# **BMJ Open** Appropriateness and acceptability of continuous glucose monitoring in people with type 1 diabetes at rural firstlevel hospitals in Malawi: a qualitative study

 

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 STRENGTHS AND LIMITATIONS OF THIS STUDY

 ⇒ Qualitative study from the first randomised control trial evaluating appropriateness and acceptability of continuous glucose monitoring in a rural, low-literacy population in a low-income country.

 ⇒ Interviewed all five health professionals responsible for providing care for people living with type 1 diabetes in participating clinics.

 ⇒ Conducted before and after interviews with people living with type 1 diabetes, representing approximately 25% of population.

 ⇒ Only interviewed 11 patients and may have limited generalisability to other settings.

 ⇒ Interviews conducted within a trial setting so may be different from routine care.

 MTRODUCTION

 Type 1 diabetes (T1D) is an endocrine disorder that affects 8 746 562 people globally with 1 665 997 people living in low and lower middle-income countries (LLMICs).<sup>1</sup> T1D

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### ABSTRACT

**Objectives** The purpose of this qualitative study is to describe the acceptability and appropriateness of continuous alucose monitorina (CGM) in people living with type 1 diabetes (PLWT1D) at first-level (district) hospitals in Malawi.

Design We conducted semistructured qualitative interviews among PLWT1D and healthcare providers participating in the study. Standardised interview quides elicited perspectives on the appropriateness and acceptability of CGM use for PLWT1D and their providers, and provider perspectives on the effectiveness of CGM use in Malawi. Data were coded using Dedoose software and analysed using a thematic approach.

Setting First-level hospitals in Neno district, Malawi. Participants Participants were part of a randomised controlled trial focused on CGM at first-level hospitals in Neno district, Malawi, Pretrial and post-trial interviews were conducted for participants in the CGM and usual care arms, and one set of interviews was conducted with providers.

Results Eleven PLWT1D recruited for the CGM randomised controlled trial and five healthcare providers who provided care to participants with T1D were included. Nine PLWT1D were interviewed twice, two were interviewed once. Of the 11 participants with T1D, six were from the CGM arm and five were in usual care arm. Key themes emerged regarding the appropriateness and effectiveness of CGM use in lower resource setting. The four main themes were (a) patient provider relationship, (b) stigma and psychosocial support, (c) device usage and (d) clinical management.

**Conclusions** Participants and healthcare providers reported that CGM use was appropriate and acceptable in the study setting, although the need to support it with health education sessions was highlighted. This research supports the use of CGM as a component of personalised diabetes treatment for PLWT1D in resource constraint settinas.

Trial registration number PACTR202102832069874; Postresults.

with 1 665 997 people living in low and lower middle-income countries (LLMICs).<sup>1</sup> T1D requires careful management as it can lead to many long-term life-threatening complications. It is a lifelong condition that requires uninterrupted access to insulin and tools to monitor blood glucose to survive.<sup>2</sup> By 2040, **D** 13.5–17.5 million people are projected to g be living with T1D, with the largest increase **3** in LLMICs.<sup>3</sup> Additionally, the number of premature deaths for people living with type 1 diabetes (PLWT1D) in LLMICs is likely to be nine times higher than deaths due to T1D in high-income countries (HICs).<sup>3</sup> In Malawi, the national burden of diabetes in adults has been estimated between 1.4% and  $3.0\%^4$ ; however, the Malawi STEPwise survey, a WHO tool for non-communicable disease

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surveillance, monitoring and reporting,<sup>5</sup> reported 41% of participants with diabetes were undiagnosed, suggesting that the actual burden may be much higher.<sup>56</sup> According to a report in 2022, there were 6530 people estimated to be living with T1D in Malawi.<sup>1</sup>

There is a wide disparity in incidence, prevalence and associated mortality between HICs and LLMICs. PLWT1D in LLMICs face unique challenges related to lack of diagnosis, difficulty in accessing care and medications and consequently not achieving optimal diabetes management.<sup>7</sup> Basic essential supplies such as insulin and glucose monitoring devices (glucose metres) are often unavailable or unaffordable in LLMICs. An achievable goal for LLMICs where there are constrained resources is 'intermediate care' as defined by Ogle and colleagues.<sup>8</sup> In this tier of care, the rates of mortality and complications are significantly lower compared with minimal care. The main components of intermediate care include basal bolus insulin regimen with multiple daily injections, selfmonitoring of blood glucose (SMBG) 2-4 times daily and diabetes education by a diabetes specialist. Other aspects of intermediate care involve point-of-care HbA1c testing, screening for complications, emergency call services and peer support.<sup>8</sup>

SMBG is an important facet of diabetes management and its effectiveness in monitoring and enhancing glycaemic control is well established.<sup>910</sup> It has improved the clinical outcomes and quality of life in PLWT1D.<sup>11</sup> In resource constrained settings, the primary limitations for SMBG use include access to test strips and glucose metres.<sup>12</sup> Even among those with access to glucose metres, stockouts and financial constraints remain prevalent. Efficacy of SMBG may be limited if patients do not use the machines or do not bring them to clinic for review by providers.<sup>2 13</sup> While SMBG is a helpful tool in the management of diabetes, it does not provide a full picture of glycaemic patterns, like data on fluctuations in blood glucose levels even if performed frequently, decreasing the possibility of detecting critical episodes of severe hypoglycaemia or hyperglycaemia.<sup>2</sup>

Increasingly, continuous glucose monitoring (CGM) is replacing SMBG as the standard of care in HICs. CGM automatically records an individual's glucose level throughout the day allowing patients and the clinicians to review extensive glucose data to guide treatment decisions. To date, there is a paucity of studies on qualitative perspectives on CGM use, particularly in LLMICs. Many studies conducted in HICs have shown that CGM has the potential to improve HbA1c and time in range, while reducing the risk of severe hypoglycaemia which is of particular concern among people with T1D,<sup>1415</sup> especially in LLMICs where food insecurity is more prevalent. Recent studies have demonstrated that CGM is beneficial in enabling selfmanagement and behaviour modification for improved quality of life in PWLT1D.<sup>16-22</sup> In low resource settings, limited studies have evaluated short-term wear of blinded CGM, but have not evaluated any qualitative data related to feasibility or acceptability of CGM.<sup>23 24</sup>

In low-income and middle-income countries (LMICs), adoption of new technologies like CGM faces numerous barriers, reflecting diverse challenges within these regions. Factors such as low literacy and numeracy present significant hurdles on implementing effective usage of CGM.<sup>25</sup> Moreover, lack of access to reliable electricity limits the feasibility of technology-dependent solutions.<sup>26</sup> Lack of smartphones poses significant barriers to access to health information.<sup>27</sup> The hot and humid climates in many LMICs pose challenges for CGM use. Perspiration may cause adhesive to loosen and can affect transmis-sion of sensor data. Risk of rash and skin irritation at the insertion site is also higher in settings with high temperatures and humidity.<sup>28</sup> These multifaceted barriers require Š holistic approaches to address the socioeconomic and 8 infrastructural barriers for better adoption and feasibility of CGM technology in LMICs.

This is a qualitative study conducted as part of the first randomised control trial (RCT) on the use of CGM among a rural population in a low-income country in sub-Saharan Africa (SSA).<sup>29</sup> Gathering perspective from PLWT1D is crucial in understanding the challenges and opportunities related to CGM use. Their first-hand experience provides invaluable insights into their daily manage-ment of their condition, lifestyle, culture and personal choices that may influence the adoption or rejection of CGMs beyond clinical efficacy. Including their perspectives helps to enhance this research and makes it more đ patient-centred.<sup>30</sup> The objective of this study is to undertext and data mini stand the acceptability and appropriateness of CGM use in this setting.

## **METHODS**

### Setting

ģ This study was conducted at Neno District Hospital and ≥ Lisungwi Community Hospital in Neno, Malawi. The two hospitals are run by the Ministry of Health (MoH) and supported by Partners In Health (PIH), a US-based non-governmental organisation. In 2018, the two hospitals opened PEN-Plus (The Package of Essential Noncommunicable Disease Interventions—Plus) clinics.<sup>31</sup> PEN-Plus is a strategy that decentralises care for severe non-communicable diseases (NCDs) including type 1 diabetes to intermediary facilities such as district hospitals. In the PEN-Plus model, mid-level providers (health workers with 2–3 years of postsecondary school training of including nurses and all including nu including nurses and clinical officers) are trained to provide integrated care for conditions for which traditionally services were only available at tertiary referral facilities.<sup>32–34</sup>

#### Study population and sampling

Semistructured interviews were conducted as part of the feasibility RCT in Neno, Malawi to study the use of CGM.<sup>29 35</sup> In the RCT, 42 participants were randomised in a 2:1 ratio to either CGM use or usual care.<sup>35</sup> Participants in the CGM arm were given Dexcom G6 CGM

sensors, transmitters, receivers and solar chargers. Participants in the usual care arm were given SDCheck glucose metres, logbooks and enough test strips to do 1-2 blood glucose tests a day. Health education was provided to all participants and their families. They received training on diabetes management including diabetes symptom recognition, insulin treatment, managing hypoglycaemia, sick day management, blood glucose monitoring, nutritional management, physical activity management and dispelling of myths and false beliefs surrounding diabetes and the device use.<sup>29 35</sup> This study was implemented between April 2022 and July 2022. All patients seeking T1D care at either of the PIH-supported MoH hospitals in Neno district were eligible for this study. A purposive sample of five participants in each arm was selected for the qualitative interviews, based on baseline characteristics and willingness to participate. Due to a transcribing error, one person interviewed at baseline was replaced by another at the end of study. We interviewed all five PEN-Plus providers. The 11 participants selected represent approximately a quarter of all participants in the trial. A detailed description on recruitment, participation and study design of the RCT is provided in the protocol paper.<sup>29</sup>

#### Qualitative approach and research paradigm

This study was conducted utilising an implementation science framework, the Proctor outcomes for implementation research framework, to systematically assess the implementation of our intervention, CGM.<sup>36</sup> Following the framework, which includes implementation, services and client outcomes, we crafted our interview tool tailored to the appropriateness and acceptability outcomes. Using these outcomes, we developed interview guides and an analysis framework by adapting Michie's work on behaviour change.<sup>37 38</sup> This approach aims to understand how acceptability and appropriateness can guide an individual's capability, opportunity and motivation for self-management.

This study was carried out and reported using the Standards for Reporting Qualitative Research (SRQR) reporting guidelines.<sup>39</sup>

#### **Researcher characteristics**

The semistructured interview guides were created by Boston-based researchers in collaboration with a Malawibased research team. The research team also comprises of researchers with personal experience living with T1D, whose unique insights and expertise contributed to a comprehensive understanding of condition and its management throughout the study. Interviews were conducted by Malawi and Boston-based researchers with backgrounds in research, medicine and epidemiology. The first round of participant interviews were conducted by a bilingual nurse trained in qualitative interviewing, and the second round by a trained bilingual researcher proficient in Chichewa and English. Interviews with healthcare providers were conducted through Zoom

by a Boston-based researcher who was not involved in clinical care. Having analysed previous research in similar cultural context, analysis was completed by two Boston-based researchers with substantial qualitative background for emerging themes. Weekly meetings were held with Malawi-based researchers working in that specific setting as well as with researchers who are living with T1D to ensure proper understanding of the material.

#### People living with type 1 diabetes

Protected Pretrial and post-trial semistructured interviews were conducted using qualitative interview guides (online by copyri supplemental appendix 1). All participating PLWT1D provided written informed consent prior to interviews. The pretrial interviews were conducted by a trained nurse igh and the post-trial interviews were conducted by a trained researcher in Chichewa (the local language). Interviews ranged between 20 and 60 min. Standardised interview guides elicited perspectives on the appropriateness and acceptability of CGM use for PLWT1D. Questions explored their experiences living and managing T1D ₫ either using CGM or glucometers, the impact of health uses related to text education sessions during the trial and the impact of device use on self-care and healthcare experience.

#### **Healthcare providers**

Provider interviews were conducted over Zoom in English by a trained researcher following verbal consent. Interviews averaged approximately 1 hour. Interviews explored healthcare providers' perception towards patients' experience as well as their own experiences as a provider caring for PLWT1D utilising both CGM and SMBG technologies. Interviews with providers explored provider's perspectives on the appropriateness and effectiveness of CGM use in Malawi.

#### **Data analysis**

, AI training The patient interviews were recorded in Chichewa and , and translated and transcribed into English by a Malawi-based researcher. The provider interviews were recorded in English and transcribed by a Boston-based researcher. Transcripts were coded using Dedoose version 9.0.62.<sup>40</sup> A preliminary codebook was developed based on the provider and patient interview guides. It was tested by two researchers (AT and LD) using interview transcripts and codes were added and reorganised as appropriate on & agreement by both researchers. Once the codebook was finalised, transcripts were independently double coded by two researchers (AT and LD) using thematic analysis and pre-post comparison. We used an inductive approach that allowed us to explore the richness of the participants perspective without predefined categories, enabling the emergence themes directly from the data. During coding and pre-post comparison, emerging themes were discussed between the coders and the research team to increase validation.

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#### Table 1 Characteristics of participants

	Arm	÷
	CGM	UC
Characteristics of PLWT1D		
Number of participants	6	5
Gender (n (%))		
Male	2 (33)	3 (60)
Female	4 (67)	2 (40)
Patients age (avg)	30.5	32.5
Median year of diagnosis	2018	2018
Characteristics of healthcare providers		
Number of participants	5	
Profession (n (%))		
Clinical officers or doctors	2 (40)	
Registered nurse	3 (60)	

CGM, continuous glucose monitoring; PLWT1D, people living with type 1 diabetes; UC, usual care.

#### **Techniques to enhance trustworthiness**

Coding was completed independently by two researchers who met regularly to address coding discrepancies, check inter-reliability and reach consensus on themes and their labelling. The themes were also discussed with the research team to increase validation. Subjectivity and bias were mitigated by pilot coding and consensus among two researchers as well as discussion of findings across the study team.

#### Patient and public involvement

PLWT1D were engaged throughout the study. Three of the outcomes of this research were feasibility, acceptability and appropriateness, so much of the study involved gaining perspectives, experiences and views of the technology by PLWT1D. Two of the study coauthors (GF and AG) are living with T1D, and were involved throughout the design of the protocol, tools, training and implementation of the study.

#### RESULTS

#### **Characteristics of participants and providers**

We conducted a total of 25 interviews. These included five pretrial interviews of participants in each of the usual care and CGM arms (10 in total), and five post-trial interviews of participants in each arm (10 in total) and five healthcare providers. Table 1 summarises the characteristics of the participants and providers. The intent was to perform both pretrial and post-trial interviews with the same individuals, but due to a transcribing error, one person who was interviewed in the pretrial interview was replaced by another individual in the post-trial interview. We included all transcripts in the analysis. The themes are summarised in box 1.

### Box 1 Themes, subthemes and corresponding quotes from qualitative interviews

#### Theme: Patient-provider relationship

Subtheme: Health education and provider training

1. Provider: My favorite part of CGM is being aware of what is going on. By being aware of what's going on you watch what you want to do. So being aware of what is going on is that is the best and you have all the power to make the decision on what you want to do.

2. Patient: During the health education we were taught ways how to manage our diabetes, they told us to check our glucose level every day, and check on our diet. Before our health education sessions, I had no idea on how to control my diet, but now I know what to eat and what not to eat.

#### Subtheme: Interaction and workload

3. Provider: For CGM there was increased workload as you need to download the data and interact with the data. For the glucometer, once the patient comes, they give you the logbook that recorded and you just go over the glucometer to re-verify. With glucometer there is less workload than with CGM. But once one has familiarized himself with CGM and is able to interact with the data coming from the patient, then one would appreciate he/she maybe able to offer superb care using the CGM because of the other advantages it brings.

4. Patient: Yes, initially I was spending a little time with the doctors but now I spend a lot of time with the doctors.

#### Theme: Stigma and psychosocial support

#### Subtheme: Stigma related to CGM

5. Provider: I think that has reminded me of the boy in the school. His friends were interested to know what he was wearing ... we had gone and talked to the teachers but we could not talk to the whole school, so other students were interested to know what was going on ... the boys would react differently. Others were okay with it and tell them it's ... for glucose monitoring. But others ... were offended, why do they ask me these questions? Why do they want to see this? I feel that one of the boys was very affected in the sense that he mentioned that he was not comfortable bringing that to the class. So, after discussion, we changed the position, instead of putting it in the arm we put it in the abdomen so that others will not see it. We always advise him not to bring in the receiver, you can keep it in the back, and then you have your shirt covering the sensor.

6. Provider: The other case that we think we experience was not necessarily the case of stigma per se but I think it was just a young lady who faced some resistance from her boyfriend was not happy to have her chip. She stopped wearing it and the decision had been made that she just bring the chip to the clinic. We don't necessarily look at it as a case of stigma, but it was a unique case.

7. Patient: The only problem was the beeping sound the CGM produces when glucose levels are too high or too low. I get many questions from people about the beeping sound, it makes me uncomfortable. *Subtheme: Friends/family support* 

8. Patient: I inject insulin three times every day with the help of my husband. This is done in the morning, afternoon and night.

9. Patient: The only time that they help in monitoring my CGM is when am not feeling okay. So in such cases they spend their nights with me so that we can monitor together during the night.

#### **Theme: Clinical management**

Subtheme: Clinical decision making

10. Provider: One change we made was in a nine year old. At visits their sugars were high. We kept adding insulin but now with the CGM we could see that sugars were low at night. So we reduced the night

Continued

### Box 1 Continued

doses of insulin and increasing the ones in the morning, improving his sugar control.

### Subtheme: Self-intervention

11. Provider: Okay, the first thing is they are able to check or monitor their blood sugar level 24 hours a day. This helps them improve their self-care knowledge and understanding of hyperglycemia, they are able to see the signs of hyperglycemia and what happens when they eat foods. So CGM was an opportunity to have real time knowledge. So okay ... let me take a drink of coke and see what will happen. They see the graph is going up and the alarm goes off .... Then oh yeah really coca cola increases the blood sugar. Okay my blood sugar is above 200 and there is an alarm, let me take a cup of water and see. They will take a cup of water and sees the graph is going down. Yeah now they are able to make a clear solution and say okay when I see this, when I feel this it really means my blood sugar is going low. When I see this or feel this my blood sugar is going high. CGM guides them on what to eat at that time. 12. Patient: Yes, because I was given the CGM so it is easy for me to check my glucose levels since I go with it everywhere I go.

#### **Theme: Device usage**

#### Subtheme: Beeping

13. Provider: Some reported alarms and knowing what was happening to their blood was irritating. It was better for them not to know. *Subtheme: 10-day expiration* 

14. Provider: Coming into the hospital for sensor changes was a challenge. We provided money for transport, so for people who lived close it was okay but for some those who are living far couldn't afford to come every 10 days.

#### Subtheme: Ability to read CGM

15. Provider: Yeah on that one we have mixed feedback. Some they find it easier. They are able to read. Because the CGM language is English, there is no Chichewa. [S]ome due to their literacy mess up the settings because of the touch screen. Then they will be like oh what is going to happen with my receiver? They end up messing up everything ... they're coming in just because they cannot read what is on the receiver because it's English and them some they never went to school. Some they went to school, but they never went far. They dropped in primary school in their classes.

16. Patient: It was sometimes hard for me to see the CGM reading properly because when blood glucose levels are high I experience blurry vision.

17. Patient: There were no serious problems. The only problem that I have encountered is that the CGM is designed in English only, so for some of us it is difficult to understand some of the things because we don't know how to read English. For example, in our family it is only her father who knows how to read and write in English so he is the only one that really understands some of the things that are written in the CGM. 18. Provider: And some the other challenge they mentioned was they can't read the numbers on the glucometers and they can't record the same in the log book, so they get to have someone at home who can read them glucometer and is able to write the same in the logbook. So the time we started implementing the use of glucometers, we had some who even come to return the glucometer who say okay my child is the one reading the glucometer and do the recording in the logbook but now my child is going somewhere else for school. There's no one at home who will be doing this for me. Yeah, we are able to do the consent ... to say okay then just do it. Don't read or record. Whenever you come here, you will be able to retrieve the data from your glucometer and it transfer it into your log book.

Continued

#### Box 1 Continued

#### Subtheme: Accuracy and reliability

19. Patient: Last week I came to the hospital with her because the CGM that she was given was showing that her blood glucose levels were very low for about 3 to 4 days, then I gave her some sugar and candies to eat. Then it was on Tuesday that I decided to take her to the hospital because there was no any change despite the sugar and the candies that I was giving her. Upon being diagnosed/screened at the hospital the results turned out contrary (sugar levels were too high up to 600 plus) to what the CGM as well as the signs that she was showing for the past 4 days.

#### Subtheme: Adhesion

20. Provider: And the with the use of CGM, there is no that pain, but with CGM, I did not meet anyone who developed some complications. Yeah, only few maybe like minor rashes around the area where we put the sensor. But not something worrisome. Yeah it was one... But the rest, everything was just OK.

Subtheme: Solar chargers

21. Provider: Solar chargers were not just used for charging CGM. They were used for lightbulbs in the house and charging phones too. This is something they were very happy about.

CGM, continuous glucose monitoring.

#### Patient-provider relationship

Pretrial, all providers were trained on CGM use and received refresher training on SMBG technique with glucose metres and interpreting logbook data. Providers had an opportunity to use CGM themselves during the training. Providers mentioned that the training they received regarding diabetes management helped them in the decision-making process and gave them better insight into their patient experiences allowing provide higher quality services to their patients. For example, one provider reported that wearing CGM made him more careful and aware of how his food habits and routine impacted his glucose levels (quote #1, box 1).

In interviews, participants and providers acknowledged the importance of health education sessions for lifestyle modifications to aid in blood glucose management. Participants continued to incorporate the learning from the health education sessions into their daily routines. They learnt about diabetes management strategies that helped them manage their glucose levels (quote #2, box 1).

Participants generally reported positive interactions **technologies** with providers in both pretrial and post-trial interviews. CGM sensors expired every 10 days which increased the number of clinic visits and interaction with providers by garticipants in the CGM arm. Both participants in the CGM arm and providers commented on how CGM use had increased patient–provider interactions and strengthened the patient–provider relationship compared with when they used a glucose metre (quotes #3 and #4, box 1). However, support from providers for device usage and diabetes management was mentioned by participants in both arms throughout the trial.

Provider-participant trust was also frequently mentioned. A majority of participants expressed an openness to discussing their concerns and felt that their concerns were addressed by providers. This appeared to be linked with increased uptake of health education; participants in both arms reported willingness to learn about diabetes management and showed increased interest in how they could use lifestyle changes to manage glucose levels. Examples included changing portion sizes and adding physical exercises to their daily routine, which they learnt from their providers during the health education session. Providers mentioned how participants in the CGM arm were more receptive to learning about the device use and its benefit.

One concern raised by several providers was an increase in workload as a result of the additional visits from participants in the CGM arm and an increase in administrative work (eg, downloading CGM data, generating CGM reports, reviewing and interpreting CGM data). Despite this, one provider mentioned feeling hopeful that participants would eventually feel comfortable making sensor changes and understand their own data, leading to reduced workload and better care for their participants in the long term (quote #3, box 1).

#### Stigma and psychosocial support

Many providers reported barriers to CGM use related to stigma. Multiple providers referred to one school-aged participant who felt uncomfortable wearing a CGM due to unwanted attention received from classmates related to the device. Providers and the participant's family discussed this and changed the position of the sensor so it was not visible (quote #5, box 1). Another patient reported not wearing a CGM because her partner discouraged her from wearing a sensor as he did not like it (quote #6, box 1). One provider shared that their patient, who worked at a gas station, was unable to wear the device because their boss worried it might cause a fire. Audible alarms from the device also contributed to stigma; for example, one patient reported being questioned about the device when an alert sounded in public (quote #7, box 1).

Participants from both arms discussed feeling motivated to talk about diabetes management with their friends and family members. Many participants described family members assisting them with diabetes management including injecting insulin (quote #8, box 1). One participant from the CGM arm mentioned that his family helped him check CGM readings through the night when he was not feeling well (quote #9, box 1).

#### **Clinical management**

Providers reported that CGM enhanced their clinical understanding of blood glucose patterns and their ability to provide guidance around diabetes management. Specifically, they found that real-time glucose readings increased their ability to manage diabetes and adjust insulin doses. One provider discussed how CGM helped them detect and address episodes of nocturnal hypoglycaemia in a patient, which had previously gone undiagnosed using SMBG (quote #10, box 1). Providers

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reported that without CGM technology management, decisions had depended on logbooks and blood glucose readings at clinic visits, and that CGM allowed them to visualise 24-hour glucose data.

Providers reported that CGM is an effective aide in teaching PLWT1D about their blood glucose and reinforcing messages about how certain foods impact glucose levels. One provider reflected on a patient who drank soda and watched as her glucose levels spiked (quote #11, box 1). Similarly, participants discussed how CGM nabled them to make decisions and take necessary of the control of the day. Cition to manage glucose levels at any time of the day. Participants in the glucose metre arm similarly enabled them to make decisions and take necessary action to manage glucose levels at any time of the day.

mentioned how being able to see their results helped them modify their routine and manage their blood 8 glucose levels. However, they were only able to monitor their glucose using test strips once or twice daily.

In pretrial and post-trial interviews, participants were asked about symptom frequency, defined as the number of occurrence of symptoms of hyperglycaemia or hypoglycaemia. Importantly, when comparing the pretrial and post-trial interviews, a higher proportion of participants in the CGM arm reported less symptom occurrence in uses related post-trial than the pretrial interviews compared with the UC arm.

#### **Device usage**

A key benefit of CGM reported by all participants in the CGM arm and providers was the ease with which they could use the device and get necessary information to manage their glucose levels. One patient noted that he could carry the device easily everywhere they went, as it was like carrying a mobile phone (quote #12, box 1)

Many participants in the usual care arm found glucose metres easy to use but listed finger pricking as the main challenge. Providers similarly reported that the main complaint from participants from the usual care arm was discomfort with finger pricking.

While participants in the CGM arm were happy that they did not have to prick themselves every day, some mentioned pain or physical discomfort from sensors. One patient mentioned pain where the sensor was inserted, which later was resolved by the provider when the provider placed the sensor in different location. Prior to initiation of the study, providers said they had been concerned that given the climate, patients would experience insertion site rashes, but were pleased that patients did not report this. While the purpose of CGM alarms is to alert wearers to hypoglycaemic or hyperglycemic events, some partic- 8 ipants expressed annoyance with alarms, particularly when the alarms went off in public. Several participants also reported that the alarms made them feel stressed about their health (quote #13, box 1).

The greatest obstacle to CGM use reported by both providers and participants was the short sensor life of 10 days. Most participants needed provider support to change them, resulting in increased clinic visits. This was a particular concern for participants who had to travel

long distances to reach the clinic (quote #14, box 1). Of note, providers expressed hope that once patients were able to change the sensors at home or if sensor life was extended, CGM use by patients would be much more viable.

Providers and participants mentioned challenges in understanding CGM readings. Since the CGM was in English, one participant mentioned that she needed a family member's help with understanding CGM readings (quote #17, box 1). Providers mentioned how even literate patients who were able to read numbers had difficulty understanding the English (quote #15, box 1). One patient mentioned that it was difficult to read the results displayed in the receiver due to blurred vision, limiting their decision-making ability from CGM readings (quote #16, box 1).

Vision problems also affected participants using glucose metres. One provider reported that some participants were not just unable to read the results but were also unable to record their readings in the logbook. One patient's son was reading blood glucose results and recording them on his behalf. Provider felt this barrier could be overcome by downloading the data from the glucose metre during clinic visits (quote #18, box 1).

Some patients discussed how the CGM device validated the symptoms they experienced. They also reported how they were able to see how their actions impacted their blood glucose levels in the CGM. Examples included seeing how foods that they ate impacted their blood glucose. However, one participant mentioned that the CGM reading did not always match their symptoms and was taken to the hospital for a further check-up (quote #19, box 1). While device adhesive issues were not reported by participants, providers mentioned that a few participants developed rashes where the sensors were placed, which resolved with ointment prescribed on clinic visits (quote# 20, box 1).

All participants were educated on safe biohazard waste management for all diabetes supplies related waste. Participants in the CGM arm were given disposal boxes which they would bring to the clinic. Some also had pit latrines at their house which they used to dispose the waste after they used the sensors.

Although only provided to CGM arm participants, solar chargers were found to be useful for charging CGM and other devices. Many providers reflected on how participants were happy with the solar chargers as they could also be used to charge their personal devices including lightbulbs in their homes (quote #21, box 1).

#### DISCUSSION

Overall, the introduction of CGM technology in this setting was considered appropriate and acceptable. Both providers and patients expressed a preference for CGM technology and felt that CGM revolutionised care delivery for PLWT1D. While feasibility, appropriateness and acceptability of CGM have been minimally studied in low-resource settings,<sup>41-43</sup> extensive research on impact of CGM on quality of life for PLWT1D has been performed in high resource settings. The primary benefits cited by patients using CGM in our study—use of real-time glucose data to make informed decisions about lifestyle and insulin usage, as well as decreasing burden of finger-sticks—are well documented in high resource settings.<sup>1718 44</sup>

This study found that the appropriateness of CGM technology was limited by the 10-day lifespan of each sensor and stigma associated with alarms and the visual of wearing sensors, a finding similar to that described in a qualitative study conducted in the USA.<sup>45</sup> However, **2** this study identified key barriers to CGM use not previ- 8 ously identified in research conducted in high resource settings, including reliable access to electricity and low literacy and numeracy. Many studies conducted in lowresource settings have used Freestyle Libre flash glucose monitors, which do not require entry of a numerical code to start the sensor.<sup>23 24 46 47</sup> While these studies did not specifically assess for feasibility, use of a CGM that does not require entry of a numerical code to start the sensor may allow for more patients to restart sensors at home, addressing one of the key barriers to CGM use identified by both patients and providers in this study that would likely improve appropriateness in this setting. To be certain, additional resources will be required to address ð challenges starting sensors due to limited literacy as CGM e becomes more widely adopted. Similarly, the distribution of solar chargers, as was done in our study, may be an effective method for ensuring these devices remain appropriate for use in settings where electricity is not  $\mathbf{\bar{a}}$ always available.

In our study, providers reported CGM technology to be a useful education tool to improve patients' understanding ≥ of the various factors that can affect glucose levels and effective management strategies. Patients themselves reported being able to monitor glucose levels and modify ğ their routines to manage them throughout the day. Participants in the CGM arm appreciated this improved understanding of their condition and enhanced ability to manage accordingly, lending to the appropriateness and acceptability of the device. Importantly, CGM arm participants' positive reported interactions with providers likely made CGM more acceptable, particularly as they were receptive to learning about the device's use and received extensive education from providers. In this way, the CGM 🖁 served as a tool to promote clinic-based delivery of health education, an important facilitator to self-management of T1D described in qualitative studies conducted in both Malawi and Liberia.<sup>48 49</sup> Of note, however, this study led to increased clinic visits which may not be sustainable, particularly in clinics with larger client sizes, so emphasis needs to be on education and newer technologies that include easier to change sensors.

At the same time, CGM technology increased providers' understanding of glucose patterns and fluctuations.

Review of CGM reports over time allowed providers to refine and tailor adjustments to insulin regimens to better fit the needs of individual patients. CGM offered rich and extensive data on patients' glucose levels at crucial time points (eg, overnight). Providers previously had no data on overnight glucose patterns, so CGM provided critical knowledge about the severity of fluctuating levels and served as a teaching tool for patients and providers, allowing them to develop and modify individualised insulin regimen plans, individualise patient education and overall provide better care.

Previous studies in SSA have typically used blinded CGM (data not available in real-time to the wearer) for shorter duration.<sup>23 24</sup> In comparison, this study used unblinded CGM which allowed for participants in the CGM arm to monitor their blood glucose and adjust management accordingly. Seeing real-time glucose readings gave CGM arm participants a better understanding of how their daily activities and diet impacted blood glucose levels, reinforcing guidance received from providers. For example, one provider reported how patients compared the effects of drinking soda on blood glucose levels with that of drinking water. This ability of patients to utilise the devices in their daily management likely had a positive impact on both acceptability and appropriateness of the intervention.

As this was a feasibility study, it had a limited sample size of only 11 participants and five providers, so may not be generalisable to other settings. CGM was also given as part of a trial setting which may be different to regular clinical care. The first round of interviews was conducted by a nurse who also delivers care to PLWT1D which may have influenced some responses. All the participants were interviewed at the clinic where they were receiving their routine care, which may impact responses. Finally although this was a feasibility study, we did not address costs.

Further research should evaluate if shorter duration of wear or flash glucose monitoring may address barriers such as cost, difficulty applying sensors independently and stigma associated with wearing the device. Newer models of CGM, including Dexcom G7 and Freestyle Libre 2 and 3, do not require sensor codes to be inputted for activation, so may be better suited to this setting. Because devices were provided for the study at no cost from Dexcom, cost was not evaluated in this study, however at current prices, it is unlikely that they could be provided large scale in LICs, so continued global advocacy efforts are needed to make intermediate care for T1D more accessible for PLWT1D in LICs.

#### **CONCLUSION**

In this study, we found that CGM was appropriate and acceptable for both patients and providers in low-resource settings. Overall, CGM in low resource settings presents a valuable and significantly underutilised tool to decrease burden of management, enhance patient education and aid providers in identifying dangerous blood glucose trends such as nocturnal hypoglycaemia while making clinically significant treatment decisions. To make the technology more feasible in low resource settings, sensor life needs to be increased and the device needs to be more accessible to individuals with limited numeracy.

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