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Do-It-Yourself Artificial Pancreas Systems: A review of the emerging evidence and insights for healthcare professionals

Dr Peter Jennings, Ph.D., B.S.N.[1, 2], Dr. Sufyan Hussain MA, MB BChir, MRCP, Ph.D.[3,4]

Author Afflilations: [1]Nottingham Trent University, Nottingham, United Kingdom; [2]University Hospitals of Derby and Burton NHS Foundation Trust, Derby, United Kingdom, Derby, UK.; [3]Department of Diabetes and Endocrinology, Guy's and St Thomas' Hospital NHS Trust, London United Kingdom; [4]Department of Diabetes, Faculty of Life Sciences and Medicine, Kings College London, London, United Kingdom

Peter Jennings
Nottingham Trent University
Room 3221 Chaucer Building
Division of Social Work & Health
School of Social Sciences
Burton Street,
Nottingham NG1 4BU
+44 115 848 5538
peter.jennings@ntu.ac.uk
twitter: @peterjjennings1

Sufyan Hussain
Department of Diabetes and Endocrinology
3rd Floor Lambeth Wing
St Thomas' Hospital
Guy's and St Thomas NHS Trust
Westminster Bridge Road
London, SE1 7EH ,
+44 207 188 7188
sufyan.hussain@kcl.ac.uk
twitter: @sugarydoc

Abbreviations: APS, artificial pancreas systems; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DIY, do-it-yourself; HbA1c, glycated hemoglobin; HCP, healthcare professional; JDRF, juvenile diabetes research foundation; PWD, people with diabetes; T1D, type 1 diabetes; TAR, time above range; TBR, time below range; TIR, time in range

Keywords: androidaps, do-it-yourself artificial pancreas systems, hybrid closed loop, open-source; openaps; type 1 diabetes

Corresponding Author: Dr Sufyan Hussain, Department of Diabetes and Endocrinology, 3rd Floor Lambeth Wing, St Thomas' Hospital, Guy's and St Thomas NHS Trust, Westminster Bridge Road, London, SE1 7EH; email: sufyan.hussain@kcl.ac.uk; twitter: @sugarydoc

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Abstract

Application of artificial pancreas systems represents a change in approach to managing complex glucose and insulin dynamics using automated features with higher levels of safety, precision and reliability than those afforded by manual adjustments. To date limited commercial systems and more widely used open-source, hybrid closed loop, Do-It-Yourself Artificial Pancreas Systems (DIY APS) have been used in non-trial real-world management of type 1 diabetes (T1D). The aims of this article are two-fold. Firstly, it aims to synthesize the emerging literature on DIY APS. It identifies a range of evidence including research, reviews, commentaries, and opinion pieces written by DIY APS users, healthcare professionals (HCP) and researchers. It seeks to summarize the emerging clinical evidence for DIY APS and provide insight into how the DIY APS movement began, has been disseminated throughout diabetes online communities and is re-shaping self-management of T1D in real-world settings. Secondly, the article provides commentaries that explore implications of DIY APS to healthcare practice. DIY APS is radically changing T1D management. Automating the process of frequently analyzing glucose readings and appropriately titrating insulin delivery is liberating PWD from some of the demands of intensively managing T1D. Within this super-specialized area of T1D management, the expertise of DIY APS users has outstripped that of many HCP. While educational, ethical and legal constraints need to be

resolved, HCP still need to stay abreast of this rapidly developing area. Further research is needed to inform policy and practice relating to DIY APS. Meanwhile, HCP continue to learn from PWD's real-world experiences of building and using DIY APS to improve metabolic and psychological outcomes.

Introduction

Improved glycemic control delays the progression towards complications in type 1 diabetes (T1D) [1]. Current outcomes highlight that only a minority of people with T1D (PWD) achieve recommended target goals for HbA1c in the US and UK [2,3]. Furthermore, the frequency of hypoglycemia has not decreased [4]. Despite recent developments in T1D management with newer insulins and technology, barriers in self-management severely limit the utility and adherence to these newer treatments. Such barriers include fear of hypoglycemia, diabetes related distress, psychological factors and intensive treatment regimens [5]. Hence, there is a strong need for further improvements in T1D care that can overcome these barriers.

The concept of automation where glucose sensor readings independently guide smartphone applications to deliver or suspend insulin delivery via insulin pumps with minimal human intervention offers the potential to overcome human barriers whilst improving diabetes-related care. Recent advances in technologies have allowed wireless connectivity of continuous glucose monitoring (CGM) and continuous subcutaneous insulin infusion systems (CSII) with controllers that can alter insulin delivery in response to changes in interstitial glucose. Following the early development of low and predictive low glucose basal insulin suspension sensor augmented insulin pump systems, more recent algorithms for subcutaneous insulin dosing have been developed that allow insulin dosing in an automated fashion via insulin pumps in response to changes in glucose detected by sensors [6–9].

In this review, we detail the emerging evidence for DIY APS. Whilst these systems are currently unregulated and not medically approved, their real-world use highlights potential metabolic and psychological benefits. We discuss the recent ethical and legal constraints which need to be remedied if more PWD are to access and safely utilize DIY APS. Using these evidence-based insights, as well as experiential learning from our evolving clinical practice, we provide a commentary that details implications of DIY APS for healthcare professionals and healthcare practice.

Background

Frustrated by the slow pace of development of artificial pancreas systems, a community of PWD and their families/caregivers united online using the hashtag '#WeAreNotWaiting' to promote the development of open source diabetes management systems. This DIY APS movement began via social media in 2013. Initially, it only included a few people who developed and shared computer codes from different programs to manage their CGM and insulin pumps [9]. Working together throughout the following year, they created and released the first open source artificial pancreas system

(OpenAPS). Throughout the last five years, the DIY movement has expanded exponentially.

DIY APS use open-source software to automate insulin delivery (e.g. OpenAPS [10], AndroidAPS [11] or Loop [12]). Each of these systems uses algorithms to continually collect and analyze data on glucose, insulin and food to predict future glucose levels. Commands are issued via a to the insulin pump to adjust insulin delivery with reference to the programmed glucose target levels and other personalized settings. This information is continuously fed-back into the system where it is analyzed to make future adjustments [13].

Some of the DIY APS set-ups require a hardware radio "bridge" (i.e. RileyLink) to communicate between the pump and the algorithm controller, due to the built-in radio communication of these particular pumps (older versions of Medtronic and OmniPod Eros pods). The software application AndroidAPS, which uses the OpenAPS algorithm in an Android app can communicate with numerous commercially available Bluetooth enabled insulin pumps (e.g. Sooil Dana R/RS, Roche Spirit Combo or Insight) and also Medtronic 512 – 554 pumps with a RileyLink. All DIY APS use existing Continuous Glucose Monitoring (CGM) Systems, and some DIY APS users choose to modify flash glucose monitors (e.g. Freestyle Libre with MiaoMiao adapter) as well [8].

People skilled in computing and self-managing diabetes continue to collaborate via social media platforms such as Twitter, Facebook and GitHub to further develop and improve technologies that help to automate the management of T1D. Current estimates suggest that there are approximately 1500 people worldwide using some form of DIY APS [14].

Evidence Base for DIY APS

A literature search was conducted via PubMed using the following terms: #WeAreNotWaiting, AndroidAPS, artificial pancreas system, automated insulin delivery; Do-It-Yourself, DIY, looping, nightscout, OpenAPS, open source and type 1 diabetes.

23 publications relating to DIY APS or related aspects (i.e. Nightscout) were identified. These included five quantitative research studies (See Table 1.); two qualitative research studies (See Table 2.); 6 conference abstracts (See Table 3.) and 10 miscellaneous publications (e.g. a review article, a monograph, a case report, commentaries and editorials) (See Table 4.).

While few randomized control trials have been conducted on DIY APS, an OpenAPS data repository has been established [14]. This provides insight into the real-world use of DIY systems and also sets the precedent for providing a free and accessible repository for researchers to access and a reporting mechanism for effectiveness and safety. A substantial proportion of the real- world experience of hybrid closed-loop systems has come from the DIY APS community [8,9].

Melmer and colleagues undertook a secondary analysis of 19495 days (53.4 years) of CGM data donated by 80 OpenAPS users [15]. They found individuals using DIY APS were achieving levels of glycemic control and variability that aligned with recently recommended clinic targets for CGM [16]. Petruzelkova, et al. conducted a pilot study comparing glycemic outcomes in 22 children (aged 6-15 years old) who were using either DIY APS (Android APS) or Smartguard systems during a 3-day winter ski camp [17]. They found that DIY APS to be ‘a safe and feasible alternative to the ‘Smartguard Technology’ during and after sustained physical activity. A survey of 209 caregivers for children and adolescents with T1D using DIY APS across 21 countries reported a reduction in HbA1c by 0.64% and an increased TIR of 16.48% [18]. These findings mirror themes identified by Litchman, et al. who analysed Twitter data from 328 OpenAPS users who reported improved HbA1c, glucose variability, and quality of life with a reduced sense of diabetes burden [19].

Using this dataset self-reported outcomes have been published that provide a wealth of data on effectiveness and safety in non-constrained trial settings. The reports all identify the following outcomes:

- Increased time in range
- Reduced glucose variability
- Reduced episodes of hypoglycemia
- Less reliance on accuracy of carbohydrate counting
- Improved overnight control
- Reduced mental burden

One limitation of these studies is that DIY users are perceived to represent a self-selected group of motivated and highly engaged individuals which skew the interpretation and generalizability of these findings. However, similar critiques have been levelled at other randomized control diabetes technology trials that mainly recruited engaged and well-informed participants [20]. Therefore, these studies reporting real-world outcomes provide relevant insights into the potential benefits and limitations of DIY APS in line with reports from commercial APS undergoing clinical trials [21].

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Why choose unregulated DIY APS systems?

The use of complex technologies such as CSII and CGM can offer improved metabolic benefits and quality of life for those with T1D [22]. However, the training required, time taken for continuous self-management and decision making with these technologies can also cause a burden that forms a barrier to achieving favorable metabolic and psychological outcomes [22]. Artificial pancreas systems that can constantly adapt to changing physiology and activities for PWD offer great advantages. As highlighted earlier, the real-world evidence base from DIY APS supports this expectation.

A recent survey presented as a poster at ADA in 2019 [23] studied motivations to pursue unregulated DIY APS systems. This survey sampled over 1058 participants of which 19.8% were caregivers. Respondents' motivations for using DIY APS were to achieve better overall glycemic control, to reduce short and long-term complications, to alleviate the burden of diabetes and to improve sleep for PWD and their caregivers.

Real-world use of the commercially available and medically regulated 670G system has highlighted some challenges. These include alarm fatigue, accurate carbohydrate meal time entry, requirement for changing to manual mode in unexpected or extreme changes (e.g. hyperglycemia, sick days),

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challenge with delayed meal absorptions (e.g. gastroparesis), and calibration requirements [24]. Such challenges may limit the widespread utility of this commercially available system despite its potential benefits.

Developers of DIY APS have designed systems that offer improved interoperability and customizable settings [25]. From our clinical experience these factors influence PWD's decisions to use DIY APS over commercial APS especially for those who prefer to use particular sensor or pump devices, to view and program APS via smartphones and smartwatches, to use remote monitoring possibilities. PWD using DIY APS also highlight challenges relating to time, effort and costs associated with building and learning to use the systems. Many seek support from the online communities [26].

Other benefits include the ability to review and adjust the code, having different features and built in training steps for some DIY APS options and responsive community support. In our practice, the use of DIY APS in situations such as surgery, pregnancy, young infants, steroid treatment, intensive prolonged exercise, religious fasting and delayed or omissions in mealtime bolus has given a wealth of clinical experience on the high level of metabolic control DIY APS can offer in extreme physiology and complex clinical, some of which have been reported previously [27]. This contrasts to experiences from working with the current commercially available regulated system (670G). Others highlight that whilst the 670G system improves time in range, it is less able to cope with variations in illnesses, lifestyles, extreme physiology or other situations which require modifications of targets [24].

Financial Drivers of DIY APS

Another motivation is potential lower costs of using DIY APS as compared to commercial systems. In the majority of the developed world, access to CSII and real-time CGM systems is limited due to high acquisition and running costs. For individuals self-funding and using older CSII systems capable of connectivity, DIY APS offers an approach to avoid further acquisition costs. For individuals who are unable to afford real-time CGM, DIY APS can analyze glucose data collected from ‘DIY CGM’ systems using adaptations to flash glucose monitoring at reduced cost [8,28]. This is raising concerns relating to the manipulation of an existing device beyond its intended use with potential pitfalls of reduced accuracy. This could impact on reliable glucose data and safe automated insulin dosing. Given the observed rise in access to flash glucose monitoring in the UK and other healthcare systems, this important topic requires further research to inform future discussions.

Ethical and Regulatory Constraints

DIY technologies are an example of a patient led care model, where technologies are developed by consumers bypassing testing and regulatory steps required for drugs and medically approved devices [29]. As discussed in this article, DIY APS may offer considerable advantages and benefits to the user over conventional methods of diabetes management and even commercially approved APS. Nevertheless, there are unresolved legal and ethical considerations for healthcare professionals who may wish to prescribe, support or even discuss these options with PWD or caregivers. Underlying this are unclear lines of accountability, in the event of an adverse event, between regulated device manufacturers, unregulated device manufacturers, algorithm coders, healthcare professionals, regulatory bodies such as FDA or MHRA and the end-user choosing to use an unregulated system.

A few diabetes advocacy groups and centers have released statements to guide healthcare professionals, as well as the wider community, especially given some recent concerns [30–35]. Our interpretation of the consensus view for healthcare professionals from these, as well as personal communication with other professional groups and medical insurers in the UK are summarized below (Table 5). It is important to note that these are not professional guidelines. Current views from these statements are that as DIY technologies are not regulated or medically approved, healthcare professionals should not prescribe, promote or initiate these options. However these statements do advise that healthcare professionals should support PWD to manage their condition in the way that they choose and should discuss unregulated DIY options if discussions are initiated by PWD to ensure open and transparent relationships.

Reporting of issues relating to DIY APS largely relies on a very responsive T1D community, where such practices are encouraged for the benefit and safety of others. Issues and improvements to the code are also posted via GitHub [36]. Formal reporting structures may need to be modified to allow healthcare professionals or PWD a channel to disclose concerns whilst maintaining confidentiality and data protection for all involved, in a manner that can be reviewed and analyzed. Medwatch by the FDA and MHRA Yellow Card Scheme are examples of generic, formal reporting structures that have been suggested in the US and UK respectively [37,38]. They are designed for medications and regulated devices. Hence, although they provide a basic reporting mechanism with free text entry of information, they may not capture sufficient detail consistently to provide contextual information regarding DIY APS use to distinguish between user and system errors. This could lead to incorrect conclusions or inferences. A recent case also highlights event reporting for patient led care models and its overall perception by regulatory bodies [35,37]. The DIY APS community is a growing international community and a reporting mechanism that extends beyond individual countries would allow a more sophisticated way of capturing and collating data on safety.

As discussed later, healthcare professionals have a strong role in supporting and educating PWD to make best use of diabetes technologies including DIY APS [39]. Whilst the above helps to provide a practice framework, it still does not resolve the ethical dilemmas or define lines of accountability or provide clarity over several situations routinely seen in clinics. For patient led care models, these aspects need further refinement. Until then, the healthcare professional groups will understandably remain cautious in their approach to DIY APS, despite the strong real-world data showing the benefits of using such systems.

Roles of HCP in DIY APS

Current regulated and DIY APS systems both require PWD to have core skills in diabetes self-management. To make best use of the systems, key numeracy, carbohydrate counting and device management skills are needed. Meal announcement, bolus dose calculations and management of special situations such as exercise, sick days or technical failure may need manual interventions in these hybrid systems. The systems are reliant on

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correct technical use of CSII and CGM systems. Hence, there is still a very strong role for HCP in understanding, implementing and supporting PWD via education, device selection and training to achieve optimal care via DIY APS [39,40].

For HCP, there is an increasing role in facilitating and supporting technological systems of care where they are able to guide PWD on the best technological options for them. This requires an understanding and insight into the various technological systems and how they can be adapted depending on the clinical context and systems being used.

The HCP may also play a key role in guiding PWD to use the automated technology. This requires support, training and behaviour change. Key aspects include managing expectations, building new habits around the technology and learning to trust the system. It also requires an understanding of the importance of patient support communities. For DIY APS, these are an integral part of support and learning for PWD, especially on technical and practical aspects that cannot be supported via HCP.

The implementation of APS requires a model where there is emphasis on increased initial training and education at initiation. The AndroidAPS integrates step by step training in a graded manner requiring the user to work through a sequence of objectives in order to unlock further automated dosing features. Our experience highlights that correct initiation and use can reduce the need for ongoing HCP and PWD or carer interaction. We have also noted that using automated systems allows HCP to spend less time on reviewing, analysing, changing treatment variables in clinic visits. It allows HCP to utilise their time with PWD more effectively and address other aspects of T1D care including psychological and emotional well-being.

DIY APS Training for HCP

Boughton and Hovorka highlight the need for diabetes specialist HCP to develop skills in using APS [41]. Traditionally, like the pharmaceutical industry, manufacturers of medical devices invest heavily in providing and sponsoring education for HCP to use their systems and promote research related to their devices to demonstrate effectiveness. This is done to develop skills, confidence and awareness to use new devices and systems. However, industry sponsored research and education may bias HCP understanding and interpretation of evidence.

Nevertheless, this approach is utilized for commercial APS. However, DIY APS, being a patient-led initiative, does not receive the same level of industry sponsored support for education and research.

Healthcare professionals supporting PWD are becoming aware of DIY APS. However, many need to develop a deeper understanding of DIY APS and its potential benefits and limitations. Given the demand and interest, training opportunities for healthcare professionals to learn about DIY APS are becoming available [42]. People using DIY APS have created online learning resources for healthcare professionals that clearly summarize relevant information about how DIY APS works [10,11,40].

Future Research Priorities for DIY APS

While the evidence on DIY APS consistently shows users achieve decreased HbA1c values and increased TIR, important research questions remain unanswered. Potential topics include identifying characteristics and motivations of PWD exploring, building and using DIY APS; assessing impact upon quality of life and diabetes burden; and, understanding potential barriers that influence PWD to not use DIY APS [43].

Future directions for DIY APS related research includes a European Commission funded initiative, The OPEN Project, which provides a patient and user-led quantitative and qualitative research approach [44]. Given the lack of resources for formal trials, it is likely that such approaches will help provide further real-world evidence including quality of life data. Tidepool, a non-profit software organization, has recently secured funding from partners like the JDRF and

Helmsley Charitable trust to deliver an FDA regulated version of Loop, which is currently a DIY closed loop application [45]. Similarly, a group in New Zealand recently received funding and approval for an RCT using a version of AndroidAPS [46]. How a regulated application would impact use DIY APS in future is unclear.

Conclusion

DIY APS is radically changing T1D management. The automation of the process of frequently analyzing glucose readings and appropriately titrating insulin delivery is liberating PWD from some of the demands of intensively managing T1D. PWD require access to CSII and CGM, motivation and peer support to access, build and use DIY APS. The rapidly growing awareness and use of DIY APS is being facilitated via social media and support from DIY APS online communities.

Within this super-specialized area of T1D management, the expertise of DIY APS users has outstripped that of many HCP. While educational, ethical and legal constraints need to be resolved, HCP still need to stay abreast of this rapidly developing area. Further research is needed to inform policy and practice relating to DIY APS. Meanwhile, HCP continue to learn from PWD's real-world experiences of building and using DIY APS to improve metabolic and psychological outcomes.

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New Era in MedicineChallenges and Opportunities for New Form of Health ProductionChallenges and Opportunities for New Form of Health Production. JAMA 2016;315:1447–8. doi:10.1001/jama.2016.1903.

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Tables

Table 1. DIY APS Quantitative Research Literature

<table>
<tr><th>Authors</th><th>Country</th><th>Research Methods</th><th>Aims</th><th>Sample (n=)</th><th>Outcomes</th></tr>
<tr><td>Melmer et al., 2019[15]</td><td>Switzerland & USA</td><td>Quantitative
Cohort Study
Secondary Analysis of donated data sets on OpenAPS Repository</td><td>Describe DIY APS Outcomes: Glycaemic control & variability</td><td>80 OpenAPS Users (Adults?)</td><td>19495 days (53.4 years) of CGM records analyzed
MG[a] = 7.6 ± 1.1 mmol/L
eA1c[b] = 6.4 ± 0.7%
TIR[c]=77.5 ± 10.5%
TBR[d]=4.3 ± 3.6%
TAR[e]=18.2 ± 11.0%</td></tr>
<tr><td>Petruzelkova et al., 2018[17]</td><td>Czech Republic</td><td>Quantitative
Pilot Study
3-day pediatric winter ski camp</td><td>Compare DIY APS vs SmartGuard outcomes: mean glucose & TIR: Predictive low glucose suspend (PLGS) vs Android APS (AAPS)</td><td>22 children (6–15 years old)</td><td><table><tr><th></th><th>PLGS</th><th>AAPS</th><th>P value</th></tr><tr><td>MG</td><td>7.7 – 2.8</td><td>7.2 – 2.7</td><td><0.042</td></tr><tr><td>TIR</td><td>82% (64 to 85)</td><td>82% (77 to 86)</td><td>0.3</td></tr><tr><td>TBR</td><td>3% (2 to 4.5)</td><td>5% (2 to 6)</td><td>0.6</td></tr><tr><td>TAR</td><td>23.6 ± 14.7%</td><td>15.4 ± 9.3%</td><td>< 0.0001</td></tr></table></td></tr>
<tr><td>Braune et al., 2019[18]</td><td>International</td><td>Quantitative
Online Survey</td><td>Assess DIY APS Outcomes: HbA1c, TIR before and after DIYAPS initiation and problems during DIYAPS use</td><td>209 caregivers from 21 countries</td><td><table><tr><th></th><th>Pre-DIY APS</th><th>Post-DIY APS</th><th>P value</th></tr><tr><td>HbA1c</td><td>6.91%
[SD 0.88%]</td><td>6.27%
[SD 0.67]</td><td><0.001</td></tr><tr><td>TIR</td><td>64.2%
[SD 15.94]</td><td>80.68%
[SD 9.26]</td><td><0.001</td></tr></table></td></tr>
<tr><td>Hng & Burren, 2018[47]</td><td>Australia</td><td>Quantitative
Online Survey</td><td>DIY APS Users' Characteristics & Outcomes</td><td>19 DIY APS Users ('Loopers')</td><td>'Loopers' reported
(i) more time in target glucose range (100%)
(ii) better sleep (79%)
(iii) less frequent hypoglycaemia (74%)
(iv) improved HbA1c (68%)
(v) less severe hypoglycaemia (53%)
(vi) more confidence (47%)
(vii) more energy (37%)
(viii) fewer mood swings (32%)</td></tr>
<tr><td>Lee, et al. 2017[48]</td><td>USA</td><td>Quantitative
Online Survey</td><td>Evaluate changes in health behaviors and health outcomes associated with Nightscout use

Compare demographic and disease charac- teristics of users versus nonusers of Nightscout

Describe the uses and personalization of Nightscout</td><td>1268 members of 'CGM in the Cloud' community (Children & Adults)</td><td>Nightscout users reported significant improvements in HbA1c and QoL

Nightscout Users' Characteristics:
• Non-Hispanic whites (90.2%)
• type 1 diabetes (99.4%)
• Using Insulin Pump Therapy (85.6%) and CGM (97.0%) with
• Private health insurance (83.8%).

• Nightscout use was more prevalent among children compared adolescents and adults</td></tr>
</table>

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[a] MG=Mean Glucose [b]eA1c=estimated HbA1c [c]TIR= Time in Range (3.9–10mmol/L) [d]Time Below Range (< 3.9mmol/L) [e]Time Above Range (>10mmol/l)

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Table 2. DIY APS Qualitative Research Literature

Authors	Country	Research Methods	Aims	Sample (n=)	Outcomes
Litchman et al., 2019[19]	USA	Qualitative 'Netnography' (Internet Enthnography) to analyze #OpenAPS on Twitter over a two-year period	Examine Twitter data to understand how patients, caregivers, and care partners perceive OpenAPS, the personal and emotional ramifications of using OpenAPS, and the influence of OpenAPS on daily life	328 participants' 3347 tweets	Overarching theme: OpenAPS changes lives 5 subthemes relating to OpenAPS use emerged from the data: (1) Improved self-reported A1C and glucose variability (2) Improved sense of diabetes burden and quality of life (3) OpenAPS perceived as safe (4) Patient/Caregiver-Provider interaction related to OpenAPS (5) Technology adapted for OpenAPS users' needs
Gavrila, et al., 2019[26]	USA	Qualitative Semi-structured interviews	Describe Nightscout Outcomes: Glycaemic control & variability	20 interviews	'Members of the CGM in the Cloud Facebook group identified peer support through giving and receiving technical, emotional, and medical support, as well as giving back to the larger community by paying it forward. Peer support also extended beyond the online forum, connecting people in person, whether they were local or across the country.'

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Table 3. DIY APS Selection of Unpublished Research

<table>
<tr><th>Authors</th><th>Country</th><th>Format</th><th>Research Methods</th><th>Aims</th><th>Sample (n=)</th><th>Outcomes</th></tr>
<tr><td>Braune et al., 2019[23]</td><td>International</td><td>Conference Proceeding</td><td>Quantitative Online Survey</td><td>Examine motivations of DIY APS users and caregivers to build and maintain DIY APS</td><td>1058 respondents from 34 countries</td><td>User Characteristics:
Adult users (80.2%; 43% female; median age 41 years) with T1D (98.9%) for 25.2 years ±13.3

Caregivers for children (19.8%; 47.4% female; median age 10 years) with T1D (99.4%) for 5.1 years ±3.9.
(Post Treatment = Post-Tx)
<table>
<tr><th></th><th>HbA1c Baseline</th><th>HbA1c Post-Tx</th></tr>
<tr><td>OpenAPS</td><td>7.07% ±1.07</td><td>6.24% ±0.68%</td></tr>
<tr><td>TIR</td><td>63.21% ±16.27</td><td>83.07% ±10.11</td></tr>
</table>
<table>
<tr><td>Cost ($USD/year)</td><td>$712</td></tr>
</table></td></tr>
<tr><td>Wilmot et al., 2019[49]</td><td>UK</td><td>Poster</td><td>Case Review</td><td>Comparing glucose outcomes Open APS vs CSII & FreeStyle Libre (FSL)</td><td>9 Open APS users

30 CSII & FreeStyle Libre</td><td>
<table>
<tr><th></th><th>Baseline</th><th>Post-Tx</th><th>P value</th></tr>
<tr><td>OpenAPS HbA1c</td><td>7.3±1.4%</td><td>6.2±0.4%</td><td>=0.046</td></tr>
<tr><td>CSII&FSL HbA1c</td><td>7.6±0.8%</td><td>7.2±0.6%</td><td>=0.030</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Post-Tx TIR</td><td>OpenAPS 83.6±7.2%</td><td>CSII&FSL 55.9±11.5%</td><td><0.001</td></tr>
<tr><td>Post-Tx TBR</td><td>2.5±1.8%</td><td>5.7±4.7%</td><td>=0.006</td></tr>
</table></td></tr>
<tr><td>Lewis et al., 2018[50]</td><td>USA</td><td>Oral Presentation</td><td>Retrospective Cross-over analysis retrospective of continuous BG (blood glucose) readings recorded during 2-week segments 4-6 weeks before and after initiation of OpenAPS</td><td>To compare mean BG, TIR (70-180 mg/dl), and time above and below clinically meaningful thresholds</td><td>20 OpenAPS users</td><td>
<table>
<tr><th></th><th>Pre-Open APS</th><th>Post-Open APS</th></tr>
<tr><td>HbA1c</td><td>6.4%</td><td>6.1%</td></tr>
<tr><td>Mean BG</td><td>135.7 mg/dl</td><td>128.3 mg/dl</td></tr>
<tr><td>TIR</td><td>75.8%</td><td>82.2%</td></tr>
</table></td></tr>
<tr><td>Provenzano et al., 2018[51]</td><td>Italy</td><td>Poster</td><td>Case Review</td><td>To assess effectiveness of OpenAPS; Primary Outcomes A1c and % of time into hypoglycemia</td><td>30 people (male/female = 19/11; age = 35.9 years ± 12.52 DS) with T1D</td><td>
<table>
<tr><th></th><th>Baseline</th><th>Post-Tx</th><th>P value</th></tr>
<tr><td>HbA1c</td><td>7.17% ± 0.49</td><td>6.61% ± 0.47</td><td><0.05</td></tr>
<tr><td>%Time Hypo</td><td>8.55% ± 5.81 o</td><td>2.48% ± 1.16</td><td>Not Available</td></tr>
</table></td></tr>
</table>

https://doi.org/10.1177/1932296819894296

<table>
<tr><td></td><td></td><td></td><td></td><td>(glycemia <70mg%) before and 3 months after closing the loop</td><td></td><td></td></tr>
<tr><td>Choi et al., 2018[52]</td><td>South Korea</td><td>Poster</td><td>Case Review</td><td>To compare HbA1c, TIR (80-180 mg/dl) time in high and low glycemic range</td><td>20 OpenAPS users (10 Female, Mean Age 11.9 ± 6.9 years; Median openAPS duration was 180 (30-240) days)</td><td><table><tr><th></th><th>Baseline</th><th>Post-Tx</th><th>P value</th></tr><tr><td>HbA1c</td><td>6.8 ± 1.0%</td><td>6.3 ± 0.7%</td><td><0.001</td></tr><tr><td>TIR</td><td>70.1 ± 16.4%</td><td>83.3 ± 10.1%</td><td><0.001</td></tr></table></td></tr>
<tr><td>Lewis et al., 2016[53]</td><td>USA</td><td>Oral Presentation</td><td>Mixed Methods Survey</td><td>Assess users' experiences of OpenAPS</td><td>18 respondents from initial cohort of 40 OpenAPS users</td><td>User Characteristics:
Users (67% male, 61% adults, median age 27 years, 15 years with T1D, 10 years on pump, 3 years on CGM<table><tr><th></th><th>HbA1c Baseline</th><th>HbA1c Post-Tx</th></tr><tr><td>OpenAPS</td><td>7.1%</td><td>6.2%</td></tr><tr><td>TIR</td><td>58%</td><td>81%</td></tr></table>94% respondents highlighted 'Improved Sleep Quality'</td></tr>
</table>

Table 4. DIY APS Other Publications

Authors	Country	Literature Type	Focus
Marshall et al, 2019 [54]	UK	Commentary	Patient physician perspective of 3 cases highlighting benefits of using DIY APS and utilising this approach in pregnancy, care of a child and surgery
Patton, 2019[55]	Australia	Case Report	User's Experience from One year of DIY APS
Crabtree et al., 2019[8]	UK	Review	DIY APS: Principles, Outcomes, Ethics
de Bock, 2019[29]	Australia	Editorial	DIY APS Dilemmas facing Healthcare Professionals
Waugh et al., 2018[7]	UK	Editorial	Need for DIY APS Research
Barnard et al., 2018[56]	International	Commentary	DIY APS Overview & Dilemmas
Lewis, 2018[13]	USA	View point	DIY History, Pro's and Con's, Impact
Lee et al., 2016[57]	USA	View point	Nightscout Overview and Regulatory Dilemmas
Lewis et al., 2018[39]	USA	Letter to Editor	Setting Expectations for Successful Artificial Pancreas/Hybrid Closed Loop/Automated Insulin Delivery Adoption
Lewis et al., 2016[53]	USA	Letter to Editor	Real-World Use of Open Source Artificial Pancreas Systems
Lewis, 2019[40]	USA	Monograph	DIY APS User's Guide

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Table 5. Consensus from various statements produced on DIY APS use for healthcare professionals

Issues	Guidance for Healthcare Professionals	Authors
Prescribing	Not regulated and not medically approved	Diabetes Australia [30], JDRF UK [31], Steno Diabetes Center Copenhagen [32], Diabetes UK [33], FDA [34]
	Cannot prescribe, promote, initiate or recommend	Diabetes Australia [30], JDRF UK [31], Steno Diabetes Center Copenhagen [32], Diabetes UK [33]
	Must only recommend authorised technology	Diabetes Australia [30], JDRF UK [31], Steno Diabetes Center Copenhagen [32], Diabetes UK [33]
Discussing	Should discuss if topic is raised by person with diabetes or carer, especially risks and medically unregulated status	Diabetes UK [33]
Supporting	Respect the right of individuals to choose how they wish to manage their or their dependant's diabetes	Diabetes Australia [30], JDRF UK [31], Steno Diabetes Center Copenhagen [32], Diabetes UK [33]
	Continue to support and provide regulated devices (pump, CGM, Flash GM) if meet criteria even if patient intends to pursue DIY APS	Diabetes Australia [30], JDRF UK [31], Steno Diabetes Center Copenhagen [32], Diabetes UK [33]
	Cannot help with procurement of medical equipment other than approved systems	Steno Diabetes Center Copenhagen [32]
	Can help with evaluation of glucose values and insulin dosing via information from DIY APS platforms but may not provide advice on DIY APS settings	Steno Diabetes Center Copenhagen [32]
	Cannot refer to unregulated information sources	Steno Diabetes Center Copenhagen [32]
	Should direct PWD to online DIY APS communities for advice	Diabetes UK [33]
Documenting	Ensure clear documentation of discussions with patients or carers, especially discussions regarding risks and unregulated status of DIY APS	Diabetes UK [33]

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