Looping with BCDiabetes

Informed Consent and Waiver for Minors (<18 years)

Author: Dr. Tom Elliott, Medical Director of Dr. T.G. Elliott Inc. ("**BCDiabetes**")

Background

Diabetes causes the level of glucose (sugar) in your blood to become too high. It happens when your body cannot produce enough of a hormone called insulin, which controls blood glucose. The advent of Artificial Pancreas Systems (APS, also known as Automated Insulin Delivery systems or AID) has provided the potential to significantly improve diabetes management and quality of life among people living with Type 1 & Type 2 diabetes in real-life conditions.

Artificial Pancreas Systems (APS or APSs) are the combination of a smart insulin pump, integrated CGM and interoperable automated glycemic controller (typically a smartphone with the necessary apps). APSs are sometimes called "closed-loop" systems, because they work near-automatically, with minimal user input. When properly managed, APSs offer eligible patients with Type 1 diabetes or Type 2 diabetes superior glycemic control and safety over conventional treatments. APSs have been in use since 2008 for people living with Type 1 or Type 2 diabetes, but until 2018 these were all experimental. Treatments and devices are called experimental when they have not been fully approved by a national regulatory agency. In Canada this agency is called Health Canada; in the United States the agency is called the FDA; in Europe the agency is called the EMA. Currently a number of APSs are available but some are still experimental including all Do-it-Yourself (DIY) APSs, those that are not solely commercially manufactured, produced, and implemented. If you are reading this document you may be considering using a DIY APS. All DIY APSs are still experimental. DIY APSs are also known as open-source APSs.

When a drug or device is approved for medical use by the Food and Drug Administration (FDA) of the United States or Health Canada, the manufacturer produces a "label" to explain its use. Once a device/medication is approved by the FDA or Health Canada, physicians may prescribe it according to the label or use it "off-label" for other purposes. They may only prescribe it "off-label" if they are well-informed about the product, based on firm scientific methods and sound medical evidence, and maintain records of its use and effects. Although both the Omnipod Eros & Dash pumps and Dexcom G6/G7 and Freestyle Libre 2, 3 & 3+ CGMs are individually approved by Health Canada, the FDA and the EMA, their use together in a DIY APS is "off-label" and the entire DIY APS is considered experimental. This is because the software driving DIY APSs is not approved by any agency.

BCDiabetes believes that it should continue to offer people who use APSs, either DIY or commercial systems, the care and support they deserve and to which they are entitled. BCDiabetes cannot recommend the use of DIY APSs because no DIY APS is currently approved by any regulatory agency, including Health Canada. BCDiabetes must ensure that

people with diabetes who are using, or planning to use a DIY APS, do so at their own risk. This is because DIY APSs, no matter how sophisticated they appear, are still considered experimental. These DIY closed-loop systems have typically been built by people with diabetes or parents of children with diabetes, for their personal use (or that of their children). Safety is a major consideration for people building and using these systems.

People intending to use DIY APSs should be aware that they do this at their own risk, they may not receive support from their healthcare professional with any technical issues and that liability is unclear if there is a malfunction, error or problem. People intending to use DIY APSs should be competent and confident in optimizing their diabetes management using an insulin pump and CGM or flash glucose monitoring device. People intending to use a DIY APS can access support from the online DIY technology community for advice and troubleshooting. However, they must be aware that this advice is not regulated and they do so at their own risk.

There are currently four commercial APSs approved by Health Canada (and more approved by the FDA and the EMA) some of which may not be fully covered by BC Pharmacare or private or public drug insurance providers. This link (see https://bit.ly/39eyA6V7b) describes all insulin pump systems, including APSs available in Canada.

> Medtronic 670G, 770G & 780G tubed systems - the pump and tubing are covered by BC Pharmacare but the Medtronic Guardian 4 CGM is not covered by BC Pharmacare.
> Tandem T-slim Control IQ system tubed system - the Dexcom G6/G7 CGM is covered by BC Pharmacare but the Tandem T-slim pump itself is not covered by BC Pharmacare.
> Omnipod 5 controllers and pods are not covered by BC Pharmacare.
> MyLifeLoop (Ypsopump + Dexcom G6/7 and Libre) is covered by BC Pharmacare.

Conflict Of Interest statement Dr. Elliott is the Medical Director & owner of BCDiabetes. Either Dr. Elliott, or one of his locum or staff endocrinologists, will be paid for the clinical work entailed in assessing your suitability for DIY APS and in supporting your use of DIY APS (installation, configuration, fine-tuning & maintenance). BCDiabetes, through payment being received by either Dr. Elliott or one of his locum or staff endocrinologists, stands to profit from your use of DIY APS.

This consent and waiver covers the experimental use of five experimental software systems: Loop, Loop Caregiver, iAPS, Trio and androidAPS (DIY smartphone apps, together “Closed Loop Apps”) that work in conjunction with approved devices like the Dexcom G6/G7 CGM and tubeless Dash & Eros Omnipod insulin pumps. None of Loop, iAPS, Trio and androidAPS are approved by Health Canada, the FDA or the EMA. However, an app almost identical to Loop known as “Tidepool Loop” was approved by the FDA on January 24, 2023 based on an observational study of 873 Loopers as its primary evidence (see http://bit.ly/loop_safety_study). In early 2021 Lum and colleagues described self-reported outcomes for 553 Loopers. AndroidAPS was shown to be safe and efficacious in a study of 12 subjects by Gawrecki and colleagues 2021-Apr-5 - because iAPS uses the same AP algorithm as androidAPS (openAPS) - it is assumed that iAPS is equally as safe and efficacious as androidAPS. As of 2025-July-24 BCDiabetes had installed and supported 2479 individuals with experimental software systems as follows: Loop (2022), iAPS (73), Trio (22) and androidAPS (362). Outcomes for the first 1442

installations on whom immediately before and 90 days post glucose data were available was presented as a poster at the American Diabetes Association meeting in Chicago 2025-Jun-21. In terms of safety, there were no deaths, four documented episodes of DKA and fourteen patient-reported severe hypoglycemic events. On average time in range (TIR) rose from 60% to 73%. A paper describing the outcomes for the first 248 installations was published 2024-Feb-01.

Loop Caregiver is a companion app to Loop, used by parent/guardians of minors, that provides for remote insulin boluses, declaring carbs consumed by the minor and to set overrides to prevent low sugar during exercise. Loop Caregiver has not been the subject of any published studies and is offered on a discretionary basis to parents and guardians, to help avoid dangerous excursions of sugar levels.

The hardware components of these five Closed Loop App systems (the Omnipod pump & Dexcom G6/G7) are both covered by BC Pharmacare and approved by Health Canada.

> BCDiabetes has observed through its support of patients using the experimental Closed Loop App APSs that these Closed Looped App systems offer equivalent or superior glucose control/incidence of severe hypoglycemia and quality of life when compared to Medtronic (see https://bit.ly/Medtronic670) and Tandem (see https://bit.ly/Tandem_C_IQ) systems approved by Health Canada and the Omnipod 5 (see https://bit.ly/Omnipod5) FDA-approved system at a lower price (hardware covered by BC Pharmacare).
> For these reasons, BCDiabetes offers to support patients wishing to use Close Loop Apps with the Omnipod pump and Riley link.

Possible risks relating to use of all APSs, including the Closed Loop App APSs, include the risk of infection, irritation and/or slight discomfort at the points of insertion for the Dexcom G6/G7 sensors and Omnipod patch pumps; certain side effects associated with participants' medical condition and their AID therapy; hypoglycemia; and hyperglycemia.

I, the undersigned, and parent/guardian of Minor (hereafter "my child") hereby consent to treatment of my child with a Closed Loop App APS and to receive services and advice from BCDiabetes with full knowledge and assumption of all associated risks. I hereby grant BCDiabetes (as well as its directors, officers, employees, insurers, agents, shareholders, affiliated corporations, predecessors, successors, beneficiaries and assigns) a full, final and complete release and discharge from any and all past, present or future complaint, demand, claims, causes of action, suits, rights, damages, losses, liabilities and costs of any nature and kind whatsoever (including for personal injury and death), howsoever arising, whether currently known or unknown, resulting from, arising out of or relating to, directly or indirectly, all services and advices rendered by BCDiabetes, including in connection with the use of any of the Closed Loop Apps.

By installing a Closed Loop App on my child’s phone, or a phone provided to me by BCDiabetes, &/or the Loop Caregiver app on my phone with the assistance of BCDiabetes employees, I, the undersigned, hereby:

- confirm that I had otherwise planned to set up a Closed Loop App for my child myself using a standard DIY installation however given its complexity I consider that it is in my best interest to have the installation done professionally at BCDiabetes;
- understand the nature and anticipated effect of what is proposed including the significant risks and Health Canada approved alternatives available have been explained to me and I am satisfied with these explanations and I have understood them;
- understand that the Dexcom G6/G7 and the Omnipod insulin patch pump are both approved by the FDA and Health Canada for the treatment of Type 1 and Type 2 diabetes in patients 2 years old and older.
- wish to have a Closed Loop App configured and installed on my child's personal phone in order to treat my child's Type 1 or Type 2 diabetes and I confirm that I understand the risks of this experimental treatment technology and the "off label" use of the Dexcom G6/G7 and the Omnipod insulin pump and I am willing to accept the potential risks that my physician has described and discussed with me.
- acknowledge that there may be other, unknown risks relating to the use of the Closed Loop Apps;
- understand that the Closed Loop Apps, the software driving my Omnipod pump based on CGM readings from a Dexcom G6/G7 (or Freestyle Libre device) relayed in some cases via a radiotransmitter device ("Orangelink" or other similar device), are part of experimental projects known as "Loop", "Loop Caregiver", "iAPS", "Trio" and "androidAPS" respectively and are not approved by Health Canada;
- assume full responsibility for running the entire system (Looping with smartphone, Omnipod, Dexcom G6/G7/Freestyle Libre, Riley Link & Loop app) and understand that I do so at my own risk;
- understand that the iOS Closed Loop Apps are shared by BCDiabetes with their patients and clients through BCDiabetes' Apple Developer TestFlight account where the Closed Loop Apps have a useful life of 90 days. To provide continuity of app support by BCDiabetes, software engineers renew the Closed Loop Apps developer license every 75-80 days, provided however that approval of Apple is obtained in order for a new app to be released. Apple has the right to refuse or delay approval of a release, which could interrupt renewal or access to the Closed Loop Apps at expiry through TestFlight. As such, I understand that BCDiabetes does not guarantee access to updated/renewed iOS Closed Loop Apps through their Apple Developer TestFlight account;
- understand and accept that, at any time without notification, the Closed Loop Apps may no longer be available without prior notice;
- in the event Close Loop App access is interrupted or canceled, I understand that I will need to immediately revert to an alternative insulin delivery system (retail such as using Omnipod PDM plus Omnipod pods or otherwise, including multiple daily injections of insulin) to manage my child's diabetes or build the app myself from source code;
- agree not to copy (except for reasons of personal secure backup) or share this Closed Loop Apps with any other individual or entity without the express written consent of BCDiabetes.

Individual Patient Data (IPD) sharing statement. The datasets generated during and/or analyzed during the patient use of any Closed Loop Apps supported by BCDiabetes will be stored in a secure non-publicly available cloud repository maintained by Google Canada. With the patient's written consent, the data collected during the use of the Closed Loop Apps will also be added to your electronic medical record at BCDiabetes. All the datasets generated during and/or analyzed during the use of the Closed Loop Apps will remain confidential to the extent provided by law. Patients will only be identified by a code number. The key to the code linking participants to their data will be kept by the BCDiabetes. BCDiabetes could forward your coded data to the DIYAID community for the purpose of improving algorithms. BCDiabetes could also forward your coded data to healthcare authorities (e.g., Health Canada) for the purpose of assessing the benefits and limitations of different AID systems. However, BCDiabetes and any entities who receive the research data will respect the confidentiality rules in effect in British Columbia and Canada regardless of the country to which your data may be transferred. The data will be stored for at least 7 years beyond your last appointment with BCDiabetes as required by the laws of British Columbia.

The Parties acknowledge and agree that the execution of this Informed Consent has not been induced by, nor do the Parties rely upon, any representations that are not expressly incorporated into this Informed Consent.

Governing Law. The Parties hereby agree that their relationship and the resolution of any and all disputes arising therefrom, including any issues related to this Informed Consent, shall be governed by and construed in accordance with the laws of the province of British Columbia and the laws of Canada applicable therein.

Jurisdiction. The Parties hereby acknowledge that the services will be provided in the province of British Columbia and that the Courts of the province of British Columbia shall have sole and exclusive jurisdiction to entertain any complaint, demand, claim, cause of action or suit whatsoever arising out of all services and advices rendered by BCDiabetes, including in connection with the use of any of the Closed Loop Apps, as well as of this Informed Consent. The parties hereby agree that if either of them commences any such legal proceedings they will only be commenced in the province of British Columbia and hereby irrevocably submit to the exclusive jurisdiction of the Courts of the province of British Columbia.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to use the Closed Loop Apps.

Today's Date: July 24, 2025