadequate insulin levels produced by the dysfunctional pancreas of a T1DM patient [2]. There are currently four major types of insulin therapies: rapid-, short-, intermediate- and long-acting. Therapy also generally comprises basal and bolus dosages. Basal therapy provides a baseline insulin level that mimics normal insulin secretion in periods between meals, whereas bolus therapy is taken during meals and simulates the typical pancreas' response to food intake. In terms of administration, there are three existing delivery methods for insulin therapy in Canada: subcutaneous injections, continuous subcutaneous insulin infusion (CSII, generally referred to as insulin pump therapy) and intravenous infusion [3]. Though various options are available, insulin pump therapy is generally considered the best method, given that it mimics “the pattern of insulin secretion by β -cells, delivers insulin with unequalled precision and allows a high lifestyle flexibility” [4].



What is an Insulin Pump?

In insulin pump therapy, a patient wears an external device that delivers a continuous, basal dose of rapid-acting insulin 24 hours per day. The user is also able to manually administer a bolus dose of rapid-acting insulin during meals by simply pressing a button on the device. To achieve this functionality, the device comprises three major components [5]:

- An electronic device, generally worn on the hip, that comprises a pump, a battery and accessible controls,
- A cartridge, placed within the electronic device, that holds the insulin, and
- An infusion set, which includes a cannula (inserted under the skin) that is connected via a tube to the insulin cartridge.

Benefits of Insulin Pump Therapy

When compared to other administration methods, the benefits of insulin pump therapy are numerous. As stated above, an insulin pump is generally considered to be the best simulation of the pattern of insulin secretion seen in the properly-functioning pancreas [4]. Medically, pump therapy has been shown to result in fewer episodes of hypoglycemia (or low blood sugar) and a reduction in the mean daily blood glucose values, when compared to multiple daily injections. Moreover, pump therapy has been shown to achieve these benefits while using an average of 26% less insulin than the multiple injection method. In terms of quality of life, use of an insulin pump has also been associated with increased lifestyle flexibility, diet flexibility and sleep patterns [6]. Insulin pumps have also been reported to significantly improve self-esteem, stress levels and mood in diabetic patients, when compared to other methods of administration [7].

Individual Challenges of Insulin Pump Therapy

Though the medical and quality of life improvements of insulin pump therapy are well-documented, these benefits do not come without a cost to the user. The annual out-of-pocket costs associated with insulin pump usage in Newfoundland and Labrador (NL) can total as high as \$6,300. This value includes the cost of the pump itself, as well as the supplies associated with pump usage [7]. Evidently, these costs present a potential obstacle for T1DM patients to access pump therapy. In fact, 57% of Canadian T1DM patients report that they do not comply with their prescribed therapy because they cannot afford their medications, devices and supplies [8]. This lack of compliance often leads to subpar T1DM management, which can result in a variety of complications such as heart attack, stroke or kidney failure. Diabetes and these related complications account for approximately 10% of acute care hospital admissions [9]. From a public funding standpoint, these complications result in massive direct and indirect healthcare costs that are absorbed by the Canadian medical system. Switching from daily injections to an insulin pump is estimated to reduce the annual incidence of myocardial infarction among T1DM patients in NL by 10%. This would result in significant cost savings for the health care system, as each case of myocardial infarction has an average cost of \$20,935. Similarly, the incidence of end stage renal disease would decline by approximately 20.4%, with each case of this disease costing upwards of \$188,771. The incidence of lower limb amputation would decline by 7%, with each case having an average cost of approximately \$28,461 [10]. Other complications that can result from uncontrolled diabetes include retinopathy, neuropathy, and foot ulcers [2], all of which add to the costs incurred by the healthcare system.



Level of Provincial Coverage for Insulin Pump Therapy

Though some insurance plans cover a portion of insulin pump and supply costs, many Canadian rely on provincial and territorial programs to offset the restrictive pump therapy costs. Each province and territory in Canada regulates the degree of coverage that their residents receive for insulin pumps and associated supplies. The provincial nature of this regulation results in a broad spectrum of coverage models, each of which includes a range of unique eligibility criteria. In performing an environmental scan of insulin pump coverage in Canada, three general levels of provincial coverage were identified [11]:



- ***Comprehensive*** – coverage for **pump and supply costs, regardless of age or income.**
 - Implemented by Alberta, British Columbia, Nunavut, Northwest Territories, Ontario and Yukon.
- ***Age-based comprehensive*** – coverage for **pump and supply costs until the patient reaches a certain age.**
 - Implemented by Manitoba (18), Newfoundland and Labrador (25), Quebec (18) and Saskatchewan (26).
- ***Age-based sliding scale*** – coverage for a **proportion (up to a maximum percentage) of pump and supply costs, generally based on household size and/or income, until the patient reaches a certain age.**
 - Implemented by New Brunswick (age = 19, maximum = 100%), Nova Scotia (age = 26, maximum < 100%) and Prince Edward Island (age = 19, maximum = 90%).

Insulin Pump Therapy Coverage in Newfoundland and Labrador

As stated above, the Government of NL provides T1DM patients with coverage for insulin pumps and supplies up until the age of 25 years. This provides patients with one insulin pump every four years, and does not cover the cost of insulin, test strips, continuous glucose monitoring systems, or insets [12]. This support is for individuals that do not possess private insurance with coverage for insulin pumps and associated supplies, or whose insurance only covers a portion of the cost. The existing plan was put into place in 2010, and also includes insulin pump coverage of up to \$2,500 for public sector employees [11].



Type 1 Diabetes and Insulin Pump Therapy in Newfoundland and Labrador

In 2012, it was estimated that 2,700 individuals were living with T1DM in NL, a number that was expected to rise to 3,400 by 2032. Within this population, approximately 70% are aged 25 years or older [10]. This age demographic indicates that nearly three-quarters of T1DM patients living in the province lack access to provincial coverage for their insulin pump and supplies. Of the population under 25 years of age, it is estimated that nearly 55% make use of publicly-funded insulin pumps. Though this value may appear low, the figure is in line with values that are reported in other parts of the country [10]. Moreover, it is worth noting that insulin pump therapy is not indicated for every T1DM patient, and that some patients prefer other methods of insulin administration.

Economic Analysis of Expanding Coverage in Newfoundland and Labrador

In 2012, it was estimated that 430 publicly-funded pumps were being used by T1DM patients under the age of 25 years in NL. By 2032, it was expected that this value would rise to 490 T1DM patients. By removing the current age restriction, it is estimated that the number of publicly-funded pumps would rise to 990 by 2032. These estimates are based on assumed pump usage rates of 60% for individuals under the age of 20 years, and 40% for individuals aged 20 years and older [10].

The annual costs of the current program implemented in NL were estimated to be \$0.7 million in 2012, a value that was expected to increase to \$0.9 million by 2032. In expanding the program to include T1DM patients of all ages, the initial program costs would increase to an estimate of \$2.0 million per year. Along with this rise in annual costs, however, there are significant cost savings that can be expected by reducing the number of T1DM-related complications. In the first year of implementation alone, it is projected that these cost savings would total \$1.6 million. With these savings considered, it is expected that expanding the program would result in a net annual cost of \$0.4 million – a value \$300,000 *less* than the current program costs. Furthermore, the savings associated with reduced T1DM-related complications are expected to grow each year, to the point where the savings will eventually exceed the costs of the program. By 2032, the expanded program is projected to result in net direct savings of \$1.2 million, a value that is \$2.1 million less-expensive than the expected \$0.9 million cost of the existing program in the same year [10].

Impact on the Patient

Due to the current provincial coverage, some patients without adequate insurance coverage may have to return to using multiple daily injections as opposed to insulin pump therapy at age 25. For patients who have been on pump therapy for most of their disease course, this can be quite an adjustment. Many patients feel greater treatment satisfaction and have a better health perception, and hence a better quality of life, when using pump therapy as opposed to daily injections. Patients on insulin pump therapy may also experience greater flexibility and freedom when it comes to things such as meal planning and exercise [13]. Returning to injections may result in inadequate control of blood glucose levels, a loss of follow-up care, patient frustration with their health, and ultimately an increased risk of future diabetes-related complications. Patient burnout is also possible in those with a chronic disease such as diabetes and may be exacerbated due to a decrease in diabetes control when switching from pump therapy to multiple daily injections [13]. Patients with better control of their condition are potentially able to be more active in their community and more productive members of society, meaning insulin pump coverage for all ages will have an impact at the societal level as well.

These challenges are compounded by the fact that the current age restriction of 25 coincides with a difficult transitional stage towards adult life. This stage has been characterized as one in which many T1DM patients see worsened self-management, deteriorated glycemic control and an elevated risk of adverse outcomes. Moreover, individuals in this age range are less likely to seek medical follow-up, furthering their risk of hospitalization from T1DM [15]. By complicating this transitional period even further by removing access to a key medical treatment, the current Insulin Pump Program fails to address the needs of T1DM patients living in NL.

Our Ask

All Newfoundlanders and Labradorians deserve access to the medications, devices, supplies and services that will give them the best chance at normal, healthy, and productive lives. T1DM is a uniquely pervasive problem in our society, and it will take both the vigilance of medical advocates and action of our representatives to curtail. Together, we can make a difference. We, the medical students of Memorial University of Newfoundland, call upon all Members of the House of Assembly to eliminate the age restriction of the current Insulin Pump Program and to, in turn, provide coverage for insulin pumps and their associated supplies to all Newfoundlanders and Labradorians without existing private coverage.

References

- [1] Diabetes Canada, "Living with Type 1 Diabetes," 2019. [Online]. Available: <https://www.diabetes.ca/diabetes-and-you/living-with-type-1-diabetes>.
- [2] D. K. McCulloch, "Overview of medical care in adults with diabetes mellitus," 25 October 2018. [Online]. Available: <https://www.uptodate.com/contents/overview-of-medical-care-in-adults-with-diabetes-mellitus>.
- [3] J. A. Galdo, M. M. Thurston and C. A. Bourg, "Clinical Considerations for Insulin Pharmacotherapy in Ambulatory Care, Part One: Introduction and Review of Current Products and Guidelines," *Clinical Diabetes*, pp. 66-75, 2014.
- [4] D. Bruttomesso, S. Costa and A. Baritussio, "Continuous subcutaneous insulin infusion (CSII) 30 years later: still the best option for insulin therapy," *Diabetes/Metabolism Research and Review*, pp. 99-111, 2009.
- [5] Government of Canada, "Insulin Pumps," 2012. [Online]. Available: <https://www.canada.ca/en/health-canada/services/healthy-living/your-health/medical-information/insulin-pumps.html>.
- [6] R. P. L. M. Hoogma, P. J. Hammond, R. Gomis, D. Kerr, D. Bruttomesso, K. P. Bouter, K. J. Wiefels, H. De La Calle, D. H. Schweitzer, M. Pfohl and E. Torlone, "Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial.," *Diabetic Medicine*, pp. 141-147, 2006.
- [7] H. Ghazanfar, S. W. Rizvi, A. Khurram, F. Orooj and I. Qaiser, "Impact of insulin pump on quality of life of diabetic patients," *Indian Journal of Endocrinology and Metabolism*, vol. 20, no. 4, pp. 506-511, 2016.
- [8] Diabetes Canada, "Diabetes in Newfoundland and Labrador," March 2018. [Online]. Available: https://www.diabetes.ca/getmedia/9f714609-55f6-422e-895e-9c57c85acd5d/2018-Backgrounder-Newfoundland-and-Labrador_JR_AB_KB-edited-13-March-2018.pdf.aspx.
- [9] Canadian Diabetes Association, "The Burden of Out-of-Pocket Costs for Canadians with Diabetes," 2011. [Online]. Available: <https://www.diabetes.ca/CDA/media/documents/publications-and-newsletters/advocacy-reports/burden-of-out-of-pocket-costs-for-canadians-with-diabetes.pdf>.
- [10] Diabetes Canada, "Complications Research," 2019. [Online]. Available: <https://www.diabetes.ca/research/research-funding/complications-research>.
- [11] Canadian Diabetes Association, "The Economic Benefit of Expanding Public Funding of Insulin Pumps in Newfoundland and Labrador," 2012. [Online]. Available: <https://www.diabetes.ca/CDA/media/documents/publications-and-newsletters/advocacy-reports/economic-benefit-of-expanding-public-funding-for-insulin-pumps-in-newfoundland-labrador.pdf?fbclid=IwAR2WpXvn-SZe2Y5WPZ9RNWYD9gPHLLaXuA1noJReJCosdyRd7Uy9wSqqR14>.
- [12] Diabetes Canada, "Access to Medications, Devices and Supplies & Your Rights," 2019. [Online]. Available: <https://www.diabetes.ca/diabetes-and-you/know-your-rights/access-to-medications-devices-supplies-your-rights>.
- [13] Eastern Health, "Newfoundland and Labrador Adult Insulin Pump Program," 2014. [Online]. Available: www.easternhealth.ca/DownFile.Asp?fileid=3147.
- [14] T. Hussain, M. Akle, N. Nagelkerke and A. Deeb, "Comparative study on treatment satisfaction and health perception in children and adolescents with type 1 diabetes mellitus on multiple daily injection of insulin, insulin pump and sensor-augmented pump therapy," *SAGE Open Medicine*, 2017.
- [15] D. K. Wherrett, J. Ho, C. Huot, L. Legault, M. Nakhla and E. Rosolowsky, "Type 1 Diabetes in Children and Adolescents," *Canadian Journal of Diabetes*, vol. 37, pp. S153-S162, 2013.