

Patient Care + Research + Clinical Trials

# Dr. Tom Elliott MBBS, FRCPC Medical Director

400 - 210 W Broadway phone: 604.628.7253 Vancouver, BC, V5Y 3W2, Canada fax: 604.398.2371 email: drtomelliott@bcdiabetes.ca

2024-Apr-13

# Loop installation in-house at BCDiabetes

On 2020-Aug-1 BCDiabetes began supporting in-house installations of open source (DIY) <u>Artificial Pancreas</u> <u>Systems</u> (APS, also termed "automated insulin delivery" AID) with the tubeless Omnipod Dash-Dexcom G6 and iPhone & Android APS algorithms. <u>Here's a picture of the setup with a phone running Android APS</u>. Although not Health Canada-approved, BCDiabetes considers the current version of <u>Loop (Master branch)</u> to be the best entry level open source APS available for most adults & children with good family support. Loop is a conservative algorithm that has been installed by our estimates on more than 35,000 individuals worldwide and 495 BCDiabetes clients to date. At BCDiabetes, Loop in its various flavors is preferred over retail APS because it is more affordable for most given coverage by BC Pharmacare of both the Omnipod system & Dexcom G6 and only partial coverage of retail APS components.

The mission of BCDiabetes is to optimize care and improve outcomes for every person living with diabetes. For those living with Type 1 diabetes, BCDiabetes considers that APS is now the standard of care. BCDiabetes' 5 year goal is to have 200,000 Canadians, or 70% of those with T1D, and an equal proportion of T1Ds worldwide, using one form of APS or another. In Canada in 2024, the Loop initiative represents the quickest route to that goal, and the recent announcement of a National Pharmacare program will hopefully accelerate this process. We welcome the collaboration of T1Ds, their mom's and dad's, family and friends, physicians, scientists, programmers, business leaders and politicians in this endeavor. BCDiabetes invites other clinicians to set up their own Looping site: for those who wish to do so as BCDiabetes affiliates, using many BCDiabetes resources at no cost, <u>click here</u> to learn more.

BCDiabetes now uses the acronym SOS-AID (supported open source AID) to describe its clinic-run, clinic-provided APS installation service. People using any version of OS-AID are still generically described as using "Loop", being "Loopers" and to be "Looping".

For the fascinating history of Looping see Ben Mammon's <u>55 minute youtube</u>; and to see how far things have come in the last four years see <u>BCDiabetes "The Weekly" webinar on APS</u> from 2020 May (during the height of COVID) which focussed on closed-loop pump systems in general comparing Loop, Tandem Control IQ and Medtronic.

For those who are looking for an APS system who are not willing to use a non-health Canada approved solution, and for whom cost is not a consideration, today we equally recommend the Tandem T-slim with Control IQ and the Medtronic 780G. Omnipod 5 was approved by Health Canada last week, however its roll-out will likely take some months to occur. The tubed Ypsomed CamAPS is also expected in the next 12 months. If you wish to start with Medtronic, Tandem, Omnipod or Ypso APSs, <u>email us</u> & we will support you by filling in the necessary forms and continue to work with you afterwards. For a CAD\$ cost comparison of the various APS options in Canada see rows 7-9 of <u>this spreadsheet</u>. It assumes no BC Pharmacare subsidy & that the up-front cost of the pump is amortized over 5 years. For a comparison of the features of all APSs

worldwide see <u>this spreadsheet</u>. For a comparison of TIR improvements with various APS from published studies <u>click here</u>.

Want to know which is the best APS algorithm in head-to-head comparisons, including open source and retail? <u>So do we</u>, which is why we are in the planning stages of a randomized control trial comparing them all. Watch this space for details.

BCDiabetes has to-date installed SOS-AID in its various flavors (Loop, iAPS & AndroidAPS =AAPS) on 790 clients (40% of pediatric age, including the youngest at 18 months, and in 95 adults older than 70). Loop's elegant interface and simple algorithm makes it our preferred choice for most clients and the only choice for age < 10.

On 2023-Sep-26 the Canadian Journal of Diabetes accepted <u>this manuscript for publication</u> describing outcomes for BCDiabetes' first 248 SOSAPS installations. See the visual abstract <u>here</u>. Briefly, the average Time in Range (TIR) immediately pre-Loop was 64% - three weeks later it was 80%. The average A1c immediately pre-Loop was 7.2 - three months later it was 6.7. Quality of Life measures (Diabetes Distress, Fear of Hypoglycemia and Insomnia index) were favorable pre Loop and 3 months later even more favorable. We saw 3 episodes of severe hypoglycemia. These results compare favorably with all published retail APS literature.

Read BCDiabetes client testimonials of the first two weeks of using Loop and iAPS. These clients (& the parents of kids on Loop) are all sleeping through the night and experiencing life without the rigors of diabetes for the first time in years. All they need to do is change their pod every 3 days, their CGM every 10 days and charge their smartphone as usual. Click here to see BCD client John Young's Nightscout tracings for 72 hours (the last 24 hours on Loop), his quote to me "I don't know how I've managed to cope before this."

All three of our apps support Dexcom G7. BCDiabetes does not currently support CGM using any versions of the Freestyle Libre. This will hopefully change soon after the upgrade to the Freestyle Libre 3 app expected in Q3 2024.

In case you want to build, install & configure one of these offerings yourself, here are the links: <u>Loop master</u> <u>branch</u>, <u>iAPS</u> & <u>AndroidAPS</u>. To build Loop or iAPS, a free Apple developer account is required and a rebuild is mandated every 3 months. With a paid Apple developer account (US\$99/year) a build will last 12 months. For step by step visuals on OS-AID installation check out our youtube "how-tos" for <u>Loop</u> and <u>iAPS</u> (AAPS is being updated shortly).

For BCDiabetes in-house staff teaching tutorials presented at our Journal Club in early 2023 see Nabeel Khan's <u>Looping 101 video</u> and <u>associated powerpoint</u> (Loop & iAPS basic settings) and <u>Looping 102</u> (openAPS advanced settings). For tips on tuning Loop <u>click here</u>. For general Looping FAQs <u>click here</u>. For support in being allowed to use Loop at elementary school <u>click here</u> or while hospitalized <u>click here</u>.

For clinician FAQs <u>click here</u>. For BCDiabetes Technology Fellow Dr. Kate Hawke's 2024-04 "DIY pumps - insights for specialists" powerpoint click <u>here</u>. For BC Pediatric endo Dr. Clare Henderson's ped-endo-focussed 2024-03 "Into the Loop" slideshow click <u>here</u>. Clinicians wishing to refer a patient for looping, click <u>here</u> for a quick referral form. Note, physicians referring from outside British Columbia, Canada should enter 99998 for "Doctor's College ID" and 0000000000 for Patient CareCard #. Clinicians

who would like to set up their own Loop site as an affiliate of BCDiabetes, providing no-cost access to BCDiabetes' Loop app and consent/waiver, <u>click here</u>.

Because Loop, iAPS & AAPS are not Health Canada approved, we require an online signed consent & waiver including an undertaking that users will not copy or distribute the installation to others without our consent. Adult BCDiabetes clients should complete this adult consent & waiver; guardians of minor BCDiabetes clients should complete this consent & waiver for minors. For parents or guardians who wish to be able to remotely give commands for carbs, boluses and overrides to their kids, BCDiabetes also offers Loop Caregiver which runs on the parent/guardian's iPhone. For a one-pager on "Looping for kids of elementary school age" click this link.

### Hardware & software requirements for first Looping appointment

Clients need to be running a DexcomG6/G7 sensor with an active connection to their smartphone (not a reader) and an Omnipod (plus a spare) running off its PDM. Note, if the Omnipod pod is an Eros pod, an additional component, an <u>Orangelink Pro</u>, must be on hand to connect the Eros pod and the smartphone. Users of Omnipod Dash do not need an Oranglink.

#### Other requirements....

an iPhone 11 (or newer) OR

**an Android** phone (OS 9+) connected to a Dexcom G6/G7 sensor, not with the usual Dexcom G6 app (uninstall first), but with either

**xDrip**, an open-source app (compatible with both Dexcom G6 & G7), or **BYODA**, an open-source modified version of the Dexcom G6 app

With an iPhone, enable Apple Health, install TestFlight from the App store and disable automatic iOS updates (disabling iOS updates is to prevent Dexcom failures which sometimes occur after iOS updates - Dexcom is typically 3 months behind).

Regardless of whether you have an iPhone or Android, or an Eros or Dash pump, you need a <u>Looping</u> <u>Safety/Emergency kit</u> in case of component failure.

If you would like to have an OSAPS installed at BCDiabetes you first need to become a BCDiabetes client. To do so you will need a referral from a licensed physician in your jurisdiction, preferably your endocrinologist/diabetes specialist - <u>click here</u> for our quick referral form (non BC physicians should enter 99998 in the "Doctor's College ID" field and 000000000 in the Patient CareCard #. *Not all endocrinologists/diabetes specialists support Loop - if this describes your endocrinologist/diabetes specialist BCDiabetes, we suggest you share this document with them to see if it changes their mind.* Once you have been established on Loop BCDiabetes recommends that its Loop clients every 6 months for a year and annually thereafter. You should continue to see your regular endocrinologist/diabetes specialist for your regular non-Looping diabetes follow-up.

In advance of the referral you may <u>email us</u> requesting an appointment or <u>register online</u>. Once we have the referral you will be seen within 2 weeks for a regular appointment either in-person or virtually. The cost of the appointment and follow up will be covered in full by your Canadian provincial medical plan with the exception of Quebec. For Quebec residents the fee is \$1500 (initial appointment plus up to two weeks of daily follow-up and routine follow-up to 6 months). *BCDiabetes does not routinely offer care to non-Canadian residents. If a non-Canadian resident has a letter from his/her referring physician asserting that BCDiabetes' level of care is not readily in their country of residence, BCDiabetes may offer its services on a case-by-case basis.* 

### Loop installation & fine-tuning - a two-step, two appointment process then daily follow-up for 3 days

The first appointment, usually virtual, is an introductory session at which time a <u>Nightscout account</u> is set up (if not already in place), and CGM and Looping-specific analytics touched upon - clients have previously been encouraged to conduct <u>insulin experiments</u> to ensure that their basal rate, ICR & ISF are optimized.

The second appointment is preferred in-person but offered virtually to most clients at the discretion of BCDiabetes staff - it lasts 60-90 minutes. For iPhone users we share a link to the latest builds of either the Loop app or iAPS on BCDiabetes' TestFlight account, at no charge. For Android users we share the latest build of androidAPS from our own cloud source, at no charge. For Loop users (and soon iAPS users) their Nightscout will have been configured pre-Loop start, with their initial Loop basal rate, ICR, ISF, max bolus and total daily dose of insulin such that once the Nightscout credentials are entered, and the Loop "closed", they are up and running immediately, with data entry errors minimized.

Post Loop installation, clients are followed up, typically virtually, on a daily basis M-F until they are independent & able to make adjustments. For most users 3 visits are sufficient. Routine follow-up visits thereafter are at 3 & 6 months. All new Loopers are directed to BCDiabetes' after-hours online support forum.

Prior to July 2023, Loop installation was a three-step process: step one was purely introductory, step two was Nightscout setup and teaching, and step three was Loop installation itself. From July 2023, the original first two steps were consolidated into a single step and the original step three visit became step 2.

**Not trained on Omnipod Eros or Dash?** If you are not trained on the Omnipod Eros or Dash & are a BC resident we will fill out & email a <u>certificate of medical necessity</u> form to Insulet (the manufacturer). Once your payment details are sorted a starter kit with 2 pods will be delivered to your home within 2-3 business days: once you have been trained online (2 sessions 3 days apart) & been certified, you are ready to Loop. Note, the pod for Omnipod 5 is not compatible with Loop/iAPS/AAPS.

#### Where to get Looping Hardware:

Looping Safety kit:

BCDiabetes requires that a <u>Looping Safety kit</u> be carried by all its clients who use insulin pumps, including all Loopers, at all times. The bare minimum is a pen of rapid insulin with needle and finger-poke glucometer. And every client on intensive insulin therapy needs to understand & follow <u>sick</u> <u>day management</u> when they are unwell and sugar is consistently > 10.

#### Omnipod pump system setup

request that a BCDiabetes staff member complete paperwork (Letter of Medical Necessity) or email Andrew Muirhead phone +1--604-754-6195.

### Omnipod pod purchase

both Eros & Dash, can also be purchased directly in Canada from <u>Diabetes Express</u> phone 1 866-418-3392 fax 1-855-233-3146 providing the client was trained in Canada.

Omnipod pods may be purchased online without a prescription & with no questions asked <u>from these</u> <u>four US sources</u> (verified 2023-Mar-23).

## Dexcom G6/G7

request that a BCDiabetes staff member complete Special Authority & prescription or <u>order online</u> or email <u>Anthony Petrovich</u> phone +1-604-363-8776

## OrangeLink Pro

Required for the Omnipod Eros (not for Dash): <u>order online</u> & pick up at BCDiabetes. <u>Medtronic 780G</u> email <u>Jennifer Rogers</u> phone +1-778-839-2750. <u>Tandem Control IQ</u> email <u>Teri Currie</u> phone +1-778-995-1268 <u>Ypsopump</u> email <u>Sarah Peterson</u> phone +1-604-805-6384

## Online Loop Support

https://www.facebook.com/groups/TheLoopedGroup/ https://www.loopnlearn.org https://loop.zulipchat.com

### Credits due:

The open-source community APS in general & specifically John Costik (first remote CGM monitoring) Lane Desborough (initial Nightscout code) Ben West (mature Nightscout code, openAPS co-founder) Dana Lewis (openAPS co-founder) Pete Schwamb (Loop founder) Ivan Valkou & Jon Martennson (iAPS) BCDiabetes clients who use SOSAPS Praveen Samuel: former BCDiabetes lead SOSAPS trainer Nabeel Khan: BCDiabetes technology lead, SOSAPS trainer, programmer, app builder, iAPS & Loop documentation Prince Sevilla: BCDiabetes SOSAPS trainer Gerri Klein: BCDiabetes in-house Omnipod pump trainer Ben Mammon: medical inspiration, OSAPS advisor, app builder, OSAPS superuser Marc Fournier: previous online support group admin, iAPS code contributor, app builder Sergey Skobkarev: systems engineer, Nightscout code contributor

Short URL = https://bit.ly/LoopingatBCD