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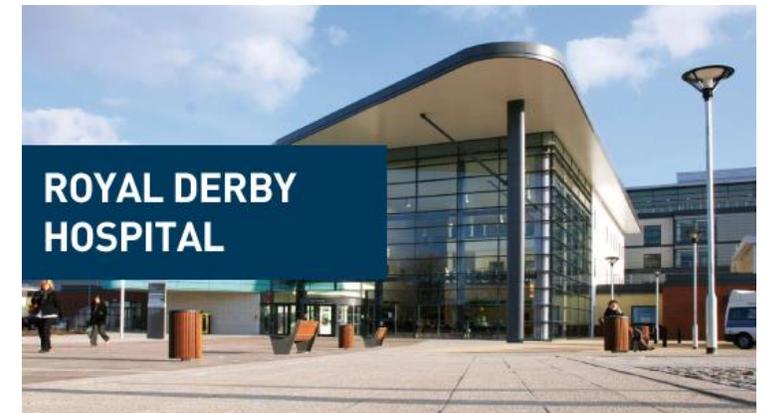
Do-It-Yourself Artificial Pancreas Systems: What you need to know

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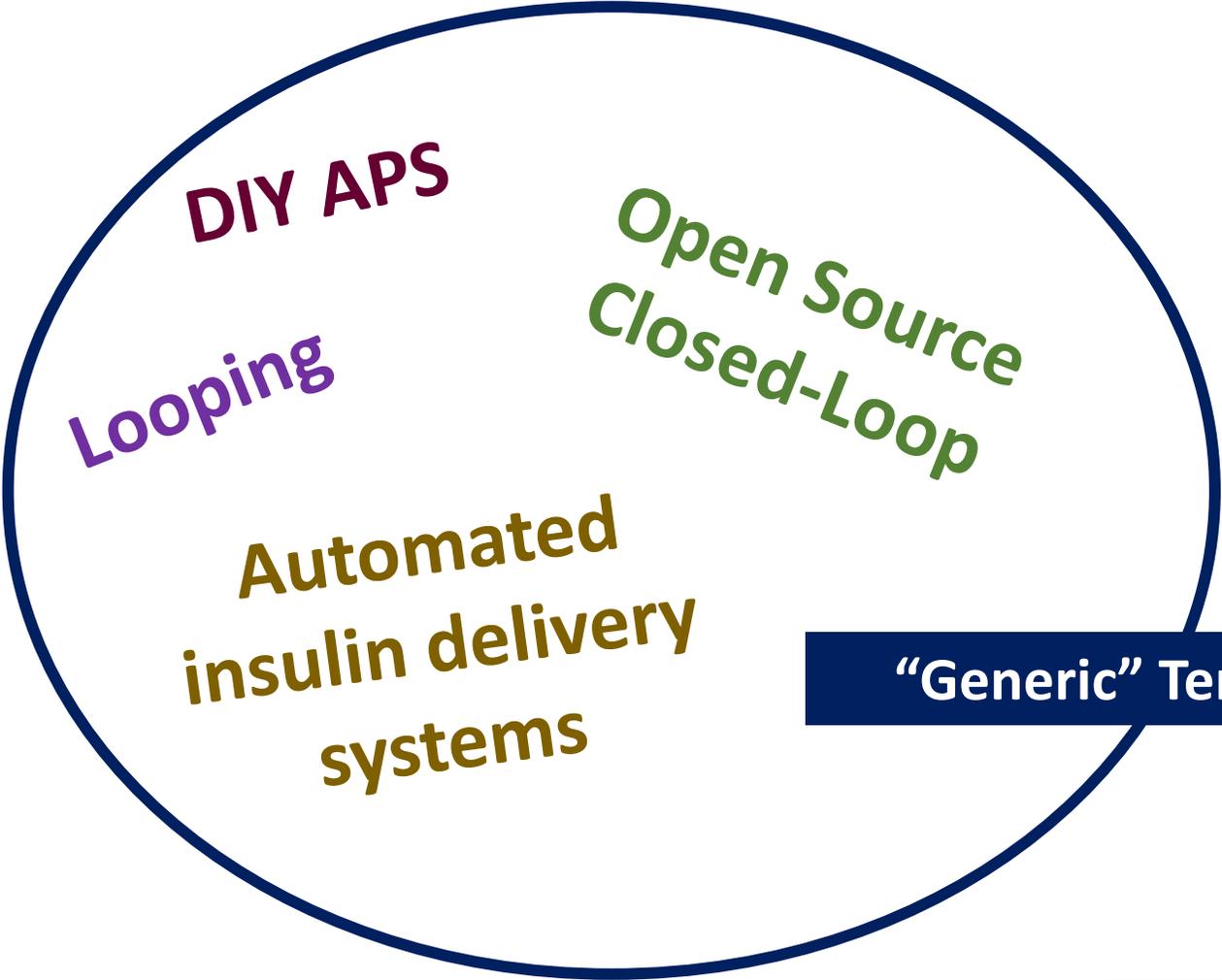
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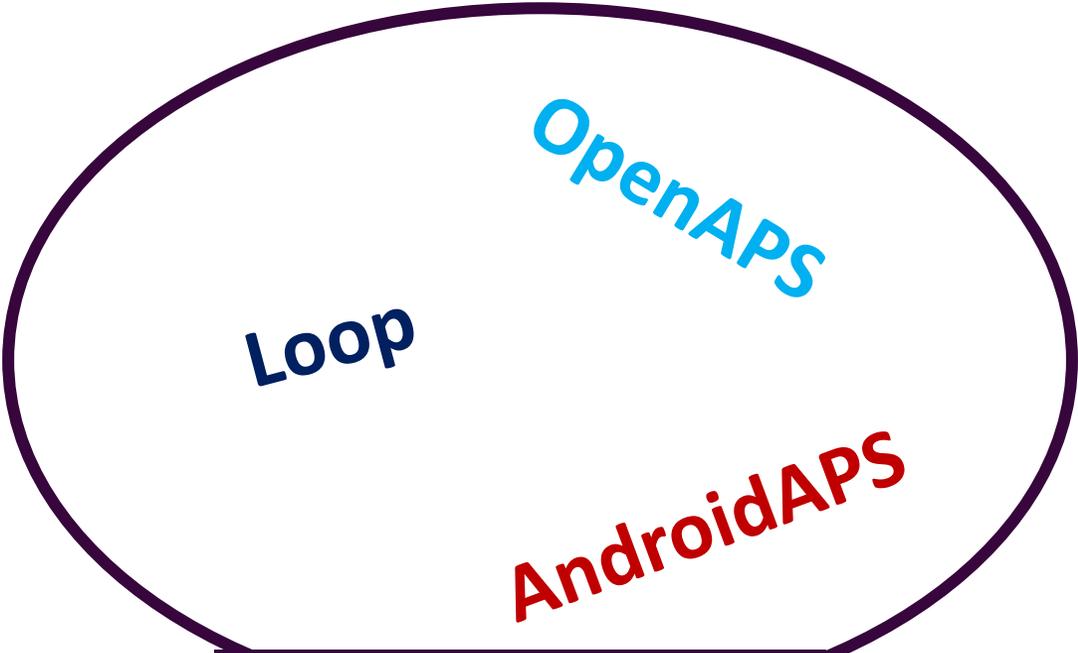
Disclosures

- I have received speaker fees and educational grants from NovoNordisk and Sanofi

A little bit on terminology...



“Generic” Terms



Specific systems

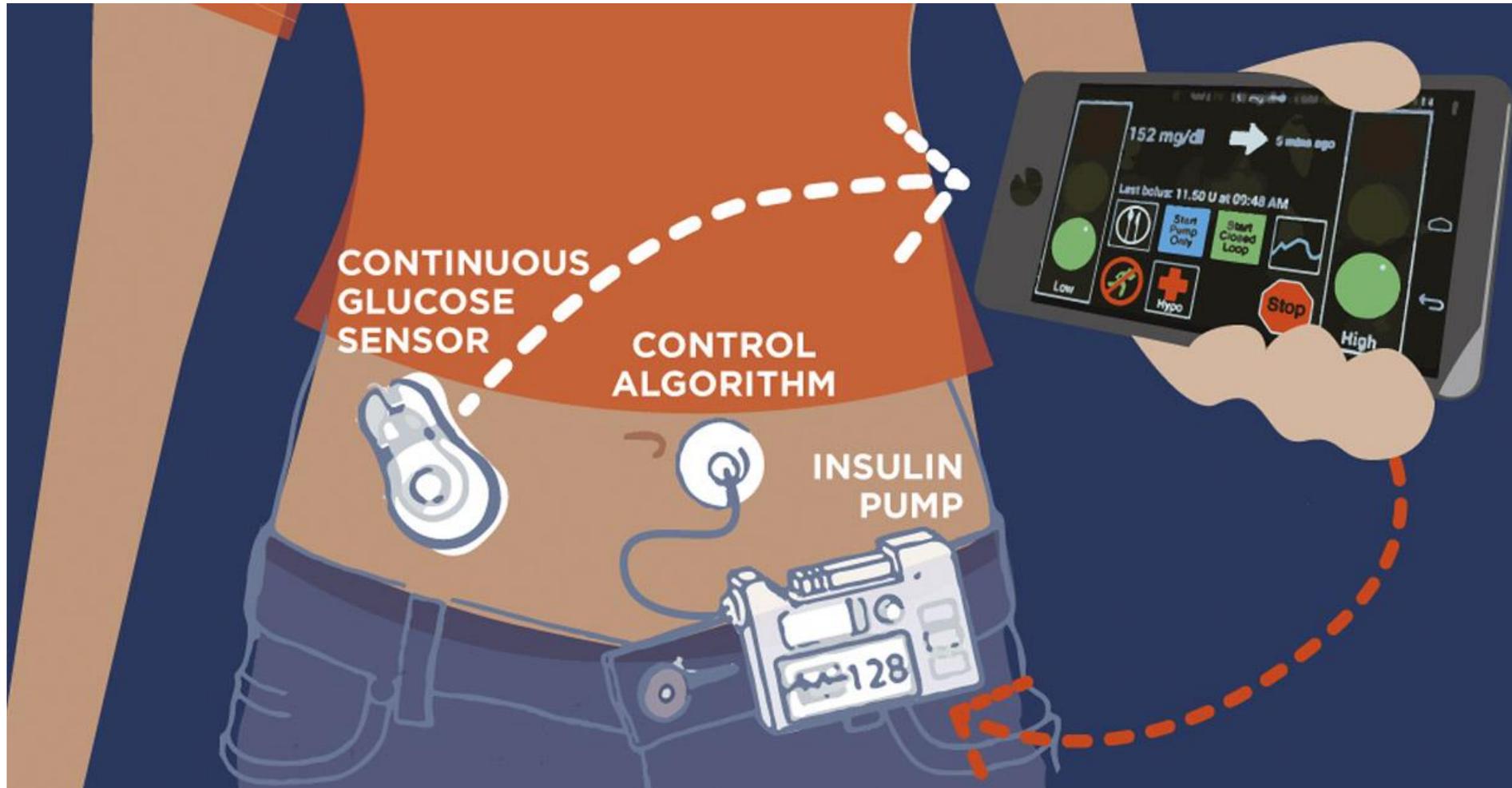


The movement

Overview

- Understand what a DIY APS is and how system works
- Understand why users choose these systems and the potential risks and benefits
- Discuss the ethical and medico-legal implications of their use
- Insight into how best to support users of these systems including participation in the ABCD DIY APS Audit programme

What is a DIY APS?



The pump, the sensor, the algorithm and the device

The pump

- Delivers the insulin

The sensor

- Measures the glucose

The algorithm

- Takes the data received from the device and decides whether to increase, decrease, suspend or maintain insulin delivery

The device

- Receives data from the pump and sensor (e.g. insulin delivery, glucose levels)
- Communicates the decision of the algorithm to the pump

The pump...



- Insulin pump therapy is **NICE recommended (NICE TA151)** and can be **NHS funded** providing criteria are met

The pump...



- **NICE TA151** recommended pumps for adults with Type 1 diabetes where:
 - attempts to achieve target HbA1c levels with injections results in the person experiencing **disabling hypoglycaemia**
 - or
 - **HbA1c levels have remained high** (8.5% (69mmol/mol) or above) on injections therapy despite a high level of care
- If less than 12 years with type 1 diabetes if pump felt to be a better option than injections

The pump...



- Insulin pump therapy is **NICE recommended (NICE TA151)** and can be **NHS funded** providing criteria are met
- Insulin pump therapy is shown to be **safe and effective**
 - *Reduces HbA1c*
 - *Reduces hypoglycaemia*
- Insulin pump use is *probably* associated with **increased quality of life**

The sensor... CGM



- Continuous glucose monitors (CGM) are **NICE recommended** (NG17 & NG18) and **NHS funded** in adults and children providing criteria are met

The sensor... Flash GM



- Guidance related to Flash GM (i.e. FreeStyle Libre) in place with NHS England targets
 - *Ring-fenced funding: 20% of population with Type 1 diabetes within each CCG*
- **Cannot** in isolation be used as part of a DIY APS system
 - Requires MiaoMiao reader (not NHS funded)
 - Requires an app to collect glucose data e.g. xDrip
- In this context... safe? Approved?

The reality...

- Only 1 in 5 clinical commissioning groups fund CGM as per recommendations
- Nationwide pump uptake is variable
 - Local availability of specific pumps

In an ideal world...

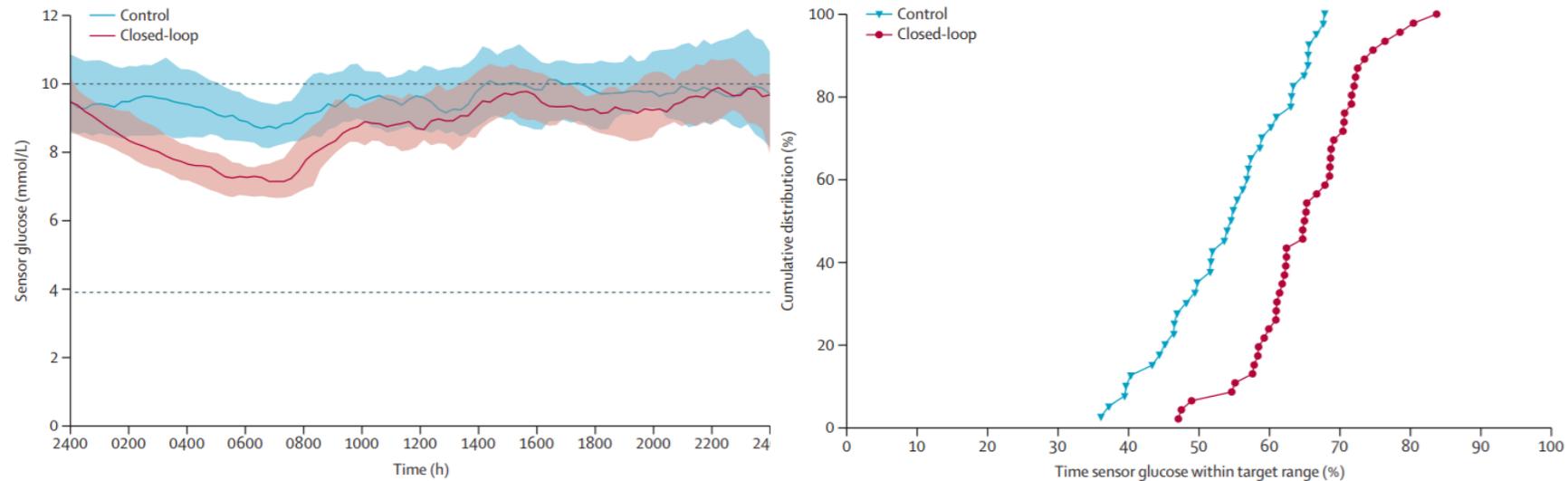
- NHS funded pump – YES
- NHS funded CGM – YES

- Therefore... why not an NHS funded closed-loop?

Commercial closed-loops

Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial

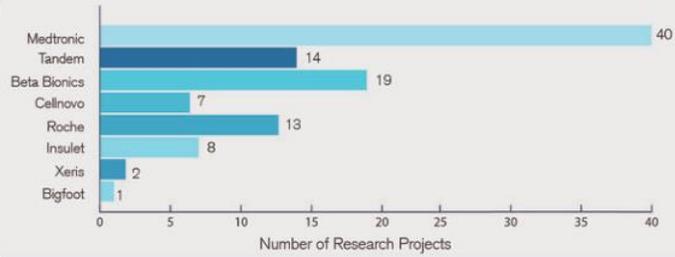
*Martin Tauschmann, Hood Thabit, Lia Bally, Janet M Allen, Sara Hartnell, Malgorzata E Wilinska, Yue Ruan, Judy Sibayan, Craig Kollman, Peiyao Cheng, Roy W Beck, Carlo L Acerini, Mark L Evans, David B Dunger, Daniela Elleri, Fiona Campbell, Richard M Bergenstal, Amy Criego, Viral N Shah, Lalantha Leelarathna, Roman Hovorka, on behalf of the APCam11 Consortium**



Tauschmann et al. Lancet 2018

The problem...

OUT OF 471 **ACTIVE T1D PROJECTS**
IN HUMAN TRIALS
39 ARE ARTIFICIAL PANCREAS



MOST ADVANCED STAGE IN HUMAN TRIALS BY COMPANY



KEY POINTS OF DIFFERENCE

- Dual Hormone
- Rechargeable Battery/Green
- Smartphone Compatible
- Tubeless/Patch Insulin Delivery
- Small Size
- Algorithm Complexity
- Insulin Pen Compatible

Juvenile Diabetes Cure Alliance
 The Voice of the Insulin For a Cure



CE



MHRA

Regulating Medicines and Medical Devices

The solution??

- #WeAreNotWaiting
- The original: OpenAPS
 - Launched in 2015
 - Dana Lewis and Scott Leibrand
- Now we estimate more than 3,000 of DIY APS globally

- Why the need?
- **Here to stay?**

#WeAreNotWaiting

...why?

- Why closed-loop?
 - Glycaemic outcomes
 - ... but QoL a much bigger factor
- Why DIY?
 - Constant evolution
 - User/Community driven
 - Reduce lead time for new developments

The algorithms...

- Three commonly used algorithms/systems
- **Built by users** and installed onto smartphones/watches/microcomputers
- System used may be dictated by local pump availability
- Multiple other programs involved, examples:
 - NightScout – cloud storage
 - xDrip – glucose data management

Evidence...

- Users report a high level of safety
- Self-reported outcomes are generally excellent
 - Reductions in A1c
 - Increases in time-in-range
 - Improvements in sleep quality
- Improvements in quality of life
- Millions of hours of DIY APS user data

openaps.org/outcomes

- Most DIY APS outcomes are self-reported
- Reliance on n=1 data (even if it is x1700)
- No control trial data
- Limited data utilising validated quality of life outcomes measures
- Medicolegal grey area
 - Unregulated
 - Unapproved

...concerns

References

- Lewis D, Leibrand S, Open APSC. Real-World Use of Open Source Artificial Pancreas Systems. *Journal of diabetes science and technology*. 2016;10(6):1411.
- Cleal BOD, Shane; Braune, Katarina; Lewis, Dana; Skinner, Timothy; Hauck, Bastian; Raille, Klemens. Detailing the Lived Experiences of People with Diabetes Using Do-It-Yourself Artificial Pancreas Systems - Qualitative Analysis of Responses to Open-Ended Items in an International Survey. American Diabetes Association - Scientific Sessions; Orlando, Florida 2018.
- Litchman ML, Lewis D, Kelly LA, Gee PM. Twitter Analysis of #OpenAPS DIY Artificial Pancreas Technology Use Suggests Improved A1C and Quality of Life. *Journal of diabetes science and technology*. 2019;13(2):164-70.
- OpenAPS Community. OpenAPS Outcomes [Available from: <https://openaps.org/outcomes/>].

Safety

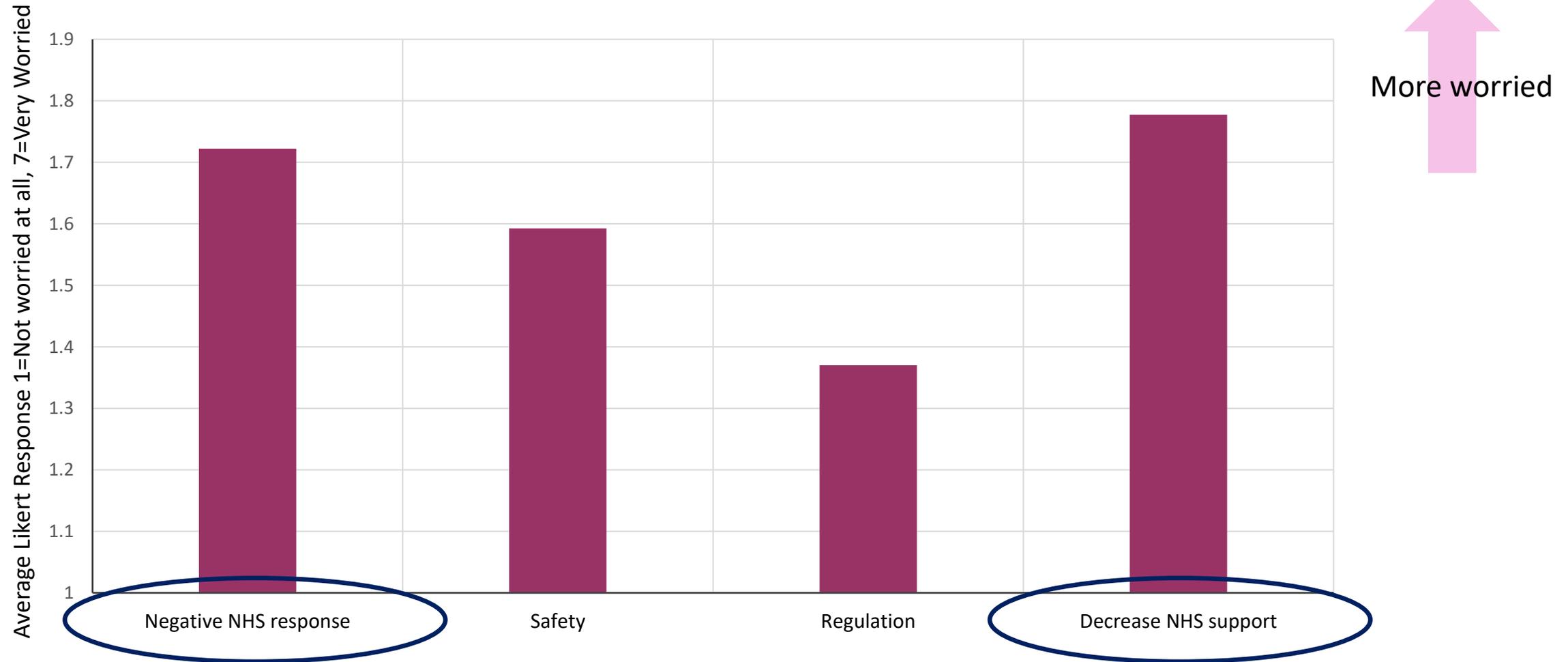
- We do not know how safe this system
- **Self-selecting** population, usually experts+++ in diabetes
- The system is **not** regulated or approved
- If there is a safety issue there is no robust means to communicate this to all users

THOSE USING THIS SYSTEM DO SO AT THEIR OWN RISK

Medico-legal

- These systems are **unregulated and unapproved**
- If something goes wrong – who is responsible?
 - Healthcare professionals liable for continuing to provide pumps and sensors knowing they are used in these systems?
- Ethically complex
- Impact on personal insurance

User concerns before commencement...



Reference – taken from

Crabtree TSJ; Maslen A; McLay A; Wilmot EG. A44 Oral Presentation: Initial insights into do-it-yourself artificial pancreas system user expectations and concerns prior to commencement: A pilot questionnaire. DUKPC 2020

Healthcare professional attitudes

THE LANCET
Diabetes & Endocrinology

CORRESPONDENCE | VOLUME 8, ISSUE 3, P186-187, MARCH 01, 2020

Health-care professional opinions of DIY artificial pancreas systems in the UK

[Thomas S J Crabtree](#) • [Pratik Choudhary](#) • [Peter Hammond](#) • [Alistair Lumb](#) • [Alasdair McLay](#) • [Emma G Wilmot](#) ✉

Published: March, 2020 • DOI: [https://doi.org/10.1016/S2213-8587\(19\)30417-6](https://doi.org/10.1016/S2213-8587(19)30417-6)

- Most healthcare professionals will not initiate discussions on the use of these systems
- However, the vast majority will help in whatever way they can
- Many recognize the limits of their own knowledge on the subject
 - Would find someone else to help if needed
 - Willingness to learn more

A question of ethics...

DIABETIC
Medicine

DiABETES UK
KNOW DIABETES. FIGHT DIABETES.

Commentary | [Free Access](#) |

The DIY artificial pancreas system: an ethical dilemma for doctors

D. Shaw , T. S. J. Crabtree, P. Hammond, A. McLay, E. G. Wilmot

- Ethically complex
- Tension in the GMC guidelines
 - To recommend alternative therapies
 - Not to recommend unapproved therapies



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

Position Statement (January 2020)

What are our goals?

To record data on DIY APS users clinical outcomes and quality of life measures

To record data on the safety of DIY APS use in clinical practice

To understand the driving factors for DIY APS use amongst the community

To understand the barriers to DIY APS use including healthcare professional attitudes, medicolegal and regulatory issues

To understand the place of DIY APS in a field of rapidly evolving diabetes technologies

Current projects

- DIY APS build-session survey
 - Prospective data on attitudes and concerns re: DIY APS prior to commencement
- Healthcare professional attitudes survey
 - To be repeated to see how attitudes may be changing
- ABCD DIY Artificial Pancreas System Audit
 - Collecting anonymised routine clinical data in order to establish the safety and effectiveness of these systems
- Medico-legal aspects

What should our approach be as healthcare professionals?

- We should not initiate discussions around DIY APS
- We should discuss the risks of DIY APS including the use of out of warranty equipment
- Should continue to support the supply of NHS funded insulin pump, CGM or Flash GM
- Should participate in the ABCD DIY APS audit

Practical advice

1. Don't be over awed by the users
 - Remember the basic things you would do in clinic
 - Don't assume they won't have complications
2. Is there a safer way?
 - If they meet pump and CGM criteria, would there be an option for a commercially available system, would they consider it?
 - Could you give them a safer pump if out-of-warranty?

Practical advice

3. Calibrations

- How often do they calibrate their CGM/FSL+MiaoMiao and in what conditions

4. Who is supporting them?

- Do they have contacts in the community if they need to troubleshoot

5. Do they have their usual back-ups?

- Back-up pens
- What will they do if an out-of-warranty pump fails?

Practical advice

6. Other specific issues

- This is the sort of thing we will get better at as we adjust to closed-loop
- Example: Exercise, Weight management

7. ABCD DIY APS audit

8. Risk disclaimer

9. Finally... talk to them about it

The big picture...

What are users' views? Paediatrics...

"Knowing your kid will wake up, and wake up in range and on target is priceless."

"We have normal glucose levels overnight and no more diving under the duvet to see what's going on with the pump and sensor."

"Managing this condition anxiety free. Being in control with a 1 year old. So NOT possible without looping."

"I can now work 4 days a week, have a social life and a daughter who is in range 90% of the time – that simply wasn't possible before"

"Made the world of difference...He's said he's not felt diabetic & his time in range has improved incredibly!"

"biggest thing is improved quality of life... helped my daughter's anxiety over BGs...now she only taps at her watch whilst in school to bolus"

What are users' views? Adults...

"I am not doing anything and I can't remember the last low I had! This looping is phenomenal. It's changed my life, given me more freedom and much more time free from worry."

"I have better time in range, a slightly better HbA1c, more importantly I get a full night's sleep and almost always a perfect result, with a massive improvement in peace of mind"

"The huge psychological benefit this has provided. I felt as if I was 'failing' so much of the time before – however much effort I made - I am no longer 'failing'."

"My worry has gone, I feel free. I have a HbA1c of 46 mmol/mol with no hypos and, finally, no fear of the dreaded complications. I feel like I no longer have diabetes."

"It's not all about HbA1c!
TIR 95%, **no disrupted sleep,**
and **waking up most**
mornings at 5.0mmol/l.
Not sure how you measure
QoL but this is **living a real**
life!"

"The **huge psychological**
benefit this has provided....
I am no longer 'failing'."

#wearenotwaiting

"...can't remember the
last low I had...
This looping is
phenomenal, it's
changed my life!"

Take home messages

- DIY APS is here to stay
- Outcomes are good but more evidence is needed
- These devices are unregulated and unapproved – use at own risk
- Healthcare professionals are generally supportive but recognise their own limitations in knowledge with these systems
- Recent position statements advocate counselling of risks but emphasise the need to continue to provide care

Questions???

ABCD.care/DIYAPS