# **CADTH Call for Feedback: Hybrid Closed-Loop Insulin Delivery Systems for People with Type 1 Diabetes**

## CNIB Foundation Feedback

### About CNIB Foundation

Celebrating 100 years in 2018, CNIB is a non-profit organization driven to change what it is to be blind today. We deliver innovative programs and powerful advocacy that empowers people impacted by blindness to live their dreams and tear down barriers to inclusion. Our work is powered by a network of volunteers, donors and partners from coast to coast to coast.

### Introduction

CNIB welcomes CADTH's Draft Science Report on Hybrid Closed-Loop Insulin Delivery Systems for People with Type 1 Diabetes. There are approximately 750,000 people living with diabetic retinopathy in Canada and diabetic retinopathy is the fourth leading cause of blindness in Canada (*CNIB, Cost of Vision Loss in Canada Report, 2018*), as well as the leading cause of blindness in working age adults in Canada (*Diabetes Canada, Diabetes 360˚: A Framework for a Diabetes Strategy for Canada, 2018*). As such, given the strong link between diabetes and sight loss, we were pleased to see recognition given in CADTH's report regarding the impacts of current insulin delivery systems being inaccessible (3413).

Effective and independent insulin management has been a long-standing struggle for people living with diabetes and sight loss, due to the visual nature of current insulin delivery methods and technologies. As far as CNIB is aware, there are no fully accessible insulin pumps on the Canadian or international markets currently[[1]](#footnote-1). There are some older models of insulin pumps that have limited audio features for certain device functions (i.e., a beep to let someone know the insulin dosage), but a person still cannot use all the features of the device, such as locking or unlocking it, and one Ontario endocrinologist estimated that their patients with sight loss can only use approximately 11 per cent of an insulin pump's features, essentially rendering it a "glorified insulin pen".

For this reason, we are greatly interested in the potential of Hybrid Closed-Loop Insulin Delivery Systems (HCLs) as a way to remedy existing accessibility challenges and provide independence and better health outcomes for people living with diabetes and sight loss, as long as this system is designed with universal design and accessibility in mind and does not merely reinforce the current inaccessibility of insulin delivery systems.

### Impacts of inaccessible insulin delivery methods

While CNIB has not had the opportunity to commission research into the accessibility of HCLs or receive direct feedback from who use them that are blind or partially sighted, in 2020 we launched an international survey on the accessibility of insulin pumps for people living with sight loss and diabetes.

In response to one of the survey questions, individuals reported having concerns over administering the correct dose of insulin and with operating the device alone. Most respondents stated that they are constantly fearful of inadvertently causing bodily harm through incorrect administration of insulin as a result of a lack of accessibility of their insulin device (65 per cent).

Furthermore, some memorable testimonies of the patient experience included:

* “I currently fear about misusing my insulin pump and killing myself with an overdose.”
* “Being able to utilize all of the features of insulin pumps would increase my independence level dramatically. At the moment I feel insecure about travelling, I don’t know what to do in case something goes wrong with my pump.”
* “Being able to utilize all of the features of insulin pumps would restore my independence. I would not have to explain what to do each time I require help and would not worry that people might make mistakes. I would be able to take care of myself.” (*CNIB, Accessibility of Insulin Devices Survey, 2020*).

### Characteristics of Included Primary Studies — Clinical Review (3773)

We note that in Table 38: Study and Patient Characteristics of Included Primary Clinical Studies that CADTH lists "poor visual acuity" as an exclusionary characteristic for McAuley (2020) and "those with serious and not corrected hearing or visual problems" for Benhamou (2019). The rationale for exclusion of low vision participants from the studies are either nonexistent (no mention is made in the exclusion criteria of one study), or methodologically based (i.e., based on the method of data collection in the other study - with no evidence the authors attempted any accessibility solutions). This has significant potential for bias, as there are no substantive reasons for excluding a significant population of individuals who are both diabetic and have sight loss.

People with sight loss comprise approximately 5 per cent of the Canadian population (*Canadian Survey on Disability, 2017*), which is a nontrivial percentage. Excluding this group from studies where the intended outcomes are directly or indirectly beneficial to them is problematic, and many studies exhibit methodological or attitudinal bias in this area. Often, the accessibility needs of this population are not accounted for in product design, and researchers do not consider accessibility in their methodology and data collection approaches. As a result, study outcomes are either intended to benefit people with sight loss but cannot be validated in this population given available evidence, or study outcomes outright exclude people with sight loss from consideration.

### Patient Coaching and Support (2990-3023)

CNIB has been informed that individuals with sight loss were being advised against using insulin pumps. In response, we designed research questions for our Accessibility of Insulin Devices Survey to probe further into this topic.

About 20 per cent of individuals that responded to this line of questions reported being advised against using insulin pumps at some point in their life. These individuals were told that the visual displays were insufficiently accessible for their use (48 per cent), told that they would not be able to operate the device alone (29 per cent), and told that the lack of alternative feedback mechanisms to device displays, such as tactile and audio feedback, would make the device unusable (24 per cent).

The sources advising individuals against the use of insulin pumps ranged from pump manufacturers (30 per cent), pump nurses (21 per cent), endocrinologists (21 per cent), to healthcare organization websites (eight per cent) (*CNIB, Accessibility of Insulin Devices Survey, 2020*).

Furthermore, we have received feedback from people living with diabetes and sight loss that device manuals for their insulin pumps and glucose monitors are not provided in an accessible digital or hard-copy format, which creates barriers to patients educating themselves on their device or troubleshooting minor issues with the device when they arise. It goes without saying, but any materials that are developed relating to HCL systems must be fully accessible.

### Confidentiality and Safety (3024)

We recognize that concerns regarding a person's HCL system being hacked and overridden by a malicious third-party are a genuine threat to a person's health and safety. However, we have also witnessed newer models of insulin pumps being equipped with additional visual-only security features, such as a person needing to press buttons in a certain order based on visual cues on-screen in order to unlock their insulin pump. This renders some users now unable to unlock their insulin pump and so they have needed to revert back to older models without this software feature.

While these decisions are often well-intentioned to protect the safety of the end user, they unintentionally create accessibility barriers and can ultimately render a device unusable. Any safety features that are designed for HCLs must incorporate accessible design and ensure that they do not lock out the very person that they are intending to protect.

Moreover, any data that is produced by an HCL device needs to be readily available to the patient in an accessible format, so that that they have equal access to their healthcare information and are empowered with the choice as to whether they would like to disclose this information or not.

### Recommendations

* Include people with varying levels of sight loss in further research regarding the use of HCLs
* Design HCLs with full accessibility and universal design practices.
* Canadian healthcare regulatory bodies should mandate that accessible design should be a condition of HCL systems being approved for the Canadian market. Otherwise, we are recreating old barriers to accessing treatment through new technologies.
* Sight loss alone should not be a condition for deeming someone an inappropriate candidate for using an HCL system. Instead, healthcare professionals and manufacturers should take into account a range of factors in order to determine a person's suitability to adopt an HCL system.
* We support any efforts that call for equal funding and access to treatment across Canada. Cost or where a person decides to live should not be barrier to accessing the most effective treatment. According to Statistics Canada's 2017 Canadian Survey on Disability, 22 per cent of Canadians living with severe or very severe sight loss are low income according to the Market Basket Measure (MBM),[[2]](#footnote-2) compared to 8.7 per cent for the general population. Access to funding for devices will be integral to vulnerable populations living in poverty and with diabetes.
* We support CADTH's conclusion that "As HCLs and associated technology evolves, more attention should be paid to the user-device interface. This includes having user-friendly and understandable reports, allowing for user customization where safe and appropriate to do so, and making devices usable and accessible for those with visual or hearing impairments." (3585-88).

### Background Materials

Burton, Darren M. et al. (2004) "Diabetes and Visual Impairment: Are Insulin Pumps Accessible?" <https://www.afb.org/aw/5/2/14770#:~:text=Insulin%20pumps%20are%20relatively%20inaccessible,insulin%20delivery%20can%20be%20lethal>.

Burton, Darren M. et al (2009) “Are Current Insulin Pumps Accessible to Blind and Visually Impaired People?”, J Diabetes Sci Technol. 3(3):613-618

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769864/>

Uslan MM, Burton DM, Clements CW. Blood glucose meters that are accessible to blind and visually impaired persons. *J Diabetes Sci Technol*. 2008;2(2):284-287. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2771496/>

Zieger, Ann (2015) ”College Students design talking insulin pumps for visually impaired diabetics” <https://innovatemedtec.com/content/college-students-design-talking-insulin-pump-for-visually-impaired-diabetics>

1. While CNIB's focus has been on insulin pumps, there have also been investigations into the accessibility of glucometers for people with sight loss, notably Uslan, MM (2008). [↑](#footnote-ref-1)
2. The Market Basket Measure is a measure of low income based on the cost of a specific basket of goods and services representing a moderate, basic standard of living. [↑](#footnote-ref-2)