

# DIY Looping Technologies

ADEA Updates Living With Diabetes

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insulin

technology

type 1

## Introduction

The Australian Diabetes Educators Association (ADEA), the Australian Diabetes Society (ADS) and the Australian Paediatric Endocrine Group (APEG) are aware that some people with diabetes are using technologies built by individuals that are not approved for use by regulatory bodies such as the therapeutic goods association (TGA). Diabetes Australia released a [position statement](#) in August 2018 regarding this issue for people with diabetes. A working group involving health professionals has been formed with members from ADEA and ADS to address issues for health professionals who consult people with diabetes who may be using these technologies or who may be contemplating their use. The aim of the position statement is to provide advice to members on the use of and support for

individuals using this technology.

## Aims of the project

Through the development of a position statement on DIY looping technology for people with diabetes, ADEA hopes to:

- Clarify types of loop technology, their use and application.
- Outline the legal framework in which health professional's work.
- Advise diabetes educators, endocrinologists and other health professionals about their legal and professional obligations.
- Assist health professionals to determine their role in respect to loop technology.

## The issues

The working group have met a few times over the past months to discuss the issues they are currently encountering in practice, as well as issues being raised by other health professionals.

The concerns being communicated by health professionals are:

- Some apparatus, hardware and software, being used is not TGA-approved, hence is this outside the evidence base for our legal scope of practice?
- Some devices being used are no longer in warranty and no longer being sold by device companies – is this OK?
- Non TGA-approved hardware and software is being used to send commands to the insulin pump to adjust insulin rates and therefore the insulin pumps are not being used in the way they were originally intended and approved for.
- As care of the person with diabetes is our concern and focus, we are mindful of the conflict that may occur when balancing our advice/assistance to the individual with our legal and professional obligations in these circumstances, especially as the glycaemic management of the person is often markedly improved with this self-care.
- If we have knowledge of where to get information on how to access DIY looping technologies, should we share it if the person with diabetes asks for it?
- If a person with diabetes (or a parent or family member) chooses to build a DIY system, they must continue to receive support and care from their diabetes healthcare professional and the health system <sup>1</sup>.
- If a severe adverse reaction occurs to a person who is DIY looping and we are seeing them professionally, who is responsible? Even if the health professional has documented that the looping technology is outside their management plan and the decision to use it is made by the person with diabetes.

- What are the implications if it is a child's parent who is managing the DIY looping technology on their behalf?

## Legal advice

ADEA has sought legal advice regarding the legal implications for their members when consulting with a person, or the person's carers, who have chosen to use DIY looping. Preliminary, high-level advice is that the Therapeutic Goods Act 1989 <sup>2</sup> prohibits the supply or promotion of a medical device not included on the Australian Register of Therapeutic Goods. Health practitioners treating or advising an individual using DIY looping need to discuss these issues with the person, and how it affects the advice they can provide. Further information will be provided once the advice is finalized.

## Conclusion

As this is not a straightforward situation and technology advancements continue, discussions towards advice for health professionals are on-going, with the aim to have a position statement finalised in 2019.

ADEA will let members know once the position statement has been finalised and is ready for publication.

### References

1. Diabetes Australia. Position Statement: People with type 1 diabetes and Do It Yourself (DIY) technology solutions. 2018.

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2. Australian Government. Therapeutic Goods Act 1989.

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