**Intermittently scanned continuous glucose monitoring (isCGM) and hypoglycaemia awareness in drivers with diabetes: Insights from the Association of British Clinical Diabetologists (ABCD) Nationwide Audit**

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**Abstract**

Introduction: Frequent hypoglycaemia results in disruption to usual hypoglycaemic autonomic responses leading to impaired awareness of hypoglycaemia (IAH) which is associated with an increased risk of severe hypoglycaemia requiring third-party assistance (SH). The UK Driving and Vehicle Licensing Agency (DVLA) does not permit car driving if they have either a complete loss of hypoglycaemia awareness or more than one SH event a year.

Methods: The FreeStyle Libre (FSL) ABCD Nationwide Audit consists of data collected by clinicians during routine clinical work, submitted into a secure web-based tool held within the NHS N3 network. Analysis of paired baseline and follow-up data for people with type 1 diabetes who also held a driving licence was undertaken.

Results: The study consisted of 6304 people who had data recorded about driving status from 102 UK specialist diabetes centres, of which 4218 held a driving licence: 4178 a Group 1, standard licence, 33 a Group 2, large lorries and buses, 7 a taxi licence; 1819 did not drive. Paired baseline and follow-up data were available for a sub-cohort of 1606/4218. At mean follow-up of 6.9 months (95% CI [6.8, 7.1]), the Gold score had improved (2.3 (±1.5) vs 2.0 (±1.3) P <0.001), and the number of people who experienced an SH episode was also significantly lower (12.1% vs 2.7%, P < 0.001).

Conclusion: This study suggests that isCGM may improve IAH and reduce the number of people with type 1 diabetes with a driving licence experiencing a severe hypoglycaemic episode.

**Introduction**

Hypoglycaemia is a common occurrence in people living with diabetes, especially those on insulin or long duration[1,2.] This results in a range of psychosocial and physical adverse effects alongside increased morbidity and mortality[3]. Increased frequency of hypoglycaemic episodes leads to disruption in the usual autonomic response to hypoglycaemia resulting in a lack of symptoms (impaired awareness of hypoglycaemia, IAH). Increased frequency of hypoglycaemia can increase the risk of developing severe hypoglycaemia (SH) requiring third-party assistance. IAH affects up to a third of people living with type 1 diabetes and increases the risk of SH by up to 6-fold[3-8]. It is estimated that 30-40% of people with type 1 diabetes have an episode of SH each year, with an annual incidence of 1 to 1.7 episodes per patient per year[9].

The UK Driver and Vehicle Licencing Agency (DVLA) states that those with Group 1 (cars and motorcycle) driving licences with either 'an inability to detect the onset of hypoglycaemia because of the total absence of warning symptoms' or 'more than 1 episode of severe hypoglycaemia whilst awake in the preceding 12 months' should not drive and should notify the DVLA (DVLA leaflet INF294). Those with Group 2 (large lorry or bus) licences must have full awareness of hypoglycaemia and no episodes of severe hypoglycaemia in the preceding 12 months (DVLA leaflet INF294).

Population data on IAH and SH in drivers with diabetes and subsequent effects on driving ability are limited both in the United Kingdom (UK) and worldwide[2]. We have recently shown that a large proportion of drivers with diabetes have IAH and severe hypoglycaemia; however, the effect of intermittently scanned continuous glucose monitoring (isCGM) on the prevalence of IAH and SH is not known.

FreeStyle Libre (FSL) isCGM uses a sensor on the arm and connects to a mobile phone app or reader to display glucose levels and alerts. It has been available on the UK National Health Service (NHS) drug tariff since 2017 and NICE currently recommend that all people with type 1 diabetes should be offered real-time or intermittently scanned CGM (NICE NG 17 1.6) [10]. The DVLA states that group 1 drivers can

now use finger prick capillary blood glucose testing or CGM for monitoring glucose levels driving; however, if the reading is 4mmol/l or below on CGMs then a confirmatory finger prick test is needed. Group 2 licence holders must still use finger prick testing (DVLA INF294). The current DVLA regulations do not recommend the use of isCGM for Group 2 licence holders due to a lack of data on the use of isCGM in drivers with diabetes.

The FSL ABCD audit has collected data on drivers with diabetes before and after they started using FSL. This data could be utilised to inform policy decisions and help optimize treatment options in drivers living with diabetes. Therefore, the objective of this study is to assess the possible effects of FSL on IAH and SH incidence along with glycaemic control, paramedic callouts and hospitalisations in people with type 1 diabetes who hold a driving licence.

**Methods**

This is a follow-up study of the ongoing Nationwide FreeStyle Libre ABCD Audit (http://www.diabetologists-abcd.org.uk/n3/FreeStyle_Libre_Audit.htm). Data collection started in November 2017 via a secure online NHS tool to ensure optimal security and permit nationwide anonymised data to be analysed. Visits during routine clinical care were used to collect baseline (covering the 12-month period prior to FSL initiation) and follow-up data (collected during routine clinical care) which included demographic characteristics, driving status, diabetes type and duration, HbA1c, diabetes distress screening scale scores (DDS2), Gold score and number of SH episodes. The Gold score identifies IAH through a seven-point questionnaire, with a score of four or more indicating impaired awareness. DDS2 consists of the average score of two grading questions one (not a problem) to six (a very serious problem) regarding the feeling of being overwhelmed by living with diabetes and the feeling of failing in their diabetes routine.

This is a live dataset with data being added contemporaneously and so a snapshot was taken on 11th April 2023 to be used as the basis for this analysis. Duplicates have been removed and for the baseline comparison of those with and without a driving licence, those without a driving licence who are 17

years old or younger have been excluded. For the baseline and follow-up paired analysis only those with type 1 diabetes and who hold a driving licence were included. Those with complete impaired awareness of hypoglycaemia were defined by a Gold score of seven. The number of severe hypoglycaemic episodes and the number of hospital admissions that included a decimal point number or were above 20 were excluded as these were felt to be not clinically viable and likely errors. The number of severe hypoglycaemic episodes includes admissions due to hypoglycaemia, paramedic callouts for hypoglycaemia and episodes of severe hypoglycaemia requiring third-party assistance but not requiring admission or paramedic callout.

**Statistical Methods**

The follow-up period was defined as the duration between the date that FSL was initiated and the most recent recorded HbA1c measurement. Mean, standard deviations and percentages were used to present baseline characteristics between those with and without a driving licence, with p values determined by t-tests or chi-squared tests where appropriate. A subset of those with type 1 diabetes and who hold a driving licence were analysed at baseline and follow-up to determine changes in mean Gold score, diabetes distress scores, HbA1c, and mean and total SH episodes, with p values determined by t-tests or chi-squared tests where appropriate. Pro rata analysis was performed due to the difference in duration before and after the FSL application. Time below range (TBR) was split into the following groups: TBR below 4%, TBR below 10% and TBR below 15%. Correlation between groups was calculated with a one-way ANOVA test. Statistical analysis was undertaken using IBM SPSS Statistics (Version 28).

**Ethical Approval**

Caldicott Guardian approval has been given to the ABCD Nationwide Audit Programme. The ABCD audit programme is designated audit work and not research. Guidelines followed stipulated that all data collected should only be from routine clinical visits and only anonymised data were submitted to the central database.

**Results**

Figure 1 shows the study flow diagram. The study consisted of 17660 people living with diabetes, of which 6304 had data on driving status (4218 held a driving licence, and 1819 did not drive). Of the 4218 with a driving licence, 4178 held a standard group 1 licence, 33 held a group 2 (large lorry or bus) licence and 7 had a taxi licence.

Table 1 compares the baseline characteristics of those that did hold a driving licence and those that did not drive. Those with a driving licence were older (45.3(±15.6) vs 43.8(±18.8) P 0.006), more likely to be male (56% vs 45% P <0.001) and had a slightly higher BMI (27.6 (±44.1) vs 26.2 (±7.0) P 0.285) when compared to those who did not drive. Those with a driving licence had a lower baseline HbA1c (71.1(±19.1) vs 76.0(±21.8) P <0.001) and lower baseline Gold score (2.3 (±1.5) vs 3.2 (±2.1) P <0.001) than those who did not drive. Those who did not drive had a significantly higher diabetes distress screening scale score (DDS2) compared to those with a driving licence (3.3 (±1.5) vs 2.8 (±1.3) P <0.001). Those with driving licences had fewer episodes of SH on average in 12 months prior to isCGM than those who do not drive (0.4 (±1.6) vs 1.4 (±3.3) P <0.001). At baseline, more had experienced an SH episode in the 12 months leading up to FSL initiation in the group that did not drive compared to those that drove (19% vs 10% P <0.001).

Table 2 compares baseline and follow-up characteristics of those with type 1 diabetes who held a driving licence at the point of isCGM initiation, with a mean follow-up period of 6.9 months. The initiation of isCGM was associated with a reduction in the percentage of people with IAH (Gold score ≥4) (20.4% at baseline vs 11.6% at follow-up, P < 0.001) and Gold scores improved (2.3 (±1.5) vs 2.0 (±1.3) P <0.001). The percentage of people with complete impaired awareness of hypoglycaemia (Gold score of 7) was similar at baseline and follow-up (1.5% vs 1.2% P 0.425). There was a significant improvement in diabetes distress screening scale scores (DDS2) between baseline and follow-up (2.5 (±1.5) vs 1.9 (±1.3) P <0.001) with a significant reduction in the percentage of people with moderate to severe diabetes distress (DDS2 score of 3 or more) at follow up compared to baseline (43.2% vs

21.7% P < 0.001). There was a reduction in the mean number of SH per month following isCGM application when compared to the mean number of SH during 12 months prior to isCGM (0.03 (±0.12) vs 0.02 (±0.27) P 0.062); however, it did not reach significance. At follow-up, the number of patients per month with type 1 diabetes who hold a driving licence and who experienced an episode of SH was significantly lower than baseline (0.4% vs 1.0%, P 0.032). A significant reduction in mean HbA1c was seen at follow-up compared to baseline (69.2 mmol/mol (±18.0) vs 62.4 mmol/mol (±13.6) P < 0.001).

Figure 2 shows resource utilisation of people with type 1 diabetes and who hold a driving licence at baseline and at follow-up of the FSL ABCD audit. It shows a reduction in the total number of people experiencing a severe hypoglycaemic episode (195 vs 44), the total number of people needing a paramedic callout for hypoglycaemia (68 vs 11), the total number of people requiring hospital admissions due to hypoglycaemia (40 vs 13) and the total number of people requiring hospital admissions due to hyperglycaemia/ DKA (83 vs 9) at follow up compared to baseline. In order to compensate for the 12 months pre-FSL application and mean follow-up time of 7 months, a sensitivity pro rata analysis per month was undertaken which showed similar reductions in the follow-up group compared to baseline. In the pro-rata analysis, there was a reduction in the total number of people experiencing a severe hypoglycaemic episode per month (16.3 vs 6.3 P 0.03), total number of people needing a paramedic callout for hypoglycaemia per month (5.7 vs 1.6 P 0.16), total number of people requiring hospital admissions due to hypoglycaemia per month (3.3 vs 1.9 P 0.65) and total number of people needing hospital admissions due to hyperglycaemia/ DKA per month (6.9 vs 1.3 P 0.03) at follow up compared to baseline.

In the study population, 628 people (39%) had time below range (TBR) below 4%, 1088 (68%) had a TBR below 10% and 1223 (76%) had a TBR below 15%. We found no statistically significant association between TBR across the above categories and severe hypoglycaemic episodes per month, hospital admissions due to hypoglycaemia per month and paramedic callouts for hypoglycaemia per month.

**Discussion**

We present follow-up data from the ABCD Nationwide Audit looking at the impact of isCGM on impaired awareness of hypoglycaemia and episodes of severe hypoglycaemia in drivers living with diabetes. We show that in those with type 1 diabetes and who hold a driving licence, episodes of SH and IAH were reduced after isCGM initiation. We also report an improvement in glycaemic control and diabetes-related distress with the use of isCGM.

There is a concern regarding under-reporting of hypoglycaemia awareness and severe hypoglycaemic episodes in drivers, as it all depends on the drivers self-reporting with the knowledge that either IAH or SH will result in driving licences potentially being revoked or suspended. Under-reporting of SH following the implementation of new EU regulations was seen in the Danish population[11] with 23 percent of drivers with diabetes holding a Group 1 licence and 16 percent of those holding a Group 2 licence stating they would consider under-reporting their episodes of severe hypoglycaemia[12]. Given this tendency to underreport it is important to understand the prevalence of IAH and SH in the national population to make evidence-based policy decisions and enhance the management of drivers with diabetes[13]. Although the ABCD dataset primarily collects data to assess the effect of isCGM on outcomes in diabetes, it is equally susceptible to under-reporting.

Recommending driving cessation and self-reporting to the DVLA in a consultation can be a very challenging process. On the one hand, we know that many people with diabetes may withhold information about hypoglycaemia and IAH to maintain their driving privileges. On the other hand, clinicians may be unwilling to recommend driving cessation to maintain their patient-doctor relationship and because they will often have implemented therapy changes to reduce the risk of hypoglycaemia. Driving cessation in the general population can lead to reduced social contacts, reduced activity, and increased dependence on others[13,14]. In people with diabetes, driving cessation can cause all the above and impact the quality of life; hence it is important to identify and intervene to improve IAH. Interventions associated with improvement in hypoglycaemia awareness include DAFNE structured education, CGM and continuing support[15-17]. This could explain the relative youth of

those without driving licences in our study, as one possibility is that they may have already been disqualified from driving prior to starting FSL and so FSL application may have been an intervention designed to enable some of this cohort to reapply for their (group 1) licence, but this cannot be proven with the data collected in this audit.

This study and previous FSL nationwide studies[2,18] have shown that Gold scores improved and episodes of SH reduced between baseline and follow-up, suggesting that isCGM may be a useful way to improve IAH and reduce SH in those who hold driving licences.

In this study, we demonstrated that isCGM use is associated with a reduction in the number of people with type 1 diabetes and who hold a driving licence experiencing an episode of severe hypoglycaemia. This is in agreement with findings from previous observational data[18] and the IMPACT trial, which found isCGM led to significantly reduced episodes of hypoglycaemia in people with well-controlled type 1 diabetes[19]. Many struggle to achieve good glycaemic control using finger prick testing for glucose monitoring, resulting in an elevated HbA1c and increased risks of complications[20-22]. CGM was introduced as a way for people with diabetes to manage their diabetes without the need for regular finger prick testing. The open-label FLASH-UK randomised control trial recruited people with type 1 diabetes with high HbA1c. It examined the impact of the FreeStyle Libre 2 vs self-monitoring of blood glucose on outcomes such as Hba1c and treatment satisfaction. Those on isCGM had significantly reduced HbA1c levels, more time spent within target glucose range and reduced hypoglycaemic burden[23]. The improvement in HbA1c as seen in our study and the FLASH-UK trial has been replicated in many trials comparing CGM to traditional finger prick testing, such as the DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) trial[24] and the GOLD trial (A Randomized Trial of the Effect of Continuous Glucose Monitoring [CGM] in Individuals with Type 1 Diabetes Treated with Multiple Daily Insulin Injections [MDI])[25].

It has been shown that diabetes can be associated with significant emotional distress, with negative impacts on self-management of diabetes, clinical outcomes, and mortality[26]. Quality of life (QOL) data

from the DIAMOND trial found that CGM was associated with significant improvement in diabetes-related quality of life metrics, such as hypoglycaemic confidence and diabetes distress, and that this effect was seen across demographics[27]. This is in agreement with our study findings although other randomised controlled trials have shown absent[19,28] or very small[15] improvements in QOL specific to diabetes. Interestingly our retrospective study, and other qualitative studies have suggested there is a benefit of CGM on diabetes related QOL[29,30]. It is not known why there appears to be a disparity between QOL findings. One possibility is that the experience of those patients and health care professionals using the equipment may differ between studies and equally the experience in interpreting the data output. Another theory is that as technology improves and becomes more reliable and accurate, more consistent improvements in diabetes related QOL will be seen as compared to older studies using older technologies[31].

We also found that resource utilisation by people with type 1 diabetes and who hold a driving licence reduced between baseline and follow-up, with a statistically significant reduction in the number of people experiencing a severe hypoglycaemic episode (which includes admissions and paramedic callouts for hypoglycaemia) and people requiring admission for hyperglycaemia or DKA. These findings are in keeping with results from the FUTURE study[32] and data from a population-based study in Scotland[33]. However, to evaluate the longer-term economic benefit and clinical utility a full cost-effective analysis will be needed after sufficient follow up[18].

The strengths of this study include the large representative cohort with data from real-world clinical practice which contributes to better generalizability of the cohort. This data provides a unique insight into the prevalence of IAH and SH in UK drivers with diabetes. However, our study has several limitations. We have shown that IAH improved in drivers between baseline and follow-up; however, we do not have information on more detailed assessments of hypoglycaemia awareness such as the Clarke Score. With regards to SH, we do not have data on the timing of the events; notable as nocturnal events do not prohibit driving for Group 1 licence holders. We have seen a non-significant reduction

in mean SH which could be due to the limited follow-up period or small sample size. Furthermore, IAH and SH, at the time of data collection, were national indications for FSL funding in England and this may have led to the over-representation of those with IAH in this cohort. Equally, this may be offset by the under-reporting of problematic hypoglycaemia in some individuals with diabetes secondary to the fear of losing their driving licence. Another limitation is that given the ongoing nature of the ABCD audit, and that this data analysis is based upon a snapshot, the population included will be those using both alarmed and non-alarmed flash CGM (FSL2 and FSL1), with the data that would enable us to subgroup FSL 1 or 2 not collected in the audit. Furthermore, many will likely have started on FSL 1 and then moved to FSL 2 and started using alarms within the timeframe of the audit. Currently, there are no studies directly comparing FSL 1 and 2, however, previous studies have shown additional benefits of alarmed CGM over non-alarmed rtCGM [23,34,35,36]. Another limitation that should be noted is that we are comparing 12-month pre and 6.9 months after FSL initiation, however this has been compensated by undertaking pro rata analysis where possible. Although we did not find any significant association between TBR and admission due to hypoglycaemia, it is possible that we do not have adequate power for this analysis due to the small sample size.

In summary, we present follow-up analysis of the FSL nationwide audit. This study suggests that isCGM use is associated with an improvement in hypoglycaemia unawareness and a reduction in severe hypoglycaemic episodes in drivers with type 1 diabetes. We also saw a reduction in HbA1c and diabetes distress scores and a possible reduction in resource utilization, suggesting that isCGM may also improve the overall quality of life and outcomes in drivers with diabetes.

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Author contributions:

- H.D., E.G.W., and T.S. conceived the presented idea. C.M.W and H.D. contributed to the data analysis. C.M.W. wrote the first draft of the manuscript. All of the authors reviewed the manuscript and made comments, criticism, and changes in the final draft of the paper. C.M.W. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of interest:

- The ABCD nationwide FSL audit is supported by a grant from Abbott Laboratories.
- The FSL audit was independently initiated and performed by ABCD, and the authors remain independent in the analysis and preparation of this report.
- R.E.J.R. has received speaker fees, and/or consultancy fees and/or educational sponsorships from Besins, BioQuest, GI Dynamics, and Novo Nordisk.
- E.G.W. serves on the advisory panel for Abbott Diabetes Care, Dexcom, and Eli Lilly and Company; has received research support from Diabetes UK; and is on the speakers bureau for Abbott Diabetes Care, Dexcom, Eli Lilly and Company, Insulet Corporation, Novo Nordisk, and Sanofi.
- No other potential conflicts of interest relevant to this article were reported.

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**Figures**

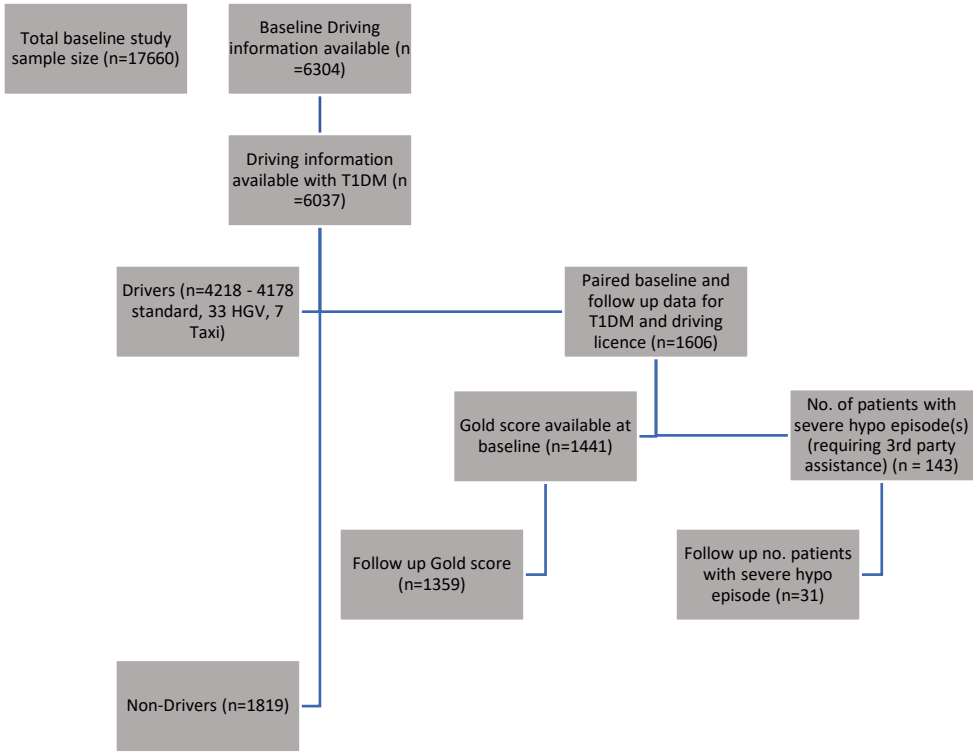


Figure 1: Study schematic showing data for Gold score and SH episodes in people with type 1 diabetes and who drive in this follow up study of the ABCD nationwide audit of FSL. Study outline shows the number of patients recruited in the study and sample size of those with paired baseline and follow-up data who have type 1 diabetes and who drive.

| | Baseline data with a driving licence (n=4386) | Baseline data without driving licence (n=1476) | P-value |
|---|---|---|---|
| Age (years) | 45.3(±15.6) | 43.8 (±18.8) | 0.006 |
| Gender (% Females) | 1908 (44%) | 816 (55%) | <0.001 |
| Baseline BMI (kg/m$^2$) | 27.6 (±44.1) | 26.2 (±7.0) | 0.285 |
| Duration of Diabetes | 21.4(±33.7) | 24.8(±86.9) | 0.069 |
| Type 1 Diabetes (%) | 4218 (96%) | 1378 (93%) | < 0.001 |
| Insulin Pump (%) | 621 (14%) | 160 (11%) | 0.001 |
| Number of tests strips used per day | 7.1(±10.3) | 5.8 (±5.5) | <0.001 |
| Baseline HbA1c | 71.1(±19.1) | 76.0(±21.8) | <0.001 |
| Mean number of severe hypoglycaemic episodes per person in 12 months prior to isCGM initiation | 0.4 (±1.6) | 1.4 (±3.3) | <0.001 |
| Total number of patients experiencing severe hypoglycaemic episodes in 12 months prior to isCGM initiation | 433 (10%) | 279 (19%) | <0.001 |
| Gold score | 2.3 (±1.5) | 3.2 (±2.1) | <0.001 |

| | | | |
|---|---|---|---|
| DDS2 | 2.8 (±1.3) | 3.3 (±1.5) | <0.001 |
| Group 1 Licence | 4344 (99%) | NA | NA |
| Group 2 Licence and Taxi Licence | 42 (1%) | NA | NA |

Table 1: Baseline demographic and clinical characteristics of people with diabetes with and without a driving licence. P-value from t-test or chi-squared test where appropriate.

| | Baseline Type 1 Diabetes with driving licence (n=1606) | Follow up Type 1 Diabetes with driving licence (n=1606) | P-value |
|---|---|---|---|
| Mean Gold score | 2.3 (±1.5) | 2.0 (±1.3) | < 0.001 |
| Impaired awareness of hypoglycaemia (Gold score 4 or more) | 294 (20.4%) | 157 (11.6%) | < 0.001 |
| Complete IAH (Gold score =7) | 22 (1.5%) | 16 (1.2%) | 0.425 |
| Mean number of severe hypoglycaemic episodes per month | 0.03 (±0.1) | 0.02 (±0.3) | 0.062 |
| Total number of patients experiencing ≥ 1 severe hypoglycaemic episodes per month prior to isCGM initiation vs after | 16.25 (1.0%) | 6.38 (0.4%) | 0.032 |
| Number of patients experiencing 1 severe hypoglycaemic episode per month prior to isCGM initiation vs after | 6.83 (0.4%) | 3.91 (0.2%) | 0.365 |
| Number of patients experiencing 2 severe hypoglycaemic episodes per month prior to isCGM initiation vs after | 3.58 (0.2%) | 1.59 (0.1%) | 0.414 |
| Number of patients experiencing ≥ 3 severe hypoglycaemic episodes per month prior to isCGM initiation vs after | 5.83 (0.36%) | 0.87 (0.05%) | 0.059 |
| DDS2 | 2.5 (±1.5) | 1.9 (±1.3) | <0.001 |
| Moderate to severe diabetes distress (DDS2 score of 3 or more) | 694 (43.2%) | 348 (21.7%) | <0.001 |
| HbA1c | 69.2 (±18.0) | 62.5 (±13.6) | <0.001 |

Table 2: Paired baseline and follow up data in people with type 1 Diabetes and have a driving licence. P-value from t-test or chi-squared test where appropriate.

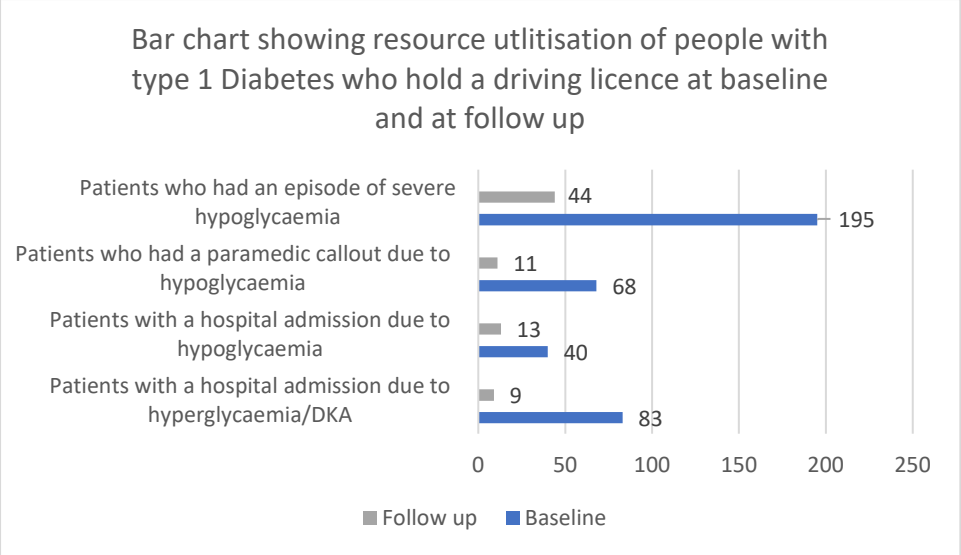


Figure 2: Bar chart showing resource utilisation of people with type 1 diabetes who hold a driving licence at baseline and at follow up of the FSL ABCD audit. Includes total number of people experiencing a severe hypoglycaemic episode, total number of people needing a paramedic callout for hypoglycaemia, total number of people requiring hospital admissions due to hypoglycaemia and total number of people requiring hospital admissions due to hyperglycaemia/ DKA.