

Short Paper

Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Children and Adolescents With Type 1 Diabetes: Online Survey and Analysis of Self-Reported Clinical Outcomes

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Abstract

Background: Patient-driven initiatives have made uptake of Do-it-Yourself Artificial Pancreas Systems (DIYAPS) increasingly popular among people with diabetes of all ages. Observational studies have shown improvements in glycemic control and quality of life among adults with diabetes. However, there is a lack of research examining outcomes of children and adolescents with DIYAPS in everyday life and their social context.

Objective: This survey assesses the self-reported clinical outcomes of a pediatric population using DIYAPS in the real world.

Methods: An online survey was distributed to caregivers to assess the hemoglobin A_{1c} levels and time in range (TIR) before and after DIYAPS initiation and problems during DIYAPS use.

Results: A total of 209 caregivers of children from 21 countries responded to the survey. Of the children, 47.4% were female, with a median age of 10 years, and 99.4% had type 1 diabetes, with a median duration of 4.3 years (SD 3.9). The median duration of DIYAPS use was 7.5 (SD 10.0) months. Clinical outcomes improved significantly, including the hemoglobin A_{1c} levels (from 6.91% [SD 0.88%] to 6.27% [SD 0.67]; $P < .001$) and TIR (from 64.2% [SD 15.94] to 80.68% [SD 9.26]; $P < .001$).

Conclusions: Improved glycemic outcomes were found across all pediatric age groups, including adolescents and very young children. These findings are in line with clinical trial results from commercially developed closed-loop systems.

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KEYWORDS

artificial pancreas; do it yourself; open source; mobile health; diabetes; type 1 diabetes; pediatric diabetes; closed loop; automated insulin delivery

Introduction

Over 30 years ago, the Diabetes Control and Complications Trial showed benefits of intensive diabetes management in delaying the onset and reducing the severity of diabetes-related complications [1]. People diagnosed at a young age are particularly at risk for developing long-term complications and comorbidities during childhood and later throughout life. Owing to this, therapeutic guidelines recommend tight glycemic control, with a target hemoglobin A_{1c} (HbA_{1c}) level <7.0% (53 mmol/mol) for all people with diabetes [2]. For children, adolescents, and young adults, guidelines even recommend the lowest achievable HbA_{1c} without undue exposure to severe hypoglycemia, balanced with quality of life and burden of care [3]. Today, despite significant advances in therapy and technological developments, only 17% of all children and adolescents with diabetes achieve an HbA_{1c} level <7.5% (58 mmol/mol) [4].

Multiple clinical trials have shown that closed-loop insulin delivery systems (also known as automated insulin delivery systems or “artificial pancreas”) designed for commercial use are safe and effective in reducing hyper- and hypoglycemia in people of all age groups with diabetes, including adolescents and children [5-9]. Closed-loop systems are characterized by automated insulin delivery in response to the user’s glucose level. Although commercial systems are under development and some have recently become available in a limited number of countries, they are not universally available, accessible, or affordable. Behind the hashtag #WeAreNotWaiting, a community of people with diabetes and their families have created new tools and systems, in addition to the existing, already approved medical devices, and shared them via open source platforms in order to help others with diabetes better utilize their devices and data. One of the most significant innovations to emerge through this movement is the Do-it-Yourself Artificial Pancreas System (DIYAPS). In DIYAPS, commercially available and approved medical devices such as insulin pumps and continuous glucose monitoring sensors are connected and remotely controlled by systems using open-source algorithms to automate insulin delivery. While these systems are cocreated by the DIYAPS community, each user has to build his/her own system and use it at his/her own risk. This includes children and adolescents whose caregivers build and maintain these systems on their behalf.

Initial observational studies have shown significant improvements in glycemic control, quality of life, and sleep quality in adult DIYAPS users [10-12]. A Czech pilot study was the first to report findings in a pediatric population and showed that AndroidAPS (an Android-based DIYAPS) was a

safe and feasible alternative to a commercially available system, with predictive low glucose suspension during a winter sports camp [13]. There remains, however, a lack of research examining outcomes of children and adolescents with DIYAPS in everyday life and their social context. This survey assesses the self-reported clinical outcomes of this specific user group.

Methods

An online survey was distributed to caregivers using DIYAPS through the Facebook groups “Looped” (>11,500 members as of May 2019) and “AndroidAPS users” (>2800 members as of May 2019), other regional subgroups on Facebook, and Twitter. In this context, a caregiver was either a family member or another person who regularly looked after the child or adolescent with diabetes. Demographics and socioeconomic status of the study population were assessed. Participants were also asked for their child’s last three HbA_{1c} measurements and mean time in range (TIR; sensor glucose level between 70 mg/dL or 4.0 mmol/L and 180 mg/dL or 10.0 mmol/L) before and after DIYAPS commencement. In an open-ended question, we asked respondents if they experienced difficulties in making the transition to DIYAPS.

The survey was designed by an interdisciplinary team of medical doctors, social scientists, public health researchers, and patient innovators. Participants were able to choose between two languages (English and German). Data were collected, managed, and analyzed using the secure REDCap electronic data capture tools hosted at Charité - Universitätsmedizin Berlin [14]. Arithmetic mean, SD, and two-tailed heteroscedastic *t* test were used to perform the statistical analysis. The survey was approved by the Charité ethics committee (EA2/140/18).

Results

Overall, 209 participants from 21 countries (74.3% from Europe, 12.0% from North America, 6.9% from Asia, and 6.9% from Australia) responded to the survey (Table 1). Of the total, 47.4% children were female, with a median age of 10 years (range: 3-20 years), and 99.4% had type 1 diabetes. The median duration of diabetes was 4.3 (SD 3.9) years, and various types of DIYAPS (AndroidAPS, 48.0%; OpenAPS, 28.4%; Loop, 28.4%; other, 3.4%; and several systems over time, 7.5%) were used. The group had used these systems for a median of 7.5 (SD 10.0) months. Analysis of caregivers’ socioeconomic status indicated that the cohort was evenly distributed across a range of income groups. The responding caregivers’ employment rate was 91.4%, with 58.4% working full-time and 31.8% working part-time. Analysis of the education level showed that 65.2% had an academic or professional degree.

Table 1. Demographic data of children and adolescents using Do-it-Yourself Artificial Pancreas Systems, who participated in this survey.

Demographic	n (%)
Child's gender	
Female	83 (47.4)
Male	92 (52.6)
Child's age (years)	
3	6 (3.4)
4	11 (6.3)
5	14 (8.0)
6	14 (8.0)
7	12 (6.9)
8	12 (6.9)
9	15 (8.6)
10	20 (11.4)
11	9 (5.1)
12	19 (10.9)
13	11 (6.3)
14	10 (5.7)
15	12 (6.9)
16	2 (1.1)
17	2 (1.1)
18	2 (1.1)
20	4 (2.3)
Child's type of diabetes	
Type 1	174 (99.4)
Type 2	0 (0.0)
Other/Unknown	1 (0.6)
Type of DIYAPS^a used	
OpenAPS	43 (28.4)
AndroidAPS	71 (48.0)
Loop	42 (28.4)
Other/Unknown	5 (3.4)
Region (country of residence)	
Europe	130 (74.3)
Austria	3 (1.7)
Bulgaria	9 (5.1)
Croatia	2 (1.1)
Czech Republic	12 (6.9)
Denmark	2 (1.1)
Finland	8 (4.6)
France	1 (0.6)
Germany	46 (26.3)
Greece	2 (1.1)
Ireland	3 (1.7)

Demographic	n (%)
Luxembourg	1 (0.6)
Poland	2 (1.1)
Slovakia	4 (2.3)
Spain	3 (1.7)
Sweden	8 (4.6)
Switzerland	1 (0.6)
United Kingdom	23 (13.1)
North America	21 (12.0)
Canada	5 (2.9)
United States	16 (9.1)
Asia	12 (6.9)
South Korea	12 (6.9)
Australia/Western Pacific	12 (6.9)
Australia	12 (6.9)
Caregiver's occupational status	
Full-time	101 (58.4)
Part-time	55 (31.8)
Unemployed	10 (5.8)
Retired	0 (0.0)
Student	2 (1.2)
Other/Unknown	5 (2.9)
Caregiver's household annual net income (US \$)	
<20,000	19 (12.0)
20,000-34,999	12 (7.6)
35,000-49,999	19 (12.0)
50,000-74,999	33 (20.9)
75,000-99,999	24 (15.2)
≥100,000	40 (25.9)

^aDIYAPS: Do-it-Yourself Artificial Pancreas Systems.

On an average, the cohort already had a baseline glycemic control level below the target HbA_{1c} recommended by the International Society for Pediatric and Adolescent Diabetes [11]. Nevertheless, a significant HbA_{1c} improvement of -0.64 percentage points, from a mean HbA_{1c} of 6.91% (SD 0.88%; or 52.0 mmol/mol) to 6.27% (SD 0.67; or 45.0 mmol/mol) after commencing DIYAPS was reported ($P < .001$; Figure 1). The mean TIR increased from 64.2% (SD 15.94%) to 80.68% (SD 9.26; $P < .001$; Figure 2). Participants also reported a continuous HbA_{1c} improvement over time, starting from a mean HbA_{1c} of 6.39% (SD 0.65%; or 46.3 mmol/mol) as their first result after commencement, which equals an improvement of -0.52

percentage points compared to the baseline level, gradually improving to a mean HbA_{1c} of 6.26% (SD 0.69%; or 44.9 mmol/mol) as their second result and a mean HbA_{1c} of 6.06% (SD 0.66%; or 42.7 mmol/mol) as their third result, which equals an improvement of -0.85 percentage points. Users of all DIYAPS systems and all age groups showed similar results (Table 2).

Among the relatively few respondents who indicated difficulties with DIYAPS ($n=29$), the primary challenge was sourcing the necessary devices and setting up the closed loop. In both cases, successful solutions were primarily found online, although for some, this was a time-consuming process.

Figure 1. Mean last HbA_{1c} levels of children and adolescents before (black) and after (white) the initiation of Do-it-Yourself Artificial Pancreas Systems. HbA_{1c}: hemoglobin A_{1c}.

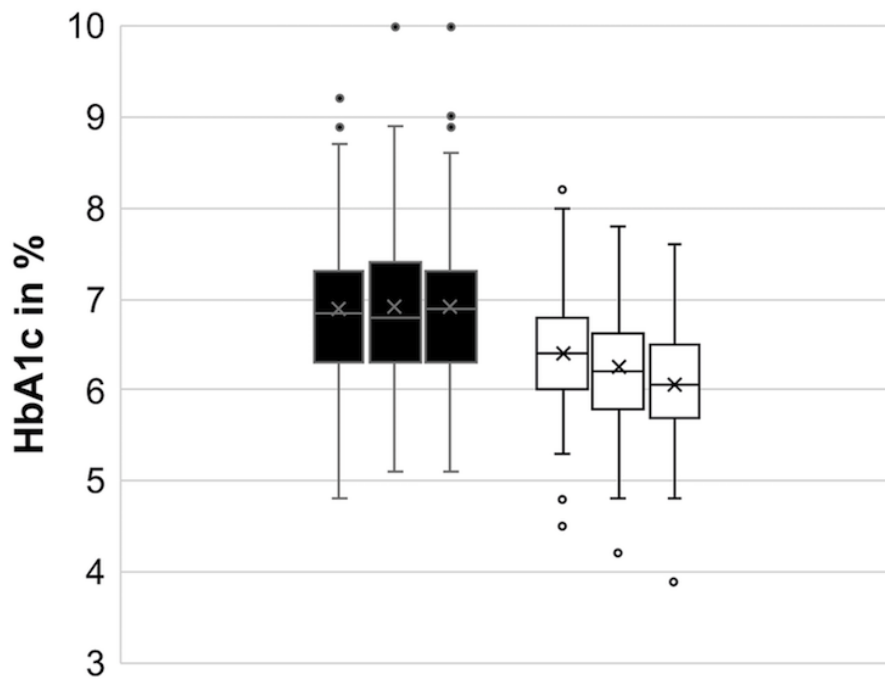


Figure 2. Mean time in range for sensor glucose levels of children and adolescents before (black) and after (white) the initiation of Do-it-Yourself Artificial Pancreas Systems.

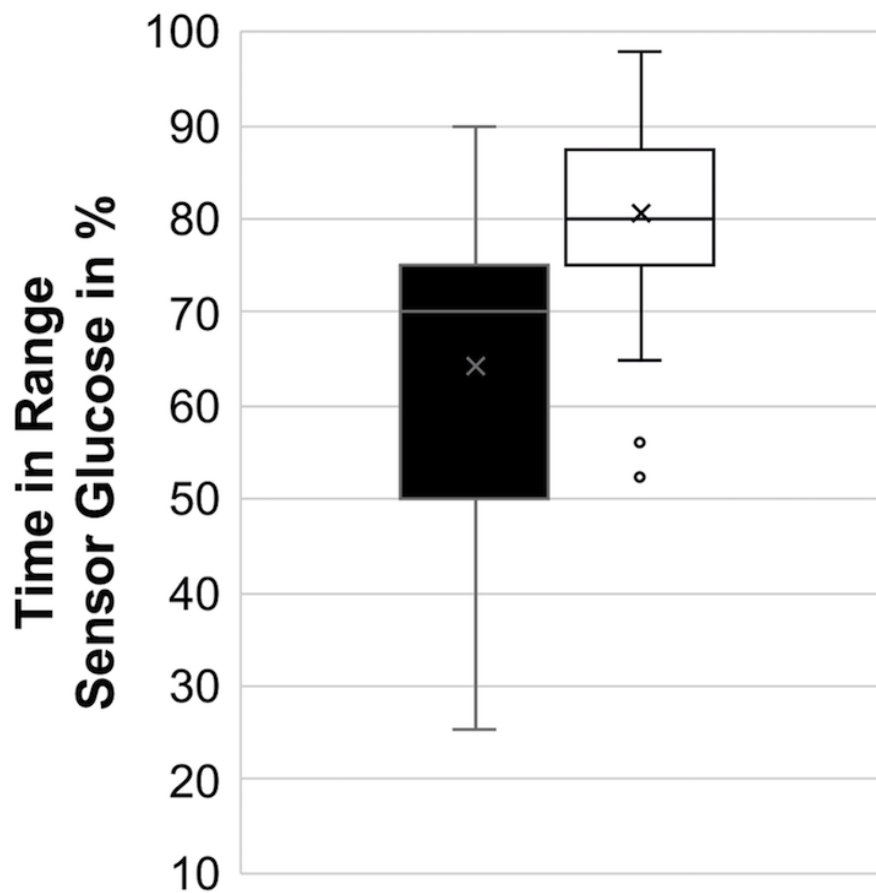


Table 2. Clinical outcomes in children and adolescents before and after initiation of Do-it-Yourself Artificial Pancreas Systems.

Outcomes and users	Mean (SD)
All DIYAPS^a users	
HbA_{1c}^b	
Before	6.91 (0.88)
After initiation	6.27 (0.67)
Time in range	
Before	64.2 (15.94)
After initiation	80.68 (9.26)
OpenAPS users	
HbA_{1c}	
Before	7.10 (0.75)
After initiation	6.36 (0.72)
Time in range	
Before	67.1 (14.4)
After initiation	81.7 (7.7)
AndroidAPS users	
HbA_{1c}	
Before	6.85 (0.79)
After initiation	6.24 (0.73)
Time in range	
Before	63.8 (15.0)
After initiation	79.5 (7.9)
Loop users	
HbA_{1c}	
Before	6.99 (1.00)
After initiation	6.39 (0.61)
Time in range	
Before	64.2 (15.4)
After initiation	79.1 (8.4)
Children (3-9 years)	
HbA_{1c}	
Before	6.89 (0.80)
After initiation	6.31 (0.59)
Time in range	
Before	66.5 (15.9)
After initiation	79.2 (8.4)
Adolescents and young adults (10-20 years old)	
HbA_{1c}	
Before	6.93 (0.95)
After initiation	6.23 (0.75)

Outcomes and users	Mean (SD)
Time in range	
Before	62.2 (15.9)
After initiation	80.1 (9.3)

^aDIYAPS: Do-it-Yourself Artificial Pancreas Systems.

^bHbA_{1c}: hemoglobin A_{1c}.

Discussion

This survey is currently the largest study of DIYAPS users on a global level and provides new evidence about real-world use of these systems in children and adolescents. Improvement of glycemic control was consistently reported across all pediatric age groups, including adolescents and very young children. Thus, the beneficial effects observed in adult users appear to apply to the pediatric population with no age limitations. These findings are in line with clinical trial results and improvements seen in commercially developed closed-loop systems [5-9].

The occupational and educational level of the responding caregivers was well above the population level; however, the household income levels varied. This finding suggests that DIYAPS may be financially accessible to a variety of socioeconomic groups. Further investigations on the role of all household caregivers' socioeconomic status and barriers to scaling up use of these systems would be of interest.

Although studies investigating DIYAPS consistently have demonstrated significant improvements in a variety of clinical and patient-reported outcomes, with no accompanying severe adverse events, various stakeholders continue to view the use of DIYAPS with skepticism. Ethical and legal questions have been raised, especially for the vulnerable group of children and adolescents. The off-label use of unregulated medical devices as well as the role of the caregiver taking the decision independently from doctors is the subject of intense debate [15]. Children are dependent on their caregivers' technological and medical knowledge and skills, both of which are prerequisites of understanding, building, and maintaining a DIYAPS. Moreover, a limited number of diabetes specialists are familiar with DIYAPS and their in-built safety mechanisms. Knowledge is also limited because research focusing on pediatric cohorts have tended to lag behind the adult population. Studies such as this one may therefore help alleviate concerns of health care

providers as they are increasingly confronted with caregivers who have opted for DIYAPS for their child's diabetes management in their day-to-day clinical practice.

This study has several limitations. Outcomes were self-reported by caregivers. Until recently, self-reported data have not been commonly used in clinical research. However, a Norwegian study previously found that self-reported outcomes showed good concordance with data from patient registries reported by health care professionals [16]. Continuous glucose monitoring data were not directly captured in this survey. Therefore, time in hypoglycemia was not assessed. Time spans between HbA_{1c} measurements and TIR as well as DIYAPS versions, settings, and targets might differ individually. With a median DIYAPS experience of 7.5 months, some participants were unable to provide all three HbA_{1c} measurements. With education level and occupational status above the average population level and previous baseline glycemic outcomes below the target, the cohort or DIYAPS community may, in general, not be representative of all families having children with diabetes. To fully evaluate both the benefits and risks of DIYAPS, safety and efficacy trials for all age groups are needed.

The growing #WeAreNotWaiting movement globally is indicative of a paradigm shift whereby traditional, top-down health care solutions are increasingly being complemented by bottom-up and patient-led initiatives. This survey, novel in both its sample size and international scope, provides new evidence that DIYAPS can offer substantial improvements in clinical outcomes for children and adolescents, even in a population that already has achieved glycemic outcomes below the target. However, more research is needed to examine the mechanisms by which these results are achieved; lived experiences of DIYAPS users; adverse events; and what can be learned from this movement in order to accelerate the diffusion of APS technology across the population.

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Authors' Contributions

KB, DL, and KR performed the literature search. KB, SO, BC, AT, DL, BH, IW, and KR designed the survey. KB and KR collected the data. KB, SO, BC, AT, DL, BH, IW, and KR performed the data analysis and interpretation. KB, SO, KR, BC, IW, and DL wrote the article. All authors read and approved the article.

Conflicts of Interest

KB reports grants from the Berlin Institute of Health (BIH) Clinician Scientist program; fees for medical consulting from Medtronic Diabetes as a member of the Advisory Board "Impact"; medical consulting fees from Roche Diabetes Care; and paid talks for Dexcom, Medtronic Diabetes, and Bertelsmann Stiftung outside the submitted work. AT reports personal fees from Dexcom, Roche Diabetes Care, IME-DC, and Ypsomed; nonfinancial support from Sooil; and personal fees from Gruber-Dehong GmbH outside the submitted work. DL reports grants from Robert Wood Johnson Foundation and personal fees from Lilly, Diabeloop, Roche Diabetes Care, Novo Nordisk, and Tandem outside the submitted work. BH reports personal fees from Roche Pharma, Roche Diabetes Care, Novo Nordisk, LifeScan, Bayer AG, and Medtronic Diabetes outside the submitted work. KR is advisory board member of Lilly Diabetes Care and Abbott Diabetes Care outside the submitted work. The remaining authors declare no conflicts of interest.

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Abbreviations

DIYAPS: Do-it-Yourself Artificial Pancreas Systems

HbA_{1c}: hemoglobin A_{1c}

TIR: time in range

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