

Key Research Summary

Parents Using Unregulated Technology to Manage Type 1 Diabetes in Children



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The Melbourne School of Population and Global Health Ethics Advisory Group approved the project, 'Personalised Closed Loop Systems for Childhood Diabetes' (ID 1953678.1)

BACKGROUND

Management of type 1 diabetes in children – the picture in Australia

Type 1 diabetes (T1D) occurs when the pancreas produces little or none of the insulin needed to regulate blood glucose. About 6,500 children aged 0-14 have T1D in Australia. Managing blood glucose levels requires a life-long daily medical regimen. Traditional management includes finger prick checks of blood glucose and insulin injections to keep glucose levels in range.

- A continuous glucose monitor (CGM) is a small wearable device that measures glucose levels throughout the day and night which alarms if glucose levels are getting too low or high. Most CGMs require users to do a blood glucose check twice a day to calibrate the device.
- Around 40% of children currently use CGM and government subsidies are available.
- Instead of multiple daily injections, insulin can be delivered through an insulin pump.
- Insulin pumps and related consumables are subsidised for some children with diabetes.

A recent development in T1D management is the hybrid 'closed loop' system. Acting as an 'artificial pancreas', the results from the CGM are applied to a computer-controlled algorithm which calculates the insulin dose to be delivered by the pump. Insulin delivery can be automated with very little user input. In 2019 the first commercial hybrid closed loop system was approved by the Therapeutic Goods Administration in Australia. Clinical trials of hybrid closed loop systems continue to take place in Australia.

However, for some people with diabetes and their families, advancements in commercial hybrid closed loop systems are not coming fast enough. Tired of waiting for an effective and accessible product, they are building their own DIY hybrid closed loop (or looping) systems:

- DIY looping is a fairly recent development in T1D management. Data is needed to understand the numbers of children who are looping in Australia.
- CGMs and insulin pumps are regulated medical devices in Australia, but may not be when used for DIY looping.
- Open source software is not regulated.
- Diabetes Australia advises patients to continue to get care from healthcare professionals if they choose to use an unregulated DIY looping system.
- There is almost no ethical or legal guidance for clinicians.

OUR RESEARCH

Interviewing stakeholders in DIY closed loop system use for the management of childhood diabetes

The aim of this project was to understand why parents of children with T1D choose to use DIY looping and the ethical and legal obligations on healthcare professionals to provide care to children using these devices. We endeavoured to interview key stakeholders on this topic: parents of children who are looping, social workers, clinicians (endocrinologists and diabetes educators), software developers, medical indemnity insurers, legal professionals, and those involved in regulation of medical devices using open source software.

WHAT DID WE FIND

The final sample consisted of 25 participants across all the stakeholder groups except for those involved in regulation. There was no response to our invitations from the Therapeutic Goods Administration (TGA). Below are the perspectives of each stakeholder group.

Parents

Experience of diagnosis and management

- When their child was first diagnosed with T1D most of the parents we interviewed described feeling shocked
- Initially, healthcare professionals' information and support are valuable – but after that, parents felt they had a better practical understanding of the day to day management of their child's diabetes
- Parents thought the role of the healthcare professionals should be to monitor outcomes and provide support to children living with diabetes and their families
- To get a continuous glucose monitor and/or pump, some parents described being extremely proactive – push the hospital to sign forms, appointments with psychologists, educators, and dietitians

Reasons for and putting systems in place to begin looping

- Parents became aware of looping through online research or their diabetes virtual social networks
- Parents expressed various reasons for initiating looping: after experiencing a desperate need for better management solutions, frustration at slow progress in technology-enabled systems for managing T1D, or due to difficulties with managing diabetes in external care or school settings
- Parents described engaging in a lot of reading and self-education in order to start looping and relying on Facebook groups for support

"I would say it was a 2 month lead up in spending time reading, preparing, collecting stuff, setting up accounts, etcetera, and then probably one weekend I sat and built the whole thing and we were up and running"

- It can take some time to prepare for looping; getting the equipment such as a suitable pump can be difficult
- Some parents started their child looping gradually – for example while the child was asleep
- Importantly, the parents recognised looping isn't a 'set and forget' endeavour – they read thoroughly about the risks, adjust settings at times, and caution parents of children newly diagnosed with T1D against looping straight away

Perceived benefits of looping

- Parents described considerably improved sleep for themselves and their child (without looping, they are up 2-8 times a night), perceived better management of diabetes, more freedom for their child to participate in school activities, more independence in general, less reliance on untrained school staff, more stable HbA1c levels and improved health in general

“So, there’s clinical benefits, there’s mental health benefits, there’s social benefits”

- For parents, improvements in management and quality of life for their families is evidence that looping is beneficial

Risk awareness, safety planning and perception of looping as being underground

- Parents spoke of having many backup systems in place if any part of the system stopped working - using offline systems if there is no Internet connection, back-up devices if the devices aren’t working, independent remote alarms, although the looping algorithm itself isn’t an issue
- Though the parents would like DIY looping to have the rigor of TGA approval as a quality assurance process, if they don’t use a DIY system, the alternative is to rely on themselves and their own insulin calculations, and as one parent described - parents are not ‘TGA-approved’ either

“Am I TGA-approved to make all these insulin decisions for every single day?”

- There was concern that if the child’s blood sugar level is low, other people will perceive it to be because they were looping
- Parents continue to see the same doctor so that:
 - there’s a written record in the health system that the child’s care was above average, with their HbA1c down significantly compared to the norm;
 - to cover parents legally if there was a question in relation to child protection and the parents using an unregulated system to manage their child’s diabetes

A commercial hybrid system

- Commercial looping devices are available on the market. Parents would like to use them, but say updates to their features are slow and DIY looping offers a wider, more convenient range of features
- Commercially approved systems may be a better option for parents who aren’t tech-savvy

Healthcare Professionals

- No clinicians interviewed were aware of children in their care currently using a DIY looping system
- There were varying degrees of understanding among clinicians of what DIY looping is and how it is used to manage T1D

“I think [parents] are quite knowledgeable, they’re very tech-savvy, I think they probably understand the equipment far better than any educator or health professional at this point”

- Principal concern about clinicians’ legal liability and indemnity insurance if they were to support families with looping

“I would certainly be concerned about the legalities and the indemnity side of things”

- Another key concern was the lack of evidence of proven benefit properly established through robust clinical trials, as opposed to parent testimonials
- Concern about DIY looping as a safe practice: out-of-warranty pumps, unregulated status of DIY systems, risk of malfunction, data security and potential of ‘hacking’ the system, lack of support for parents if there is a technical issue, whether parents can successfully manage DIY looping, and risk of harm to child

Social Workers

- When assessing whether a child is at risk of harm in general, the factors social workers take into account include: the environment in which the child lives, the parents’ capacity (influence of drugs, alcohol, etc.), medical records (e.g. frequent admissions to the ED)

“Children can be at risk if the parents are not following medical advice and that might lead to significant harm for that child”

- Cumulative informative is important in painting a picture of the risk

Technical experts (mainly software developers)

- It was expressed that the term ‘DIY’ is unhelpful for looping, giving the impression that it’s not developed or rigorous
- The term ‘hacking’ is concerning and is misused in the context of looping – they did not view looping codes and software as ‘hacking’ into built and older equipment

“Assembling software is not hacking.”

- Open source -testing of the system is a very important process – though new codes can be suggested, nothing is added into the system without testing

“I don’t think the TGA has the growth mindset”

- Software developers have experienced difficulty engaging with Australian regulatory bodies

Legal professionals and medical indemnity insurers

- There were varied responses to clinicians’ liability if they support parents whose children are looping – ranging from the perception that clinicians wouldn’t be legally covered, to not seeing how a case could be made against them

“With the creation of more and more machine delivery or computer delivery of product, whether it’s diabetes or whatever else, I think there will be new areas of liability”

- There were also varying views on regulation – from it being vital, to not seeing how regulation could work with open source software that keeps changing
- In terms of medical insurance, interviewees stated that doctors who support parents of children with diabetes with DIY looping would not be covered. Their concern is with patient and clinician safety and they say it is perceived that the risks are too high

Conclusions

We found that each stakeholder group had different perceptions of the risk of looping and what is appropriate evidence to show the benefits of looping to manage T1D.

There is a gap between practice and regulation – some parents are using DIY looping for their children, but open source software is not regulated and therefore not supported by healthcare professionals and medical insurers. Healthcare professionals are concerned about their legal liability if they support the use of looping.

A possible way forward

Based on the experiences that participants shared with us these are our suggestions to develop understanding and way forward:

1. Resolve the disconnect between stakeholder groups, through collaborative engagement focused on supporting positive health outcomes
2. Explore collaborative and proactive regulation of looping with the TGA
3. Provide ethical and legal guidance for clinicians who provide care to parents of children with diabetes using DIY systems.

THANK YOU

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