The utility and security of data from wearable devices in the management of T1 diabetes in children

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1. Introduction
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   - Closed Loop systems (looping) to manage type 1 diabetes in children

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Setting the Scene – Type 1 diabetes

- Type 1 diabetes is an auto-immune disease where the pancreas stops producing insulin – a hormone that allows the body to get energy from food.

- The burden of disease due to diabetes has increased significantly over the past two decades. In Australia an estimated 1.2 million (6%) of adults aged 18 years and over had diabetes in 2014–15.

- Type 1 diabetes is one of Australia’s most common serious childhood diseases; 7,000 children aged 0–14 have type 1 diabetes in Australia and the Royal Children’s Hospital Melbourne diagnose about 2 children a week.

- Currently no cure for diabetes.

- Requires lifelong management.

- Diabetics have to monitor their blood sugars all day, every day, using devices: continuous glucose monitoring systems (CGM) and insulin pumps.
Emerging technologies to manage T1D

- In the US a group of tech-savvy parents, tired of waiting for technology to better manage their children's diabetes, created an open-source system.
- NightScout #WeAreNotWaiting
- Open source DIY project
- Allows access to real time CGM data via personal website, smartphone, Artificial Pancreas System (APS)
- CGMs are modified
- Glucose readings are transmitted to the Cloud
#WeAreNotWaiting: Diabetics are hacking their health, because traditional systems have failed them
Experience: I built my own pancreas

Having a computer make adjustments while I sleep is far safer than trying groggily to make decisions in the early hours.

▶ Dana Lewis: ‘More than 725 people worldwide have now built various types of DIY closed-loop systems.’

Photograph: Annabel Clark for the Guardian
Closed loop systems

- Closed loop systems – ‘looping’
- Link between continuous glucose monitor and insulin pump using open source software.
- Downloaded from the internet to modify the algorithm settings which automate insulin delivery.
Project aims

- Closed loop systems currently available to consumers and patients
- Adequacy of regulation by the Therapeutic Goods Administration
- Security of data
- Perceptions of clinicians and family using wearable health devices to monitor and manage diabetes, in particular, hybrid closed loop systems.
The Problem:

- These closed loop systems are not regulated by the Therapeutic Goods Administration (TGA).
- The emergence of these DIY diabetes technologies poses concerns for healthcare professionals, including medico-legal risks and issues with registration and practice.

The Study:

- We seek to further our understanding of the use of closed loop systems to manage type 1 diabetes in children under 18, and the associated risks and perspectives of key stakeholders.

Participants:

- We will be inviting paediatric endocrinologists, diabetes educators and general practitioners working in paediatric diabetes in Australia to tell us about their views and experiences of supporting children using closed loop systems for children.
Ethical and Legal challenges
Hacking diabetes: DIY artificial pancreas systems

Ethical issues arise when patients create their own systems. Conor Farrington reports.

Published Online, November 29, 2016, http://dx.doi.org/10.1016/S2213-8587(16)30397-7

All we ask is that you pay it forward because #wearenotwaiting.

Join the CGM in the Cloud Community at Facebook!

Are you looking for technical support for your existing Nightscout installation or do you have questions about your existing Nightscout installation? Please visit the CGM in the Cloud group on Facebook for help!

Note: There is no support or any warranty of any kind. The quality and performance of the project is with you if you choose to use it. This is a project that was created and is supported completely by volunteers.
Diabetes Australia considers that people who ‘loop’ must continue to receive support and care from their diabetes healthcare professional and the health system.

However, loopers are most likely to obtain the information from social media rather than healthcare professionals. The looping movement is changing the landscape of diabetes management.
Regulation of medical devices

Therapeutic Goods Administration

A ‘medical device’ includes *the software necessary for its proper application*

Open source software outside the regulatory framework

The TGA recognises that is has ‘become an issue of real concern’

Medical devices are becoming more networked, but in some cases security procedures are not keeping pace.
TGA and CSIRO project: CSIRO will engage with industry to understand their activities and their needs for further engagement in order to appropriately support their knowledge of regulatory requirements relating to medical software innovations.

See: https://research.csiro.au/tga/
The Artificial Pancreas Device System

FDA's Efforts to Advance Artificial Pancreas Device Systems

The FDA supports and fosters medical device innovation as it upholds its mission of ensuring that medical devices are safe and effective. The FDA is helping advance the development of an artificial pancreas device system, an innovative device that automatically monitors blood glucose and provides appropriate insulin doses in people with diabetes who use insulin.

Sometimes an artificial pancreas device system is referred to as a "closed-loop" system, an "automated insulin delivery" system, or an "autonomous system for glycemic control." NOTE: The Artificial Pancreas Device Systems described on this site do not involve biomaterial, synthetic or artificial tissue or organs.

The FDA has been working together with diabetes patient groups, diabetes care providers, medical device manufacturers, and researchers to advance the development of an artificial pancreas. FDA’s efforts include prioritizing the review of research protocol studies, providing clear guidelines to industry, setting performance and safety standards, fostering discussions between government and private researchers, sponsoring public forums, and finding ways to shorten study and review time.

There have been tremendous strides made in the research and development of an Artificial Pancreas Device System. On September 28, 2016, the FDA approved the first hybrid closed loop system, the Medtronic’s MiniMed 670G System®, intended to automatically monitor blood sugar and adjust basal insulin doses in people with type 1 diabetes. There are also many research projects underway looking at the feasibility of these device systems in hospital settings. For more information on these and other clinical trials, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

On this Artificial Pancreas Device Systems website, you can learn more about what an artificial pancreas device system is, research challenges associated with its development, and the FDA’s ongoing commitment to a safe and effective artificial pancreas device system for patients with diabetes.

Additional Resources
Data Challenges
IoMT
Internet of Medical Things
1. Continuous glucose monitor
2. Computer ("controller")
3. Battery
4. Radio stick ("translator")
5. Insulin pump

Illustration by Clint Ford for Popular Science
https://fordillustration.com/Medical-Illustrations
How much of a barrier are these inhibiting adoption of the Internet of Things in your organization?

- Privacy concerns: 14% Extensive Barrier, 41% Moderate Barrier, 26% Little to Minimal barrier, 19% Not a Barrier
- Legacy systems and/or equipment (e.g., no connectivity or embedded sensors): 19% Extensive Barrier, 36% Moderate Barrier, 31% Little to Minimal barrier, 14% Not a Barrier
- Security concerns: 16% Extensive Barrier, 38% Moderate Barrier, 28% Little to Minimal barrier, 18% Not a Barrier
- Technology immaturity (e.g., large scale analytics): 19% Extensive Barrier, 34% Moderate Barrier, 32% Little to Minimal barrier, 15% Not a Barrier
- Lack of budget: 18% Extensive Barrier, 35% Moderate Barrier, 28% Little to Minimal barrier, 19% Not a Barrier
- Lack of skilled workers (e.g., data scientists): 12% Extensive Barrier, 40% Moderate Barrier, 30% Little to Minimal barrier, 18% Not a Barrier
- Lack of interoperability or standards: 15% Extensive Barrier, 37% Moderate Barrier, 34% Little to Minimal barrier, 14% Not a Barrier

Source: Accenture 2017 Internet of Health Things Survey
Cybersecurity in Artificial Pancreas Experiments

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Abstract
Medical devices have transformed modern health care, and ongoing experimental medical technology trials (such as the artificial pancreas) have the potential to significantly improve the treatment of several chronic conditions, including diabetes mellitus. However, we suggest that, to date, the essential concept of cybersecurity has not been adequately addressed in this field. This article discusses several key issues of cybersecurity in medical devices and proposes some solutions. In addition, it outlines the current requirements and efforts of regulatory agencies to increase awareness of this topic and to improve cybersecurity.
Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities

David Rodbard, MD

Abstract

Continuous glucose monitoring (CGM) provides information unattainable by intermittent capillary blood glucose, including instantaneous real-time display of glucose level and rate of change of glucose, alerts and alarms for actual or impending hypo- and hyperglycemia, “24/7” coverage, and the ability to characterize glycemic variability. Progressively more accurate and precise, reasonably unobtrusive, small, comfortable, user-friendly devices connect to the Internet to share information and are sine qua non for a closed-loop artificial pancreas. CGM can inform, educate, motivate, and alert people with diabetes. CGM is medically indicated for patients with frequent, severe, or nocturnal hypoglycemia, especially in the presence of hypoglycemia unawareness. Surprisingly, despite tremendous advances, utilization of CGM has remained fairly limited to date. Barriers to use have included the following: (1) lack of Food and Drug Administration approval, to date, for insulin dosing (“nonadjuvant use”) in the United States and for use in hospital and intensive care unit settings; (2) cost and variable reimbursement; (3) need for recalibrations; (4) periodic replacement of sensors; (5) day-to-day variability in glycemic patterns, which can limit the predictability of findings based on retrospective, masked “professional” use; (6) time, implicit costs, and inconvenience for uploading of data for retrospective analysis; (7) lack of fair and reasonable reimbursement for physician time; (8) inexperienced and lack of training of physicians and other healthcare professionals regarding interpretation of CGM results;
Cybersecurity Risks

- Cybersecurity risks can be external (e.g., wireless vulnerability) or internal (e.g., software integrity);

- Internal security threats include malware which are ubiquitous, even on hospital computers;

- Wireless link between a CGM and the microcontroller unit in an AP system; if the link is not encrypted, it may be possible to introduce erroneous data to the target device;

- AP devices communicate using standard wireless technologies such as Bluetooth and Bluetooth low-energy. Some insulin pumps use data encryption and obscuring to prevent link tampering, but others use simple open networks
FDA guidelines are not yet regulations
Responsibility remains on the clinical research group or device manufacturers to ensure that best practice is followed while testing algorithms/hardware architectures in artificial pancreas (AP) experiments.
Recently the FDA has introduced a programme of online validation.
Diabetes Technology Society (DTS) is pleased to announce that the steering committee members, advisors, and consultants of the DTS Cybersecurity Standard for Connected Diabetes Devices (DTSec) project have developed the **DTS Cybersecurity Standard for Connected Diabetes Device Security** and the **DTS Protection Profile for Connected Diabetes Devices.**

https://www.diabetestechology.org/dtsec.shtml
Research: Software as a Medical Device and Cyber Security for Medical Devices

8 October 2018

Globally, regulators of therapeutic goods are faced with numerous challenges concerning emerging medical device technology. The Therapeutic Goods Administration (TGA) recognises that, to continue providing a clear regulatory environment for medical devices in Australia, it is essential that we engage with the medical devices ecosystem during the development of new regulatory recommendations and guidelines.

The TGA has commenced consultation, through CSIRO Futures, in the areas of Software as a Medical Device (SaMD), and Cyber Security for Medical Devices (CSfMD). Regulation of SaMD is challenged by the emergence of new players that may not have had the opportunity to engage with the TGA, or are lacking an awareness of the regulatory requirements in Australia. CSfMD challenges arise due to the increasing impact and complexity of the cyber threat landscape, and the lack of current regulatory guidelines to effectively address this.
Medical Device Cyber Security Research

Date: 14 September 2018       Time: 2:00 pm (Australia/Melbourne UTC+11:00)       Duration: 02:00

Captions and a transcript will be available for this video soon.

Advances in digital technology have resulted in increasing numbers of programmable, connected and software-based medical devices. These devices bring significant benefits to both patients and clinicians, however these digital technologies also come with the potential risk of harm to patients due to cyber security threats. This consultation event explored the complexities of the Australian medical device cyber security landscape to inform the Therapeutic Goods Administration’s development of new Australian industry guidance.

Related information


Therapeutic Goods Administration: Software as a Medical Device and Cyber Security for Medical Devices

CSIRO: Cyber security for medical devices guidelines

https://www.hisa.org.au/cybersecurity/
Self-quantifiers and personalized health self-management

A new proactive participant in healthcare:

Quantified Self, PatientsLikeMe, 23andMe, uBiome ... DIY Hackers, and #WeAreNotWaiting etc
Patients’ and caregivers’ experiences of using continuous glucose monitoring to support diabetes self-management: qualitative study

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Abstract

Background: Continuous glucose monitoring (CGM) enables users to view real-time interstitial glucose readings and provides information on the direction and rate of change of blood glucose levels. Users can also access historical data to inform treatment decisions. While the clinical and psychological benefits of CGM are well established, little is known about how individuals use CGM to inform diabetes self-management. We explored participants’ experiences of using CGM in order to provide recommendations for supporting individuals to make optimal use of this technology.

Conclusions: CGM can be an empowering and motivational tool which enables participants to fine-tune and optimize their blood glucose control. However, individuals may benefit from psycho-social education, training and/or technological support to make optimal use of CGM data and use alarms appropriately.
Quoted from:
TechRepublic, November 2016
Jo Best, #WeAreNotWaiting
https://www.techrepublic.com/article/wearenotwaiting-diabetics-are-hacking-their-health-because-traditional-systems-have-failed-them/

“The beauty of it is it provides a recommendation in real time with real-time data. While a person with diabetes may make that calculation a dozen times a day, the system is doing it every five minutes.”
Dana Lewis, co-founder of OpenAPS
Chris Hannemann showed how the OpenAPS solution combines hardware and software at the DiabetesMine D-Data ExChange event in 2015.
John and Evan Costik at home in New York, in early 2018.

http://genomemag.com/nightscout-diabetes-type1/
How Nightscout Works

- Nightscout allows CGM data to be published online, by connecting a mobile device with the Nightscout app installed to the receiver part of the CGM.
- CGM data can then be viewed through the Nightscout website or any web-enabled device, e.g. another mobile device, smartwatch, etc.

http://www.nightscout.info/
How Do You Get Your CGM in the Cloud?

Features of a Nightscout site include:

- Two-day graph
- Basal visualization
- Bolus Wizard Preview
- Browser access
- Carbs on Board (COB)
- CarePortal
- CarePortal app (Pedale)
- Custom alarms
- Delta (change in bg)
- Insulin on Board (IOB)
- Pushover notifications
- Reports
- Viewing apps/widgets
- OpenAPS integration

Loop is a do-it-yourself closed-loop insulin delivery system, which consists of 4 components:
1. Open-source Loop app running on an iPhone
2. CGM (Dexcom G5, or Dexcom G4+share, or Medronic Enlite)
3. A compatible insulin pump
4. RileyLink, an open-source hardware device, which serves as a bridge between iPhone’s Bluetooth Low Energy (BLE) radio and pump’s radio
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Important

Please understand that this project:

- Is highly experimental
- Is not approved for therapy

You take full responsibility for building and running this system and do so at your own risk.

https://forum.fudiabetes.org/t/loop-getting-started/2216
Project Information and Call for Participation

Collaborators and participants are sought: clinicians, public health educators, software developers, policy-makers, insurers, consumers (caregivers/T1D patients), researchers

Enquiries and expressions of interest - please contact:

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Thank you