

Real-time Continuous Glucose Recording: An analysis of end user self-reported experiences

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Abstract

Objective:

This study analyzed user's views on their use of real-time continuous glucose recording (CGR) systems in relation to their diabetes.

Research Design and Methods:

CGR users completed an anonymous online survey relating to their use of CGR. Questions with multiple choice or numerical answers included age, diabetes type, type of CGR used, money spent on CGR, duration of CGR use, HbA1C before and after using CGR, time in range reported before and after CGR, qualitative questions relating to use or otherwise of CGR, relation to fingerprick testing amounts and for those in the UK, local Clinical Commissioning Group. There were also free narrative response fields for those that wished to provide further information. I have used data analysis techniques to analyze 551 responses.

Results:

The majority of responses showed an improvement in reported metabolic control, with 78.6% reporting an HbA1C below 7.5% after using a system compared to 45.9% beforehand. Changes in Time in Range were also seen by most users, with the majority moving from not knowing to having this information. 75% of participants had used a system for less than two years. 44% of participants were using the Abbott Freestyle Libre system, with 42% using a form of Dexcom system. Only 14% of participants were using Medtronic systems. 60% of the responses came from the UK. 18% of the responses were funded by some form of insurance or healthcare system, with the majority being self-funded. Users spending more annually on systems showed greater average reductions in HbA1C, although there was little difference in time-in-range. Fewer Flash Glucose Monitoring (FGM) users reported a reduction in number and severity of hypoglycaemic events compared to those using Continuous Glucose Monitoring (CGM).

From the qualitative responses, positive experiences outweighed negative ones, although there were understandable issues with cost. The key themes identified from the freeform answers were alleviation of over-riding worries; early warning of hypos; better testing; insight and action and improved quality of life. Insight into the interaction between insulin, glucose levels, food and exercise was the most stated of these.

Conclusions:

Survey participants indicated that use of CGR provided them with clear benefits, in spite of the costs of the systems. On average, there were very clear improvements in metabolic control, demonstrated in both HbA1C changes, improvements in or knowledge of time in range and reductions in frequency and severity of both hypoglycaemic and hyperglycaemic events. They also reported that use of the systems made them less anxious about living with diabetes.

Introduction

Continuous Glucose Recording (CGR) technology is not widely available within healthcare payment systems throughout most of the world. As a result, a significant proportion of people pay for it themselves. Meta-analysis of Randomised Control Trials shows that in a trial setting, metabolic benefits are seen [1], in reduced HbA1C, and also evidence of reduced occurrences of hypoglycaemic events [2] [3] [4]. More recent randomised control trials have backed this evidence up [5] [6].

User satisfaction and Quality of Life have been explored in relation to use of CGR by multiple questionnaire based studies [7] [8] [9] and also by analysis of user narratives using a qualitative analysis framework [10]. All of these studies have focused exclusively on Type 1 Diabetes, in spite of the use of these technologies by an increasing number of those with Type 2 Diabetes.

This survey sought to provide insight into metabolic changes by obtaining feedback from those who use and pay for CGR systems, understand the benefits that they consider they obtain and issues they may have (through both preconceived and free answer questions) and to determine how much they are willing to spend in order to obtain these benefits.

Research Design and Methods

Participants

An online survey was designed to capture user data (available at <https://diabetetech.typeform.com/to/TwXH4V> and in Appendix B.). The survey was advertised worldwide via various sources, including the diabetes.co.uk forum, the [Diabetes UK](#) forum, various Facebook sites linked to the Diabetes Community, the [Diabetes Daily](#) forum and also Twitter. I received 551 anonymous responses, which were then reviewed for data integrity. All responses are self-reported outcomes.

Survey Questions

Questions 1-12 were multiple choice or numerical and provided data that has been used to show variation in metabolic indicators, participant spending on their systems, plus some background as to the people on which the systems are in use, including multiple types of Diabetes and age. Questions 13 and 14 provided both preconceived

issues and benefits and additional free text fields that allowed participants to enter their own views. The results and conclusions of the survey range across all the question sets.

Survey Analysis

Numerical answers were reviewed and formatting was normalised to allow exploratory data analysis. Where data provided was uninterpretable, the answers were marked invalid. Simple statistical analysis was undertaken on questions with a distribution.

For the freeform answers, a qualitative analysis was undertaken using Thematic Content Analysis [11] by T.S.

- *Open Coding* — the raw data is reviewed and a word or phrase to describe elements of the content noted.
 - *Categorisation* — the words or phrases from the Open Coding process are reviewed and duplicated items removed. Categories where overlaps occur are combined.
 - *Final Coding* — Informed by the analytical and theoretical ideas developed during the research, these categories are further refined and reduced in number by grouping them together.
-

Results

The survey was responded to by people with different types of diabetes, with different Hba1Cs before and after using their systems. Due to the split of the results, high level data is presented across all participants, and a deeper dive is taken into only the type 1 responses. A further paper will detail the type 2 responses.

Population

There were 551 responses although not all provided metabolic indicators. The results from those who did are available in table 1. The average reduction in Hba1C across all participants was 1.1mmol/l (± 1.3 mmol/l).

Diabetes Type	Number of Participants	Percentage of participants	Mean Hba1C before system	Mean Hba1C after system
MODY	2	0.4%	7.3	7.7
Type 1	475	91.9%	7.7	6.7
Type 1.5/LADA	16	3.1%	8.2	6.5
Type 2	21	4.1%	7.9	6.5
Type 3	3	0.6%	10.0	7.2
Grand Total	517	100%	7.8	6.7

Table 1 Participant data

System use of participants was largely the Abbott Freestyle Libre and a combination of various Dexcom systems, as shown in table 2. 75% of participants had used a system for less than two years.

Continuous Monitoring Type	Percentage of users
Abbott Freestyle Libre	44.1%
Abbott Navigator	0.2%
Dexcom G4	19.6%
Dexcom G4 with Animas VIbe	8.7%
Dexcom G5	13.4%
Medtronic 640G with Smartguard	9.8%
Medtronic standalone CGM	0.5%
Older Medtronic pump with CGM	3.6%

Table 2 Split of system use in responses

Medtronic CGM was the least popular, and mostly used in conjunction with the 640G using SmartGuard.

The average age of users of the systems was 37.7 years (± 17.9 yrs). The distribution of age is shown in figure 1.

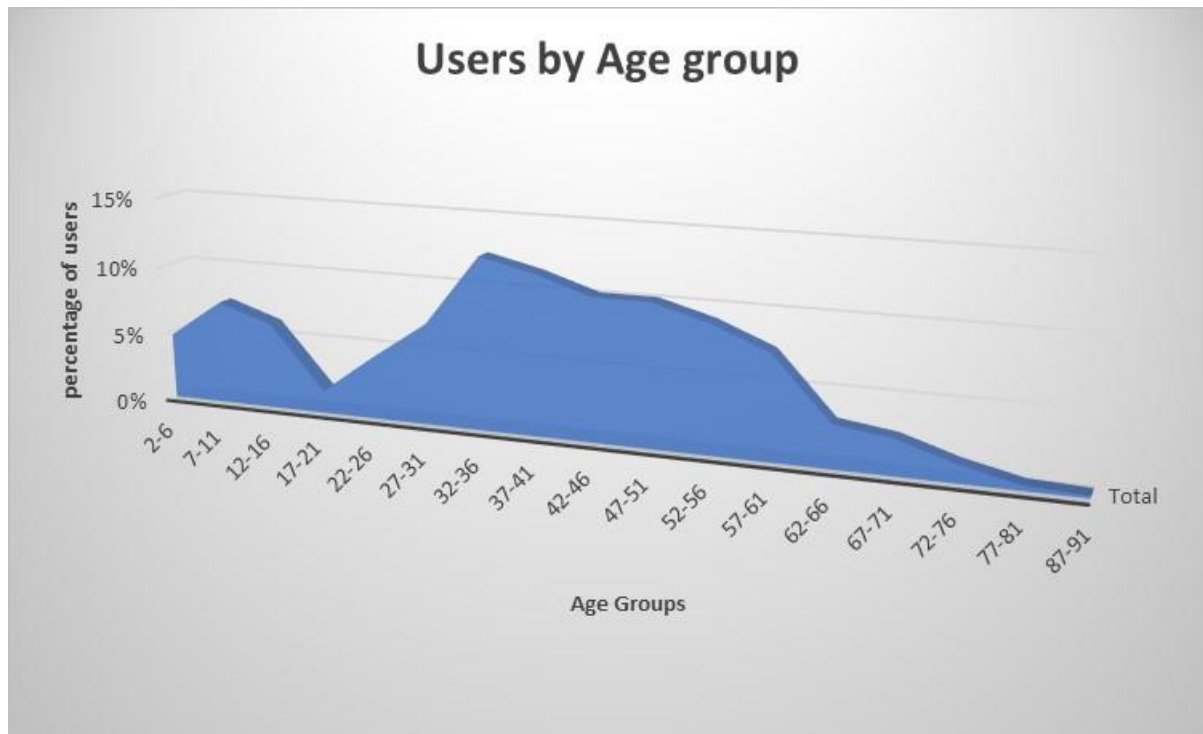


Figure 1 Distribution of age of those on which sensors are used

For all users, the number of fingerpricks daily currently being done was reported. The mean was 4.0 (± 3.7) times, with the distribution as shown in figure 2. An additional frequency distribution can be found in [Appendix A](#).

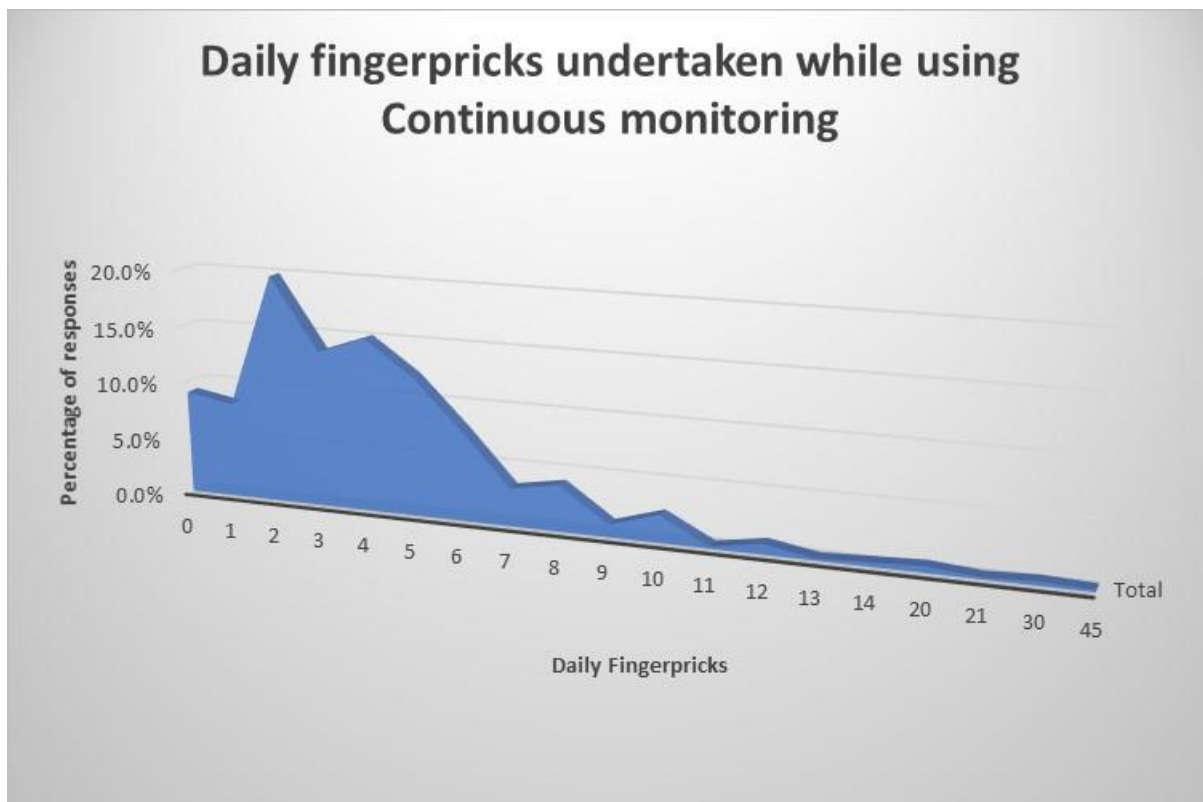


Figure 2 Distribution of daily fingerpricks when using a system

Type 1 Participants

Metabolic Indicators

Hba1C results, as reported by the participants in the survey showed noticeable change. Hba1C results may be from either clinical or software estimates. The average Hba1C of those who responded (475) dropped from 7.7% (± 1.6) using DCCT units to 6.7% (± 0.9), with a clear shift in the distribution of results.

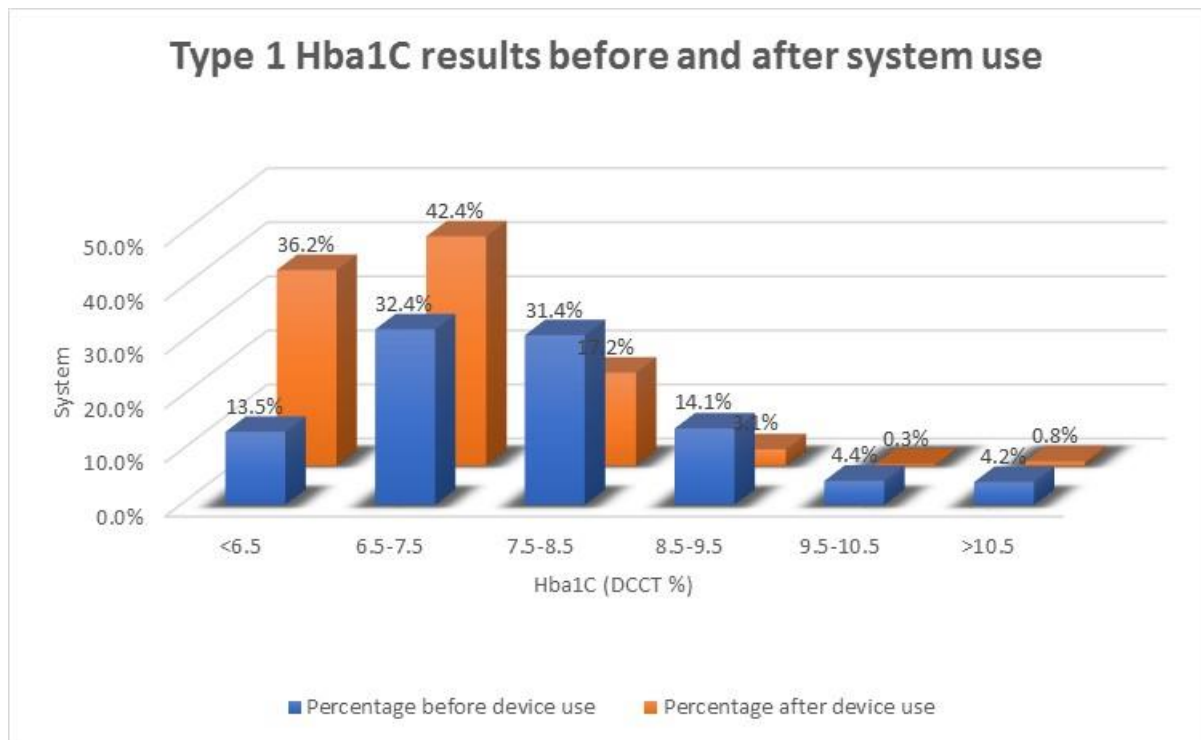


Figure 3 Comparison of Hba1C results before and after using system in Type 1s

Time-in-range was also reported on by participants. For the purposes of the survey, the participants were left to determine their own range.

Prior to using their systems, 45.5% of participants with type 1 diabetes didn't know their time-in-range and only 20.2% were able to report their time in range as greater than 50%.

Post use of a device, the proportion that did not know their time in range dropped to 16.4% and 68.2% of the participants reported time in range as greater than 50%.

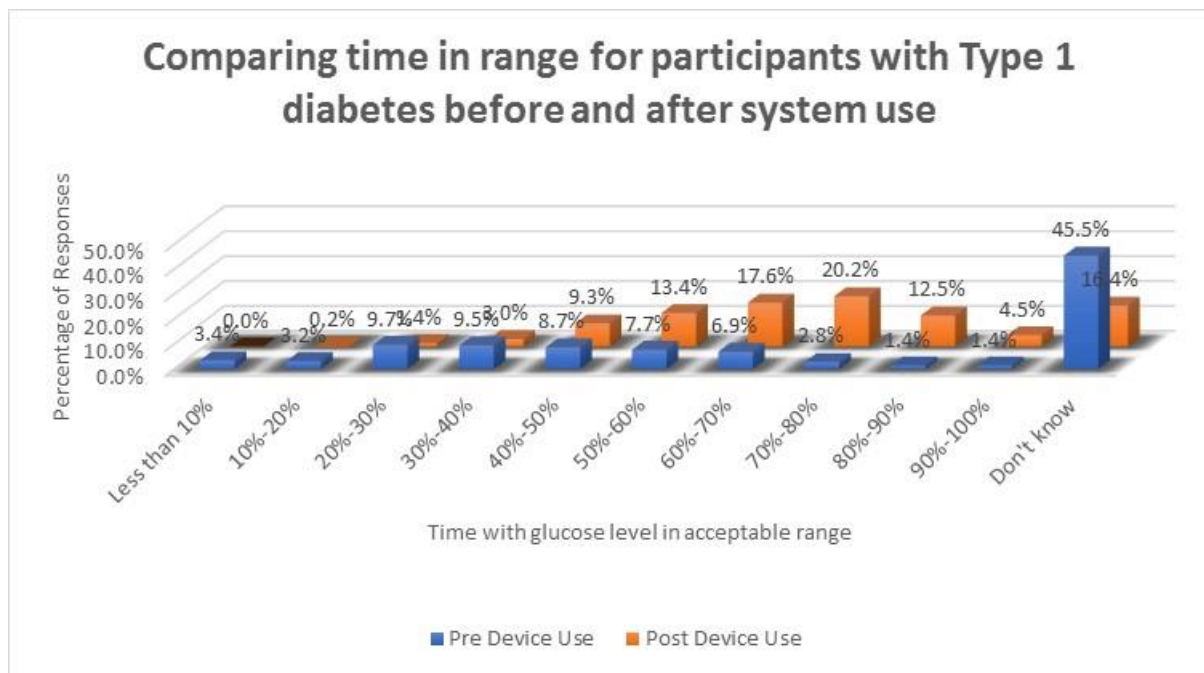


Figure 4 Comparison of time in range before and after using a system

Participants were also asked whether use of a CGR system had impacted their experience of living with diabetes, in terms of frequency and severity of hypo and hyperglycaemic events.

61% of those responding reported that hypo-glycaemic events had reduced, while 59% reported that hyper-glycaemic events had been reduced. 52% equally responded that the severity of the lows and highs they experienced were reduced. 43% equally said that hypo- and hyper-glycaemia count and severity had reduced.

46% felt that the number of both hypo- and hyper-glycaemic events had dropped, with 40% saying they had seen a reduction in the severity of both hypo- and hyperglycaemic events.

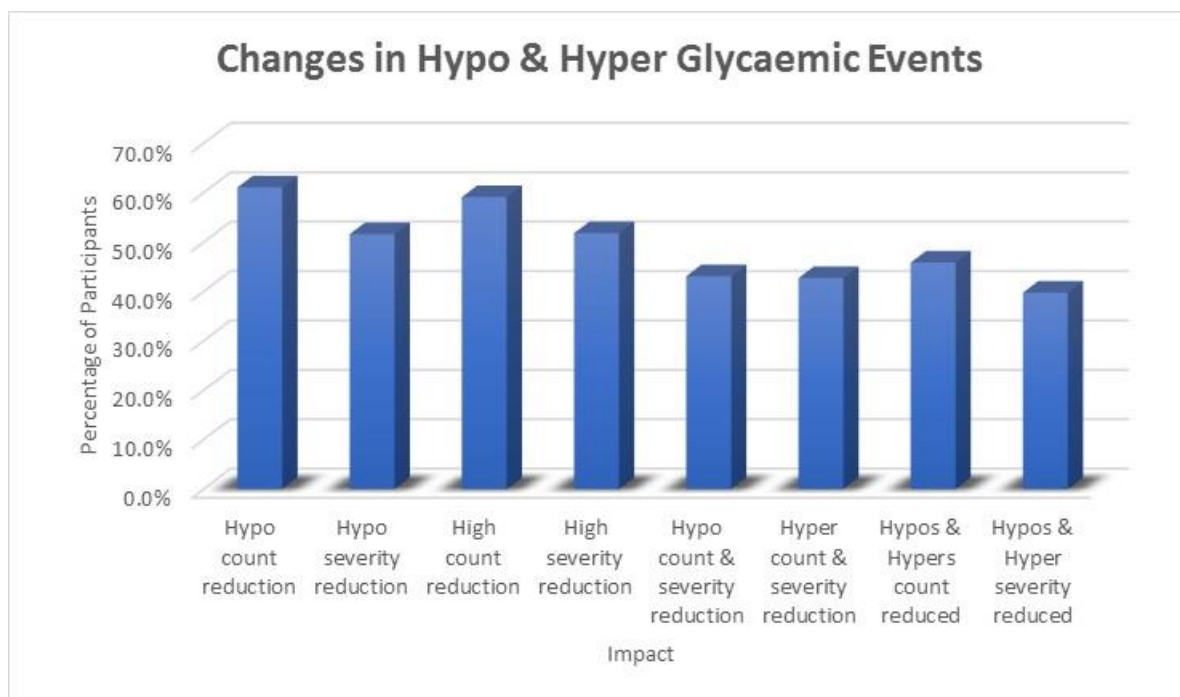


Figure 5 Percentage of participants reporting metabolic benefits by type

When compared across different systems, participant feedback showed that a greater proportion of the users that used Continuous Glucose Monitoring systems compared to the Flash Glucose Monitoring system felt they benefited from reductions in hypoglycaemic events, although the reduction in hyperglycaemic events was reported to be similar.

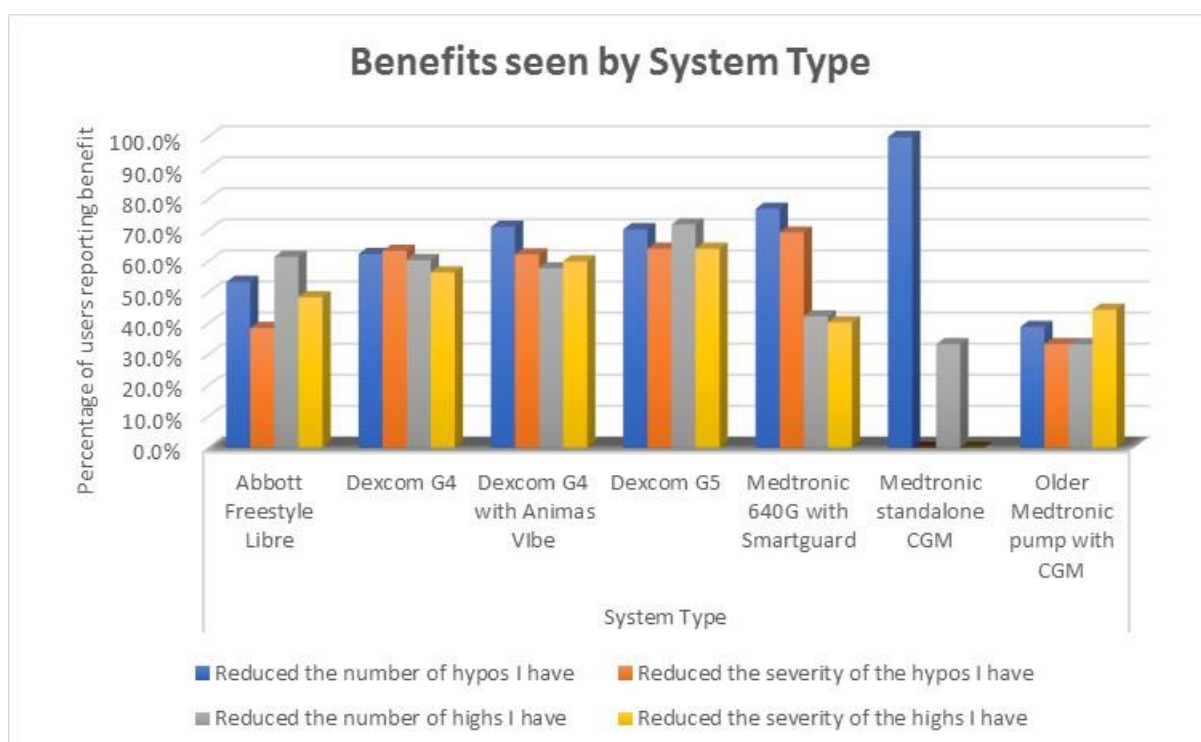


Figure 6 Users reporting metabolic benefits split by system type

The largest reduction in number and severity of hypoglycaemic events was reported by those using the Medtronic SmartGuard systems. Due to the small number of responses from users with the standalone Medtronic CGM, the results for that device overlay the impact.

Participant spend and choice

Spend on continuous recording systems is dependent on the type of system used. Overall the distribution of spend on systems showed that the majority of T1 participants spent £1000 to £1500 annually on the consumables required to use their choice of system.

Users of the Medtronic systems had the largest percentage of health system coverage within their system type, with while those under-16 had the largest percentage of all costs covered by a healthcare provider, at 37%.

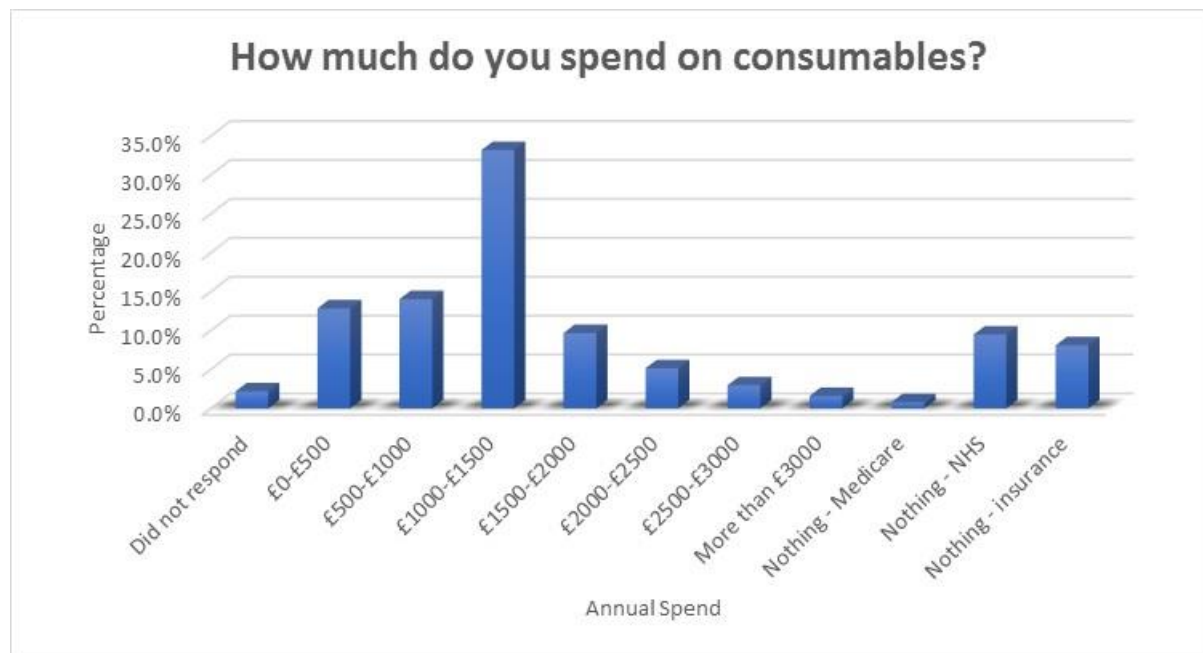


Figure 7 Distribution of participant annual spend on consumables

This is largely influenced by the amount spent on Libre and Dexcom G4 consumables. The Libre system showed a lower annual spend than most of the other systems.

Medtronic standalone CGM data was removed from the chart for clarity purposes, although it reflected the wider trend in Medtronic CGM use of having a higher proportion of healthcare provider paid users.

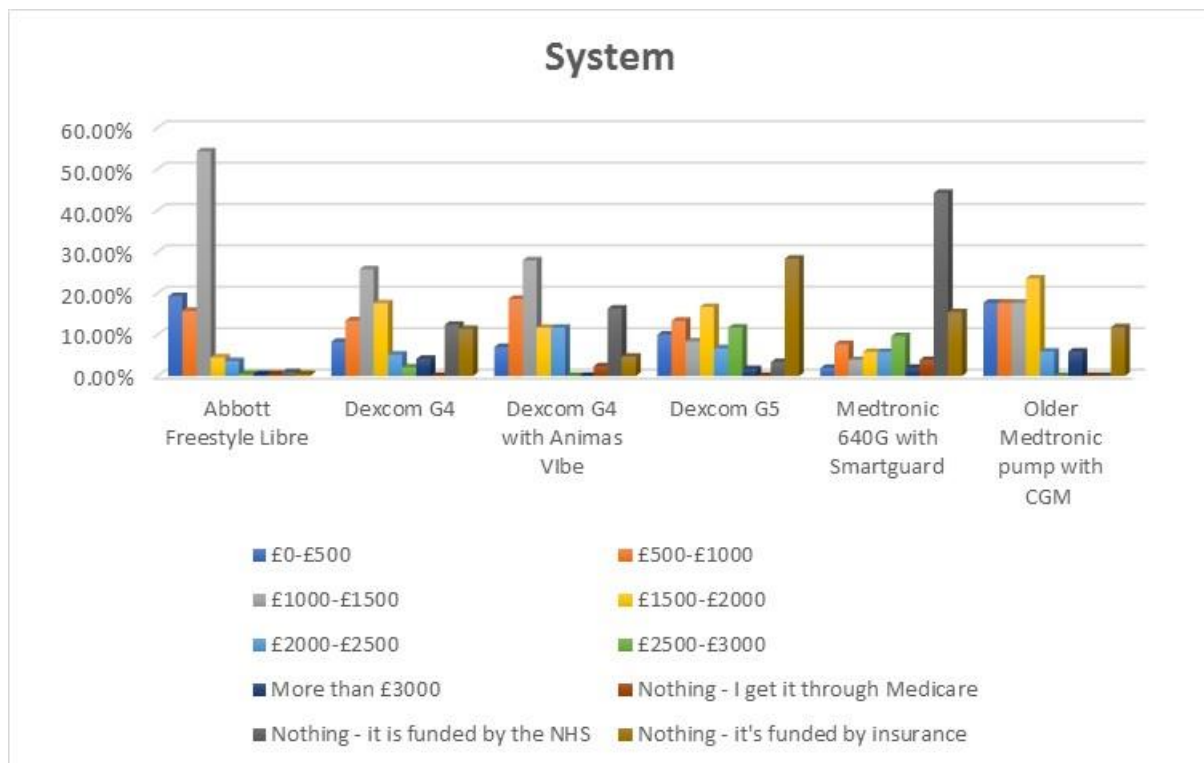


Figure 8 Breakout of annual participant spend on consumables by system

When a two-sample t-test assuming unequal variances was undertaken with a null hypothesis that those spending £0-£1000 annually on their system have an average change in Hba1C that is similar to those spending more than £1000 annually, the null hypothesis was rejected with $P < 0.05$.

With a two-sample t-test assuming unequal variances undertaken with a null hypothesis that those receiving NHS funding have an average change in Hba1C similar to those spending more than £1000 annually, the null hypothesis was accepted, although $P = 0.090$.

When a similar t-test to the first was run for those using Libre alone, the results were that spend appears to influence average change in Hba1C level ($P = 0.005$).

Additional Benefits from using a system

In addition to the metabolic benefits stated earlier, participants also reported that that additional benefits came in the form of peace of mind in relation to looking after either themselves or someone else in their family, and also gave peace of mind to their families and friends. When taken together, the percentage finding peace of mind in relation to themselves or somebody else in the family with diabetes accounted for 82.6% of the responses.

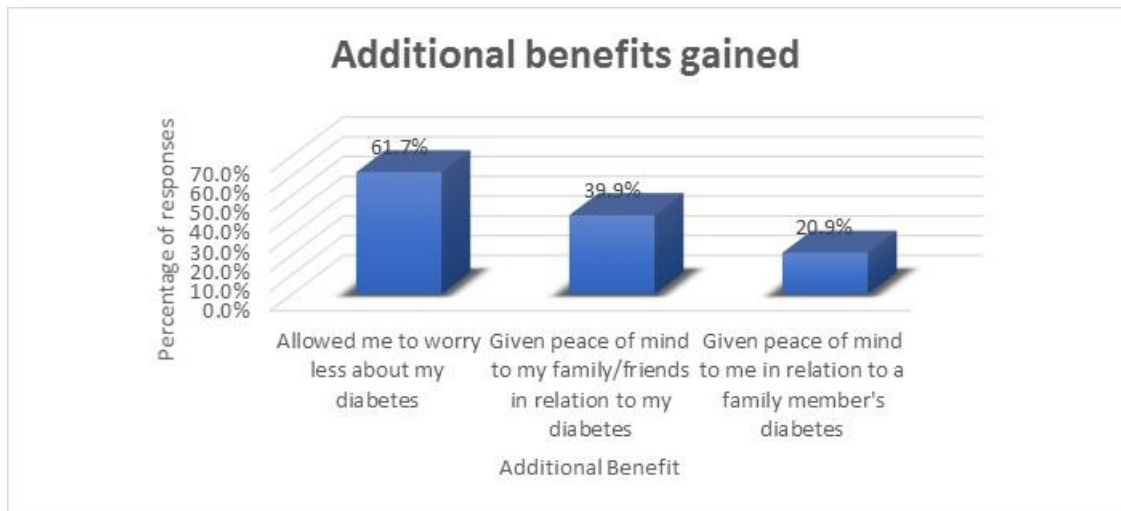


Figure 9 Percentage of participants reporting additional non-metabolic benefits

I identified five themes from the 65 freeform responses provided by participants. These were alleviation of over-riding worries; early warning of hypos; better testing; insight and action and improved quality of life.

Theme	Percentage of Responses	Subtheme
Alleviation of over-riding worries	12%	Concern about overnight hypos Anxiety over diabetes
Early warning of hypos	7%	
Better testing	7%	Reduced SMBG More discrete the SMBG
Insight and action	56%	General pattern observation and action on patterns Understanding effects of exercise and acting on them Understanding effect of food and acting on it Allowing better bolus timing Understanding basal and refining dosage Reduced variation of glucose levels
Improved Quality of Life	18%	Allowed less focus on diabetes Improved quality of life overall Gave a confidence boost Allowed focus on work

Table 3 Themes and subthemes of freeform responses to benefits seen

These were listed in addition to the previously mentioned benefits. Of those responding in free text, the majority of benefits came from the ability to observe patterns and react to them as a result of the data. This was identified by 56% of participants that responded to this section of the survey.

Inhibitors to use

Although 15% of the participants stated that they were either no longer using a system or only used a system sometimes, 26% responded to the question about inhibitors to use. By far the largest response (71% of responses) was that the systems cost too much.

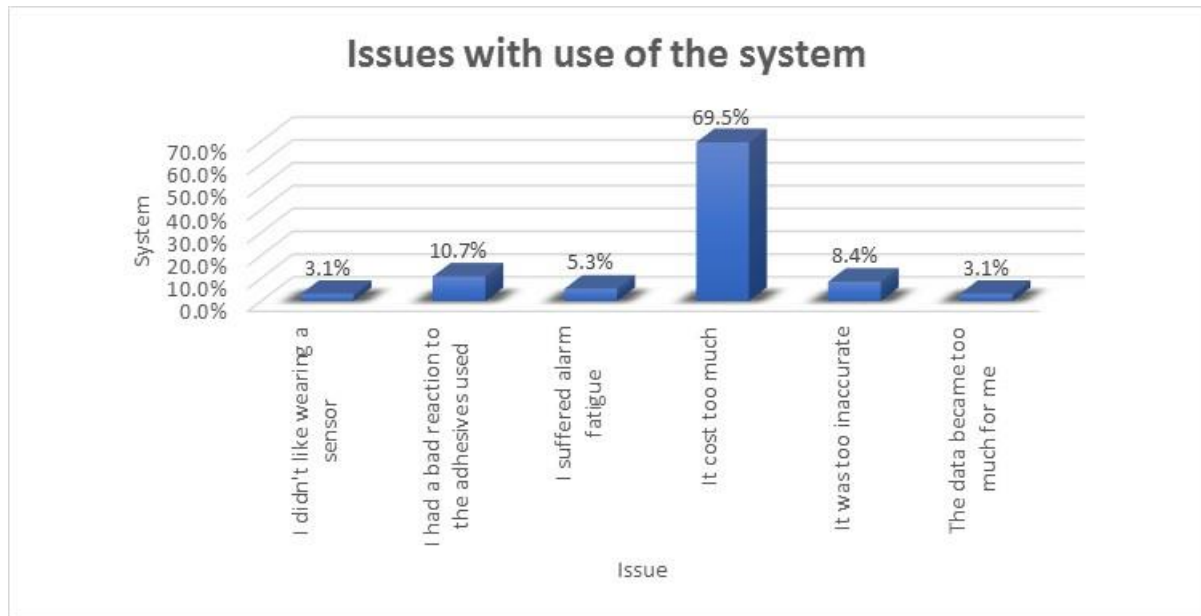


Figure 10 Distribution of issues reported with a system, as percentage of issues reported

When broken out by whether a system was still in use, cost was stated to be the biggest issue that participants raised. Amongst those who are still using a system, issues with volume of data, alarm fatigue, sensor inaccuracy, not liking wearing a sensor and adhesive reactions were stated.

Of those that had stopped using the systems, cost was cited as the most frequent reason for stopping, but system inaccuracy and a bad reaction to the adhesive were also raised.

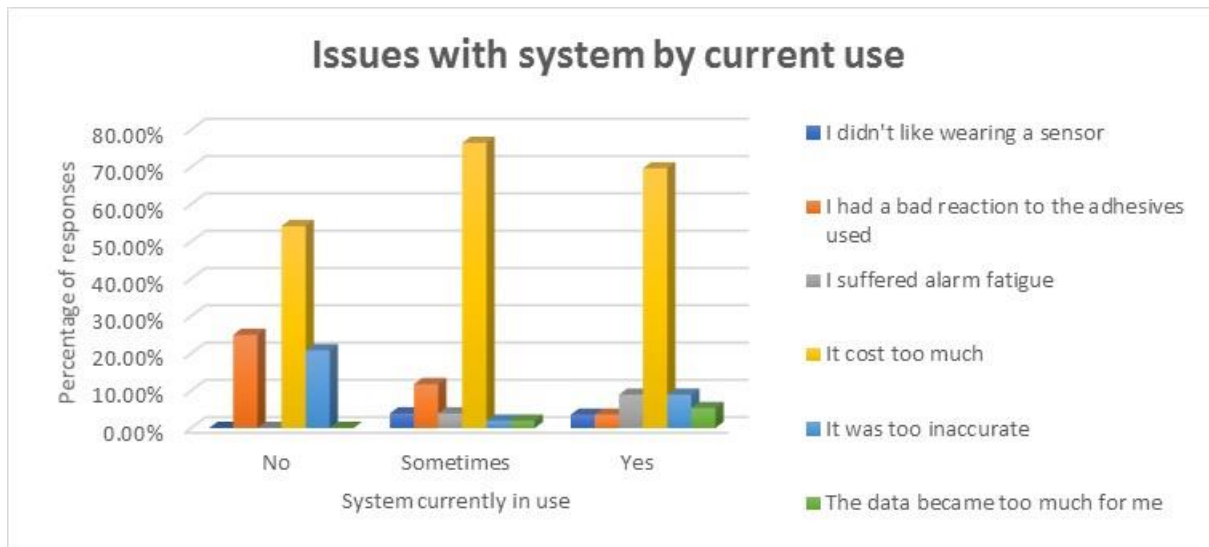


Figure 11 Distribution of reported issues by whether system is in use

Other reasons given for variability of usage were issues with supply, by two participants and choice of using only for diagnosis of issues, rather than full time.

When comparing the Hba1C change between those who were still using the system, those who sometimes used it and those who no longer did, there was a difference in the reduction noticed, as shown in table 4.

Is the system still being used?	Average change in Hba1C (%)	Std Dev of change in Hba1C (%)
No	-0.8	1.1
Sometimes	-0.9	0.9
Yes	-1.1	1.4

Table 4 Change in Hba1C in relation to continuous use of a system

Discussion

The data presented in this report was taken from a survey allowing users to self-report all the aspects covered. It is clear that those who participated do not follow the typical profile of UK people with diabetes, as demonstrated by table 5, which compares the distribution of Hba1C measures versus the UK National Diabetes Audit. The survey participants, prior to any use of continuous recording systems had nearly twice as many people with an Hba1C below 7.5% as the 2015-2016 National Diabetes Audit. The responses do not therefore reflect the average person with diabetes, and it is likely that this is linked to the participants receiving notification of the survey through various social media.

Type 1 Hba1C Level	Share at level (%)	
	NDA 15-16	Survey
HbA1c <6.5% (48 mmol/mol)	8.4	13.5
HbA1c ≤7.5% (58 mmol/mol)	29.2	45.9
HbA1c ≤10.0% (86 mmol/mol)	84.1	95.8

Table 5 Comparison of Hba1C of participants before using a system with 2016 NDA

The reductions in Hba1C and Hypoglycaemia that were reported by the participants were consistent with recent RCTs [1, 2, 6, 5]. The reported improvements in time in range and reduction in hyperglycaemia were also consistent with the reduction in Hba1C. Whether the system was paid for out-of-pocket or by a healthcare provider or insurer had no impact on the average change in Hba1C of participants.

While the majority of participants reported a reduction in frequency and severity of hypoglycaemic and hyperglycaemic events, when this was broken out by system type, the proportion of participants reporting reductions in frequency and severity of hypoglycaemic events when using flash glucose monitoring (FGM) was lower than those using continuous glucose monitoring (CGM). 53% of FGM users reported a reduction in hypoglycaemic events versus more than 62% on all other systems except older Medtronic pumps. Likewise, 39% of FGM users reported a reduction in the severity of hypoglycaemic events, versus more than 60% on all other systems except older Medtronic pumps. Based on this, I hypothesise that while the benefit provided by FGM in terms of visibility of the vector of glucose levels provides benefit, it is likely that the ability to be alerted about a dropping glucose level is of more benefit in taking action to avoid the outcome.

In light of the above, what was notable was the percentage of FGM users reporting reduced frequency and severity of hyperglycaemia was in line with those using CGM, and that fewer of those using the Medtronic 640G with SmartGuard reported a reduction in frequency and severity of hyperglycaemia. This may be due to those using this system having issues with hypoglycaemia awareness and as a result managing things differently, however the average reduction in Hba1C by system was reasonably consistent.

Most participants stated they are spending between £0 and £1500 annually on the consumables for their system of choice. This is not entirely reflective of off the shelf costs of the various systems, as there are many users of the Dexcom range of systems that use the sensors “off label” and get considerably more than the manufacturer stated seven days use. What the data also appears to show is that while many users of the Abbott Libre system stated they were still using it, they are not necessarily using it full time, due to the expenditure on the consumables.

Running hypothesis tests using spend on consumables and average change in Hba1C, a two-sample t test assuming unequal variances showed that the reported average reduction in Hba1C of those spending more than £1000 per annum on consumables

was greater than that of those spending less than £1000 per annum, and the difference was statistically significant.

I suspect that annual spend on consumables is likely to be the best proxy to determine whether a user is using their system “full time”. The rejection of the null hypothesis, that those spending less than £1000 per annum have the same average change in HbA1C to those spending more than £1000 per annum, suggests that those using their systems full time achieve greater average reductions in reported HbA1C, which reflects other studies on the use of CGM [5, 6].

Using the clear cost differential for Libre as a way of indicating if a system was being used full time (spending less than £1,000 per month does not align with the cost and deterministic nature of the lifespan of Libre consumables), when the same t-test was run on Libre results alone, there was significant rejection of the null hypothesis, with $P=0.005$. Whilst this strongly suggests that part-time use of a glucose recording system does not yield as good results as the full-time use, as previously mentioned, it also doesn't take into account whether this was the intended aim of the participant, and further research would be needed to establish this.

When comparing the variation of time in range identified by these two groups, the variation is much smaller. As time in range can only be effectively measured when using the CGR system, the results are also biased towards those periods when they are in use. Further research into the effects of using CGR part time or full time on glucose variation is needed.

A similar hypothesis test, looking at whether those with NHS funded systems had a lower average reduction in HbA1C than those who paid more than £1000 per annum rejected the null hypothesis, and showed average reductions were quite similar, although $P<0.1$.

This potentially gives an unfair view of the performance of NHS funded systems, as a key reason for NHS funding relates to impaired awareness of hypoglycaemia, and the expected outcome of use in this context is more likely to be an increase in or stability of average HbA1C levels.

Whilst the metabolic benefits were clear for participants, psychological benefits were also reported, with 61.7% of participants stating that they worried less about their diabetes and 20.9% reporting that they had peace of mind over someone else in the family as a result of using the system. This and the benefits of being able to identify patterns and act on them, that 56% of the freeform answers stated, reflects what other studies have found in relation to well-being and continuous monitoring [7, 8, 10].

Reflecting that the survey was generally completed by people that currently use these systems, 26% of participants reported issues with the systems and amongst those still using them 14% felt that the cost of consumables was too high.

Further research on the demographics of participants would provide useful insight into whether they are sacrificing in order to obtain these technologies, and if so, how much, giving a view of the real value to individuals.

This study has some limitations. As a self-reported set of data, accuracy of factors such as HbA1C and hypoglycaemic events cannot be confirmed. Likewise, the responders were left to provide their own determination of the range for time in range rather than any range being specified, so there are no objective measures for reported benefits.

Participants were engaged through a number of social media mechanisms, some of which included notable bias towards the use of continuous recording systems. As this was intended as a survey to show how those who used systems benefited from them, this is understandable, however it may also have provided a more positive bias in the results than a wider data collection exercise.

I also acknowledge that my use of technology and living with type 1 diabetes may influence my analysis of the data, however the data is available for anyone who wishes to use it to review, as it is anonymous.

In conclusion, the participants of the survey reported metabolic and psychological benefits of the systems they use. In spite of spending thousands of pounds on them, to those who continue to use them at the current cost, they provide a benefit that makes it worthwhile.

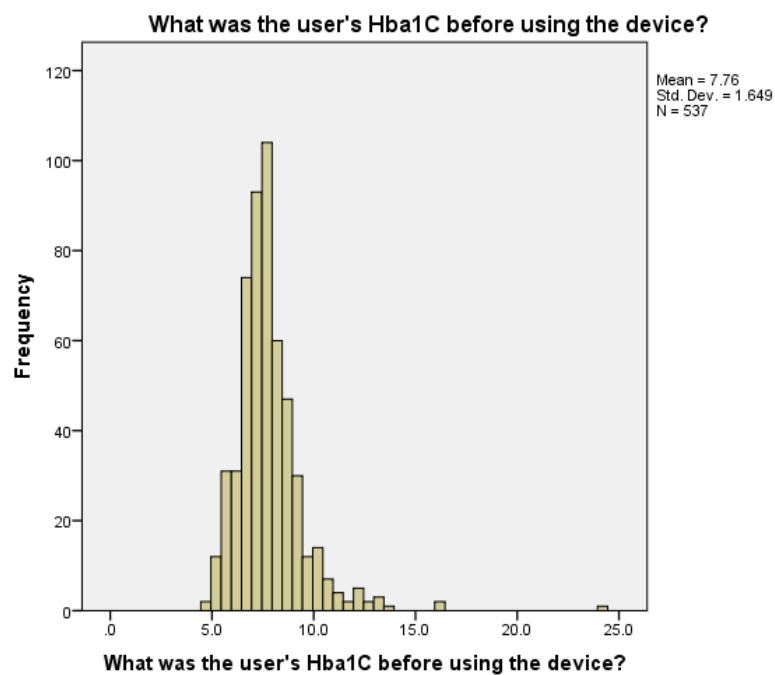
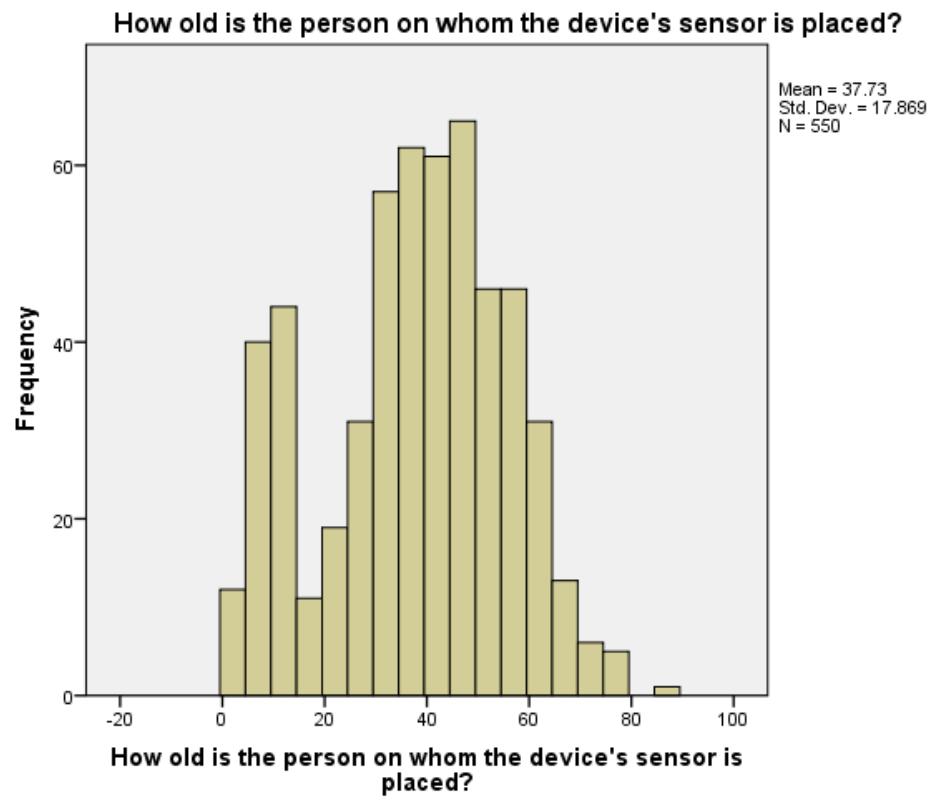
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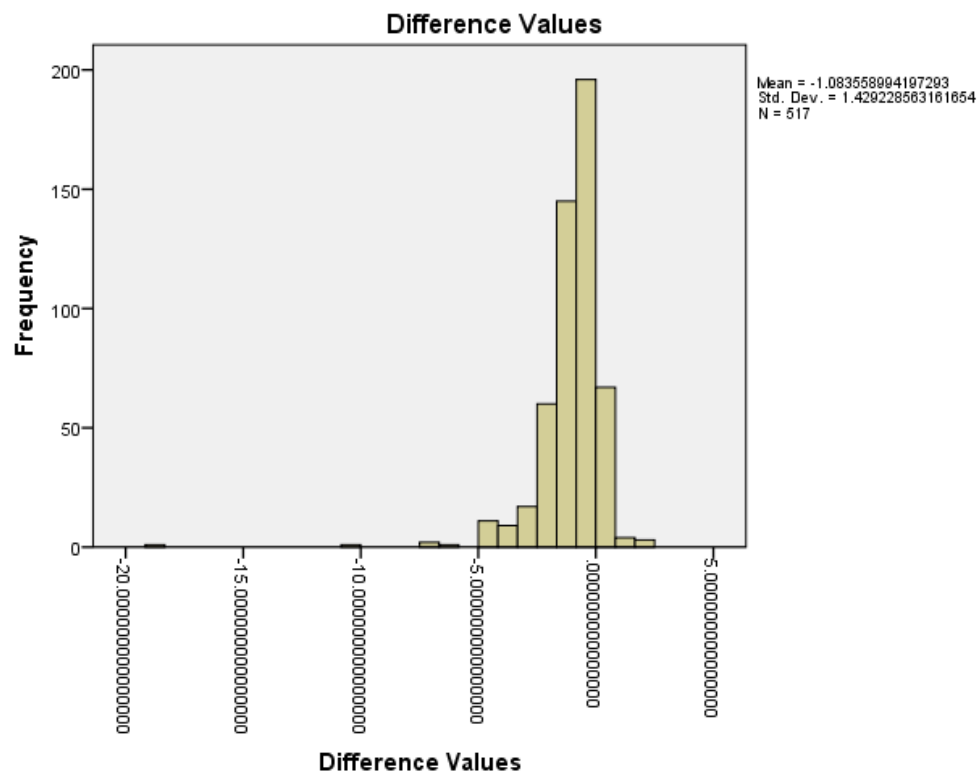
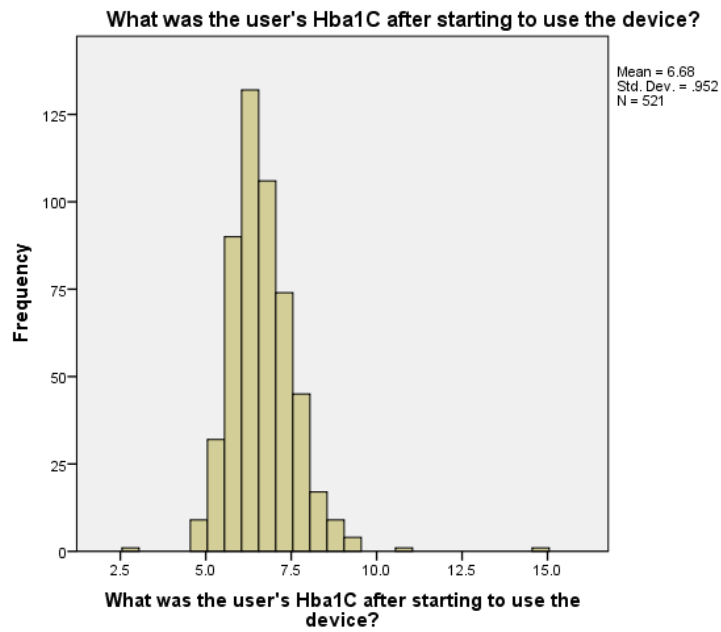
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Citations

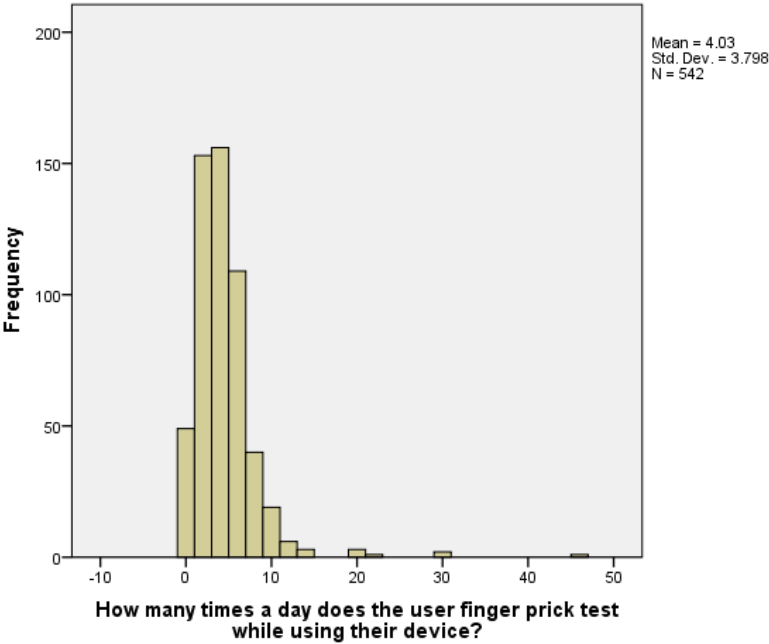
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Appendix A: Supplemental Chart Data

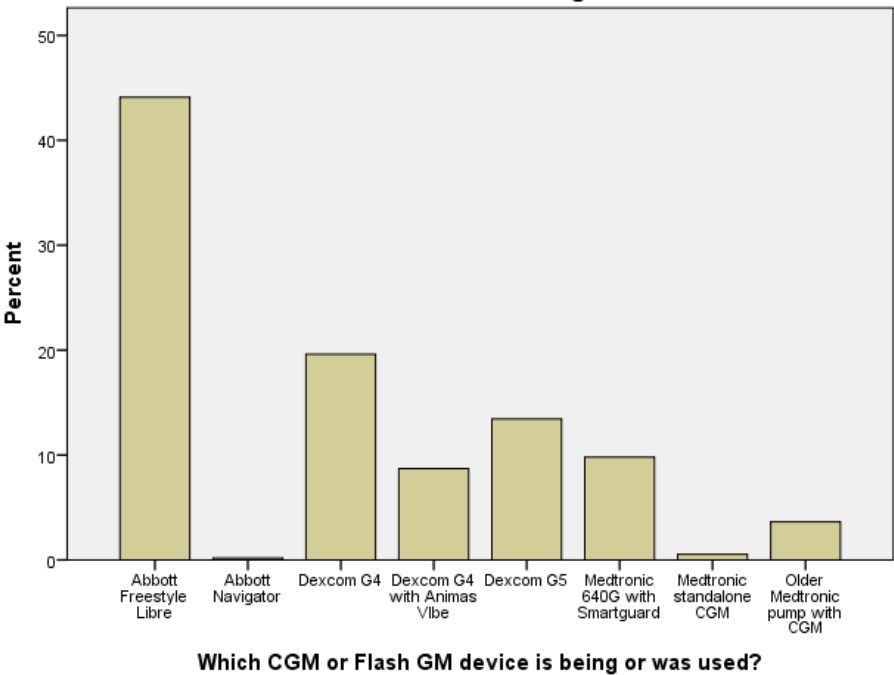


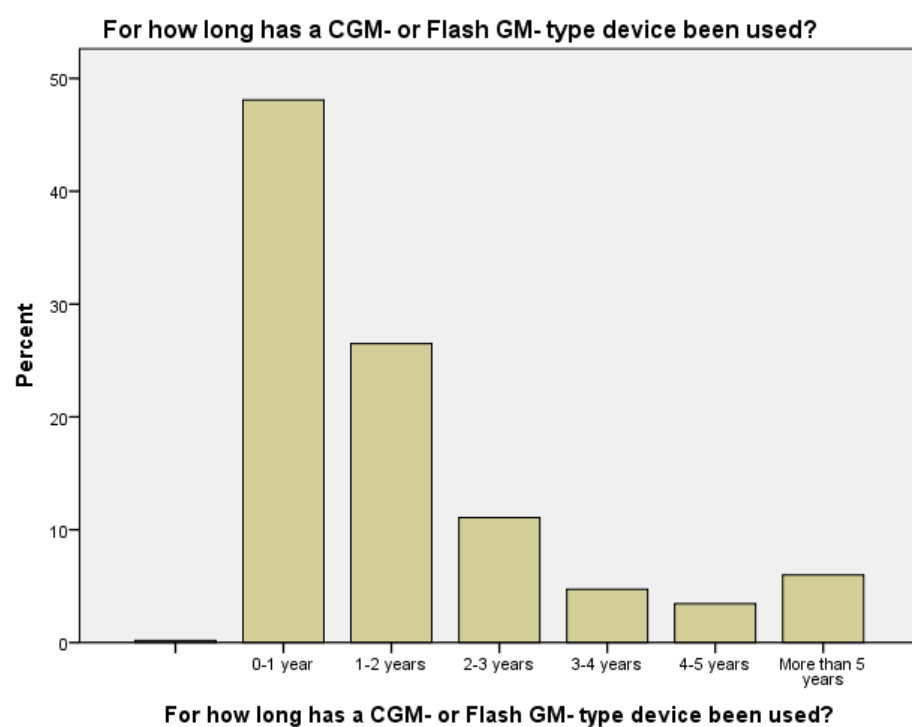


How many times a day does the user finger prick test while using their device?



Which CGM or Flash GM device is being or was used?





Appendix B: Survey Questions

1	<input checked="" type="checkbox"/> * What type of diabetes does the person who uses the device have?
2	<input type="text"/> * How old is the person on whom the device's sensor is placed?
3	<input type="text"/> If you are not in the UK, please choose non-UK or skip this question. If you are in the UK, please provide the...
4	<input type="text"/> * Which CGM or Flash GM device is being or was used?
5	<input checked="" type="checkbox"/> How much do you spend annually on the consumables (sensors, transmitters, etc)?
6	<input type="text"/> * What was the user's Hba1C before using the device?
7	<input type="text"/> * What was the user's Hba1C after starting to use the device?
8	<input type="text"/> * What was the user's time in range prior to using the device?
9	<input type="text"/> * What was the user's time in range after starting to use the device?
10	<input type="text"/> How many times a day does the user finger prick test while using their device?
11	<input checked="" type="checkbox"/> * For how long has a CGM- or Flash GM- type device been used?
12	<input checked="" type="checkbox"/> * Is the device still being used?
13	<input checked="" type="checkbox"/> If the device is no longer used or is used occasionally, please can you select the primary reason why? If the...
14	<input checked="" type="checkbox"/> How has using a continuous recording/monitoring device changed your experience of Diabetes? If there a...