

ORIGINAL ARTICLE

Glycaemic measures for 8914 adult FreeStyle Libre users during routine care, segmented by age group and observed changes during the COVID-19 pandemic

Pratik Choudhary MD¹ | Calvin Kao BS² | Timothy C. Dunn PhD² |
Laura Brandner BS² | Gerry Rayman MD³ | Emma G. Wilmot PhD^{4,5}

¹Diabetes Research Centre, University of Leicester, Leicester, UK

²Research and development, Abbott Laboratories, Alameda, California, USA

³Ipswich Diabetes Centre, East Suffolk and North East Essex Foundation Trust, Ipswich, UK

⁴Diabetes Department, Royal Derby Hospital, University Hospitals of Derby and Burton NHS Foundation Trust, Derby, UK

⁵Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK

Correspondence

Pratik Choudhary, MD, Diabetes Research Centre, University of Leicester, Leicester LE5 4PW, UK.

Email: pratik.choudhary@leicester.ac.uk

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Abstract

Aim: To evaluate the impact of the stay-at-home policy on different glucose metrics for time in range (%TIR 3.9-10 mmol/L), time below range (%TBR < 3.9 mmol/L) and time above range (%TAR > 10 mmol/L) for UK adult FreeStyle Libre (FSL) users within four defined age groups and on observed changes during the coronavirus disease 2019 (COVID-19) pandemic.

Methods: Data were extracted from 8914 LibreView de-identified user accounts for adult users aged 18 years or older with 5 or more days of sensor readings in each month from January to June 2020. Age-group categories were based on self-reported age on LibreView accounts (18-25, 26-49, 50-64 and ≥65 years).

Results: In January, prior to the COVID-19 pandemic, the 65 years or older age group had the highest %TIR (57.9%), while the 18-25 years age group had the lowest (51.2%) ($P < .001$). Within each age group, TIR increased during the analysed months, by 1.7% (26-49 years) to 3.1% (≥65 years) ($P < .001$ in all cases). %TBR was significantly reduced only in the 26-49 years age group, whereas %TAR was reduced by 1.5% (26-49 years) to 3.0% (≥65 years) ($P < .001$ in both cases). The proportion of adults achieving both of the more than 70% TIR and less than 4% TBR targets increased from 11.7% to 15.9% for those aged 65 years or older ($P < .001$) and from 6.0% to 9.1% for those aged 18-25 years ($P < .05$). Mean daily glucose-sensor scan rates were at least 12 per day and remained stable across the analysis period.

Conclusions: Our data show the baseline glucose metrics for FSL users in the UK across different age groups under usual care. During lockdown in the UK, the proportion of adults achieving TIR consensus targets increased among FSL users.

KEYWORDS

adults, continuous glucose monitoring, COVID-19, FreeStyle Libre system, time above range, time below range, time in range, UK

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1 | INTRODUCTION

Subsequent to the spread of coronavirus disease 2019 (COVID-19) during the pandemic, separate analyses in China, the United States and the UK¹⁻⁵ showed that people with diabetes have higher risks of adverse outcomes with COVID-19, including death. Within the UK, this was quantified in more detail to show that people with type 1 diabetes (T1D) or type 2 diabetes (T2D) had a 3.5- and 2.0-fold increased risk of dying in hospital with COVID-19, respectively, compared with those without diabetes.^{4,5} An increased risk of adverse outcomes, including death, was observed in those with a higher HbA1c, older age and greater deprivation ranking.⁵ These data supported the shielding advice for people considered clinically extremely vulnerable that was issued on 23 March 2020 by the UK government, requesting people with T1D or T2D to 'stay at home' to minimize the risks of COVID-19 infection.

A key concern was the possible deterioration in glucose control during the period of social isolation and restricted access to standard care, particularly in those with T1D. However, evidence has emerged that, during 'stay at home', measures of glycaemic control did not deteriorate for adults with T1D in the UK and in Europe who were using the FreeStyle Libre (FSL) flash glucose monitoring system.⁶⁻⁹ In fact, at one UK diabetes centre, for in a cohort of 572 adults with T1D (median age 39 years) who used the FSL system,⁶ % time in range (TIR 3.9-10 mmol/L) increased by a mean of 3.0% ($P < .001$), with an associated 1%-2% reduction ($P = .05$) in % time below range (TBR < 3.9 mmol/L).⁶

The FSL system has been reimbursed for people with T1D in England and across the UK since 2019,^{10,11} with more than 60% of those living with T1D (>150 000 people) accessing this system according to data available at the time of writing.

The Association of British Clinical Diabetologists (ABCD) national audit showed a significant improvement in glucose control during the first 7.5 months of use of the FSL system.¹² The use of FSL has also led to the emergence of time in range and time below range as key targets of therapy, with the Advanced Technology & Treatments for Diabetes congress setting out consensus guidance¹³ on targets for time in range (>70%), as well as time below range (<4%).

What is not known is how many people using the system are actually able to achieve the target levels for time in range and time below range across different age groups, and whether that changed during the stay at-home period because of changes in lifestyle as well as the risks involved with COVID-19. The aim of the current study was to evaluate the impact of the stay-at-home policy on different glucose metrics (i.e. %TIR 3.9-10 mmol/L, %TBR < 3.9 mmol/L and % time above range [TAR] > 10 mmol/L) across four different age groups in this large UK dataset.

2 | METHODS

2.1 | Data and sensors

Glucose data from FSL sensors can be stored in an online database (LibreView) and shared with clinical teams. As part of consent to use LibreView, users can also consent to their glucose and product-related

data being de-identified and aggregated for research purposes. Data were extracted from 8914 de-identified LibreView-user accounts for adult users aged 18 years or older with 5 or more days of sensor readings in each month from January to June 2020, because this quantity of automatically stored readings ensures reliable glucose control measures.¹⁴ For the purpose of this study, because the date of the stay-at-home directive was 23 March 2020, data across March and April are designated as either 'early March', which consists of 1-22 March, or 'April', covering 23 March-30 April. These accounts included data collected from people who used apps and/or readers to scan their sensors. Age-group categories were based on self-reported age in LibreView accounts (18-25, 26-49, 50-64 and ≥ 65 years). The separate age groups are the categories available to LibreView users for describing their age upon account creation, and were selected to help identify differences in glucose metrics that may reflect the different lifestyle and self-care behaviours of FSL users at different ages. Mean %TIR, mean %TAR and median %TBR were assessed for each month from January to June 2020 for each age group. Users whose TIR increased by at least 5% from January to June were classified as responders, as indicated in the international consensus recommendations,¹³ which define each incremental 5% increase in TIR as associated with clinically significant benefits. Other measures identified for comparison were mean daily scan rates, as well as the proportions of users meeting international consensus targets¹³ of more than 70% TIR and of less than 4% for %TBR.

2.2 | Statistical analysis

In anticipation of a significant result from a one-way analysis of variance (ANOVA), we planned a post hoc test comprised of pairwise independent sample t-tests to compare the means of age groups in January (for comparing %TBR between age groups in January, the 95% confidence intervals of the median were used). Comparisons of proportions of each age group achieving more than 70% TIR, less than 4% TBR, or both in January were derived from two-proportion z-tests. This procedure captured the evaluation of differences in normative glucose metrics between age groups prior to the 'stay at home' directive in the UK, as well as the change in %TIR, %TBR and %TAR for each age group from January to June 2020. These changes were then also compared between age groups using independent sample t-tests. Data for overall %TBR are presented as group medians in January and June. Within separate age groups, comparisons of proportions of users achieving more than 70% TIR and less than 4% TBR from January to June were derived from two-proportion z-tests. Similarly, proportions of responders in each age group were compared using two-proportion z-tests.

3 | RESULTS

3.1 | Time in range 3.9-10.0 mmol/L before and during the COVID-19 lockdown by age group

The longitudinal changes in mean %TIR for each age group are shown in Figure 1 and are summarized in Table 1. Before lockdown in

January 2020, mean %TIR was lowest among the 18-25 years age group (51.2%) and highest among the 65 years or older group (57.9%) ($P < .001$). All age groups increased %TIR from January 2020 to June 2020, from before to during lockdown.

For all age groups, the repeated measures ANOVA detected a significant difference in mean %TIR across the months analysed. Within the longitudinal period, the post hoc tests identified that: (1) from January to March, only the 65 years or older age group had a statistically significant change ($P < .001$), but this change was not clinically significant (57.9% to 58.7%); (2) from March to April, all age groups showed a statistically significant change ($P < .001$) in TIR: 50.0%-53.4%, 54.1%-55.5%, 54.6%-56.5% and 58.7%-60.7% for the 18-25, 26-49, 50-64 and 65 years or older age groups, respectively; and (3) from April to June, only the 26-49 and 50-64 years age groups showed a statistically significant change in mean TIR ($P < .001$), and their changes were not clinically significant: 55.5%-56.2% and 56.5%-57.4%, respectively. From January to June, the 65 years or older age group showed the greatest increase (3.1%; $P < .001$) and the 26-49 years age group improved least (1.7%; $P < .001$) (Table 1). The difference in the mean change between these groups was statistically

significant ($P < .001$). The highest proportion of responders was among the 18-25 years age group (40.1% responders), and had a statistically significant difference from the corresponding proportions of the 26-49 and 50-64 years age groups ($P = .009$ and $P = .03$, respectively).

3.2 | Time below range less than 3.9 mmol/L before and during the COVID-19 lockdown by age group

For any age group from before to during lockdown, %TBR less than 3.9 mmol/L did not increase (Figure 2, Table 2). Although %TBR was lowest in January 2020 for the 65 years or older age group (median 3.6%) and highest for FSL users aged 18-25 and 26-49 years (median 4.2%), this difference was not statistically significant. The greatest mean change in %TBR was -0.2% for the 26-49 years age group, indicating that %TBR changed very little for all age groups. The difference in mean change between age groups was also not statistically significant.

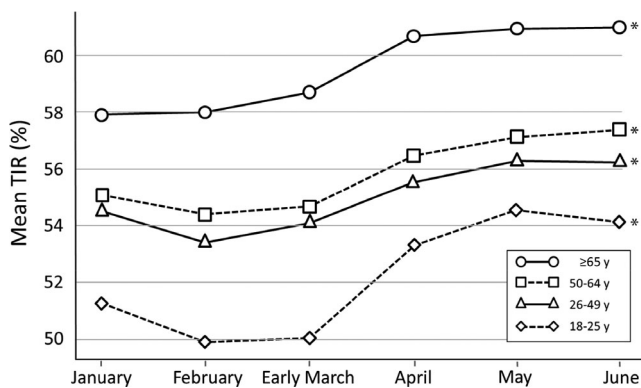


FIGURE 1 Mean %TIR for adult FSL users by age group. Data shown are mean %TIR with glucose 3.9-10.0 mmol/L. The date of ‘stay at home’ is 23 March 2020. ‘Early March’ consists of 1-22 March. ‘April’ covers 23 March-30 April 30. *All within age-group comparisons from January to June are significant, $P < .001$. FSL, FreeStyle Libre system; TIR, time in range

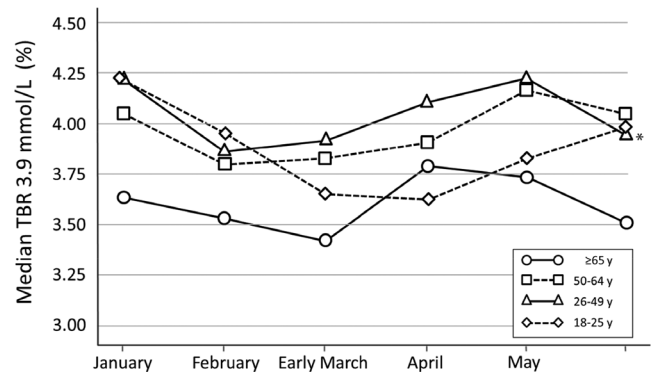


FIGURE 2 Median %TBR for adult FSL users by age group. Data shown are median %TBR with glucose <3.9 mmol/L. The date of ‘stay at home’ is 23 March 2020. ‘Early March’ consists of 1-22 March. ‘April’ covers 23 March-30 April 30. *Only the 26-49 y age-group comparison from January to June is significant, $P = .02$. FSL, FreeStyle Libre system; TBR, time below range

TABLE 1 Change in %TIR for adult FSL users by age group during lockdown

Age group, y	N	Mean TIR (%)		Change in TIR (%)	P value*	Responders ^a (%)
		January 2020	June 2020			
18-25	736	51.2	54.1	+2.9	<.001	40.1
26-49	3446	54.5	56.2	+1.7	<.001	34.9
50-64	2873	55.1	57.4	+2.3	<.001	35.7
≥65	1859	57.9	61.0	+3.1	<.001	39.3

Note: Data are mean %TIR 3.9-10.0 mmol/L for 8914 adult FSL users.

Abbreviations: FSL, FreeStyle Libre system; TIR, time in range.

^aResponders indicates FSL users who increased %TIR ≥5% over the period January to June 2020.

*P values derived from paired t-tests.

TABLE 2 Change in %TBR and %TAR for adult FSL users by age group during lockdown

Age group, y	N	Median %TBR			Mean %TBR		Mean %TAR			
		January 2020	June 2020	Change in median TBR (%)	Mean change in TBR (%)	P value*	January 2020	June 2020	Mean change in TAR (%)	P value*
18-25	736	4.2	4.0	-0.2	-0.1	.6	43.1	40.4	-2.8	<.001
26-49	3446	4.2	4.0	-0.3	-0.2	.02	39.8	38.3	-1.5	<.001
50-64	2873	4.1	4.0	-0.01	+0.01	.9	39.5	37.2	-2.3	<.001
≥65	1859	3.6	3.5	-0.1	-0.1	.3	37.2	34.2	-3.0	<.001

Note: Data are median %TBR <3.9 mmol/L, mean change in %TBR <3.9 mmol/L and mean change in %TAR >10.0 mmol/L for 8914 adult FSL users. Data for overall %TBR are presented as group medians in January and June. For the comparative change in %TBR from January to June we have tested the mean change between paired %TBR observations.

Abbreviations: FSL, FreeStyle Libre system; TAR, time above range; TBR, time below range.

*P values derived from paired t-tests.

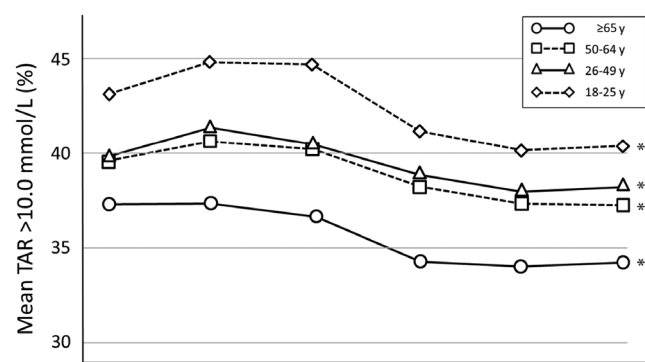


FIGURE 3 Mean %TAR for adult FSL users by age group. Data shown are mean %TAR with glucose >10.0 mmol/L. The date of 'stay at home' is 23 March 2020. 'Early March' consists of 1-22 March. 'April' covers 23 March-30 April. *All within age-group comparisons from January to June are significant, $P < .001$. FSL, FreeStyle Libre system; TAR, time above range

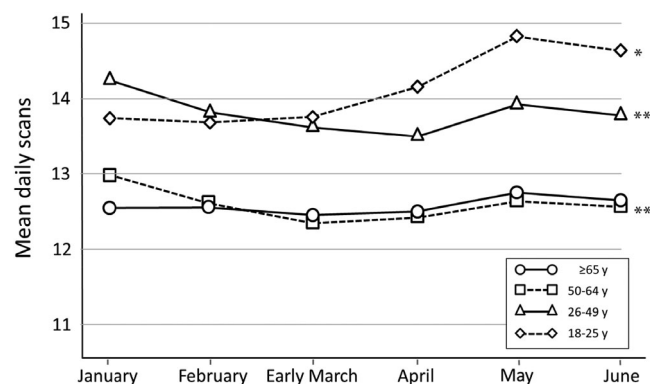


FIGURE 4 Mean daily scans for adult FSL users by age group. Data shown are mean daily scan rates. The date of 'stay at home' is 23 March 2020. 'Early March' consists of 1-22 March. 'April' covers 23 March-30 April. Within age-group comparison from January to June significant, * $P = .004$, ** $P < .001$. FSL, FreeStyle Libre system

3.3 | Time above range more than 10.0 mmol/L before and during the COVID-19 lockdown by age group

Before lockdown, mean %TAR more than 10.0 mmol/L was highest for the 18-25 years age group (43.1%) and lowest among the 65 years or older age group (37.2%) ($P < .001$) (Figure 3, Table 2). All age groups showed a significant reduction in %TAR from January to June 2020. The reduction was greatest in the 65 years or older age group (-3.0%; $P < .001$) and lowest in the 26-49 years age group (-1.5%; $P < .001$), and the difference in mean change between these groups was statistically significant ($P < .001$).

3.4 | Daily scans before and during the COVID-19 lockdown by age group

Daily scans in January 2020 were lowest in the 65 years or older age group (mean 12.5 scans/day) and highest in the 26-49 years age group (mean 14.3 scans/day) ($P < .001$) (Figure 4). The scan rate increased slightly during lockdown for the 18-25 years age group (+0.9 scans/day; $P = .004$), whereas the 26-49 and 50-64 years age groups saw a slight reduction in scan rate (-0.5 and -0.3 mean scans/day, respectively; $P < .001$ in both cases). No change was evident in the scan rate for the 65 years or older age group.

3.5 | Achievement of consensus targets for %TIR and %TBR before and during the COVID-19 lockdown by age group

International consensus recommendations have set clinical targets for adults with T1D or T2D of more than 70% for %TIR and of less than 4% for %TBR.¹³ In January 2020, prior to lockdown, the target for more than 70% TIR was met by 23.8% of FSL users aged 65 years or older, compared with 14.9% of users aged 18-25 years ($P < .001$) (Table 3). In June 2020, during the lockdown period, the proportion of

TABLE 3 Proportion of adult FSL users achieving consensus targets for %TIR and %TBR by age group during lockdown

Age group, y	N	% achieving >70% TIR				% achieving <4% TBR				% achieving >70% TIR and <4% TBR			
		January 2020	June 2020	Change	P value*	January 2020	June 2020	Change	P value*	January 2020	June 2020	Change	P value*
18-25	736	14.9	20.1	+5.2	.01	47.8	50.4	+2.6	.35	6.0	9.1	+3.1	.03
26-49	3446	18.9	22.4	+3.4	.005	48.1	50.3	+2.3	.06	8.3	9.6	+1.3	.06
50-64	2873	19.6	23.7	+4.1	.005	49.4	49.4	0.0	1.0	9.3	11.5	+2.3	.006
≥65	1859	23.8	30.7	+6.9	<.001	53.6	55.8	+2.2	.19	11.7	15.9	+4.2	<.001

Note: Data are proportion of 8914 adult FSL users with TIR >70%, TBR <4% and with both.

Abbreviations: FSL, FreeStyle Libre system; TBR, time below range; TIR, time in range.

*P values derived from two-proportion z-tests.

people meeting the TIR target increased to 30.7% in the 65 years or older age group ($P < .001$) and to 20.1% in the 18-25 years age group ($P = .01$). As indicated above, achievement of the less than 4% TBR target stayed comparatively constant from January to June (Table 3) for all age groups. Notably, the proportion of FSL users who achieved both targets of more than 70% TIR and of less than 4% TBR significantly increased from January to June 2020 (Table 3). The proportion of the 65 years or older age group achieving both targets increased from 11.7% to 15.9% ($P < .001$) and the proportion of the 18-25 years age group achieving both targets increased from 6.0% to 9.1% ($P = .03$), with increases from 8.3% to 9.6% for the 26-49 years age group ($P = .06$) and from 9.3% to 11.5% for the 50-64 years age group ($P = .006$). The difference in this proportion between the 65 years or older and 18-25 years age groups in January (11.7% and 6.0%, respectively) was significant ($P < .001$).

4 | DISCUSSION

This analysis of a large population of adult FSL users in the UK reveals notable differences in glucose control between different age groups, both prior to the COVID-19 pandemic and during the subsequent stay-at-home period and restricted access to standard diabetes care. First, the data presented here on %TIR and %TAR are consistent with the real-world experience of diabetes care teams that, under normal standard care, young adults often have suboptimal glucose control, as measured by HbA1c and confirmed by registry data.¹⁵ Second, they show how difficult it is for most people living with T1D to achieve international targets, irrespective of their age or duration of diabetes.

The longitudinal changes reported here provide several observations of note. First, during the period January-June 2020, covering the period when vulnerable people, including those with diabetes, were directed to stay at home, adult FSL users showed improved measures of glucose control across all age groups, including increased mean %TIR and reduced mean %TAR. The significant increase in %TIR is evident for all age groups from March to April 2020, suggesting a change in behaviour that was associated with the timing of the stay-at-home guidance, but which was unlikely to be related to changes in the

number of daily glucose scans, which were reasonably frequent prior to lockdown and remained stable after the start of the lockdown period. A significant change in %TBR was not detected during the stay-at-home period, confirming that the improvements seen in %TIR were not at the expense of hypoglycaemia and were driven by significant reductions in %TAR. Second, despite having the lowest %TIR baseline in January 2020, the young adult group aged 18-25 years had the largest proportion of responders (40.1%).

This observation is consistent with previous findings that improvements in %TIR during lockdown have been greatest for those with higher pre-COVID-19 glucose levels,⁷ but the high proportion of responders among young adults is especially notable for achieving a clinically significant increase of 5% or higher TIR over 6 months. This suggests that the extreme social distancing after 23 March 2020 may have significantly changed the diabetes self-care behaviours of this age group. Two possible factors may explain the high proportion of responders in the young-adult group. First, this may reflect the fact that many of the social factors that affect day-to-day glucose control in young adults the most, such as travel, work and socializing, were severely restricted. In addition, many people may have been furloughed, or have started working from home, which may have added a greater degree of predictability to life. In particular, eating out, which makes carbohydrate counting and prebolusing difficult, was also banned. These factors may have provided people with diabetes with more time to focus on their diabetes self-care behaviours, with consequent improvements in %TIR and %TAR. Indeed, in the youngest group there was an increase of almost one scan per day. A second important consideration is the fear factor during the pandemic. Pre-COVID-19 behaviour for young adults is unlikely to have focused on immediate threats to their health, whereas during the lockdown many will have been aware of the disproportionate risks for COVID-19-related morbidity and mortality for people with diabetes. This may have driven their lockdown focus on improved diabetes management, including ensuring optimization of insulin delivery.

The noted improvements in glycaemic control during the stay-at-home period were also evident in the proportion of FSL users in the UK who achieved consensus targets for %TIR in June compared with January 2020. Prior to the stay-at-home period, the proportion of

adult FSL users who met the target for more than 70% TIR was highest among the 65 years or older age group and lowest among the young adult 18-25 years age group (Table 3). The proportion of FSL users who met the TIR target of more than 70% increased significantly during the stay-at-home period for both groups, by 6.9% in the 65 years or older age group ($P < .001$) and by 5.2% in the 18-25 years age group ($P = .01$). The proportion of adults who met both targets of more than 70% TIR and of less than 4% TBR increased significantly among three out of four age groups during the stay-at-home period, except for the 26-49 years age group, probably driven by the increase in those meeting the consensus target for TIR. This supports the previous hypothesis that young adult users were able to change their diabetes self-management behaviour during the stay-at-home period to improve metrics of glucose control.

Of considerable importance is the observation that significant improvements in %TIR were seen among the 65 years or older age group, who exhibited the best glucose prior to the stay-at-home directive. The fact that improved control was most evident among the group with the highest initial %TIR is a novel finding and indicates that the benefits of FSL can be further optimized for all adult users in the UK, irrespective of their established use of the FSL system. In particular, the proportion of users meeting the international consensus targets for %TIR and %TBR might be increased above current levels.

The current study has several strengths and limitations. The strengths of the study are the large number of individual de-identified users (8914) and the unique insights into real-world UK baseline measures for % time in ranges aligned to the international consensus recommendations.¹³ In the context of the COVID-19 shielding advice, the UK data reflect that the UK-based guidance to stay at home for vulnerable people with T1D was substantially adhered to, which is another strength. The limitations of the study are that no contextual information is available regarding demographics other than age, and no other health status measures are identified (e.g. HbA1c, symptomatic hypoglycaemic events, quality of life). Also, the inclusion criteria included a requirement for 5 days of data in each of the 6 months reported, which means these data are most probably from those people using the mobile phone FreeStyle LibreLink app, or from those using the FreeStyle Libre reader with frequent contact with their health care provider team. A further limitation is that the type of diabetes is unknown, but a valid assumption is that the data reflect mainly people with T1D, because UK reimbursement guidance is for T1D, and the recent ABCD audit of FSL in the UK reported on 10 370 FSL users, 97% of whom were people with T1D.¹² Finally, it is not possible to compare our glycaemic outcomes with a matched population of people with diabetes who did not have access to FSL or real-time continuous glucose monitoring, which would have enabled a more direct conclusion regarding the value of FSL for users during the period in question.

In conclusion, these are the first age-related data on mean %TIR, mean %TAR and median %TBR for a large UK population of FSL users under real-world conditions, with analysis of the longitudinal change from before to during the COVID-19 stay-at-home period, segmented by age groups for adults aged 18 years and older. The young adult 18-25 years age group had the lowest %TIR prior to stay-at-home

(mean 51.2%), but also had the largest proportion of responders (those who improved by $\geq 5\%$ TIR) during this period (40.1%). In contrast to other studies, the 65 years or older age group had both the highest pre-COVID-19 mean %TIR (57.9%) and also the greatest increase in %TIR (+3.2%) during the stay-at-home period. For adults, the changes during the stay-at-home period may reflect reduced social activities, work-related travel and stress. Fear of COVID-19-related adverse outcomes for people with diabetes and high glucose may also have influenced self-management behaviour among young adults and older people with diabetes.

AUTHOR CONTRIBUTIONS

All the authors contributed to the concept and design of the manuscript and worked collaboratively to review and prepare the final version of the manuscript. All the authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole and have given their approval for this version to be published.

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CONFLICT OF INTEREST

PC has received personal fees from Abbott Diabetes Care, Dexcom, Diasend, Eli Lilly, Insulet, Medtronic, Novo Nordisk, Roche and Sanofi Aventis; EGW has received personal fees from Abbott Diabetes Care, Dexcom, Diasend, Eli Lilly, Insulet, Medtronic, Novo Nordisk, Roche and Sanofi Aventis.

GR has received personal fees from Abbott Diabetes Care, Sanofi Aventis and Eli Lilly. KK, TCD and LB are employees of Abbott Diabetes Care.

PEER REVIEW

The peer review history for this article is available at <https://publons.com/publon/10.1111/dom.14782>.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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