The Value of Optional Alarms in Continuous Glucose Monitoring Devices: A Survey on Patients and their Physicians

B. Varughese[1], M. Silvey[2], G. Harper[2], I. Rajkovic[2], P. Hoffmann[3]

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Introduction

The global prevalence of diabetes among adults is expected to grow from 425 million (9.3 %) in 2019 to 700 million (10.2 %) by 2030 [International Diabetes Federation 2020]. More than 1.1 million children worldwide have type 1 diabetes with type 2 onset during childhood showing a continuing upward trend [International Diabetes Federation 2020]. Numerous studies have shown that achieving and maintaining near-normal glucose levels reduces the incidence of both the acute and long-term complications of diabetes [Diabetes Control and Complications Trial Research Group 1993, Hayward 2015, Holman 2008, Ismail-Beigi 2010, Nathan 2005, UK Prospective Diabetes Study Group 1998]. However, many people with diabetes fail to achieve their glycaemic targets [American Diabetes Association 2018, Khunti 2013, Mauricio 2017, Meneghini 2017, Stone 2013], which could result in poor clinical outcomes and potentially increase the cost of care [Gilmer 2005].

Early studies have shown frequent blood glucose monitoring using fingerstick testing to help individuals with diabetes improve their glycaemic control [Diabetes Control and Complications Trial Research Group 1993, Franciosi 2011, Kempf 2012, Polonsky 2011, Skeie 2009, Strowig 1998]. Even so, many individuals show poor compliance with prescribed testing regimens; this is often due to the associated pain or discomfort and inconvenience [International Diabetes Federation Europe 2017, Moström 2017, Ong 2014, Vincze 2004].

1) Abbott Diabetes Care Inc., Alameda, California, USA
2) Adelphi Real World, Bollington, UK
3) Abbott GmbH, Wiesbaden, Germany

Summary

The increasing adoption of continuous glucose monitoring (CGM) calls for more knowledge as to the strengths and limitations of current CGM systems. This cross-sectional survey involved 50 physicians and 500 patients with diagnosed type 1 or type 2 diabetes with MDI therapy. The patient survey assessed rates of satisfaction and adherence behaviour with respect to their current CGM devices. The physician survey assessed satisfaction and likelihood of recommending current CGM devices to colleagues and patients, focusing on FreeStyle Libre 2 (FSL2) with optional alarms and seven other CGM systems (OS) with alarm function. A higher percentage of patients currently using FSL2 reported complete satisfaction compared to OS users with their devices overall (57 % vs. 43 %, respectively, p = 0.003). The option to switch the alarm on or off played an especially prominent part in complete satisfaction. FSL2 system users that had used other systems reported keeping the device switched on all or almost all day on more days than their previous OS device (p < 0.0001). A higher percentage of physicians reported that they were more likely to recommend FSL2 than OS devices to their colleagues for use in MDI-treated type 1 (88 % vs. 24–60 %, respectively) and type 2 diabetes patients (66 % vs. 28–54 %, respectively). A higher percentage of physicians reported that they were more likely to recommend FSL2 than OS devices directly to their type 1 (88 % vs. 18–54 %, respectively) and type 2 diabetes patients (82 % vs. 30–48 %, respectively) on MDI therapy. FSL2 has the potential to improve adherence to CGM use, particularly in patients who find alarms troublesome.

Key words
continuous glucose monitor, optional alarm, patient satisfaction, physician preference, real-world

Der Wert von optionalen Alarmen bei Systemen zum kontinuierlichen Glukosemonitoring: eine Umfrage bei Patienten und ihren Ärzten

Zusammenfassung

Die zunehmende Verwendung von CGM-Systemen erfordert mehr Wissen über deren Stärken und Grenzen. An dieser Querschnittsbefragung nahmen 50 Ärzte und 500 Patienten mit Typ-1- oder Typ-2-Diabetes mit ICT teil. Die Patienten bewerteten Zufriedenheit und Adhärenz in Bezug auf ihre aktuellen CGM-Systeme. Die Ärzte bewerteten Zufriedenheit und Wahrscheinlichkeit des Weiterempfehlens, der Schwerpunkt lag auf FreeStyle Libre 2 (FSL2) mit optionalen Alarmen und sieben anderen CGM-Systemen (AS) mit Alarmfunktion. Ein höherer Prozentsatz der Patienten, die FSL2 verwenden, berichtete im Vergleich zu den AS-Nutzern über vollständige Zufriedenheit mit ihren Geräten (57 % vs. 43 %, p = 0,003). Die Möglichkeit, den Alarm ein- oder auszuschalten, spielte dabei eine besonders große Rolle. Nutzer des FSL2 gaben an mehr Tagen eine ganztägige Nutzung an als bei ihrem vorherigen AS (p < 0,0001). Ein höherer Prozentsatz der Ärzte gab an, ihren Kollegen eher FSL2 als AS für den Einsatz bei Patienten mit ICT und Typ-1- (88 % vs. 24–60 %) bzw. Typ-2-Diabetes (66 % vs. 28–54 %) zu empfehlen. Ein höherer Prozentsatz der Ärzte gab an, ihren Patienten mit ICT und Typ-1- (88 % vs. 18–54 %) bzw. Typ-2-Diabetes (82 % vs. 30–48 %) eher FSL2 als AS direkt zu empfehlen. FSL2 hat das Potenzial, die Adhärenz bei der CGM-Nutzung zu verbessern, insbesondere bei Patienten, die Alarme als störend empfinden.

Schlüsselwörter
kontinuierlicher Glukosemonitor, optionaler Alarm, Patientenzufriedenheit, Arztpräferenz, Real-World

The last decade has seen innovation in glucose monitoring technology leading to a variety of continuous glucose monitoring (CGM) devices. The latest include FreeStyle Libre 2 (FSL2) from Abbott Diabetes Care, Alameda, CA (USA), a simple-to-use device allowing users to scan their glucose sensor manually using a hand-held reader or smartphone to retrieve glucose data.

Unlike other CGM devices, earlier versions of the FreeStyle Libre system did not offer active alarms to warn users about immediate or impending hypoglycaemia and hyperglycaemia. One rationale for not offering this feature was to help users avoid 'alarm fatigue' that could cause some users to start ignoring alarms or discontinue CGM altogether [Roberts 2014, Shivers 2013]. However, large randomised controlled trials and observational/prospective real-world studies have demonstrated that FreeStyle Libre significantly improves glycaemic control with fewer diabetes-related hospitalisations in type 1 and type 2 diabetes patients even without active alarms [Bolinder 2016, Charleer 2020, Fokkert 2019, Haak 2017 (a), Haak 2017 (b), Hirsch 2020, Miller 2020 (a), Miller 2020 (b), Oskarsson 2018, Paris 2018, Pintus 2019, Roussel 2020, Tyndall 2019, Wright 2020].

Active alarms may provide an added level of safety and security especially in patients with hypoglycaemia unawareness, so FSL2 now offers optional alarms to counter alarm fatigue while increasing personal freedom in diabetes management. With the alarm turned on, FSL2 automatically alerts users about low or high glucose or loss of signal between sensor and reader or smartphone. Users may select acoustic or vibration alarms on their readers or smartphones, and the smartphone app alarm can be set to override 'do not disturb' or muted status.

Increasing CGM adoption will lead to patients with diabetes asking their physicians for guidance in selecting a CGM system that best suits their individual needs and preferences. Physicians need to become more knowledgeable about the strengths and limitations of current CGM systems to provide this guidance, especially in view of its effect it has on preference and adherence.

We report the key findings from a large cross-sectional survey assessing satisfaction, adherence, and experience with current CGM devices amongst patients with diabetes and their physicians.

Methods

Study design

This cross-sectional survey targeted patients diagnosed with type 1 or type 2 diabetes requiring multiple daily injections of insulin as well as their physicians. The survey was conducted in Germany with data collection between March and May 2020. All patients and physicians provided informed consent to participate in the study and were able to opt out at any time; the data was anonymised and aggregated before analysis. The study protocol (Ref #: 112605251) was reviewed by the Western Institutional Review Board (WIRB) on 2 February 2020. Institutional review board approval was not deemed necessary as the research only comprised a survey that did not collect personal information, and the information that was collected would not readily reveal the identity of the participants either directly or by identifiers linked to the participants.

Physicians were identified and contacted by Adelphi Real World (ARW) through rapa Market Research, a local fieldwork partner in Germany, from an established list of confirmed physicians. All participating physicians were sent an online link to access the physician survey where they were screened to ensure compliance with inclusion criteria (see 'Participants'). A verification check on the names of all the participating physicians was also performed to verify identities at the end of data collection.

Abkürzungen

ARW	Adelphi Real World
CGM	continuous glucose monitoring
FSL2	FreeStyle Libre 2
HbA_{1c}	haemoglobin A_{1c}
MDI	multiple daily injections
OS	other CGM systems
WIRB	Western Institutional Review Board

Physicians invited patients with diabetes that met the pre-specified inclusion criteria to participate in the survey. Patients were asked to complete a short online questionnaire to confirm eligibility. Participation was voluntary and compensation was offered to physicians and patients who completed the survey in accordance with local regulations.

Participants

Eligible physicians were currently living and practising in Germany after qualifying in their speciality between 1984 and 2017 and self-identified as either diabetologists, endocrinologists or primary care physicians specialising in diabetes. Inclusion criteria also required that recruited physicians were personally responsible for managing the patients they enrolled into the survey, and that they had experience with FSL2 and at least one of seven other CGM systems (OS) devices. Each physician recruited around ten eligible patients.

Inclusion criteria were as follows: Age eighteen or above, confirmed diagnosis of type 1 or type 2 diabetes, multiple daily injection (MDI) insulin regimen, and use of at least one CGM device. Recruitment was based on specific prior use of CGM devices according to two requirements: 1) Patients that had been using FSL2 for at least three months; or 2) Patients that had been using a CGM device other than FSL2 or the earlier FreeStyle Libre system for at least three months. Soft quotas were applied to ensure an approximately equal mix of patients in both groups. Patients currently or most recently using the FreeStyle Libre system without alarms were excluded from the survey as the survey objectives were focused on comparing optional and mandatory alarms in devices, and the FreeStyle Libre has neither.

Data collection

Data collection comprised a patient survey and a physician survey conducted separately with responses kept isolated from one another. Physicians and patients with diabetes were each asked to complete one structured questionnaire independently of one another. Participants

	Total patients (n=500)	Total type 1 diabetes patients (n=289)	Total type 2 diabetes patients (n=211)
Mean age (years, SD)	46.0 (14.9)	37.5 (11.3)	57.7 (10.8)
Biological sex (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Male	263 (52.6)	147 (50.9)	116 (55.0)
Female	234 (46.8)	141 (48.8)	93 (44.1)
Prefer not to say	3 (0.6)	1 (0.3)	2 (0.9)
Employment status (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Working full-time	291 (58.2)	207 (71.6)	84 (39.8)
Retired	61 (12.2)	7 (2.4)	54 (25.6)
Working part-time	58 (11.6)	20 (6.9)	38 (18.0)
Student	43 (8.6)	40 (13.8)	4 (1.4)
Homemaker	28 (5.6)	8 (2.8)	20 (9.5)
Not working, seeking employment	7 (1.4)	3 (1.0)	4 (1.9)
On disability	6 (1.2)	1 (0.3)	5 (2.4)
On long-term sick leave	3 (0.6)	1 (0.3)	2 (0.9)
Not working, not seeking employment	0 (0.0)	0 (0.0)	0 (0.0)
Other	3 (0.6)	2 (0.7)	1 (0.5)
Education level (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
No school or professional/vocational training graduation	12 (2.4)	5 (1.7)	7 (3.3)
With school and/or professional/vocational training graduation	336 (67.2)	171 (59.2)	165 (78.2)
Attended university	146 (29.2)	108 (37.4)	38 (18.0)
Other	6 (1.2)	5 (1.7)	1 (0.5)
Type of diagnosed diabetes (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Type 1	289 (57.8)	289 (100.0)	–
Type 2	211 (42.2)	–	211 (100.0)
Previous experience with CGM devices (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
CGM naïve (no previous CGM devices)	381 (76.2)	218 (75.4)	163 (77.3)
CGM experienced (1+ previous CGM device)	119 (23.8)	71 (24.6)	48 (22.7)
Mean age at DM diagnosis (years, SD)	32.1 (14.5)	18.8 (8.9)	50.3 (11.2)
Insurance coverage (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Statutory health insurance	417 (83.4)	242 (83.7)	175 (82.9)
Private health insurance	77 (15.4)	44 (15.2)	33 (15.6)
Other	1 (0.2)	1 (0.3)	0 (0.0)
No health insurance	5 (1.0)	2 (0.7)	3 (1.4)
Current level of patient perceived diabetes control (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Completely controlled	175 (35.0)	97 (33.6)	78 (37.0)
Well controlled	286 (57.2)	172 (59.5)	114 (54.0)
Somewhat controlled	34 (6.8)	18 (6.2)	16 (7.6)
Poorly controlled	4 (0.8)	2 (0.7)	2 (0.9)
Not at all controlled	1 (0.2)	0 (0.0)	1 (0.5)
Feeling about how well diabetes is currently controlled (n, %)	**500 (100.0)**	**289 (100.0)**	**211 (100.0)**
Happy (NET)	*458 (91.6)*	*264 (91.3)*	*194 (92.0)*
I'm happy and believe it's the best I can realistically achieve	303 (60.6)	168 (58.1)	135 (64.0)
I'm happy with it but believe I can achieve better control	155 (31.0)	96 (33.2)	59 (28.0)
Unhappy (NET)	*37 (7.4)*	*23 (8.0)*	*14 (6.6)*
I'm not happy but believe it's the best I can realistically achieve	18 (3.6)	6 (2.1)	12 (5.7)
I'm not happy and believe I can achieve better control	19 (3.8)	17 (5.9)	2 (0.9)
I'm not sure	5 (1.0)	2 (0.7)	3 (1.4)

Tab. 1: Patient demographic characteristics.

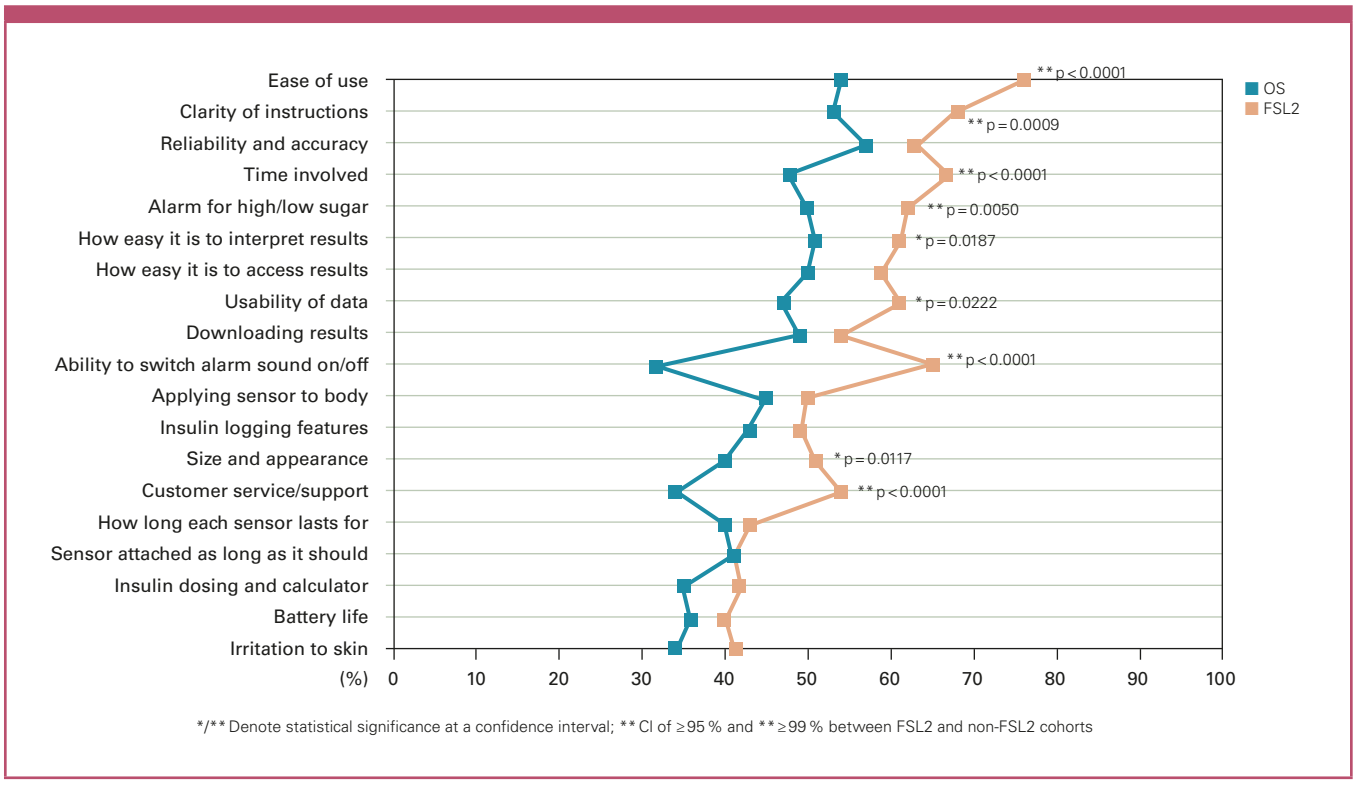

Fig. 1: Comparison of patient percentages 'completely satisfied' with current CGM device across attributes.

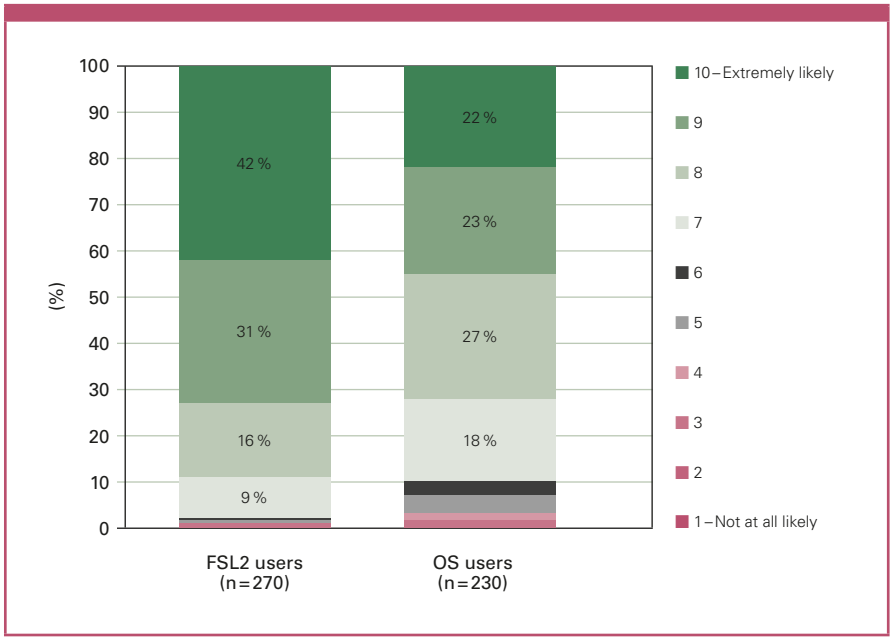

Fig. 2: Likelihood to recommend current device to another diabetes patient.

took the survey online using a computer or mobile device such as a smartphone or tablet. All participants were provided with standardised instructions to complete the fifteen-minute survey. First, the data collected from a small subset of the sample was tested and reviewed to make sure that the survey was correctly programmed and working before engaging the full study population. ARW collected the data through rapa Market Research, a local fieldwork partner in Germany.

Survey questionnaire

Variables collected from the patient survey included, but were not limited to: demographic characteristics, diabetes history, device characteristics, experience with the current CGM device, experience with the previous recent CGM device, diabetes management and control, and any hypoglycaemic episodes. Questions covered satisfaction, adherence, device preference, perceptions of the optional and mandatory alarms, and capturing and recording glucose data.

Data collected from the physician survey included demographics and practice settings. Questions covered satisfaction, device preferences, influencers in CGM selection, switching behaviour, and experience with existing CGM devices. Physicians were asked to rate devices they had sufficient experience with.

Copies of both survey documents are provided online as supplementary information.

Outcomes

The primary objectives in the patient survey were to assess satisfaction with current CGM devices, changes in CGM adherence (daily/intra-day usage), perceptions of the value of optional alarms, and unmet needs. The physician survey

was aimed at assessing satisfaction and preferences amongst physicians as relevant to current CGM devices.

Analysis

There were no formal sample size calculations; however, we aimed at a study sample size of 50 physicians and 500 patients. Stata statistical software version 16.1 (StataCorp, 2015. Stata statistical software: Release 16.1, College Station, TX, StataCorp LP) was used for statistical analysis as well as IBM® SPSS® Data Collection Survey Reporter v7.5 software for descriptive analysis. All analyses were performed by ARW. There were no missing values as respondents needed to answer each question before moving on to the next one in the online survey. However, 'don't know', 'not applicable' or 'I prefer not to say' were valid responses in some cases where appropriate. Participants removed from one analysis remained eligible for inclusion in other analyses,

	Total patients (n=500)	Total CGM naïve (no previous CGM) (n=381)	Total CGM experienced patients (1+ previous CGM) (n=119)
Previous experience with CGM devices (n, %)	**500 (100.0)**	**381 (100.0)**	**119 (100.0)**
CGM naïve (no previous CGM devices)	381 (76.2)	381 (100.0)	– (–)
CGM experienced (1+ previous CGM device)	119 (23.8)	– (–)	119 (100.0)
Current CGM device used (n, %)	**500 (100.0)**	**381 (100.0)**	**119 (100.0)**
FreeStyle Libre 2	270 (54.0)	225 (59.1)	45 (37.8)
OS devices (NET total)	*230 (46.0)*	*156 (40.9)*	*74 (62.2)*
Dexcom G6	67 (13.4)	27 (7.1)	40 (33.6)
Eversense	66 (13.2)	49 (12.9)	17 (14.3)
Guardian Sensor 3	39 (7.8)	33 (8.7)	6 (5.0)
Enlite Sensor	28 (5.6)	23 (6.0)	5 (4.2)
Dexcom G5 Mobile	17 (3.4)	13 (3.4)	4 (3.4)
Medtrum A6TouchCare	8 (1.6)	6 (1.6)	2 (1.7)
Dexcom G4 Platinum	5 (1.0)	5 (1.3)	– (–)
Type of CGM device switched from/to (n, %)	**500 (100.0)**	**– (–)**	**119 (100.0)**
Switch from: OS device to OS device	51 (10.2)	– (–)	51 (42.9)
Switch from: OS device to FreeStyle Libre 2	45 (9.0)	– (–)	45 (37.8)
Switch from: FreeStyle Libre 2 to OS device	23 (4.6)	– (–)	23 (19.3)
Immediate previous CGM device used (n, %)	**500 (100.0)**	**– (–)**	**119 (100.0)**
FreeStyle Libre 2	23 (4.6)	– (–)	23 (19.3)
OS devices (NET total)	*96 (19.2)*	*– (–)*	*96 (80.7)*
Dexcom G5 Mobile	25 (5.0)	– (–)	25 (21.0)
Dexcom G4 Platinum	24 (4.8)	– (–)	24 (20.2)
Guardian Sensor 3	15 (3.0)	– (–)	15 (12.6)
Eversense	13 (2.6)	– (–)	13 (10.9)
Enlite Sensor	10 (2.0)	– (–)	10 (8.4)
Medtrum A6TouchCare	0 (0.0)	– (–)	0 (0.0)
Other	5 (1.0)	– (–)	5 (4.2)
Mean duration of time using current CGM device (months, SD)			
FreeStyle Libre 2	8.7 (6.3)	8.7 (6.7)	8.4 (4.4)
OS devices (NET total)	*9.8 (6.0)*	*10.3 (6.1)*	*8.7 (5.6)*
Dexcom G6	7.6 (3.7)	8.0 (3.9)	7.4 (3.6)
Eversense	11.1 (7.3)	10.8 (7.0)	11.8 (8.1)
Guardian Sensor 3	9.3 (4.6)	9.8 (4.7)	6.2 (3.0)
Enlite Sensor	12.0 (7.4)	11.3 (7.6)	15.4 (5.9)
Dexcom G5 Mobile	10.8 (4.5)	12.1 (4.2)	6.8 (2.4)
Medtrum A6TouchCare	9.1 (5.9)	10.5 (6.3)	5.0 (1.4)
Dexcom G4 Platinum	12.8 (8.6)	12.8 (8.6)	– (–)

Tab. 2: Patient CGM device characteristics.

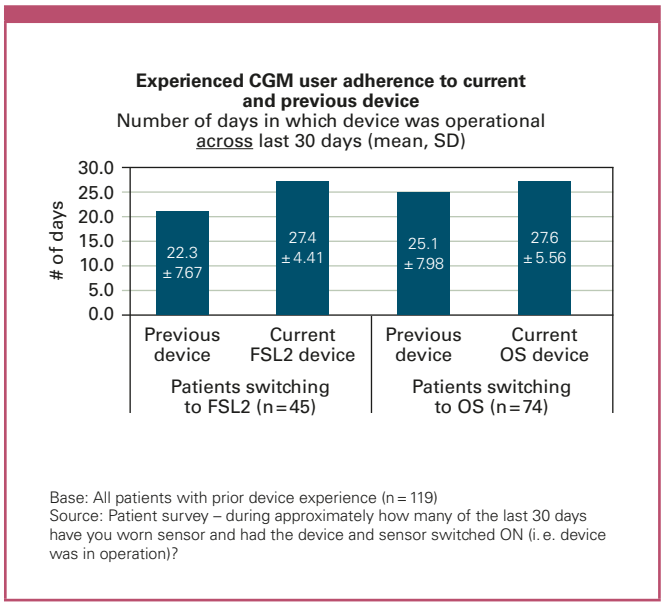

Fig. 3a: Adherence – number of days with device in operation over the past 30 days.

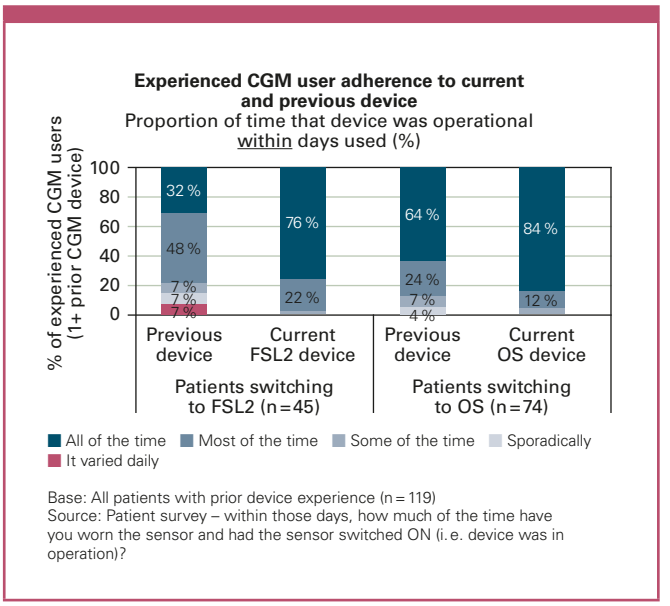

Fig. 3b: Adherence – proportion of time the device was in operation on the individual days used.

so the patient/physician base varied between variables.

Numeric variables were summarised by mean, standard deviation, median, inter-quartile range, minimum, maximum and number of non-missing values, and categorical variables by the total number of non-missing subjects and the number and proportion of subjects in each category. Groups were compared by univariate tests appropriate to the type/distribution of the outcome variables and the number of groups of variables being tested. Statistical tests were interpreted at a 5 % significance level (two-tailed). Continuous variables were compared using Student's t-test (2 groups) or ANOVA (3 or more groups). Non-parametric variables (normality assumption violated) were compared using the Mann-Whitney U test (2 groups) or Kruskal-Wallis test (3 or more groups). Categorical variables were compared using either Fisher's exact test (2 x 2 comparisons) or the chi-squared test (comparisons larger than 2 x 2).

Results

A total of 500 patients on an MDI (multiple daily injections) insulin regimen comprising 289 (58 %) type 1 diabetes and 211 (42 %) type 2 diabetes patients completed the survey. The sample was largely geographically representative across Germany and relatively well-balanced in gender (Tabl. 1). Type 1 diabetes patients were significantly younger with longer diabetes duration and higher frequency of hypoglycaemia than type 2 diabetes patients. A higher percentage of type 1 diabetes patients were university-educated and worked full-time compared to type 2 diabetes patients. The two groups showed similarly high percentages of patients covered by statutory health insurance. Self-reported perceptions of level and satisfaction with diabetes control were similar.

As shown in Table 2, most of the patients (54 %, n = 270) were currently using FSL2 for a mean duration of 8.7 ± 6.3 months. OS devices used by 46 % of patients (n = 230) included Dexcom G6 (13 %), Eversense (13 %), Guardian Sensor 3 (8 %), Enlite Sensor (6 %), Dexcom G5 Mobile (3 %), Medtrum A6 TouchCare (2 %) and Dexcom G4 Platinum (1 %). The patients had been using their respective OS devices for 9.8 ± 6.0 months.

Of the 500 patients surveyed, 76 % (n = 381) were on their first CGM device ('CGM naïve') whilst 24 % (n = 119) had used at least one other CGM device in the past ('CGM-experienced'). Among the CGM-experienced users (n = 119), 43 % (n = 51) had switched from one OS device to another, 38 % (n = 45) had switched from another OS device to FSL2, and the remaining 19 % (n = 23) had switched from FSL2 to another OS device (Tab. 2).

50 physicians participated in the survey and consisted of 47 (94 %) diabetologists/primary care with diabetes speciality and 3 (6 %) endocrinologists. Most of the physicians (n = 43, 86 %) practised in office settings and 7 (14 %) in ambulatory/outpatient clinics.

Patient survey

Satisfaction

A higher percentage of FSL2 vs. OS users reported complete satisfaction with their device overall (57 % vs. 43 %, respectively, p = 0.003). Complete satisfaction was also significantly higher amongst FSL2 users across 9 of the 19 system attributes assessed. A higher percentage of FSL2 considered 'ability to switch alarm on or off' as a key contributor to their complete satisfaction compared to OS users (65 % vs. 32 %, respectively, p < 0.0001). More FSL2 than OS users also considered 'time involved' to use their device (67 % vs. 48 %, respectively, p < 0.0001) and customer service/support (64 % vs. 34 %, respectively, p < 0.0001) to be key attributes associated with complete satisfaction (Fig. 1). Experienced CGM users that had switched to FSL2 (n = 45) were

asked why they switched; more than one answer could be selected. The users reported being more likely to switch for the benefits of an optional alarm (42 %, n = 19), better companion smartphone app (40 %, n = 18), and to eliminate the annoyance caused by the mandatory alarm on their previous device (27 %, n = 12).

More FSL2 users reported that CGM contributed 'very much' to their ability to manage their diabetes compared to OS users (56 % vs. 40 %, respectively, p = 0.0005). A higher percentage of FSL2 users reported being 'extremely likely' to recommend their current device to other diabetes patients than did OS users (42 % vs. 22 %, respectively, p < 0.0001). Analysis of individual device attributes corroborates the overall satisfaction findings. This was especially true of the option to switch the alarm sound on or off (optional alarm feature); a higher percentage of FSL2 users reported 'complete satisfaction' with this feature compared to OS users (65 % vs. 32 %, p < 0.0001). FSL2 use was also associated with significantly greater satisfaction in ease of use (p < 0.0001), clarity of instructions (p = 0.0009), time involved (p < 0.0001), ease of interpreting data (p = 0.0187), alarm for high/low glucose levels (p = 0.005), size and appearance (p = 0.0117) and customer service/support (p < 0.0001).

A higher percentage of FSL2 users reported that they would likely recommend their current CGM device to another patient with diabetes compared to OS users (score 8–10 out of 10: 89 % vs. 72 %, respectively, p < 0.0001) (Fig. 2).

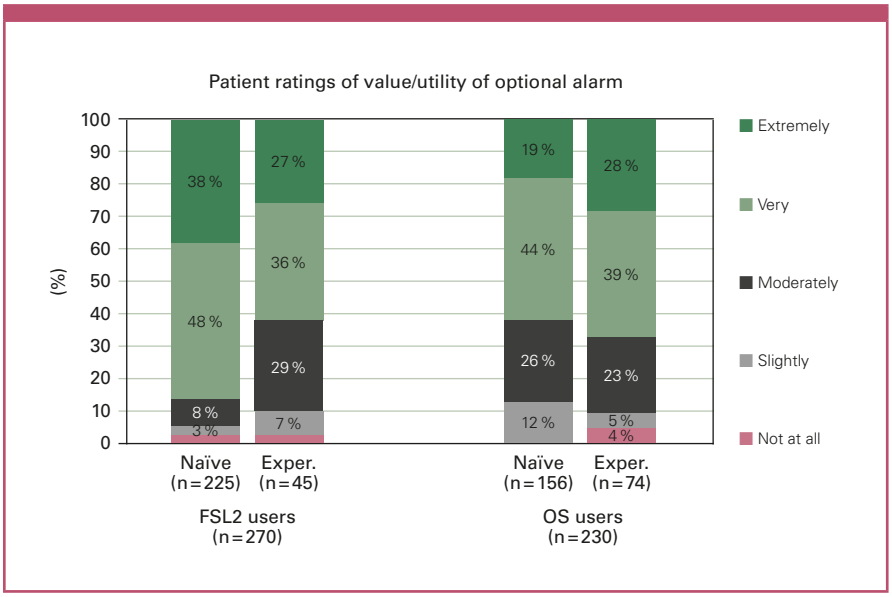

Fig. 4: Value and utility of optional alarm alerts for low or high glucose levels and signal loss.

Adherence and usage

Self-reported adherence was high amongst all CGM users regardless of device or prior experience. However, we did observe a trend toward greater

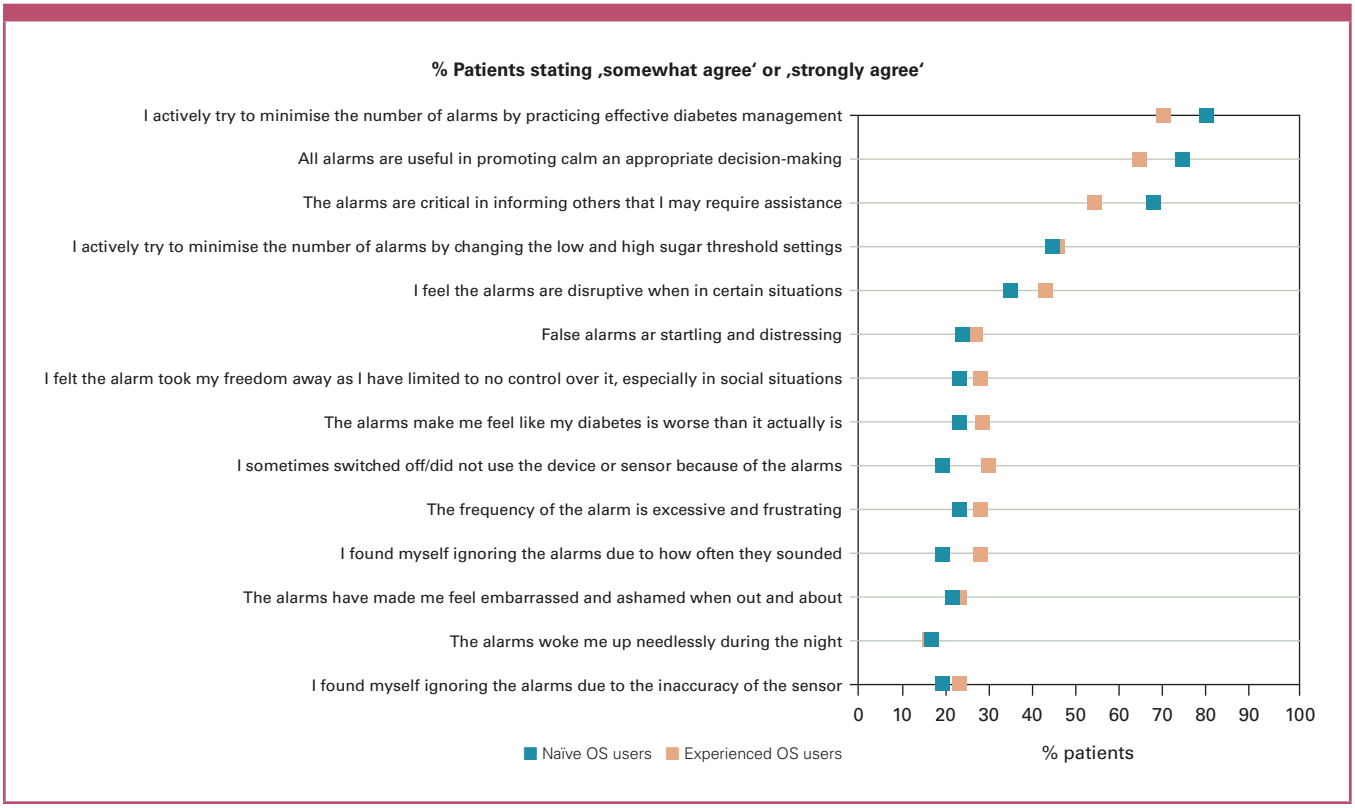

Fig. 5: Agreement with mandatory alarm-related statements: OS users.

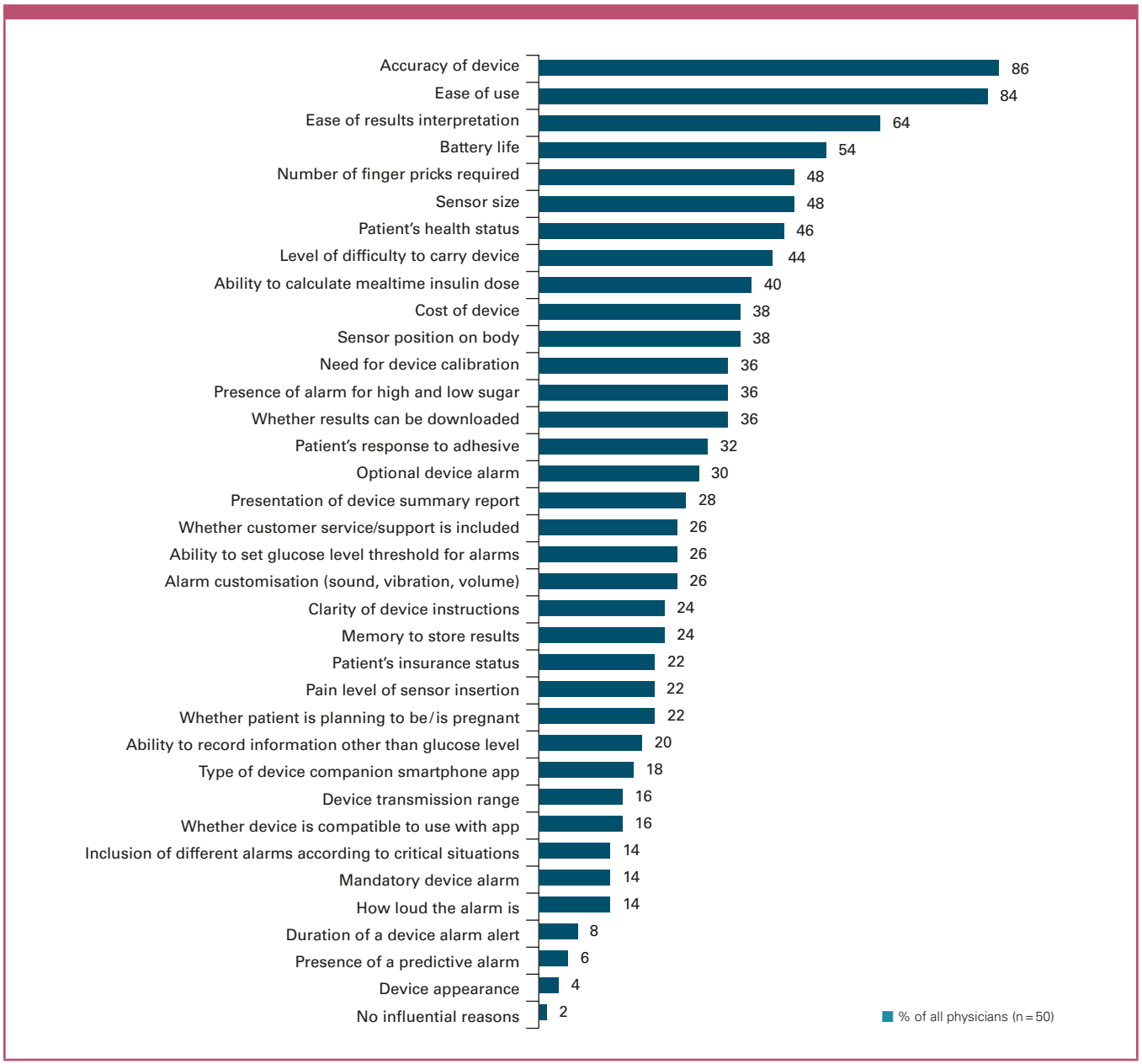

Fig. 6: Physician-reported factors influencing selection amongst different CGM devices.

usage of FSL2 compared to OS use (28.6 vs. 27.4 days, respectively) during the past 30 days with a higher percentage of all FSL2 users reporting daily usage as 'all or almost all the time' compared to OS users (85 % vs. 76 %, respectively, p = 0.0086).

Patients with prior CGM use who had switched to FSL2 (n = 45) increased their days of use compared to those switching to an OS device (5.1 vs. 2.6 days, respectively, p = 0.0469) (Fig. 3a). These patients also reported operating their devices all or almost all the time compared to their previous devices, such as by wearing the sensor with both device and sensor switched on more frequently (p < 0.0001) (Fig. 3b).

Those that had switched to FSL2 (n = 45) reported a significantly greater increase (44 %) in operating their current devices 'all or almost all the time' over the past 30 days compared to their previous devices in contrast to the increase (20 %) in those that had switched to an OS device (n = 74; p = 0.0114) (Fig. 3b). Patients in the latter group that had switched from FSL2 to an OS device (n = 23) reported an increase of 8 % in operating their current devices 'all or almost all the time' compared to their previous devices. Given the greater increase in using devices 'all or almost all the time' after switching to FSL2 coupled with the impact of the mandatory alarms on lower adherence rates among OS users, it is reasonable to assume that the optional alarm contributed to this high level of improvement as described below.

Perceived value of optional alarms

Most patients felt that the optional alarm was very or extremely valuable or useful. Value ratings were highest among FSL2 users naïve to CGM (86 %); however, most OS users (naïve 63 %; expe-

rienced 67 %) reported control over the alarm as being very/extremely valuable (Fig. 4).

A high percentage of FSL2 users that had prior experience with a mandatory alarm device considered the flexibility to turn off the alarm when needed (61 %) and eliminate disruptions at inappropriate times (59 %) to be the two greatest benefits of an optional alarm. Among OS users, 22 % reported that the optional alarm would be a major improvement over their current device, allowing them to feel more in control and empowered. Aside that, 19 % reported that alarm control would help them take alarms far more seriously. According to 15 %, optional alarms greatly improved their situation by eliminating disruptions at inappropriate times and allowing the respondents to keep the device and sensor on longer, especially in social situations.

A large minority (24 %) of OS users expressed dissatisfaction with the device's ability to turn off the alarm, and 25 % considered the mandatory alarm to be a moderate (20 %), serious (5 %) or significant problem (< 1 %). A high percentage of OS users also reported turning their CGM device off during the past 30 days due to excessive alarms during inappropriate situations compared to FSL2 users (27 % vs. 11 %, respectively, p = 0.0091). Around 20–30 % of OS users agreed that the mandatory alarm on their device led to several issues: distress, frustration, lack of control or freedom, temporary abandonment of the device, and stigma or embarrassment (see Fig. 5). Apart from that, approximately 30–45 % of OS users agreed that the mandatory alarm of their device was disruptive in certain situations.

Unmet needs

More OS than FSL2 users reported the need for alarm customisation (35 % vs. 13 %, respectively, p < 0.0001), alarm settings to trigger only on certain events (23 % vs. 10 %, respectively, p < 0.0001), different alarm types based on various situations (22 % vs. 14 %, respectively, p = 0.0258) and easier carrying ability (19 % vs. 13 %, respectively, p = 0.0232). Conversely, more FSL2 than OS users reported the need for longer battery life (36 % vs. 24 %, respectively, p = 0.0083) and flexibility in sensor placement on body (33 % vs. 23 %, respectively, p = 0.0285). However, 14 % of FSL2 users felt no changes were needed compared to 4 % of OS users (p < 0.0001).

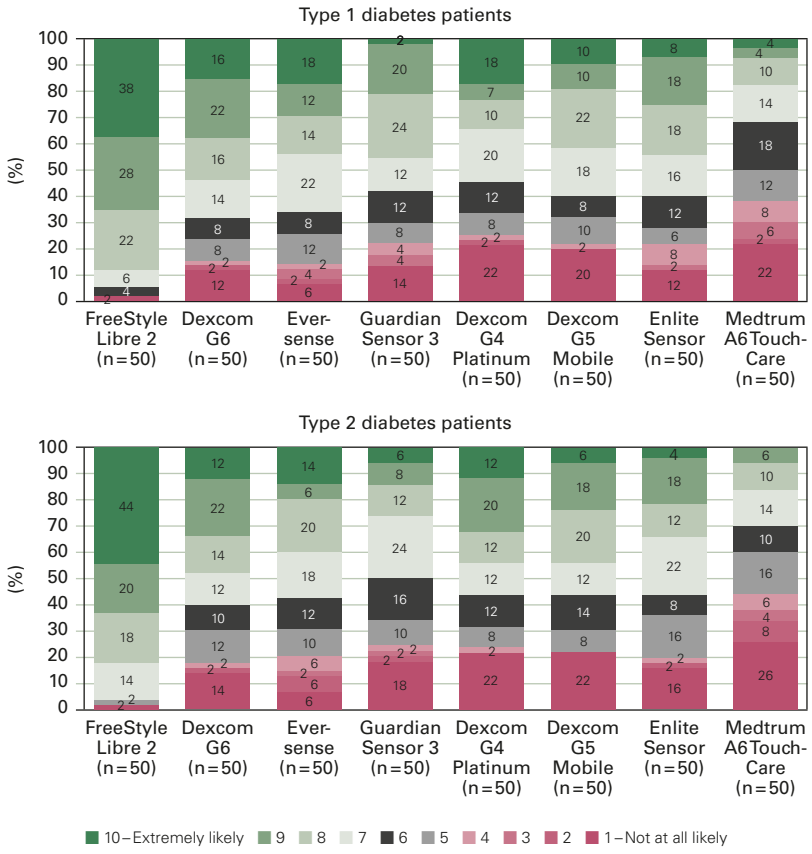

Fig. 7: Likelihood of recommending specific CGM devices to their MDI-treated type 1 and MDI-treated type 2 diabetes patients.

Physician survey

Satisfaction

Physician satisfaction with CGM was ≥ 90 % across all devices in MDI-treated type 1 and 2 diabetes patients. Satisfaction rates ('completely satisfied') were higher for FSL2 use in type 1 diabetes (50 %) and type 2 diabetes (60 %) compared to all the other CGM system devices (type 1 diabetes: 17–43 %, type 2 diabetes: 21–39 %). The main factors reported by physicians as influencing their selection of different CGM devices comprised device accuracy (86 %), ease of use (84 %) and ease of interpreting results (64 %). Device cost (38 %, 10th out of 35) and health insurance cover of the patient (22 %, 23rd out of 35) took lower priority as reasons for device selection than practicality or performance (Fig. 6).

A higher percentage of physicians reported that they were more likely (score 8–10 out of 10) to recommend: FSL2 over OS devices to their MDI-treated type 1 diabetes patients (88 % vs. 18–54 %, respectively) and MDI-treated type 2 diabetes patients (82 % vs. 30–48 %, respectively) (Fig. 7); FSL2 over Dexcom G6 to MDI-treated type 1 diabetes patients (88 % vs. 54 %, respectively, p < 0.001) and MDI-treated type 2 diabetes patients (82 % vs. 48 %, respectively, p = 0.0002); FSL2 over OS devices to colleagues for use on MDI-treated type 1 diabetes patients (88 % vs. 24–60 %, respectively) and MDI-treated type 2 diabetes patients (88 % vs. 28–54 %, respectively) (Fig. 8); and FSL2 over Dexcom G6 to colleagues for use on MDI-treated type 1 diabetes

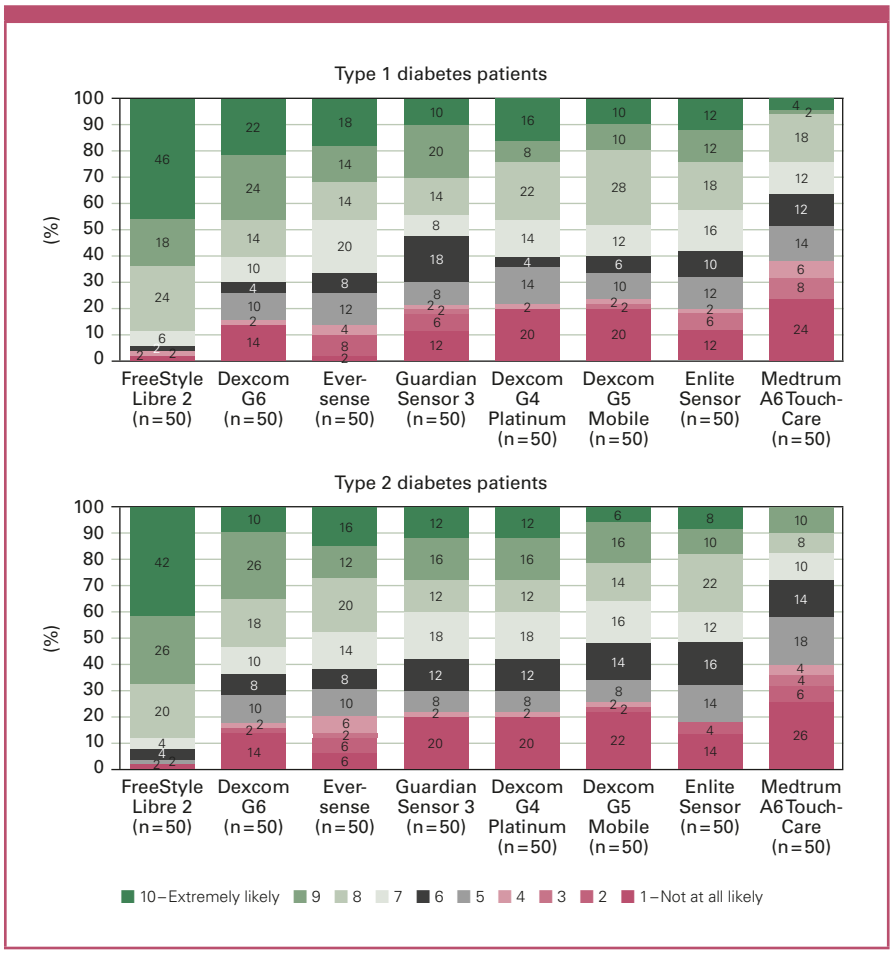

Fig. 8: Likelihood of recommending specific CGM devices to a colleague for MDI-treated type 1 and MDI-treated type 2 diabetes patients.

patients (88 % vs. 60 %, respectively, p = 0.001) and MDI-treated type 2 diabetes patients (88 % vs. 54 %, respectively, p < 0.0001).

Discussion

Numerous studies have demonstrated that CGM lowers haemoglobin A_{1c} (HbA_{1c}), reduces the risk of acute glycaemic events, and is associated with reductions in diabetes-related hospitalisations and associated costs [Bolinder 2016, Charleer 2020, Fokkert 2019, Haak 2017 (a), Haak 2017 (b), Hirsch 2020, Miller 2020 (a), Miller 2020 (b), Oskarsson 2018, Paris 2018, Pintus 2019, Roussel 2020, Tyndall 2019, Wright 2020]. New CGM metrics assessing glycaemic status and treatment decision-making focused on percentages of time in range and time below range as a composite metric of glycaemic control also provide more actionable information than HbA_{1c} alone [Battelino 2019, Danne 2017]. Importantly, accurate and meaningful CGM interpretation requires adequate data for evaluation; at least 70 % of 14 days is recommended [Battelino 2019]. The availability of these metrics will likely encourage greater adoption of CGM in primary care and diabetes speciality practices.

However, frequent and persistent use of CGM is critical to optimising clinical outcomes. Studies have consistently shown that the largest improvements in glycaemic control are associated with frequent sensor wear [Chamberlain 2015, Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group 2008]. Greater treatment satisfaction is also associated with improved adherence and persistence with prescribed treatment regimens [Barbosa 2012, Emechebe 2018].

The findings from our survey demonstrate that satisfaction with the CGM devices covered was very high across both physicians and patients, with the vast majority satisfied or completely satisfied with their current devices. As reported, physician-reported complete satisfaction rates and likelihood of recommending FSL2 were higher relative to all other CGM devices in both type 1 and type 2 diabetes patient cohorts on MDI regimens. However, rates of 'complete satisfaction' in patients were significantly greater amongst current FSL2 users compared to current OS users. FSL2 users were also more likely to recommend their current device to another person with diabetes compared to OS users, indicating a greater sense of satisfaction with FSL2 overall as further supported below.

It should be noted that given the large number of CGM devices available, the OS user cohort is heterogenous with seven devices represented. This approach has ensured the inclusion of many OS devices. Analyses of each individual OS device vs. FSL2 would be impractical in devices used infrequently with small numbers of ratings, while inclusion of only a limited number of OS devices in the study would provide an incomplete view of the market. Our approach was inclusive but has the limitation that OS device ratings may be driven by devices observed at greater frequency where extreme values were observed. Further research focusing on specific device pairings could address these limitations; we sought to understand the distinction between devices with mandatory and optional alarms in this study to support decisions on specific device selection.

Analysis of individual device attributes further corroborates the overall satisfaction findings, demonstrating higher levels of patient-reported complete satisfaction of FSL2 compared to OS devices across all the features tested. This was especially true regarding the optional alarm.

Importantly, most FSL2 users reported that the optional alarm was valuable, and most of those using an OS device would also find the ability to control the alarm very useful. Almost 20 % of OS users also felt that the optional alarm function would enhance their feeling of control and empowerment in diabetes management while prompting them to

respond to alarms more consistently.

Although all patients reported wearing and using their device for most days each month, we found an increase in both the number of days and hours of sensor operation amongst patients that had switched from OS to FSL2 devices. This suggests that some patients find continued use of OS devices difficult; these patients may benefit from switching to a device with an optional alarm such as FSL2. It is also important for healthcare providers to have discussions with their patients as to which CGM device best meets their diabetes management needs, and how to utilise their different design features in the most effective way.

This leaves us with a need and an opportunity to improve both convenience and usability in future CGM devices towards further improvement in treatment satisfaction and persistent use of this valuable technology. Our findings showed a high level of satisfaction with all current CGM devices, but FSL2 has the potential to improve adherence with CGM use especially in patients who find alarms troublesome.

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FÜR DIE PRAXIS

Diese Studie untersuchte Zufriedenheit, Adhärenz und Erfahrung mit aktuellen CGM-Geräten bei Patienten mit Diabetes und ihren Ärzten:

- Ein höherer Prozentsatz der FreeStyle-Libre-2-Anwender im Vergleich zu den Anwendern anderer CGM-Systeme (AS) gab an, mit ihrem Gerät insgesamt zufrieden zu sein (57 % bzw. 43 %). Die Gesamtzufriedenheit war bei den FSL2-Anwendern auch bei 9 der 19 bewerteten Systemattribute signifikant höher.
- Die Benutzer würden wegen der Vorteile eines optionalen Alarms (42 %) eher das System wechseln.
- Mehr FSL2-Nutzer würden das aktuelle Gerät mit „sehr hoher Wahrscheinlichkeit" anderen Patienten empfehlen als AS-Nutzer (42 % vs. 22 %).
- Wer auf FSL2 umgestiegen war, nutzte signifikant häufiger sein aktuelles System „ganz oder fast ganz" in den letzten 30 Tagen im Vergleich zum vorherigen System.
- Die Zufriedenheit der Ärzte war bei Verwendung des FSL2 bei Patienten mit Typ-1- bzw. Typ-2-Diabetes höher als bei allen anderen CGM-Systemen.

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Address for correspondence
Biju Varughese, RPh, MBA
Abbott Diabetes Care Inc.
1420 Harbor Bay Parkway
Alameda, California, 94502
Tel.: +1-510-749 6391
E-mail: biju.varughese@abbott.com

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Mark Silvey, Gavin Harper and Ivana Rajkovic are employees of Adelphi Real World.

Author contributions
Biju Varughese wrote, reviewed and approved the manuscript for submission. Mark Silvey is the guarantor of this work and takes responsibility for the integrity of the data and the accuracy of the content. Gavin Harper and Ivana Rajkovic provided critical review and supported the analyses used.