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2023

BACKGROUND

One of the major public health concern facing our nation is the widely discussed chronic non-communicable disease (NCD) known as diabetes. According to a national survey report, in Malaysia in 2019, one in five adults in Malaysia had diabetes. Globally, estimation of people with diabetes was 463 million in 2019 and it is projected to reach 578 million by 2030 and 700 million by 2045. Of these, approximately 10% have Type 1 diabetes (T1DM).

Diabetes does end up receiving chronic disease treatment in the form of insulin therapy to help control their blood sugars in conjunction with a blood glucose meter. Without adequate blood sugar control, diabetes can lead to many debilitating complication, life-threatening conditions and ultimately death. Glycaemic control in participants with insulin-treated diabetes remains challenging and suboptimal in the majority of adolescents and young adults with T1DM. Ninety percent (90%) patients with type 2 diabetes (T2DM) contributed to a significant proportion of adults that have poor glycaemic control.
In order to receive the appropriate dose of insulin, an accurate measurement of blood glucose is required, typically with a finger- prick glucose meter. Self-monitoring of blood glucose (SMBG) is now recognised as a core component of diabetes self-management. This procedure is required throughout the day, with measurements taken before meals, after meals, before and after physical activity, before driving, and during the night. Thus, with the advance in diabetes technology, continuous glucose monitoring system (CGMS) devices with or without insulin pumps, allow frequent blood glucose measurements with no need for numerous needle pricks.

Continuous Glucose Monitoring Systems
The development of this new technology allowed patients to monitor their blood sugars by inserting a device subcutaneously. The CGMS measures a patient's glucose levels in their interstitial fluid over the entire day. A CGM works through a tiny sensor inserted under skin, usually on your belly or arm. The sensor measures the interstitial glucose level, which is the glucose found in the fluid between the cells. The sensor tests glucose every few minutes. A transmitter wirelessly sends the information to a monitor. The monitor may be part of an insulin pump or a separate device, which carry in a pocket or purse. Some CGMs send information directly to a smartphone or tablet. With CGMS, instead of the four readings per day, patients and medical providers now have a more in-depth knowledge of the fluctuations each unique patient experiences throughout their day. Real-time (RT-CGM) or flash continuous glucose monitoring displays the current glucose, direction and velocity of glucose change and provides programmable alarms.

Due to the rapid emerging of the diabetes technology using these wearable devices therefore, this assessment will evaluate whether it would be effective, safe and cost-effective to use CGM in the management of diabetes patients required insulin management in Malaysia as requested by Medical Endocrinologist Consultants from Putrajaya and Malacca Hospital.

Policy Question
Should continuous glucose monitoring devices be utilised and provided as an approach for glucose monitoring for insulin-requiring diabetes patients' management?

Objectives

i. To assess the comparative effectiveness and safety of CGMS for glucose monitoring in insulin-requiring diabetes patients.
ii. To determine the economic, organizational, social, ethical and legal implications of CGMS for glucose monitoring in insulin-requiring diabetes patients.
iii. To assess the economic implication, social, ethical, and organisational aspects related to the used of CGM for glucose monitoring in insulin-requiring diabetes patients.

Research questions

i. How effective and safe are the CGMS for glucose monitoring in insulin-requiring diabetes patients?
iii. How cost-effective are the CGMS or devices for glucose monitoring in insulin-requiring diabetes patients?
iv. What are the organizational, social, ethical and legal implications of CGMS or devices for glucose monitoring in insulin-requiring diabetes patients?

METHOD

PART A: SYSTEMATIC REVIEW

Literature search was developed by the main author and an Information Specialist who searched with the following electronic databases; the Ovid interface: Ovid MEDLINE® and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions® 1946 to Jan 2023, EBM Reviews - Health Technology Assessment (4th Quarter 2016), EBM Reviews - Cochrane Database of Systematic Review (2005 to January 2023), EBM Reviews - Cochrane Central Register of Controlled Trials (Jan 2023), and EBM Reviews - NHS Economic Evaluation Database (1st Quarter 2016). Parallel searches were run in PubMed, US FDA and INAHTA database. There was no limitation in language, however, in the end only articles in English were included.. Detailed search strategy is as in Appendix 3. The last search was performed on 28 February 2023. Additional articles were identified from reviewing the references of retrieved articles.

The risk of bias or quality assessment (methodology quality) of all retrieved literatures was assessed depending on the type of the study design; using the relevant checklist of National Collaborating Centre for Methods and Tools (ROBIS) for Systematic Review and Meta-analysis, a revised Cochrane Risk of Bias Tool (RoB2) for Randomised Controlled Trials, and Critical Appraisal Skill Programme (CASP) for Observational and Economic Studies. All full text articles were graded based on guidelines from the U.S. / Canadian Preventive Services Task Force

PART B: LOCAL ECONOMIC EVALUATION

A simplified state transition model, consisted of six health states was used to estimate the cost-effectiveness of continuous glucose monitoring (CGM) for diabetic patients. It followed a hypothetical cohort of intensive insulin regimen patients with CGM versus self-monitoring of blood glucose (SMBG). Effectiveness was based on a meta-analysis and assumptions about the relationship between time in range (TIR), HbA1c reductions, and complications. Acute complications differed between type 1 and type 2 diabetes, and costs were calculated for device acquisition, hospitalization, follow-up visits, and diabetes-related management. The model compared T1DM and T2DM cohorts and applied a cost-effectiveness threshold of one-time per capita GDP of Malaysia in 2022 (MYR 53,043/QALY) from the perspective of MOH with a 3% annual discount rate. A Microsoft Excel cost calculator was created to assess the budget impact of increasing CGM use for T1DM patients. It considered glucose monitoring costs and costs of treating severe hypoglycaemic events. The analysis targeted T1DM patients with more than one severe hypoglycaemic event. Sensitivity analysis was conducted, and scenario analysis examined variations in test strip usage and sensor frequency. The prevalence and incidence of T1DM in Malaysia were estimated based on available data.

PART C: PATIENT AND PUBLIC INVOLVEMENT IN HTA – FOCUS GROUP DISCUSSION ON CGMS FOR DIABETES PATIENTS

A qualitative study was conducted with the aim of exploring patient perspectives on the use of Continuous Glucose Monitoring Systems (CGMS) for diabetes management. The research was conducted through focus group discussions, involving adults, adolescents, and caregivers. Participants were recruited through purposive sampling, and data was collected from May to September 2023. Ethical approval was obtained. The study collected demographic information and conducted discussions using a semi-structured interview guide, exploring the impact of diabetes, benefits, barriers, and attitudes toward CGMS. Thematic analysis was used to analyse the data.

Results:

PART A: SYSTEMATIC REVIEW

All studies included were published in English language between 2012 and till recently 2023 and were conducted in UK, USA, Canada, Italy, Spain, Australia, New Zealand, China and Singapore. The 15 full text articles which were finally selected in this review consist of seven systematic reviews (SR) with meta-analyses, one SR, two RCTs, two (2) HTA reports and three economic related papers.

1. EFFECTIVENESS

i. GLYCAEMIC CONTROL

Hypoglycaemic events in T1DM patient:

- CGM significantly lower severe hypoglycaemic events among patients and also incidence of severe hypoglycaemic events (SHE) in CGM group was significantly lower, RR = 0:52, 95% CI 0.35-0.77, p = 0:001 and RR= 0.61; 95% CI 0.33 to 1.15); Z = 1.53, p=0.13) when compared with SMBG; (I2 = 50%, p=0.04) when compared with SMBG. (Wang Y, 2022; Teo E, 2022) The risk of getting episode of hypoglycaemia was increased for CGM users, was not significant because of the CIs were wide (RR= 3.26, 95% CI 0.38 to 27.82) vs (RR 1.24, 95% CI 0.67 to 2.29) Langendam M 2012)

Hypoglycaemia in T2DM patients:

- CGM was more effective than SMBG in reducing the average time spent in hypoglycemia (−0.47h [95% CI −0.73 to −0.21]) and the average number of hypoglycemia events (−0.16 [95% CI −0.29 to −0.03]) among adults with T2DM requiring intensive insulin therapy. Hypoglycaemia events in T2DM patient, among hospitalised high risk for hypoglycaemia insulin-treated demonstrated that RT-CGM/GTS group experienced 60.4% fewer hypoglycemic events (<70 mg/dL) when compared with point of care/ standard of care or usual care (POC) group = [(0.67 events/patient; 95% CI 0.34 to 1.30] versus [1.69 events/patient [1.11 to 2.58], P = 0.024)]; with absolute RRR = 1.02 (RCT by Singh LG, 2022 In addition, the RT-CGM/GTS group experienced 60.4% fewer hypoglycemic events (<70 mg/dL) when compared with POC group = [(0.67 events/patient; 95% CI 0.34 to 1.30] versus [1.69 events/patient [1.11 to 2.58], P = 0.024)]; with absolute RRR = 1.02

Hypoglycaemia and hyperglyacaemia in GDM

- CGM detects a higher number of hypoglycaemia episodes than SMBG and showed a significant role in pregnant women qualify for insulin therapy. CGM group with GDM had significantly lower number of patients with hypoglycaemic events and also showed significant a difference in the duration of time spent in hypoglycaemia, with lower results in the CGM group
- In this review demonstrated that CGM is better at detecting episodes of hyperglycaemia as compared to SMBG (from 2 studies) found that CGM detected more hyperglycaemic events when compared with SMBG and in all patients the incidence rate of hyperglycaemia = 5.65% using CGM versus 14.2% using SMBG (p < 0.05).

Episode of diabetic ketoacidosis (DKA)

- There is no statistical difference in the probability of occurrence of diabetes ketoacidosis between the CGM group when compared with the SMBG (RR = 1:34, 95% CI 0.57-3.15, and p = 0:5 (Wang Y, 2022) CGM group demonstrated no significant reduction in DKA events (RR= 1.06; 95% CI 0.49 to 2.32); Z = 0.15, p=0.88) when compared with SMBG; (I2= 0%, p=0.59) (Teo E, 2022) There is no significant difference in risk of ketoacidosis between CGM and SMBG users.; RR= 0.94, 95% CI 0.36 to 2.40, I2=0%). (Langendam M 2012)

ii. REDUCING HBA1c

In T1DM & T2DM:

- CGM was associated with greater reduction in HbA1c from baseline compared with usual care SMBG) (-0.28%, 95% CI -0.36% to 0.21%, I2 = 0%, p < 0.00001). The benefit was observed both in patients with T2DM (-0.31%, 95% CI -0.41% to -0.21%, I2 = 14%, p < 0.00001) and T1DM (-0.27%, 95% CI -0.46% to -0.09%, I2 = 0%, p = 0.004).
- The results showed that CGM lowers HbA1c level by 0.17% (95% CI 20.29 to20.06, p < 0.003) when compared with the SMBG, among T1DM or T2DM with an extensive insulin regimen. In a subgroup analysis, the mean reduction of HbA1c was 0.23% in the 13 comparisons using rt-CGM. Neither is-CGM nor sensor-augmented pump (SAP) significantly changed mean HbA1c levels, with no evidence of statistically significant heterogeneity for the three comparisons using is-CGM (I2= 0%) and high heterogeneity for the two comparisons using SAP (I2=85.5%).
- CGM showed greater HbA1c reduction and was aimed at improving glycaemic control MD= (-0.31, 95% CI -0.43 to -0.19, p< 0.001) a significant 0.16% decrease of HbA1c was associated with people T1DM but not people with T2DM.
- Overall, when compared with the usual care, CGM was associated with modest reduction in HbA1c (WMD= 20.17%, 95% CI 20.29 to 20.06, I2= 96.2%).

In T1DM only:

- CGM showed a statistically significant absolute improvement in HbA1c percentage points (MD = -0.22; 95% CI (−0.31 to −0.14) when compared with SMBG. The effects were strongest with adjunctive technology (Medtronic Paradigm, FreeStyle Navigator, Guardian REAL-Time, Dexcom series, MiniMed series, Enlite and Paradigm Veo) MD=−0.26%; 95% CI (−0.36 to −0.16), and no evidence of a difference in HbA1c was seen for intermittent scannings – CGM (is-CGM). CGM significantly reducing the HbA1c level when combined with SMBG, the combined result is WMD = −2:69, 95% CI (-4.25, to 1.14), and p < 0:001. After six months, Rt-CGM users showed a significant larger decline in HbA1c level in starting insulin pump therapy when compared with patients using MDI and SMBG; MD in change in HbA1c level = (-0.7%, 95% CI -0.8% to -0.5%, 2 RCTs, 562 patients, I2=84%).

In pregnant women (GDM)

- One RCT by Paramasivam S found that CGM significantly lower HbA1c concentration (CGM group: 5.2 ± 0.4% when compared with SMBG group: 5.6 ± 0.6%, p < 0.006.

Head-to-head comparison

- Head-to-head comparison between RT-CGM and open-loop continuous subcutaneous insulin infusions (CSII) when compared with RT-CGM Multiple Daily Injections (MDI) group showed that mean in overall HbA1c in RT-CGM+CSII = 63.3 ± 9.2 (mmol/mol) versus RT-CGM+MDI groups = 63.5 ± 10.2 (mmol/mol) and there is no significant reduction of HBA1c between groups.

iii: EFFECTS ON TIME IN RANGE (TIR); TIME SPENT BELOW RANGE (TBR)

In T1DM and T2DM

- The CGM group showed beneficial effect on change in TIR from baseline and a greater increase in TIR = (5.59%, 95% CI 0.12 to 11.06, I2 = 0%, p = 0.05) and a neutral effect on change in TBR range from baseline = (-0.11%, 95% CI -1.76% to 1.55%, I2 = 33%, p = 0.90). In patients with T1DM and T2DM with an extensive insulin regimen CGM showed a significant increase of TIR WMD= 70.74 min, 95% CI 46.73 to 94.76, p< 0.001; I2= 66.3%, p< 0.001). In the pre-specified subgroup analysis, TIR increased more in trials using rt-CGM (83.49, 95% CI 52.68 to 114.30, p <0.001) than intermittently scanned (is-CGM) (53.91, 95% CI 28.54 to 79.27, p< 0.001) or SAP (37.10, 95% CI 0.74 to 73.45, p< 0.045). The increase in TIR was significant and robust independently of diabetes type, method of insulin delivery, and reason for CGM use. Another finding from flash CGM demonstrated that CGM group spent on average one hour more in the target glucose range (95% CI 0.41 to 1.59) and 0.37 hours (22 minutes) less in a high glucose range (95% CI −0.69 to −0.05) compared with SMBG.

In T2DM among hospitalised high risk for hypoglycaemia insulin-treated

- An RCT by Singh LG (2020) demonstrated that CGM group lower percentage of time spent below range (TBR): <70 mg/dL

(0.40% [0.18 to 0.92%] versus 1.88% [1.26 t0 2.81%], p= 0.002) and <54 mg/dL (0.05% [0.01 to 0.43%] vs. 0.82% [0.47 to 1.43%], p= 0.017) when compared with the POC/usual care group.

In T1DM patients only

- CGM group showed an overall absolute TIR increased by 5.4% (95% CI 3.5 to 7.2) when compared with control (SMBG), with heterogeneity (I2= 71%). The effects were strongest with non-adjunctive technology - Dexcom G5 and Dexcom G6; TIR = 6.0% 95% CI 2.3 to 9.7). The CGM improved the percentage of time patients spent in the target glycemic range by 9.6% (95% CI 8.0 to 11.2) to 10.0% (95% CI 6.75 to 13.25).

2. SAFETY

- An RCT by Haak T, 2017 (RCT) reported that there is no serious adverse events (SAEs) related to the device or study procedure. There were four hypoglycemia SAEs experienced by four participants (7% in CGM groups versus 9% in control participants) but none of the severe hypoglycemic episodes or hypoglycemic adverse events were associated with the device. Six (4.0%) in the CGM group reported nine device-related adverse events which were sensor-adhesive reactions and resolved after treatment with topical preparations.

3. COST-EFFECTIVENESS

- A CEA study by Roze S (from the U.K. health care payer (National Health Service and personal social services) found that DEXCOM G6 rt-CGM was associated with a mean incremental gain in quality-adjusted life expectancy = 1.49 quality-adjusted life years (QALYs) versus SMBG with (mean [SD] 11.47 [2.04] QALYs versus 9.99 [1.84] QALYs). A total mean (SD) lifetime costs were also higher with rt-CGM (GBP) £14,234 (GBP £102,468 [35,681] VS GBP £88,234 [39,027]) resulting in ICER of GBP £ 9,558 per QALY gained
- Ose TK conducted a SR on economic concluded that two studies have explored the CEA of CGM from the payer perspective and have favoured their cost-effectiveness, while another study was inconclusive results due to more data and long-term studies are needed to better understand how CGM use relates to diabetes complications.
- Jiao Y et al. conducted a CEA in Australian populations and reported that the estimated ICER range was [$18,734–$99,941] and the (QALY) gain range was [0.76–2.99]. Use in patients with suboptimal management or greater hypoglycaemic risk revealed more homogenous results and lower ICERs. Most studies (n = 17) concluded that CGM is a cost-effective tool.

ORGANIZATIONAL

Patient Reported Outcomes (PRO)

- A systematic review involving six previous systematic reviews found that CGM consistently yielded high patient satisfaction (87.5%) compared to other monitoring methods. Continuous Glucose Monitoring (CGM) was also linked to increased treatment satisfaction for both T1DM and T2DM, despite the presence of study heterogeneity. Additionally, two RCTs demonstrated notable improvements in patient satisfaction, particularly among T2DM patients, when using CGM. In 2020, a study by Pease et al. favoured FGM over Self-Monitoring of Blood Glucose (SMBG) based on Diabetes Treatment Satisfaction Questionnaire (DTSQ) results, though statistical significance values were not reported.

GUIDELINES

- International guidelines according to The American Diabetes Association (ADA) released its 2022 Standards of Care, which provides an annual update on practice guidelines and expanded recommendations for CGM and Time in Range (TIR) use in adults and for CGM and automated insulin delivery (AID) use in children. The guidelines also include using diabetes technology in hospital settings. The use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management. This allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent SMBG. In addition, early CGM initiation after diagnosis of T1DM in youth has been shown to decrease A1C level and is associated with high parental satisfaction and reliance on this technology for diabetes management.

CONCLUSION: PART A - SYSTEMATIC REVIEW

Based from the review:

1. CGM demonstrated significantly improved of glycaemic control especially in lowers severe hypoglycaemic events (SHE) in T1DM when compared with SMBG, more effective in reducing the average time spent in hypoglycaemia and the average number of hypoglycaemia events among adults with T2DM requiring intensive insulin therapy. Hypoglycaemia events in T2DM patient, among hospitalised high risk for hypoglycaemia insulin-treated demonstrated that CGM group experienced 60.4% fewer hypoglycaemic events (<70 mg/dL) when compared with POC group. In special group such as GDM mothers, CGM detects a higher number of hypoglycaemia episodes than SMBG and showed a significant role in pregnant women qualify for insulin therapy. However, CGM group showed no significant reduction in DKA events or statistical difference in the probability of occurrence of diabetes ketoacidosis between the CGM group when compared with the SMBG.
2. CGM was associated with greater reduction in HbA1c from baseline compared with usual care SMBG) in both T1DM and T2DM patients. CGM group showed a statistically significant absolute improvement in HbA1c percentage points especially in T1DM.
3. CGM group showed beneficial effect on change in TIR from baseline and a greater increase in TIR and a neutral effect on change in TBR range from baseline. In patients with T1DM and T2DM with an extensive insulin regimen CGM showed a significant increase of TIR. TIR increased more in trials using RT-CGM than intermittently scanned (is-CGM) or SAP. The increase in TIR was significant and robust independently of

diabetes type, method of insulin delivery, and reason for CGM used. In T2DM among hospitalised high risk for hypoglycaemia insulin-treated CGM group demonstrated a lower percentage of time spent below range (TBR) when compared with SMBG.

4. Limited evidence showed no serious adverse events were related to the device or study procedure. A small percentage of participants experienced hypoglycaemia, with similar rates in both the CGM and control groups. Additionally, a few participants in the CGM group reported device-related adverse events, specifically sensor-adhesive reactions, which were resolved with treatment.
5. Patients in CGM group were very satisfied and all the included studies showed better results with the CGMS. In this review also showed that CGM improved treatment satisfaction for individuals with T1DM or T2DM but the quality of this evidence was low due to substantial clinical and statistical heterogeneity.

PART B: LOCAL ECONOMIC EVALUATION

Base-Case Analysis

In both simulated cohorts of T1DM and T2DM patients, the use of Continuous Glucose Monitoring (CGM) was found to be not cost-effective at the current cost-effectiveness threshold. The incremental cost per patient for CGM compared to Self-Monitoring of Blood Glucose (SMBG) was notably high, primarily due to the cost of the CGM system. Key factors influencing the Incremental Cost-Effectiveness Ratio (ICER) were the cost of CGM sensors, SMBG testing frequency, and relative risk (RR) for complications. Shortening the time horizon resulted in varying ICER values (MYR 365,336 for 10 years and MYR 245,581 for 20 years). While CGM reduced hospital resource costs for severe hypoglycaemic events in T1DM patients by 48%, it also raised the total annual cost by 28% compared to SMBG under base-case assumptions.

Budget Impact Analysis

The budget impact analysis focuses on increasing the use of CGM among Malaysians with T1DM, considering the reduction in severe hypoglycaemic events (SHE). The analysis shows that the yearly cost difference ranges from 4% to 3.6% as CGM usage increases from 10% to 70% over five years. Scenario analysis demonstrates that lower test strip usage in SMBG results in a higher cost difference with CGM, and reducing CGM sensor use can offset monitoring cost with a decrease in SHE management costs. Reducing CGM sensor and reader costs by 30-60% can make CGM more cost-competitive with SMBG.

Conclusion:

PART B - LOCAL ECONOMIC EVALUATION

Blood glucose monitoring using CGM system was not a cost-effective option when compared to SMBG in both T1DM and T2DM populations with only small gain in the benefit shown in the former population over the simulated lifetime horizon. Nevertheless, CGM system may reduce the health care resource utilisation cost for managing T1DM patients who are at risk for frequent episodes of SHE. Additionally, the combination strategy of CGM and SMBG may improve adherence with lesser financial impact among diabetic patients requiring tight glycaemic control.

Part C:
FOCUS GROUP DISCUSSION (FGD)

The focus group discussions revealed five key themes: the impact of diabetes, perceived benefits of CGMS, perceived barriers to CGMS, issues for long-term use and hopes for CGMS, and overall attitudes and recommendations for CGMS use.

Impact of diabetes

- Individuals with diabetes experienced a profound impact across various aspects of their lives, leading to significant lifestyle adjustments, especially in diet, exercise, and daily management. Managing Type 1 diabetes was particularly demanding, with continuous blood sugar monitoring, precise meal planning, and insulin dosing, causing disruptions to daily routines. Emotional challenges were more pronounced among Type 1 diabetes patients and caregivers, manifesting as anger, stress, and feelings of being different. Health and medical consequences included inconvenient monitoring, medication complexities, glucose fluctuations, and susceptibility to diabetic complications. Socially, individuals with Type 1 diabetes faced challenges in socializing and encountered misunderstandings, particularly in school settings.

Perceived benefits of CGMS

- Participants found numerous benefits associated with using Continuous Glucose Monitoring System (CGMS) for diabetes management particularly among adolescent and adult Type 1 diabetes patients. These included medical advantages such as real-time monitoring, proactive insulin management, and fewer hypoglycaemic events. CGMS served as an educational tool, fostering better understanding of diabetes, while also offering social benefits, saving time and enhancing freedom. It reduced emotional stress and improved quality of life, providing peace of mind, better sleep, and a sense of control over diabetes. Adolescents and caregivers particularly appreciated CGMS for its convenience and impact on independence.

Perceived barriers of CGMS

- The financial burden emerged as the primary barrier for CGMS use. High device costs and frequent sensor replacements led some to discontinue use due to financial constraints, exacerbated by a lack of insurance or government support. Participants also faced issues with device malfunctions, including sensor problems, data loss, and dislodgement during physical activities. Limited access to newer CGMS versions, inadequate technical support, lack of awareness, social stigma (especially among adolescents), and occasional skin irritation further hindered their CGMS experience.

Issues for long-term use & hopes for CGMS

- Participants shared concerns about the high long-term costs of CGMS, hoping for more affordability and solutions to address skin irritation. A consistent theme across all participants was the desire for CGMS access for specific patient groups and government subsidies for those with lower incomes, the elderly, or high diabetes-related risk. They also expressed a need for improved access to advanced CGMS versions with alarm features in Malaysia. Additionally, they called for healthcare professional training on effective CGMS use and preventive measures to combat the rising prevalence of Type 2 diabetes in the country.

Overall attitudes and patients' recommendation

- Findings from this focus group discussion, collectively reflect the overwhelmingly positive attitudes towards CGMS among diabetes patients and caregivers. They strongly recommended CGMS use, especially for specific groups like Type 1 diabetes patients at high risk of hypoglycaemia and adolescents to enhance daily life control. Caregivers particularly suggested early adoption of CGMS during the initial diagnosis stages, aiding patients, caregivers, and healthcare professionals in refining medication regimens and establishing effective diabetes care routines

Conclusion:
PART C - FGD
The focus group discussions have revealed noteworthy insights into the experiences of individuals with diabetes and their caregivers using CGMS. These discussions highlighted a range of perceived benefits for CGMS including medical benefits, social enhancements, emotional well-being, and an overall improvement in their quality of life, particularly among adolescent and adult Type 1 diabetes patients. Most participants regarded CGMS as a valuable educational resource for both patients and caregivers. However, participants also emphasized significant barriers, such as the high financial burden, technical challenges, limited accessibility, and support alongside concerns about social stigma and skin irritation. Participants also stressed issues related to long-term CGMS use, the need for improved technical support and access, as well as the absence of patient support groups. Despite these barriers, both diabetes patients and their caregivers held overwhelmingly positive attitudes towards the utilisation of CGMS for diabetes management and strongly endorsed CGMS use for individuals with diabetes particularly Type 1 diabetes, especially those at high risk of hypoglycaemia. Participants emphasized the need to address financial barriers, access issues, and technical support for CGMS, as well as the need for patient support groups and training for healthcare providers in utilizing CGMS data to improve diabetes care plans.

POLICY RECOMMENDATIONS
Continuous glucose monitoring device (CGMS) may be offered in aiding glucose monitoring for insulin-requiring especially for Type 1 Diabetes (T1DM) patients. In view of high cost associated with continuous glucose monitoring device use, it may be considered in selected T1DM patients who are at risk or suffering from frequent severe hypoglycaemic events (SHE), with data collected on its effectiveness in reducing such events to inform further decision on continuation/ expansion of CGM coverage. While patients recognise CGMS as a valuable resource, significant barriers like cost, accessibility, and support must be addressed to maximise its potential in diabetes management.