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ORIGINAL RESEARCH

Association of British Clinical Diabetologists, Diabetes Technology Network UK and Association of Children's Diabetes Clinicians Survey of UK Healthcare Professional Attitudes Towards Open-Source Automated Insulin Delivery Systems

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ABSTRACT

Introduction: Automated insulin delivery (AID) systems can enable improved glycaemic outcomes with reduced mental burden. Open-source AID (OS-AID) systems overcome some of the developmental and access barriers enabling a wider use of these systems. Limited data are available on healthcare professional (HCP) opinions and current practice regarding these systems. The aim of this survey was to gain insight into HCP perceptions and practices around OS-AID.

Methods: This survey was developed collaboratively with OS-AID users and distributed to adult and children's teams, using an online survey tool. Results were received between February and April 2019. Responses were assessed using simple descriptive statistics with analyses stratified by respondent characteristics.

Results: 317 responses were obtained from a range of HCPs in both adult and paediatric services. Key results include: HCP perception of OS-AID as "risky in the wrong hands" (43%); 91% felt uncomfortable initiating discussions around OS-AID because of lack of regulation (67%) and/or their own lack of knowledge

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(63%). Half of HCPs (47%) reported that they would choose OS-AID if they themselves had type 1 diabetes.
Conclusions: HCPs are generally supportive of OS-AID users but many feel uncomfortable with the technicalities of the systems given the lack of approval. Knowledge around the use of these systems was limited. Re-assessment of HCP perceptions should be performed in the future given the evolving landscape of diabetes technology, recent consensus statements and emerging ethical and legal perspectives.

PLAIN LANGUAGE SUMMARY

Open-source automated insulin delivery systems are an increasingly encountered diabetes technology. These involve a small glucose sensor and an insulin delivery device called an insulin pump. These two devices interact to allow adjustment of insulin delivery to maintain glucose levels in a desirable range. The computer codes which drive these systems are developed by people with diabetes or their families rather than by device companies; as such, they have not been through formal approval processes and therefore there is limited formal evidence concerning whether they are safe or beneficial to use. Users report high satisfaction with these devices and improvements in their diabetes management. This survey was performed to assess the opinions of UK healthcare professionals and their usual practice. Key results include: UK healthcare professionals would not routinely recommend the use of these devices and there was concern about the medicolegal implications of use. However, UK healthcare professionals were generally supportive of those who chose to use the devices. Interestingly, almost half of the healthcare professionals would use the systems if they had diabetes.

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Key Summary Points
Little is known about healthcare professional perceptions of open-source insulin delivery systems.
This novel survey, conducted in 2019, provides valuable novel insights into the perceptions of some healthcare professionals opinion of open-source automated insulin delivery (OS-AID) systems.
Healthcare professionals were cautious in their approach to OS-AID and some viewed devices as potentially risky in the wrong hands.
However, healthcare professionals wished to support users as best possible and would not routinely discontinue insulin pump supplies.
Consultants tended to be more confident than other allied healthcare professionals in describing these devices.
Further surveys are due to be conducted with international collaborators to assess the evolution of opinion overtime.

INTRODUCTION

Type 1 diabetes (T1D), characterised by severe insulin deficiency, is a challenging condition to manage. To meet targets, people with diabetes must undertake frequent glucose measurements and insulin dose adjustments, which can create a significant psychological burden. This likely contributes to the observation that in the most recent data from the UK National Diabetes Audit, less than a third of people with type 1 diabetes achieved the glycaemic target (< 58 mmol/mol) in 2018/2019 [1].

Increasing access to diabetes technologies such as continuous glucose monitoring (CGM) and insulin pumps (continuous subcutaneous insulin infusion or CSII) supports people with diabetes to improve glucose levels and offset some of the burden of living with diabetes. Combining CGM with CSII with an algorithm can create an automated insulin delivery (AID) system, demonstrated in clinical trials to improve time in range and reduce hypoglycaemia [2, 3]. While academic and commercial teams have been developing these systems for many years now, commercial access to AID systems has been limited in the UK [4]. Open-source Automated Insulin Delivery (OS-AID) or Do-It-Yourself Artificial Pancreas Systems (DIY APS) combine available technologies with open-source algorithms held on a smart device. These algorithms have been developed by the diabetes community (#WeAreNotWaiting) keen for early access to these systems without regulatory red-tape. OS-AID systems have previous been described in detail in other papers [5] and their uptake by the diabetes community has grown steadily over the past few years. In addition to overcoming access issues, a recent international study of OS-AID users and caregivers highlighted a number of other motivations to use open-source AID systems [6].

The OS-AID community believe these systems are safe and effective based on the available user data [7]. Recent reviews of the evidence highlight high levels of user satisfaction and quality of life outcome measures are positive, with excellent self-reported outcomes [8, 9]. Validated safety and efficacy outcomes have also been reported with encouraging results from a study of Loop in the USA and a recent real-world comparison between MedTronic MiniMed 670G and OS-AID systems in UK [7, 8, 10, 11]. Despite many of the individual component parts being approved, tested and available on the NHS, given the strict requirements for MHRA licensing and CE marking these systems, OS-AID systems remain unapproved at present.

At the time of this survey the closest commercially available alternative was the Medtronic MiniMed 670G with hybrid closed-loop technology, which has less functionality than OS-AID [10]. Additionally, professional guidance was not available for use of open-source AID systems and it was unclear where doctors stood ethically in openly supporting these systems. The users of OS-AID systems, often highly motivated, can achieve impressive HbA1c levels [7, 8]. This means that refusing to support a person with diabetes who chooses to use an unregulated and unapproved open-source AID could be seen as denying access to a successful treatment and therefore ethically questionable. That person could also become alienated from their local diabetes service (and healthcare providers in general) and risk a breakdown in care in the future. Diabetes UK and the Juvenile Diabetes Research Foundation (JDRF) have released separate position statements on the use of open-source technologies [12, 13]. These recognised the will of the diabetes community in guiding and choosing their own care and acknowledged the "frustrations" felt by many at the slow progress being made via the conventional routes. More recent works have highlighted a potential ethical duty to discuss OS-AID as an option with patients who may benefit, although without clear guidance this would go beyond what many HCPs would find comfortable [14, 15]. Formal guidance and consensus, endorsed by an international body of HCPs and professional societies including International Diabetes Federation, ISPAD as well as ABCD DTN-UK, has just been published [16].

Given the complexities of the issues around OS-AID systems from clinical, regulatory and ethical viewpoints, the aim of this work was to establish the prevailing opinions and

perceptions of HCPs and their approaches to users of these systems in everyday practice. Exploration in detail beyond superficial results [17] will help assist in the understanding of how different members of the diabetes MDT perceive these systems in the context of a time period where access to commercial AID systems were limited and OS-AID was in its infancy.

METHODS

A survey was conducted of diabetes healthcare professionals (HCPs) to establish the prevailing opinion and practice regarding OS-AID. This was distributed via the Association of British Clinical Diabetologists (ABCD) Diabetes Technology Network UK (DTN-UK) and the Association of Children's Diabetes Clinicians (ACDC).

Questions were written collaboratively by a group of diabetes specialists with expertise or interests in pump therapy (including adult physicians and paediatricians) and also included input from a member of the OS-AID community. Questions were designed to either be answered on a Likert scale of 1–5, simple binary yes/no responses or selection of pre-populated responses with an option for free text answers if needed and a copy of the complete survey used can be found in Online Appendix 1.

The need for ethical approval for this questionnaire was assessed by the MRC online tool and was deemed not to require it. The Association of British Clinical Diabetologist's Diabetes Technology Network committee approved the study. Survey participation was entirely voluntary; therefore, completion was deemed to be consent to participate.

The survey responses were collected from February 2019 to April 2019 receiving a total of 317 responses. All responses were initially assessed and analysed using simple descriptive statistics using Microsoft Excel. Where questions were answered on Likert scales, further stratified analysis to compare of scores between groups of healthcare professionals was undertaken. Strata used included: number of known users of OS-AID in the service; number of pump users in the service and professional occupational background (e.g. nurse, doctor). Statistical testing was done using ANOVA with Bonferroni corrections for pairwise comparisons in Stata SE 16.

RESULTS

Demographics

A total of 317 responses were obtained and a summary of the main demographics (location, role, branch of practice) are displayed in Table 1 and the distribution of number of pump users and number of known open-source AID users in the respondents' services is summarised in Table 2. The vast majority of respondents were members of the team caring for those receiving insulin pump therapy (288/317; 90.9%) although the size of the service varied considerably as demonstrated in Table 2. The majority of respondents (200/317; 63.1%) knew of fewer than two open-source AID users in their service at the time of answering (see Fig. 2).

Healthcare Professional Knowledge of OS-AID

The majority (233/317; 73.5%) of respondents indicated that they were "somewhat confident" or less (score ≤ 3) in describing the setup of an open-source AID with only 8.8% (28/317) self-rating as "extremely confident" in this regard. Of these, 5 respondents (out of 28) were from services with 5 or more OS-AID users.

HCPs were not generally confident in describing the risks of the systems, with the majority (247/317, 77.9%) self-rating themselves as "somewhat confident" or less (score ≤ 3). Very few, only 3.7%, felt "extremely confident". The results were similar for describing the benefits; 81.4% (258/317) self-rated as somewhat confident or less (score ≤ 3), with only 5.3% (17/317) feeling "extremely confident". These results are summarised in Fig. 1.

Stratifying by occupation, there were significant differences (ANOVA $P < 0.001$) between different occupations for all three scores. Pairwise comparisons revealed consultants self-rated as more confident than diabetes specialist

Table 1 Regional and professional distribution of respondents

	Adult	Paediatrics	Joint	Total
England (n = 204)				
DSN	42	22	3	67
Consultant	53	32	4	89
Dietician	11	8	1	20
Specialist Registrar	10	2	2	14
Other	6	7	1	14
Scotland (n = 80)				
DSN	12	2	1	15
Consultant	34	6	2	42
Dietician	6	2	0	8
Specialist Registrar	8	0	0	8
Other	5	0	2	7
Wales (n = 27)				
DSN	7	0	0	7
Consultant	7	2	3	12
Dietician	1	2	0	3
Specialist Registrar	2	0	0	2
Other	1	0	2	3
N. Ireland (n = 3)				
DSN	0	0	0	0
Consultant	1	0	0	1
Dietician	1	0	0	1
Specialist Registrar	0	0	0	0
Other	1	0	0	1
Other (n = 3)				
DSN	1	0	0	1
Consultant	1	0	1	2
Dietician	0	0	0	0
Specialist Registrar	0	0	0	0
Other	0	0	0	0
Total	210	85	22	317

nurses for all three items, thus driving the statistical significance across the groups as a whole. Mean scores for each group are displayed in the bar chart in Fig. 2.

Stratifying by numbers of known OS-AID users in the service, significant differences were noted across the six groups (ANOVA $P < 0.001$) for all three self-rated items. Pairwise comparisons demonstrated that those working in services with 2–5 or 6–10 users had more confidence in describing the systems, as well as their risks and benefits, than those respondents from services with < 2 users. Mean scores for each group are displayed in the bar chart Fig. 3.

The number of pump users in the service was also a factor for confidence, with significantly different self-ratings for all three items (ANOVA $P < 0.05$). This was driven by the difference between small pump centres (0–100 users) and very large pump centres (> 500 users) when assessed by pairwise comparison. Mean scores from each group are displayed in Fig. 4.

No significant differences in responses were found between adult or paediatric respondents for self-rated Likert scores in describing the setup of open-source AID or risks or benefits.

HCP Perceptions of and Attitudes Towards OS-AID and their Current Practice

Overall, 287 HCPs selected a pre-populated response; a summary of the responses is given in Fig. 5a. Thirty selected "other (please specify)" and entered a free-text response. These free-text comments often highlighted concerns that HCPs did not know enough about the systems and therefore this made them risky, that respondents did not know enough to come to a decision regarding risk or simply that the risks were unknown.

On average, HCPs felt uncomfortable with providing ongoing support with a mean Likert score of 2.4 and with 187/317 (59.0%) stating they felt "not so" (38.2%) or "not at all" (20.8%) comfortable. Very few HCPs, only 16/317 (5.0%), felt "extremely comfortable". A number of "Other (please specify)" free-text responses were received. The percentage of respondents selecting each of the prefilled options is

Table 2 Table summarising the number of respondents from services by number of pump users and number of known open-source AID users

Number of pump users	
0–100	107
101–200	99
201–301	41
301–400	39
401–500	7
> 500	22
No response	2
Number of open source AID users (known)	
< 2	200
2–5	71
6–10	25
11–15	10
16–20	3
> 20	4
Not sure	4

summarised in Fig. 5b. Demonstrative free-text comments included:

- "Happy to provide compatible pumps and equipment etc. and standard diabetes care. If there were issues with the actual rig we would not be able to help. This would obviously be part of the discussion when the patient/parent was considering DIY pump."
- "Advise that as a health care professional we are limited on what we can advise as this is a DIY system. Advise where additional sources of information can be found: other patients, social media, wiki etc. Advise that we can't encourage the use, but will support as a HCP team in the general diabetes management, and will not stop them exploring this route of management if this is what they desire."
- "Warn against it but that if they insist as a team we would continue to provide care support and advice."
- "I would warn them of the risks and provide support if I believe that the person/family is able to look well after insulin pumps and understand the use of CGM sensors. I would suggest Medtronic 670G as an alternative."
- "Balanced discussion risks/benefits and support patient whatever their decision as best I could."

Many HCPs would not initiate discussions around OS-AID (289/317; 91%) and reported that the "not regulated/approved" nature of the system (212/317; 67%) and their own limited knowledge of the systems (200/317; 63%) were the main barriers. Approximately one third were concerned about their own professional indemnity (101/317; 31.8%) or with concerns about invalidating the warranty of an NHS provided pump (88/317; 28%). Demonstrative free-text responses included:

- "I will discuss it if the patient brings it up."
- "Surely that is up to the person, if they want to initiate they should/would bring it to the table for discussion; otherwise you could discuss it with all patients."
- "Would need HCP education along with patients. Ensuring that whole wider HCP team feel confident in use and can discuss potential problems before discussing."

Almost all respondents (94%) felt able to provide ongoing care, with 2% being unsure. The 12/317 (4%) answering no were asked to provide free-text responses to explain their reasoning. These reflected that, although OS-AID users remained in the service, the HCPs felt ill-equipped to advise on management of the system and thus less able to provide ongoing care. In addition, 34/317 (10.7%) of respondents indicated they had been unable to provide insulin pump consumables for patients wishing to use a open-source AID system. Local access to is/rtCGM or the requisite types of pump was the recurring reason. A single response indicated a purposeful decision to not provide equipment to open-source AID users in the service purely on grounds of the person with diabetes

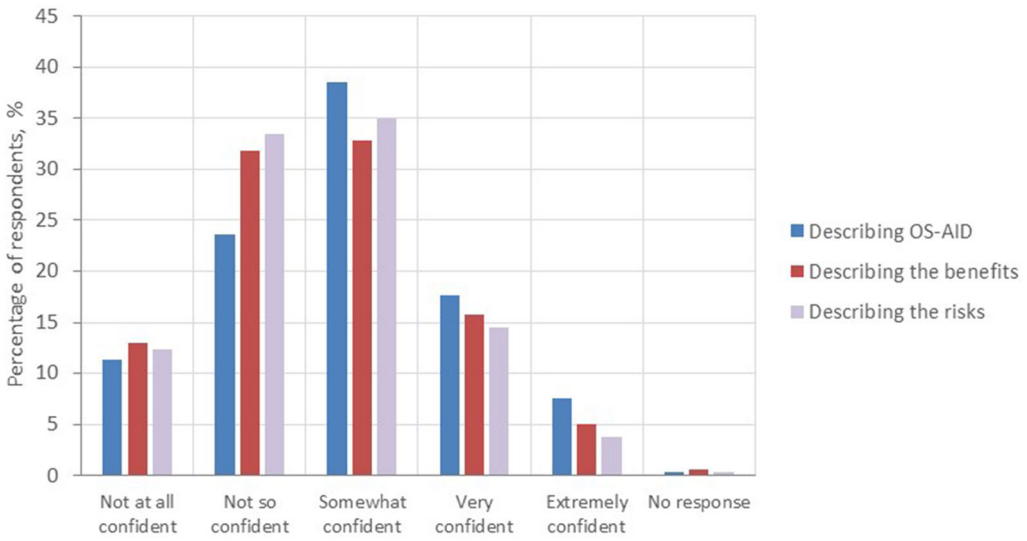

Fig. 1 Chart showing the frequency of responses of each score to Likert scale self-ratings (1–5) for confidence in describing open-source AID, its risks and its benefits

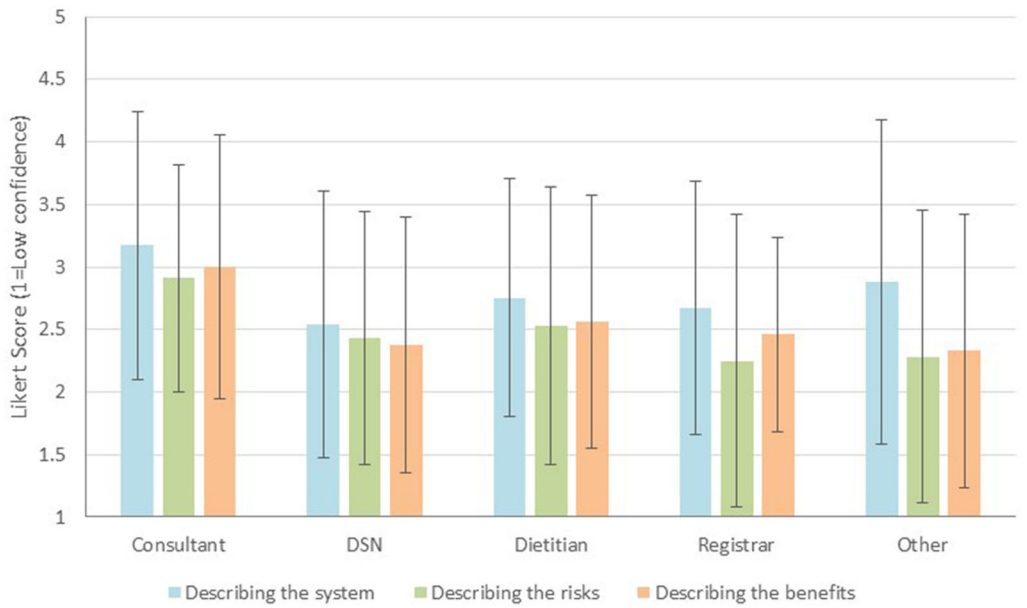

Fig. 2 Bar chart showing mean self-rated Likert scores on confidence describing open-source AID, its risks and its benefits stratified by occupation of the respondent, error bars showing SD. **DSN* Diabetes Specialist Nurse

choosing using these systems, citing reasons of warranty invalidation.

Finally, we asked HCPs whether they would use an automated AID system if they had type 1 diabetes? Overall 47% (149/317) would use open-source AID if they had type 1 diabetes; 6 survey respondents were already using the system. Only 39/317 (12%) stated they would not use the system themselves.

Future Learning

Almost all respondents believed HCPs should learn more about open-source AID (306/317,

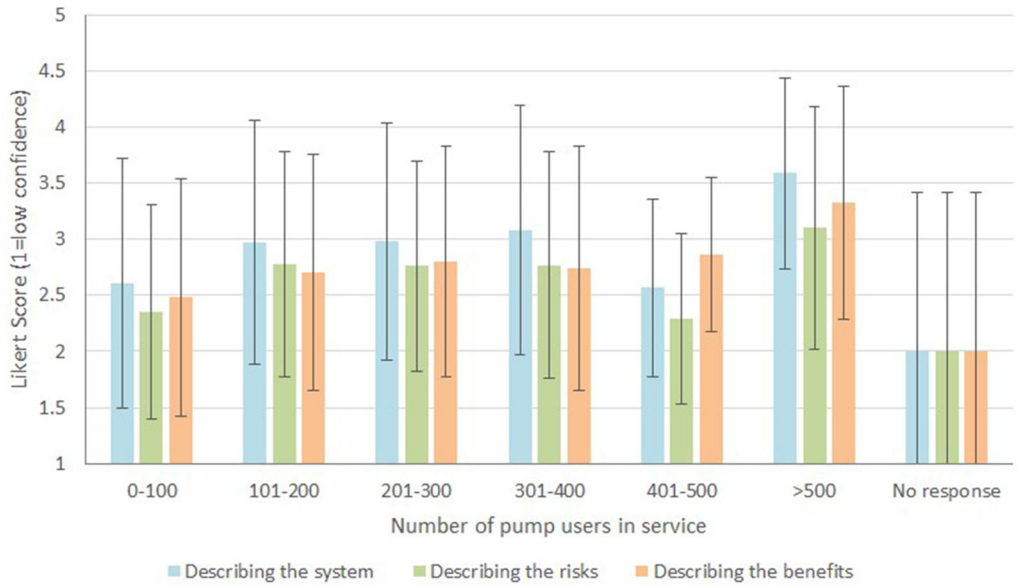

Fig. 3 Bar chart showing mean self-rated Likert scores on confidence describing open-source AID, its risks and its benefits stratified by number of pump users in the respondents service, error bars showing SD

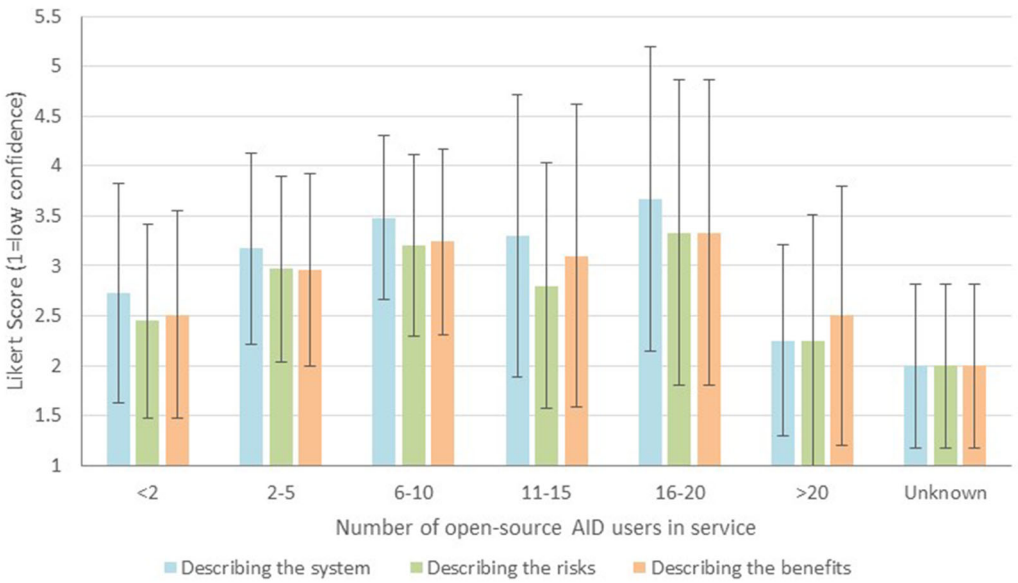

Fig. 4 Bar chart showing mean self-rated Likert scores on confidence describing open-source AID, its risks and its benefits stratified by number of known open-source AID users in the respondents service, error bars showing SD

96.5%) and wanted to learn more about open-source AID systems (304/317, 95.9%). Of the pre-filled options available, HCPs selected classroom learning (230/304, 75.7%), online learning (191/304, 62.8%), lectures (115/304, 37.8%) or distance learning (86/304, 28.3%) as the preferable options in order of frequency.

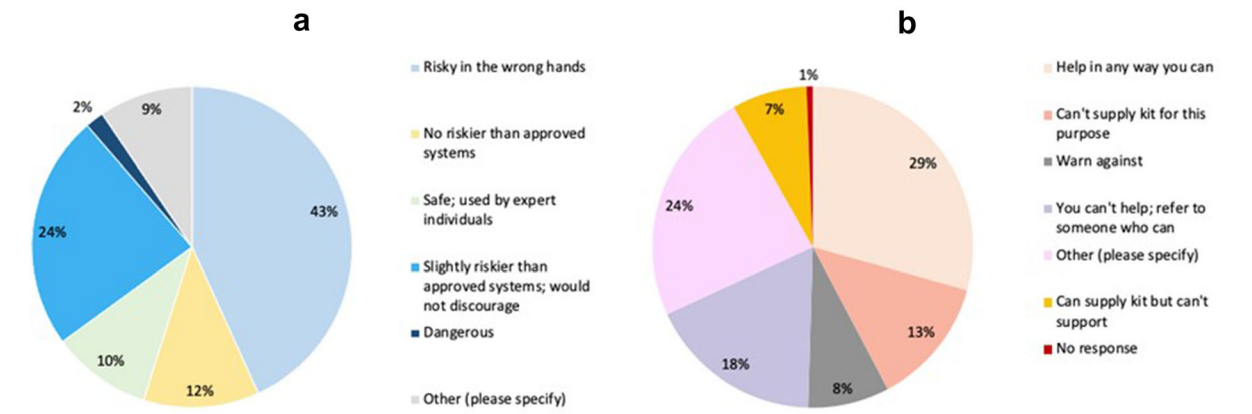

Fig. 5 **a** HCP responses regarding their perceived risks of OS-AID and **b** how they would respond to being asked about OS-AID in clinic

DISCUSSION

This large survey of UK healthcare professionals provides unique insights into their perceptions of OS-AID system use. Overall, most HCPs were keen to support users with few actively warning against use. Most HCPs will not initiate discussions about OS-AID use largely related to the unregulated/unapproved nature of the systems, their own lack of knowledge and concerns about indemnity. Generally, HCPs do not feel entirely comfortable providing clinical support for users of OS-AID, likely a reflection of their self-reported lack of knowledge of the systems, as well as relative lack of exposure due to current limited numbers of users. It appears some HCPs are already utilising OS-AID to manage their own type 1 diabetes, and many others would adopt this approach to their diabetes management, even though their clinical practice may differ.

Most HCPs would be willing to try and support people with diabetes who use OS-AID or to find someone else who can. It is certainly reassuring for users of these systems that few of those surveyed would withhold consumables if they knew this system was being used. With this knowledge OS-AID users might feel more able to discuss their use of these systems with their diabetes multidisciplinary team (MDT), which will also increase exposure and awareness amongst HCPs. Equally, HCPs are conscious of the risks of OS-AID and the ethical grey area it may foray into with many choosing to continue to provide equipment, including consumables, but to warn about the risks or go as far as to absolve clinical responsibility for any harm that may arise. Although perhaps this is understandable for systems with an absence of MHRA approval or CE marking, more recent ethical analysis assures us we should support and perhaps even discuss the uptake of these systems more openly [15]. The sparse robust safety evidence and absence of regulatory approvals combined with HCPs reported lack of knowledge provide insight into why HCPs did not tend to initiate discussions in clinic.

The data suggest that most HCPs are vigilant of the potential risky nature of open-source solutions, although there is a perception of safety in current users given that they are self-selecting and thus often driven and highly motivated. HCPs reported that if this technology were to end up being used by an individual less fastidious about their diabetes management, then the risks could be much higher, with some going as far as to suggest they may manage consumables/pump renewals differently in those who they perceive to present a higher risk.

HCPs are aware that there are gaps in their knowledge of OS-AID systems, in terms of both the actual functioning of the systems and the potential risks and benefits which may make it

difficult to counsel users appropriately in clinic. Consultants were more confident than their nursing colleagues in describing these systems as well as their potential risks and benefits, but confidence was broadly the same amongst all other groups. It is unclear whether this truly reflects superior knowledge of OS-AID possessed by consultants or is more generally reflective of higher levels of confidence in practice of consultants compared to other MDT members. There was a trend towards increased confidence in larger pump services and in services with larger numbers of known OS-AID users—likely related to increased exposure to these systems in daily clinical practice.

HCPs clearly wish to learn more about OS-AID, both for their own benefit and to better support users. Efforts should continue to be made to provide additional training and encourage people to attend courses focused on commercially available or OS-AID (some have already been run in the UK). Alternatively, they could be provided with online training to suit specific needs. Users should unquestionably be involved in the creation of learning materials to be distributed to HCPs.

At the time of the survey, there was a paucity of evidence for some of the most important information HCPs will want to know, notably whether OS-AID is safe and effective and the medicolegal implications of supporting use. Efforts are being made by users and clinicians to capture outcomes of OS-AID use in the real-world and support the safety and efficacy of these systems [18, 19].

In paediatric practice, some HCPs have expressed concern about possible safeguarding issues that may arise from lack of safety data or insurance coverage as well as consent processes as carers make the decision to use this unlicensed therapy on behalf of the child. Many feel that as more regulated and licensed hybrid closed loops are now available, HCPs should perhaps now be encouraging families to use licensed and regulated closed loop systems instead of the open-source AID systems[4]. We currently do not have an understanding about how families using these systems for their children would feel if offered a switch to a commercial system—time will tell.

Strengths and Limitations

This survey managed to capture a wide range of both adult and paediatric members of the diabetes MDT across all four countries of the UK and the results are formed from respondents working in pump services of varying sizes. The data collected are, however, from a relatively invested group of HCPs who generally work as part of the diabetes MDT and more often than not also part of the pump service where OS-AID users are likely to be found. It is therefore not possible to generalise the findings to the wider diabetes HCP community and the findings may not reflect wider healthcare professional perceptions of open-source AID.

Additionally, this survey was developed in a rapidly evolving situation with the aim of gauging early perceptions. Some of the questions ask for nuanced responses (e.g. the differentiation between being able to explain risks, benefits and describe the systems) which may be difficult to generalise. As a result of the methods used and wide dissemination, we are not clear on the characteristics of those who did not respond and our exact response rate. Further study and repeated assessment of HCP attitudes is clearly warranted, and future surveys are planned which will adopt methodologies to attempt to address the shortcomings of this earlier survey. Furthermore, further studies could include demonstrative case studies to assess HCP responses to varying individuals using OS-AID to see if factors such as frequency of monitoring, HbA1c, family support, financial and socioeconomic status and presence of complications mediate the perception of safety of these devices for a given individual.

We welcome the recently published consensus guidelines produced by international collaborators to support HCPs working with users of OS-AID [19]. Since this survey was conducted, more commercially available systems have become available, with proven safety and efficacy, and a NICE multiple-technology appraisal for approved hybrid closed-loop systems is currently being undertaken in England [20]. Although access to commercially available closed loop systems is increasing, given the multiple reasons to pursue OS-AID systems use

and on-going evolution of patient-driven innovations in diabetes technologies, it seems likely that OS-AID systems will continue to feature at some level [6]. This may require consideration for on-going guidance and education for HCPs involved in type 1 diabetes care and makes it paramount to regularly repeat an assessment of prevailing opinions of OS-AID in clinical practice.

CONCLUSION

The number of OS-AID users continues to increase globally. The ethical and educational challenges this presents for HCPs cannot be underestimated with the majority being uncomfortable initiating discussions on this topic in clinic. HCPs find their own lack of knowledge to be a barrier to caring for users of OS-AID and so education needs to be key. It is prudent for this to be provided via collaboration from the OS-AID community and organisations such as ABCD DTN-UK. In this ethically complex setting, HCPs must balance their concerns about the risks of using OS-AID against supporting individual choice and autonomy. User-driven innovation has formed these technologies and it is clear that as advocates for people living with diabetes that HCPs want to help in whatever way they can to support improvements in outcomes. Most interestingly, many HCPs put in the same position as the people with diabetes who were early adopters of this technology would choose to use OS-AID themselves.

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Compliance with Ethics Guidelines. The need for ethical approval for this questionnaire was assessed by the MRC online tool and was deemed not to require it. The Association of

British Clinical Diabetologist's Diabetes Technology Network committee approved the study. Survey participation was entirely voluntary; therefore completion was deemed to be consent to participate.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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