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Open Source APS: the HCP Perspective

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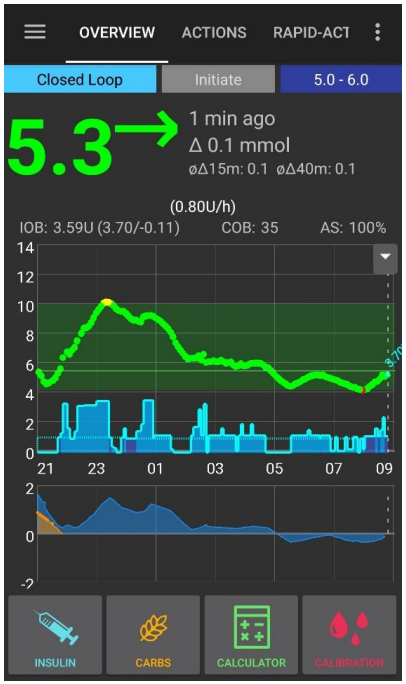
#wearenotwaiting

#whatintheheck

Is it safe?

Where do I stand?

HELP!



HCP and Open APS

Somebody asking us about it

Somebody telling us they will be starting

Finding out someone is already using

Problem solving…

Where do we stand medico-legally?

GMC recommendations

- 22. “You should encourage your patients to be open with you about their use of alternative remedies”

- 74. “You should be careful about using medical devices for purposes for which they were not intended.”

GMC?

Dear Dr Wilmot

"…can't provide clinical advice or comment … outside of our fitness to practise proceedings"

"..should make a clear records of discussions with the patient.."

GMC- Someone asking about APS

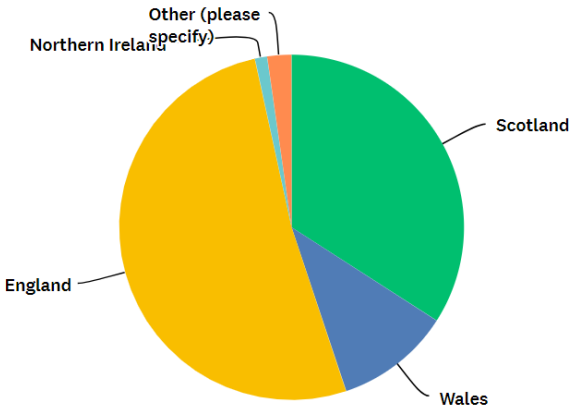
“If a doctor were to suggest or recommend this treatment as an option for a patient then they would be responsible because that advice would count as a prescription ”

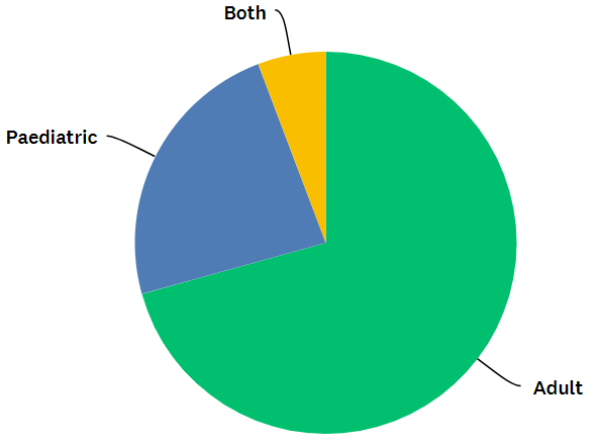
“..that does not mean that doctors cannot discuss this treatment if a patient asks them about it. Doctors can explain what it is, that it is unlicensed and the risks involved.”

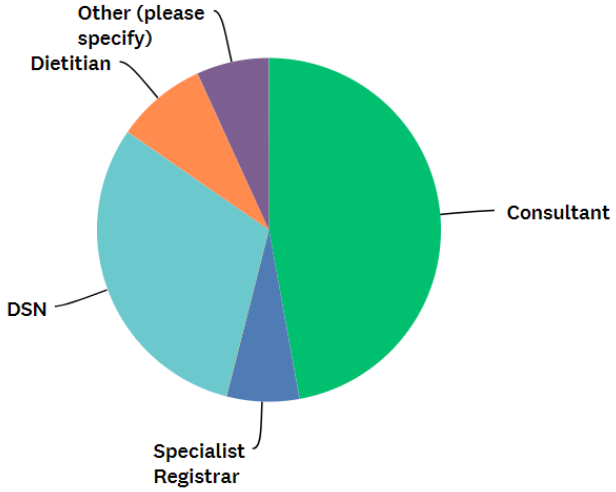
“…aware that their patient is using medical devices outside of the clinical guidelines, they should consider this risk when balancing the risks and benefits of different treatment options when deciding to prescribe.”

HCP Attitudes Survey

- Survey monkey distributed via DTN-UK
- 249 responses

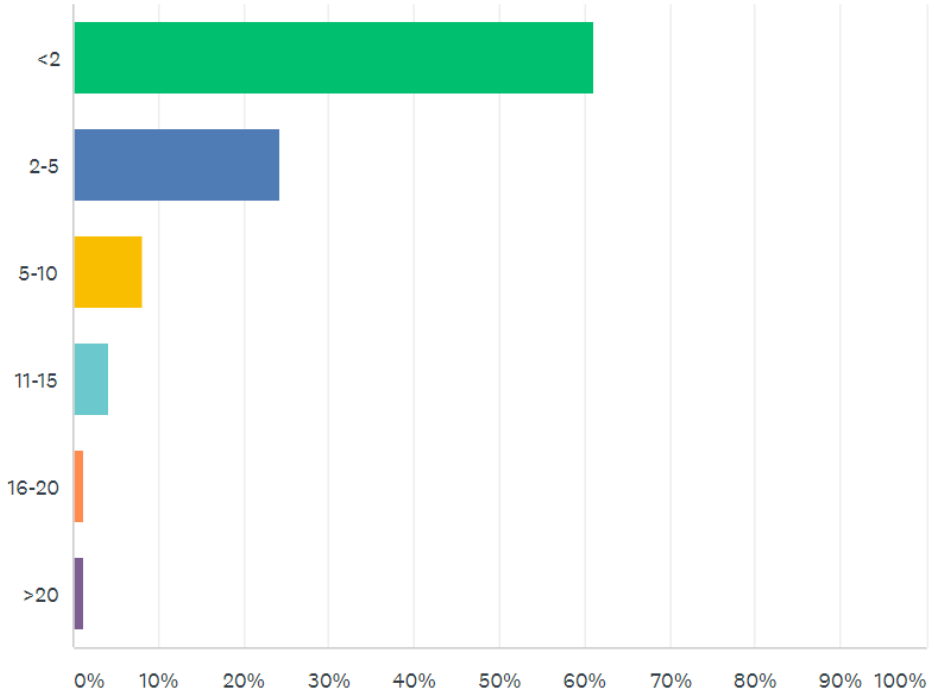






How many people in your service are you aware of who use a DIY Artificial Pancreas System?

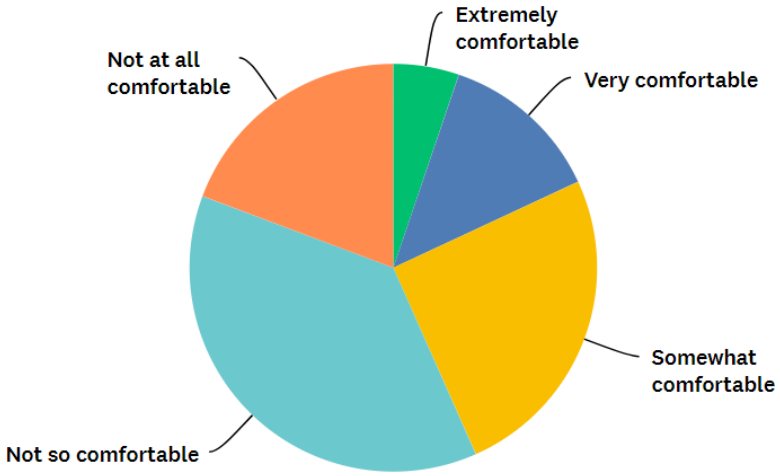
Answered: 244 Skipped: 5



ANSWER CHOICES	RESPONSES	
<2	61.07%	149
2-5	24.18%	59
5-10	8.20%	20
11-15	4.10%	10
16-20	1.23%	3
>20	1.23%	3
TOTAL		244

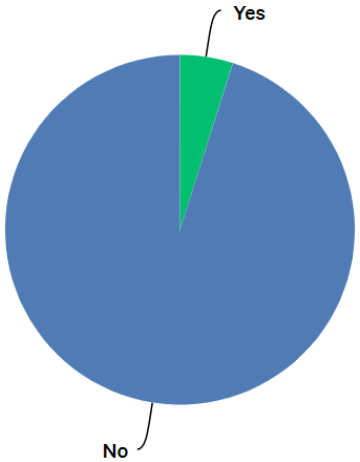
How comfortable do you feel providing ongoing clinical support for people using DIY Artificial Pancreas Systems?

Answered: 249 Skipped: 0



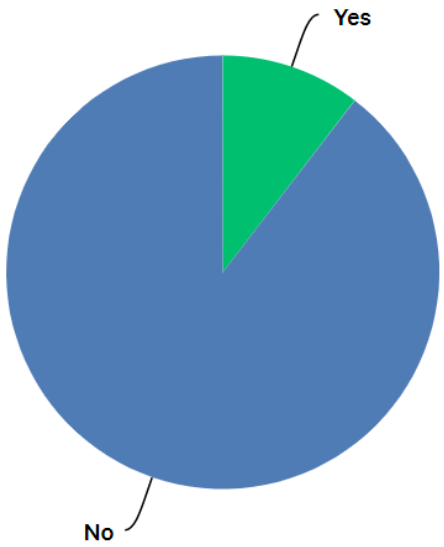
Have you declined or been unable to provide ongoing care for any users of a DIY Artificial Pancreas System?

Answered: 245 Skipped: 4



Do you initiate discussions on DIY Artificial Pancreas Systems as a treatment option in your consultations?

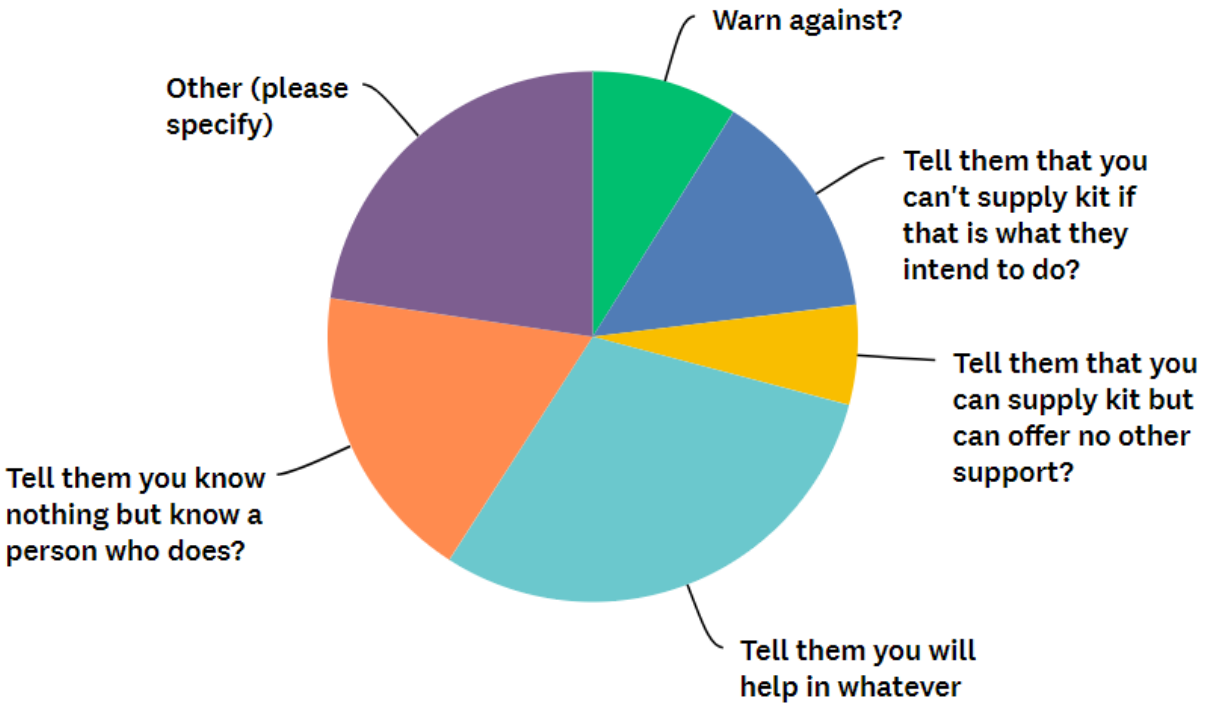
Answered: 249 Skipped: 0



ANSWER CHOICES		RESPONSES	
Not regulated/approved		63.91%	147
Limited knowledge of the system		59.13%	136
Fears around indemnity		30.43%	70
Potential concerns on effect on pump warranty		26.52%	61
Other (please specify)	Responses	14.35%	33

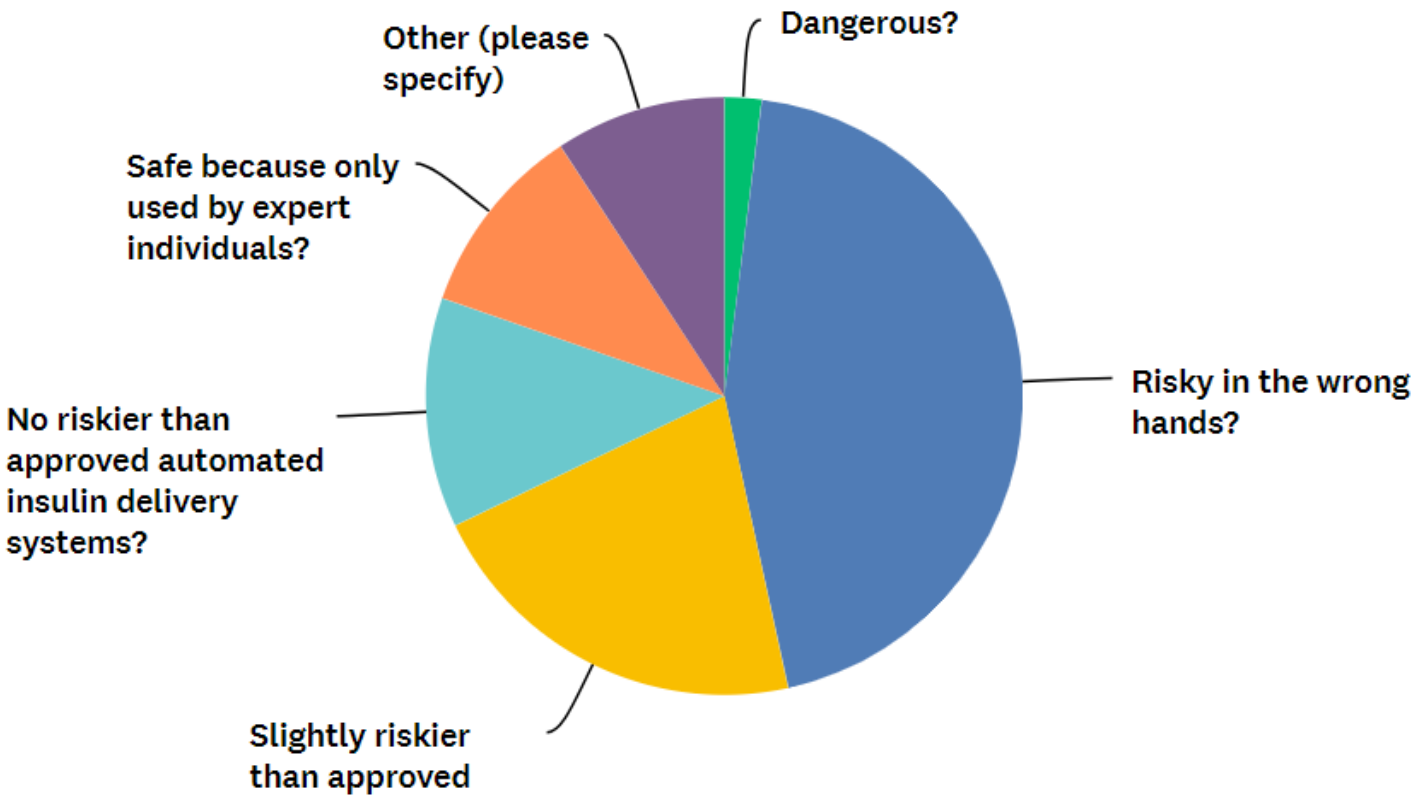
If a person in clinic asks you about DIY Artificial Pancreas Systems would you

Answered: 247 Skipped: 2



Do you think DIY Artificial Pancreas Systems are:

Answered: 249 Skipped: 0



Improvements in A1C and Time-in-Range in DIY Closed-Loop (OpenAPS) Users

Dana Lewis, Richard Swain, Thomas Donner

ADA 2018

Self-crossover comparison of selected 14-day time segments 4-6 weeks before and after initiation of OpenAPS (n=20).			
	Control	OpenAPS	P-value
Overall Findings (day and night)	*Blood Glucose Measure [mean (SD)]*		
Mean BG	[illegible]	[illegible]	0.0084
Mean Estimated HbA1c	6.4 (0.78)	6.1 (0.66)	0.0084
Time (%) below 50	1.9 (2.5)	1.1 (1.5)	0.0399
Time (%) below 70	[illegible]	[illegible]	0.1248
Time (%) in range 70 to 180	75.8 (14.9)	82.2 (11.1)	0.0042
Time (%) above 180	18.3 (13.9)	13.3 (11.1)	0.0092
Time (%) above 250	5.0 (5.4)	2.5 (3.3)	0.0138
Time (%) above 300	1.7 (2.3)	0.35 (0.57)	0.0138

Demographics:	
Age (years)	30.2 (15.5)
Years living with Type 1 Diabetes	18.4 (12.8)
Years with an insulin pump	15.7 (25.9)
Years with a CGM	4.7 (3.9)
Years with a DIY closed loop	1.0 (0.5)
Self-reported total daily insulin dose (units)	41.0 (19.3)
Self-reported total daily basal insulin (units)	20.0 (9.5)
Self-reported total daily carbohydrates (grams)	125 (43)

63 years old female, T1D since age 12

- CSII 2001
- Self funded DANA RS May 2018
- We endorsed and changed consumable supplies
- Open APS

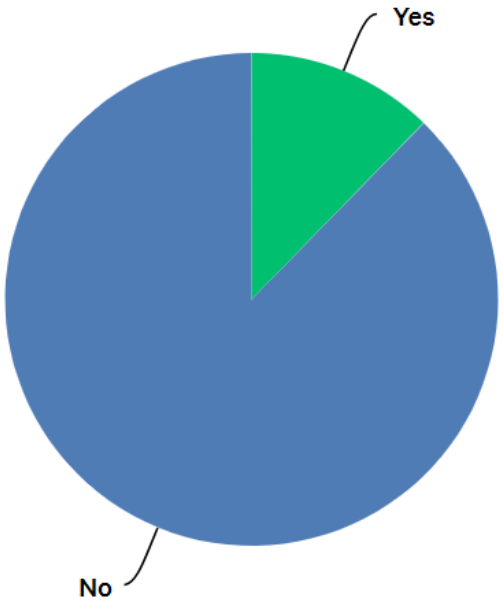
63 years old female, T1D since age 12

- HbA1c
  - 56 mmol/mol March 2018
  - 45 mmol/mol Oct 2018
  - 46 mmol/mol March 2019

- How was she feeling?
  - Alone!

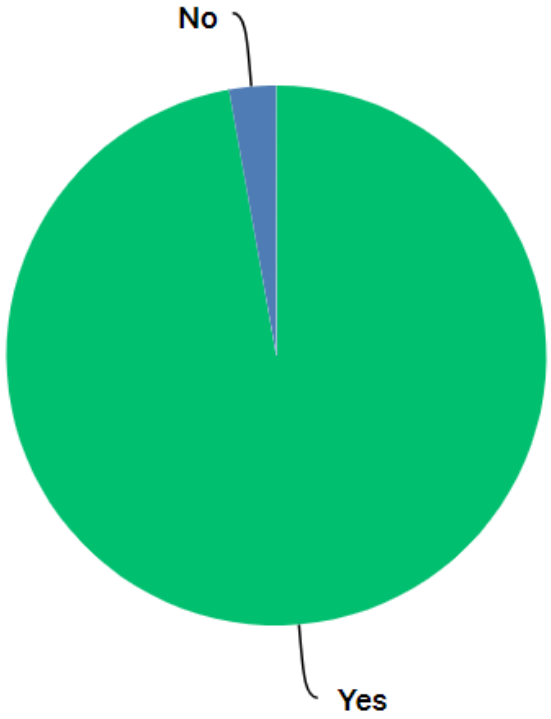
Have you declined or been unable to provide the required insulin pump or consumables for individuals wishing to develop their own DIY Artificial Pancreas System?

Answered: 244 Skipped: 5



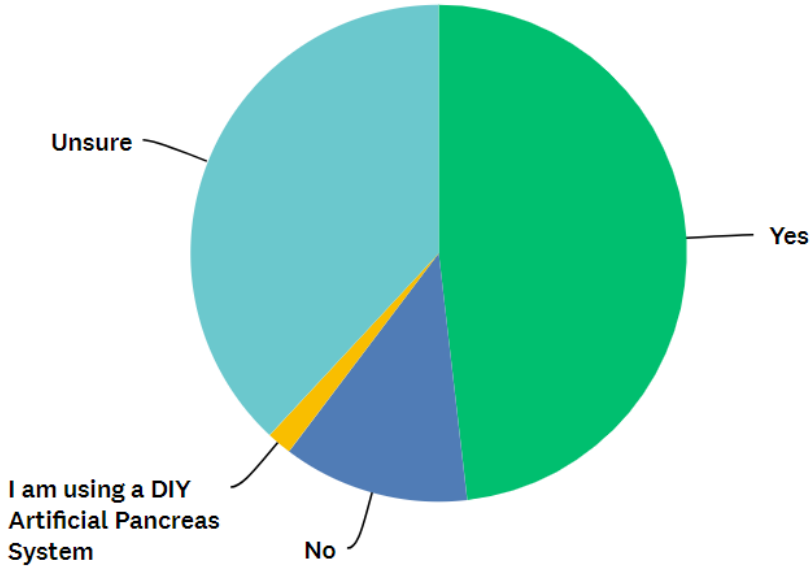
Do you believe that HCPs should learn more about DIY Artificial Pancreas Systems to support people with diabetes?

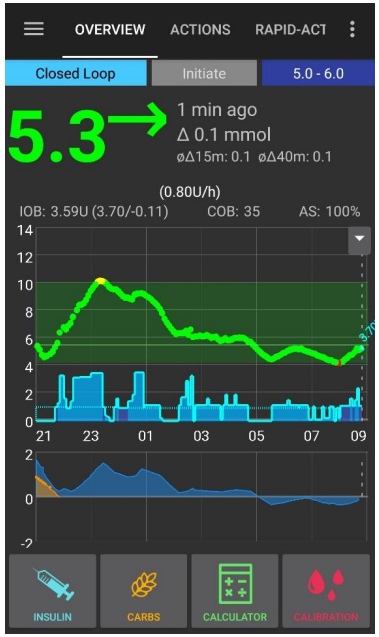
Answered: 249 Skipped: 0



If you had Type 1 diabetes, would you use a DIY Artificial Pancreas System?

Answered: 247 Skipped: 2





In summary, for those HCP responding to survey

- Most, in general, do not actively recommend DIY APS in their clinics
- Most will support users and provide ongoing care; however some will not
- Concerns about the safety of the system in ‘the wrong hands’
- Can make us feel uncomfortable (not regulated/approved, lack of knowledge)
- Few feel unable to provide ongoing care

Going forward

- The number of Open Source Closed Loop users in the UK is growing rapidly - we need reliable information on the potential risks and benefits

- ABCD National audit planned

- National position statement from key stakeholders in development

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