Barriers to Uptake of Open-Source Automated Insulin Delivery Systems: Analysis of Socioeconomic Factors and Perceived Challenges of Adults with Type 1 Diabetes from the OPEN Survey.

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Novelty Statement

- Although interest in open-source automated insulin delivery (AID) has increased in recent years due to its potential clinical and quality of life gains, less than 1% of people living with diabetes are using them.
- Few studies have sought to examine the perceived challenges to adoption among people with diabetes who are not (yet) users of open-source AID.
- This study identifies a number of core barriers to wider use of the AID systems: sourcing components, low self-perceived levels of IT literacy and fear of loss of support from healthcare providers.

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Abstract

Background:
The central role that technology plays in the #WeAreNotWaiting community has raised questions about who can participate in and benefit from its innovations. Few studies have examined the perceived barriers to adopting open-source automated insulin delivery (AID) solutions among non-users within this community.

Methods:
This is a multinational study based on a cross-sectional, retrospective web-based survey of non-users of open-source AID. Participants were administered a questionnaire that sought to elicit their perceived barriers towards the building and maintaining of an open-source AID system.

Results:
Sourcing the necessary components, lack of confidence in one's own technology knowledge and skills, perceived time and energy required to build a system as well as fear of losing healthcare provider support appear to be major barriers towards the uptake of open-source AID. Neither the absence of approval by a regulatory body nor the open-source nature of the innovations appeared to act as a deterrent to embarking on building an open-source AID.

Conclusions:
This study identified a range of structural (e.g. accessibility of open-source AID components) and individual-level (e.g. self-perceived low levels of IT literacy and fears of losing healthcare provider support) barriers to uptake of open-source AID. Some of these individual-level barriers may be overcome over time through the peer-support of the DIY online community as well as greater acceptance of open-source innovation among healthcare professionals. The findings have important implications for understanding the possible wider diffusion of open-source diabetes technology solutions in the future.

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1. Introduction

Social and technical trends are empowering communities with a diverse array of medical conditions to co-create or self-develop medical devices and treatments to address their unmet healthcare needs[1–3]. One patient group for which such trends are particularly evident is people with diabetes. Behind the hashtag #WeAreNotWaiting, they have created new tools and systems, in addition to the existing approved medical devices, and shared them for free via open-source platforms, meaning the original source code is freely available for possible modification and redistribution [1,2]. One of the most noteworthy examples of these innovations is open-source automated insulin delivery systems (open-source AID), more commonly known as “Do-it-Yourself Artificial Pancreas Systems” (DIYAPS). In these systems, open-source algorithms interoperate with commercially available and approved insulin pumps and continuous glucose monitoring (CGM) sensors[4]. In OpenAPS[5], the algorithm runs on a Linux-based mini-computer, whilst AndroidAPS [6] and Loop [7] are smartphone applications. Depending on the set-up, additional hardware (e.g. OpenAPS rig[8]; Riley-, Orange- or EmaLink [9]) and software (e.g. Nightscout) components may be required[4]. In closed-loop mode, insulin dosing is automatically adjusted in response to glycaemic levels, based on various customisable settings and user-provided information. There is a growing body of evidence showing that open-source AID users have comparable clinical and quality of life outcomes to the most state-of-the-art commercial devices currently available on the market [4,10–12].

The central role that technology plays in the Do-It-Yourself (DIY) community has raised questions about who can participate in and benefit from its innovations[13,14]. Barnard et al., for example, have questioned the extent to which the benefits of open-source innovations are accessible to people with diabetes beyond a cohort of “highly tech-savvy users willing and able to engage in the demands of building and maintaining their open-source AID” [13]. A small number of mostly qualitative studies have begun to highlight and characterise the typical challenges faced by individuals in embarking on the journey of building an open-source AID system [2,15–18]. Notably, these studies have shown how a high degree of IT literacy is not necessarily a prerequisite.

However, this body of research has almost exclusively relied upon the reflections and testimonials of people with diabetes who have already successfully managed to build an open-source AID system and, as such, may not provide a complete picture of the potential barriers faced by those who have yet to build a closed-loop system. Indeed, as evidenced by the

sizable membership of the online support groups such as ‘Looped’ on Facebook (N=27,729, October 2021), the DIY community encompasses not only users but also a much larger cohort of people with diabetes and caregivers who are not (yet) users of an open-source solution (hereafter referred to as non users).

To the best of the authors' knowledge, only one existing study has examined the potential barriers of building a closed-loop system among non-users[19]. However, this study was conducted among a relatively small number of people with diabetes attending open-source build workshops in the UK. The overall aim of this study is to address this evidence gap through surveying non-users of open-source AID within the wider international #WeAreNotWaiting community to ascertain what they perceive as the most significant barriers to building an open-source AID. The objectives are as follows: 1) to identify the most common barriers to building an open-source AID among adults living with diabetes and 2) to examine if any differences in these perceived barriers can be found across socioeconomic status, gender and geographic location.

2. Methods

Study Design

A questionnaire entitled “DIWHYnot” (appearing to participants as “Your Thoughts about DIYAPS”) was administered to non-users to elicit their perceptions of barriers towards building an open-source AID. The questionnaire was part of a multinational study with a cross-sectional, retrospective web-based survey design (“The OPEN Survey”; September to November 2020) of the DIY community (see figure 1). For the purposes of the research anyone who is a member of an online DIY social media group is considered a member of the DIY community. Individuals—both users and non-users—were recruited via Facebook groups such as the multinational “Looped” groups, “AndroidAPS users”, “CGM in the Cloud” and “Nightscout Deutschland”. The study was also promoted on the OPEN website and social media accounts such as “Diabetes Daily”.” This paper focuses on the responses of adult non-users to the DIWHYnot questionnaire.

Study Setting and Survey Tool

This research was conducted as part of the OPEN project which comprises an international and interdisciplinary research group—healthcare professionals, biomedical, social, data and computer scientists—the majority of whom live with type 1 diabetes. The questionnaire items were formulated based on the collective experiences of the OPEN team and previous studies conducted as part of the OPEN project[15,20]. At the time of the design, individual team members living with type 1 diabetes were at various stages on the journey of building a closed-loop system: some had been actively using open-source AID for many years and were leading members of the DIY community; others were in the process of building a system; some wished to build a system but lacked access to the requisite components, while others had opted not to build a system. An initial list of statements related to the challenges of building a closed-loop system was formulated by a non-user of the OPEN team (TF) and then reviewed and added to by users (SO, DL, KB, MW) and non-users (KAG). Once an initial set of statements had been formulated, these were reviewed by the entire research group until a final list was agreed upon.

The DIWHYnot questionnaire (Appendix A) combined check-box items, open-field inputs, and rating of the relevance of specific statements using a 5-point Likert scale (“strongly agree”, “agree”, “neither agree nor disagree”, “disagree”, and “strongly disagree”). These questions employed the use of branching logic, where answering in the affirmative (“strongly agree” or

"agree") triggered a series of follow-up questions. Questions that did not use a 5-point Likert scale allowed participants to answer with "Other", which then offers an open-response field to enter text, or "I don't know" or "I'd rather not say".

Participants

Participants in this study were non-users of open-source AID (18+ years) with type 1 diabetes. The survey was hosted using the REDCap electronic capture tool through Charité – Universitätsmedizin Berlin. Ethical approval for the overall survey was granted by the Life Sciences Human Research Ethics Committee at University College Dublin (LS-20-37).

Data Analysis

After data cleaning and de-identification, analysis was performed using SPSS 27, Microsoft Excel 2014 and Google Sheets. The analysis began with validity (factor analysis) and reliability tests (cronbach's alpha) of certain survey items followed by descriptive and inferential analysis (e.g. independent t-test) to explore the key barriers among non-users referring to their demographic characteristics.

Validation of the Survey Tool

The questionnaire initially contained 20 items, with an overall acceptable internally consistent reliability (Cronbach's alpha = 0.853). Two items were specifically relating to acquiring the underlying components needed for open-source AID use: sourcing and expenses. Among the 20 items within the questionnaire (apart from the two items 'sourcing' and 'expenses'), reliability was improved by the deletion of three items: use of commercial AID, lack of pump therapy knowledge, and discouragement from diabetes teams in building an open-source AID (Cronbach's alpha = 0.866). An exploratory factor analysis was performed on these remaining 15 items utilising principal component analysis with the varimax rotation method. As the results suggested, the 15 items were reduced into four dimensions (Kaiser-Meyer-Olkin = 0.774, P<0.001, cumulative proportion = 65.57%): "*Building and Maintenance*", "*Support and Liability*", "*Trust in Technology*", and "*Therapy Knowledge*". As the results from principal components analysis indicated, the item "*My diabetes team has no expertise in diabetes technology and I will have no support in DIYAPS use*" (loading <0.5) was also removed as it did not fit in any dimension, leaving a final count of 14 items (Supplementary Table 1).

3. Results

Participant Characteristics

Responses from 129 adult non-users were included in the analysis for this study (*Figure 1*). 31 countries were represented; five countries accounted for 61% of the overall responses (Canada n=15, Germany n=20, Ireland n=9, United Kingdom n=18, USA n=17). Most participants (n=113; 90%) wanted to learn more about open-source AID. The majority (n=79, 61%) indicated that they might consider building a system and were interested in determining what kind of support might be available to them (n=91; 73%). A considerable minority (N=33; 26%) were using a commercial AID system. Only a few (n=8; 6%) had previously built an open-source AID system and subsequently abandoned it. *Table 1* summarises the demographic data of the study participants. Participants tended to be White, with high levels of educational attainment and occupational status.

Types of Barriers

For “Building and Maintenance”, more than half (n=77, 60%) indicated that they strongly agreed or agreed that they lacked the necessary technical knowledge to build the system on their own. Some (n=55, 43%) reported that the resources for open-source AID are too overwhelming and difficult to understand. Some also (n=47, 37%) reported they can find help to build the open-source AID but are concerned about maintaining their system. Additionally, some reported that they do not have the energy (n=50, 39%) or time (n=43, 34%) for building an open-source AID system.

Regarding “Support and Liability”, some indicated they were afraid of losing their healthcare providers’ support (n=45, 36%) once they started using open-source AID. Only minor barriers were found in the theme of “Trust in Technology” and “Therapy Knowledge” (*Figure 2*). Notably, a very low number indicated they did not trust open-source technology (n=10, 7%) and products which have not been approved by a regulatory body (n=10, 7%). Although not fitting into any of the themes generated by factor analysis, it is also worth noting a high proportion of (n=53; 42%) felt their diabetes team lacks expertise in diabetes technology to support them building an open-source AID.

Barriers and socioeconomic factors

As can be seen from Table 2, Women were found to be significantly more likely to report barriers in the building of open-source AID compared to men. Highest level of educational attainment was used as our main indicator of socioeconomic status. We compared those without a Bachelor's degree vs those with a Bachelor and above. However, the statistical analysis was found to be non-valid as the number of participants holding degrees below a Bachelor's degree is too small.

To examine if there were any differences in these barriers per region, countries with the most participants in North America (US and Canada) and Europe (Germany, Ireland and UK) were compared. Participants in North America did not trust open-source technology compared to those in Europe ($t=-2.282$, $p<0.05$); they were more afraid to lose the support of their healthcare provider if they start looping ($t= -2.123$, $p<0.05$) and of losing health insurance if they start using an open-source AID. ($t= -2.057$, $p<0.05$); and they were more reluctant to increase their level of responsibility by using open-source AID ($t= -3.133$, $p<0.05$). No significant differences could be found between North America and Europe in relation to concerns about sourcing components ($t= -1.0$, $p=0.31$) or expenses ($t= 0.59$, $p=0.56$). This was in spite of participants from North America reporting that they pay significantly higher for diabetes supplies compared to those in Europe ($t= 4.767$, $p<0.001$). Due to low response rates from countries outside of Europe and the US, no other regions could be compared.

4. Discussion

To the best of the authors' knowledge, this is the first study to extensively report on the perceived challenges of building an open-source AID among non-users within the #WeAreNotWaiting community. Its findings add to the literature as the needs of this cohort may differ from those of existing users captured in previous studies of open-source AID[15–18]. Of particular strength is that the study has been designed by researchers with personal experience with type 1 diabetes and members of the open-source community. Additionally, the multinational scope provides a wider geographic diversity than prior research carried out in this area.

Participants in this study identified a range of structural and individual-level barriers to uptake of open-source AID. The most significant *structural-level* barrier was found to be the sourcing of compatible insulin pumps and access to CGM systems. The most likely explanation for this observation is that while the number of compatible devices has grown in recent years, there are restrictions in availability depending on location for prescriptions, and supply and demand of second-hand insulin pumps of earlier models. Currently, people with diabetes interested in open-source AID are limited in that they cannot get earlier models of Medtronic and OmniPod pumps via prescription, as these models are no longer distributed to new customers[4]. In Europe, there may be a wider range of compatible in-warranty pumps (e.g. Dana RS, AccuChek Spirit Combo and Insight) available that are partially or fully reimbursed in some countries. However, in practice, people with diabetes may experience difficulties in navigating the healthcare systems with respect to personal choice and reimbursement coverage schemes for these devices[21]. It was hypothesised that the barriers of sourcing and expenses would be more commonly reported by participants based in North America (US and Canada) than those from Europe (Germany, Ireland, UK). However, no statistically significant difference was found between the two regions, which could be attributed to smaller sample sizes in the reported groups. While previous reports have highlighted access to requisite components as a major barrier within individual countries such as Australia and the UK [3,15,22,23], this study's findings highlights the extent of the issue across a number of high income countries, including those with universal health coverage. Moreover, patients' views of their clinician's knowledge of pump theory may reflect the large variation in access to technologies not only *between* but also *within* countries. For example, access to pump therapy is almost twice as high in the east of Ireland compared to the west, so there are some systemic issues within health care delivery that need to be addressed at both local and international levels[24].

The most significant *individual-level* barrier reported by participants was self-perceived lack of programming knowledge. Participants also appeared to be concerned about the potentially high opportunity cost of investing time and energy in building an open-source AID and the extent to which they would be able to maintain the system. These observations were more prominent in women, which may explain the gender imbalance in adult open-source AID users compared to children and adolescents[2,18,25,26]. These barriers may add to wider gender disparities in diabetes outcomes, such as the challenges associated with sex-hormone related variations in insulin sensitivity[27–31]; and women with diabetes being less likely to achieve target haemoglobin A1c, LDL cholesterol and blood pressure levels as recommended by guidelines [32,33], and more likely to develop eating disorders and depression[34–37]. Improving uptake of open source AID may help to improve clinical outcomes among some women.

Previous studies detailing the journey of those who have successfully built an open-source AID have demonstrated how the capacity to draw on support within the #WeAreNotWaiting community is key to overcoming many of the challenges undergone by less experienced users[15,38]. Participants described how their self-perceived limited IT literacy was overcome through the online advice and support of more technically-savvy community members and how they derived an enhanced sense of agency and empowerment after successfully building a system for themselves. The ability to engage with and utilize social ties within the #WeAreNotWaiting community can help to transcend individual-level barriers in knowledge and lack of IT confidence that might otherwise have been a barrier to adoption of open-source AID[38].

Finally, it is important to note that the lack of regulatory approval for open-source AID systems did not act as a deterrent for the vast majority of the participants. However, a sizable number indicated they feared losing their healthcare provider's support if they embarked on building an open-source AID. This may reflect that while there has been a growing acceptance of open-source innovation among healthcare professionals in recent years, many people with diabetes have no way of knowing in advance whether their healthcare team has a positive or negative stance on the use of open-source AID. Furthermore, a sizable proportion of participants perceived their healthcare provider knowledge of diabetes technology as not sufficiently adequate to support their decision to build an open-source AID. Trepidation around the impact that their decision to use these systems might have on their relationship with their healthcare

provider is thus to be expected. More widespread endorsement of clinical guidance on the use of open-source AID may help to assuage the fears of people with diabetes and reduce this barrier to adoption, as well as encourage more open communication in clinical environments[4] This finding is supported by others who have previously commented on healthcare provider perspectives, where this was highlighted as an ethical 'dilemma' for doctors [14,22,39–41].

Limitations

It is acknowledged that this study has limitations. Firstly, the survey was deployed amongst people who already have expressed an interest in open-source AID and also tended to be White and of higher socioeconomic status; therefore their views will not fully represent the entire population of people living with diabetes. Prior research has shown that the uptake and usage of insulin pumps and continuous glucose monitors has occurred at a faster rate among higher socioeconomic status groups relative to those of lower socioeconomic status[42-45]. Within this context, it is not surprising to find interest in adoption of open-source AID largely conforms to a similar pattern given that the ability to build an AID system is predicated on access to insulin pumps and CGM. Secondly, the survey mostly reached those of the #WeAreNotWaiting community who are part of online networks. The potential barriers to uptake of people with diabetes outside these networks but with interest in open-source AID may not have been captured in this study. Thirdly, responses were concentrated among five high income countries; findings may not be representative among people with diabetes in middle and lower income countries[46]. Finally, based on the current reliability and validity test results, revisions will be made to subsequent versions of the survey to evaluate barriers and enablers for open-source AID uptake that may not have been adequately captured in this study. This should include examining healthcare providers' knowledge and attitude toward open-source AID as well as the impact of the increasing availability of commercial AID.

Future studies could also build upon these findings by using qualitative research methods to understand the lived experiences of those aspiring to build—or choosing not to build—open-source AID and how these might differ both within and between different user groups and countries. In particular, studies with a more purposive sampling approach could examine the socially differentiated nature of access to open-source forms of innovation across different social contexts and therefore the barriers and enablers towards its wider scale-up. These studies should also take into account the challenges of access to underlying components (pump, insulin, and CGM supplies) as additional barriers to implementing open-source AID systems.

Conclusion

In conclusion, the study has identified how structural-level barriers—such as sourcing requisite components—and individual-level barriers—such as lack of confidence in one's own IT knowledge and programming skills and fear of losing healthcare provider support—both play a role in constraining uptake of open-source AID. The study paints a mixed picture regarding the possible wider diffusion of open-source innovation in diabetes care. Raising awareness of the available resources and peer-support from the community, and disseminating success stories of users with little prior tech-literacy, may help to significantly increase the global footprint of open-source AID. Simultaneously, improving educational resources on diabetes technology for healthcare professionals as well as growing scientific evidence on the safety and effectiveness of open-source AID would enable them to support the safe and ethical use of these technologies in clinical settings[39,47,48]. On the other hand, current inequalities in access to [interoperable] insulin pumps are likely to also put limitations on the wider diffusion of open-source innovation. Facilitating access to CGM technology, real-time availability of CGM data, and interoperable in-warranty insulin pumps may therefore help a wider group of people with diabetes to benefit from open-source AID technology.

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