Co-designing Accessible Insulin Infusion Pumps for Individuals who are Blind or Partially Sighted

October 2021



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**Co-designing Accessible Insulin Infusion Pumps for Individuals who are Blind or Partially Sighted**

## Executive Summary

Diabetes and sight loss are closely linked, where diabetic retinopathy is a potential complication for people living with diabetes. Insulin pump therapy is an alternative type of diabetes treatment offering insulin infusions rather than multiple daily insulin injections. However, despite their vital function, many features of an insulin pump have not been designed to be universally accessible for people who are partially sighted, Deafblind, or blind who live with diabetes. An environmental scan was conducted to obtain information on insulin pump accessibility, policy and regulatory landscape for medical devices, existing features, and user instructions. Following the scan, co-design was used to recognize and refine the design features of an accessible insulin pump.

Data was obtained from co-design sessions involving nine participants who spoke English or French, with diabetes and sight loss, aged 18 years and older. Sessions were conducted virtually and over the phone between late July and early August 2021. General themes included which features were most beneficial, practical adaptive strategies, proposed modifications for improved designs and the relative impacts of inaccessible features on insulin pump accessibility. Our results demonstrate that Insulin pump end-users’ needs are still not fully met, generating major barriers for the provision of equitable diabetes care and medical device design. Findings uncovered the need for customizable haptic features, adaptable speech-output capabilities, user-friendly operating handbooks in several formats and descriptive notification tones for greater autonomy in diabetes management.

## Keywords

Co-design, Medical Devices, Insulin Infusion Pumps, Accessibility, Diabetes, Sight loss, Canada

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## Acknowledgments

Many thanks to my supervisor, Dr. Mahadeo Sukhai, for his instruction and support. I'd also like to express my gratitude to Michaela Knot for her valuable assistance with interpretation and analysis. Thank you, Kat Hamilton, for always encouraging us and for being willing to help during the project. Finally, I'd like to express my gratitude to all the participants who willingly took part in the study and made this research possible.

## Introduction

Diabetes and sight loss are closely linked, with diabetic retinopathy as a possible complication for people living with diabetes and is the leading cause of sight loss among working age Canadians. Nearly 750,000 Canadians are affected by diabetic retinopathy and this population of insulin pump users will only continue to grow in number. Insulin pump therapy is a treatment option for diabetes mellitus, in which insulin is delivered via infusion rather than multiple daily insulin injections. Insulin pumps are often frequently preferred over multiple daily insulin injections as an efficient method of maintaining normal blood glucose levels.

Despite their vital function for insulin delivery, insulin pump features, have not been designed to support the health care needs of all Canadians, especially for those who are partially sighted, or blind and living with diabetes. Insulin pumps are complex medical devices and can sometimes lead to severe health effects if insulin dosage selections are set-up or entered incorrectly (Burton et al., 2009). Thus far, there is not an insulin pump and continuous glucose monitor (CGM) available that promotes an ideal interaction and wearability for users (Harper & Aflatoony, 2021). Therefore, this research focused on accessible design elements of insulin infusion pumps based on the current research evidence and consumer feedback. Accordingly, information was collected from an environmental scan for analysis of pump features in combination with using co-design methods.

## Background

The purpose of this report is to support CNIB's efforts addressing the topic of inaccessible insulin infusion pumps for Canadians living with diabetes and sight loss (M. Trollio et al., In Press). As well, licensing approval process stands in need of integration for accessibility testing earlier in the product development lifecycle combined with data from the widest range of current and future user-needs. Currently, limited unbiased results exist about accessible medical device designs and little transparency from regulatory agency approval processes (Heinemann et al., 2014). This calls for more research into the perspectives of patients on this new technology, as well as how these individuals function with and how their trust in the device evolves over time (Grando et al., 2019). Findings will help outline clear user-centered design features for medical devices for greater accessible diabetes management for people who are blind, partially sighted, or Deafblind living with diabetes.

## Co-Design Methods

This co-design approach was centered around universal design principles and focused on operational features such as unlocking access to the device functions and task routine from the device’s interface menus from a person's wearing position. Adapted from consultation with Erin Lee, using insights from a previous online [co-design model](https://ocaduinclusivedesign.wordpress.com/2020/04/03/co-designing-at-a-distance-testing-a-job-interview-simulator-for-blind-and-partially-sighted-individuals/) for inclusive design research involving individuals who are blind or partially sighted, testing job-interview simulations (Casanova, Chung, & Lee, 2020). Additionally, the co-design questions aimed to comprehend user’s daily interactions with the pump including feedback tones and alerts, ease of use for inputting dosage and influence of insulin pumps on social activities. At the request of the participants, co-design sessions were held online via Zoom and over the phone in July and August 2021. The goal of the sessions was to engage with participants in co-design a new insulin pump for one’s own needs.

## Participants

We spoke with nine insulin pump users, ranging from ages 18 to 65, who identified as male or female, spoke English or French and were from across Canada. All the participants had Type 1 diabetes and had been using an insulin pump for at least three months or more. Participants identified as blind or partially sighted and answered questions related to personal experiences with insulin pump devices. Participants discussed the features they found to be most beneficial, which features could be modified for ideal/optimal use and which features were found inaccessible for diverse lifestyle needs. Notably, participants discussed feature preferences based on various daily activities including daily exercise to formal events to charging the battery and refilling the reservoir of the pump. Participants’ autonomy levels outweighed any operational limitations generating expectations for accessible features in upgraded device designs as part of future prospects of co-design with industry.

## Experiences Shared by Insulin Pump Users:

Speech output was considered one of the most important features missing from insulin pump design. This feature would alleviate many accessibility barriers, allowing any user, including blind and partially sighted persons, or sighted, to fully engage with all the functionalities of an insulin pump. Participants agreed that individual customization options are necessary based on their needs and feature preferences.

As well, improved accessible and inclusive knowledge-sharing tools will largely benefit individuals with diabetes and their support groups. It is necessary to establish guidance for healthcare providers on how to provide the relevant information to best advise clients who are considering this form of treatment. Given the cognitive load of handling these devices autonomously, this medical equipment requires a human error threshold, which is outlined in Universal Design Principle 5 [(Appendix A)](#_Appendix_A:_Universal).

## Desire for and Maintaining Independence and d’être autonome:

In summary, we found from the co-design sessions, that individuals who are blind and partially sighted are successfully using insulin infusion pumps to manage their diabetes, in some cases for many years. Nevertheless, several end users called for modified tactile buttons to manage their insulin options autonomously as opposed to settings which are mainly controlled using visual menu features on the display screen. Justifiably, participants pointed out the advantages of using an insulin pump over traditional insulin pen delivery methods, outlining the potential risks in manually managing their own diabetes between tools and devices to meet their health care needs for the promises of increased independence presented by these devices. In addition, participants mentioned device technical support was primarily from diabetes educators, health care workers, or other forms of sighted assistance for information about their insulin pump features.

## Key Modifications Requested

1. Streamlining device settings and shortcut menu navigation buttons.
2. Development of insulin reservoir level notifications.
3. Discernable audible feedback tones for selected tasks.
4. Regulation of insulin pumps via an accessible smartphone app.

## Recommendations for Insulin Pump Manufactures & Medical Device

### Engineers

Recognize accessibility requests to be incorporated into design process and apply user inputs to develop frameworks for ease of use. Majority of participants were asking to be included into the design process of these devices by consultations with manufacturers and engineers. Some participants have reached this level of involvement on their own. User needs must also consider gender dynamics and diverse perspectives from those who may be in early stages or sight loss to others with more severe and complexity with co-occurring disabilities. Individuals with sight loss are hesitant to upgrade to newer devices, because they fear that new features are not addressing their needs, and therefore more likely on remain on older devices. This is a fear with many consumers with electronic devices and software, where devices claim accessible features and then can be removed or broken through upgrading.

**Suggested Solution**:Follow user-design and co-design research methodologies with participation from diverse communities and users’ needs who can improve the usability of devices and share valuable inputs on how devices are used (post-market), and individuals adapt them to their needs.

### Design of Bolus Menus:

People who are partially sighted benefit from increased display contrast and control over levels of information presented. Collectively, however the current bolus menu selections are far too difficult to navigate, and insulin dosage history is a desired feature. Furthermore, to detect and fix insulin dosage complications, design changes must focus on descriptive alert sounds and secondary confirmation of insulin dosages.

**Interoperability with existing smartphone accessibility features**

1. Features for secure dose admin and independence in management.
2. Bodily integrity, public health and charter of rights and freedoms.
3. Interoperable combination seen with the Dexcom G6 used with Apple’s Siri voice-enabled features for improved control (Akturk et al., 2021).

## Recommendations for Health Care Systems & Health Care Providers

### Recommendations for Government & Regulatory Bodies

**Recommendations for Health Care Regulatory Bodies, Health Canada Technical Scientific Committees, Decision-makers**

1. Include more diverse perspectives and individuals who are and understand lived experience of the diversity of client perspectives and heterogeneity of the Canadian population into various levels of regulation, scientific, technical committees, and decision-making roles.
2. Apply a disability lens to medical device standards and approval stages processes.
3. Medical devices manufacturers must provide evidence of co-design, usability and accessibility guidelines are met from a Universal Design perspective with diverse groups of users – potentially impacted by the devices.
4. ISO and CSA guidelines incorporate usability and accessibility criteria in future reviews of standards and examine standards from benchmarking if and where possible.
5. Patient safety organizations and monitoring bodies address the needs of persons with disabilities in medical devices.

### Recommendations for Health Care Providers and Health Systems:

1. Discuss insulin pump therapies with those who are blind and partially sighted – as they may be curious about the devices and do not know where to and whom to ask questions.  Lack of discussions can make individuals question the standard of care they are receiving.
2. Greater sharing of information on insulin pump users who are blind, partially sighted, and Deafblind.
3. Ensure all client information is accessible at all levels (accessible formats and documents).
4. Support for users that may be off hours when diabetic programs are closed on weekends.  Individuals are resorting to volunteer sighted assistance that were not created to support medical circumstances and issues of liability can arise.
5. Virtual programs such as using Facetime by one’s healthcare team to help troubleshoot any issues for this user group, one’s health care team is in a better position to understand the individual’s diabetes and health care needs.

### Discussion

Although insulin pumps do give some limited audio output, it has been established that it is of little descriptive benefit to people who are blind or partially sighted. Users have pointed out significant design aspects that would be therapeutically and competitively advantageous. Apart from helping with establishing a bolus injection, this current audio output was found to be of limited benefit to those who are blind or partially sighted. Speech output was an important feature lacking from insulin pump design. This feature would address several accessibility concerns by allowing all users, including blind and partially sighted persons, to fully engage with all operations of an insulin pump device to the greatest extent one may require.

Namely, personally customizable haptic and notification features were mentioned across participant lifestyle choices and strongly points to the levels of independence for diabetes management that are promised by this medical device. Insulin pumps must include a user-friendly operating handbook in several formats, as user guides were mentioned as being rather unhelpful in booklet format (i.e., large print, braille and in an electronic format that can be read by screen-reading or magnifying software), including accessible websites for manufacturers.

Many pumps offer a variety of programmable bolus options depending on the type of meal ingested, on the other hand, these options are managed differently through menu options, posing a challenge for non-sighted end-users and for support personnel teaching and training. This gap highlights the request for stronger evidence collection prior to feature implementation to fully ensure usability testing from diverse communities of end users.

### Limitations:

Although a small sample size we were able to capture a diverse array of experiences and breadth of perspectives across Canada. We have been able to collect intersectional perspectives, but due to confidentiality we cannot disclose this information.  Although, we have only incorporated co-design into the earliest phase of the design process, through relying on inclusive research practices we have demonstrated that engaging with this user-group in a meaningful and collaborative manner can be a positive and rewarding experience. Although an advocacy organization, we have ensured to pose open-ended questions that would allow participants to raise their own perspectives and words. Feedback from participants is that they have also enjoyed sharing their experiences with other members in the community when in a safe and inclusive group session.

## Conclusion

Future research should confirm with end-user testing that the latest accessible features can be further adapted within different lifestyle contexts.  Additional research is needed for progress towards feature settings with speech output capabilities, improved ease for reservoir refills, vibration alert setting and discernable maintenance tones.

Finally, there is opportunity to expand user support options and foster greater collaborations and partnerships among organizations, end-user testing groups and the manufacturing industry.  Co-design methodologies and following inclusive research practices has shown to capture a diversity of human experiences that are often excluded from many “traditional” scientific protocols. In this report, we hope that accessible medical devices, such as insulin infusion pumps, in their future iterations brings in the perspectives of those who have unique needs and incorporate them as valuable and in equitable partnerships. If these methods and principles were embedded in decision-making, policy and regulatory frameworks then patient safety and disability as a risk can shift to conversation towards innovation as part of the human factor. As universal design benefits those who are blind, those who do not want others seeing their device, and parents who want safety to monitor their children’s health as well.

## Appendix A: Universal Design for Medical Devices

Universal Design (UD) has been defined as a design that is appropriate for people of all ages and widest range of abilities (Williams, 2012). A design such that it can be recognized, accessed, understood, and used in as many natural and autonomous contexts as possible (Ontario Regulations, 2005). As a result, medical devices should be suitable for use by any individual regardless of age, capacity, size, or enabling device use with any physical, sensory, mental health, or intellectual ability, without requiring any adaptations, or any additional modifications, assistive devices, or specialized solutions; outlined in the seven principles below (Bettye Rose Connell et al., 1997). Currently, many resources do not address universal design principles and in turn, the needs of these insulin pump users are largely unmet creating barriers for provision of equitable diabetes care in Canada.

### Principle 1: Equitable Use

The design is useful to people with diverse abilities and lifestyles. Voice-output capabilities will ultimately benefit all users, not only blind, partially sighted, and Deafblind users.

### Principle 2: Flexibility in Use

Design accommodates a wide range of individual preferences and abilities.

### Principle 3: Simple and Intuitive Use

Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level.

### Principle 4: Perceptible Information

The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.

### Principle 5: Tolerance for Error

The design minimizes hazards and the adverse consequences of accidental or unintended actions.

### Principle 6: Low Physical Effort

The design can be used efficiently and comfortably and with a minimum of fatigue.

### Principle 7: Size and Space for Approach and Use

Appropriate size and space are provided for approach, reach, manipulation, and use regardless of user's body size, posture, or mobility.

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