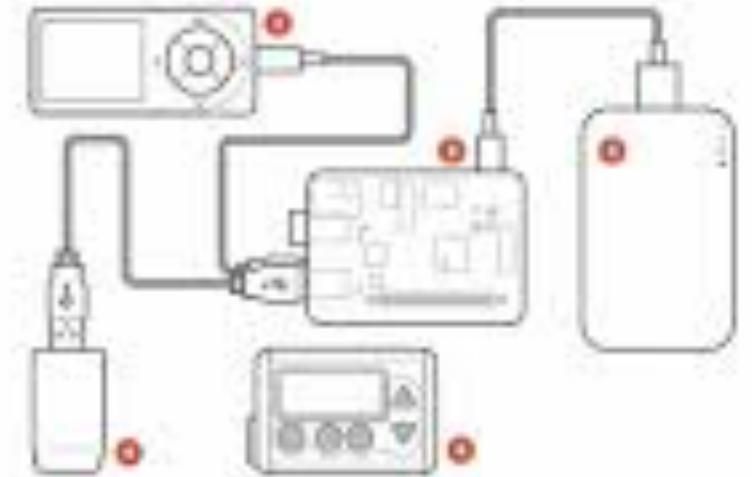


Looping, closed loop and open APS – do you know the difference?
Is your service ready?



[Illustration by Clint Ford for Popular Science]

Challenges with DIY Technologies

Those choosing to use a DIY tech system do so at their own risk. DIY systems are not currently regulated by any official authority, anywhere in the world, so there is no official mark of approval indicating the system is safe to use. We do recognise that as these systems are built by people for their own use, safety will be at the forefront of their minds however.

There are always risks with using devices that are old or out of warranty and many manufacturers state that using a device in a way other than it is designed to be used will void the warranty.

As stated on page 1 of this briefing, healthcare professionals should be able to support patients no matter what tools they choose to use to manage their condition, without fear of legal action or risk to professional reputation if something goes wrong when a patient chooses to use a DIY system. It is also not as simple as a patient offering to write the healthcare professional a letter to indemnify them, JDRF would like to see clarity on this issue so that health professionals can feel protected in these situations, as well as resources and protected time for professional learning and development, so that they can continue to care for patients who choose to use DIY systems.

There have not yet been any academic publications of prospective clinical studies with DIY systems determining their safety, although observational data is available. Results of such studies will be one of the requirements for regulatory approval of DIY systems just as they would be for any conventionally developed system.

Recommendations

- People who wish to use DIY closed loop systems should continue to receive support and care from their diabetes team
- Diabetes healthcare professionals should respect an individual's right to make informed choices about their own care, or that of their child. They should continue to offer people who use DIY closed loop systems the care and support they are entitled to as detailed in Diabetes UK's [15 healthcare essentials](#) and [Type 1 essentials for children and young people](#)
- Healthcare professionals cannot recommend the use of DIY closed loop systems as they are not approved by any regulatory bodies, and must ensure that people with diabetes who are using them are aware that they do so at their own risk
- Healthcare professionals should not initiate a discussion with people with diabetes about using a closed loop system. However, in order to ensure openness around treatment, they should engage in the conversation if the person initiates it.
- Healthcare professionals should document in the person's notes that they have discussed with the user that DIY closed loop systems are unregulated and have no published, high quality research trials to support their use. Therefore the person with diabetes uses the technology at their own risk.
- Healthcare professionals should document in the person's notes that they have discussed the risks of using DIY closed loop systems, including the use of out of warranty equipment if relevant
- Healthcare professionals should continue to support the supply of NHS funded insulin pump, CGM or Flash Glucose Monitoring (Flash GM) if they are used for DIY closed loop systems, unless it is deemed unsafe or clinically inappropriate to do so

Do it yourself (DIY) closed loop for people living with Type 1 diabetes

Position Statement (August 2019)

- Healthcare professionals who have people with diabetes using DIY closed loop systems should work closely together to deliver a consistent approach to managing the systems and document how they have done so
- Healthcare professionals should participate in the ABCD audit in order to support a better understanding of benefit and risk of DIY closed loop systems
- People intending to use DIY closed loop systems should discuss their intention with their healthcare professional. This allows full consideration of potential risks and clinical factors that may preclude use of the technology, eg retinopathy
- People intending to use DIY closed loop systems should be aware that they do this at their own risk, they may not get 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 closed loop systems should be competent and confident in optimizing their diabetes management using an insulin pump and CGM or Flash GM
- People intending to use DIY closed loop systems can access support from the on-line DIY technology community for advice and trouble shooting. However they must be aware that this advice is not regulated and they do so at their own risk