Investment Case for CGM Access for People Living with Type 1 Diabetes Accessing Care in the Public Sector in South Africa

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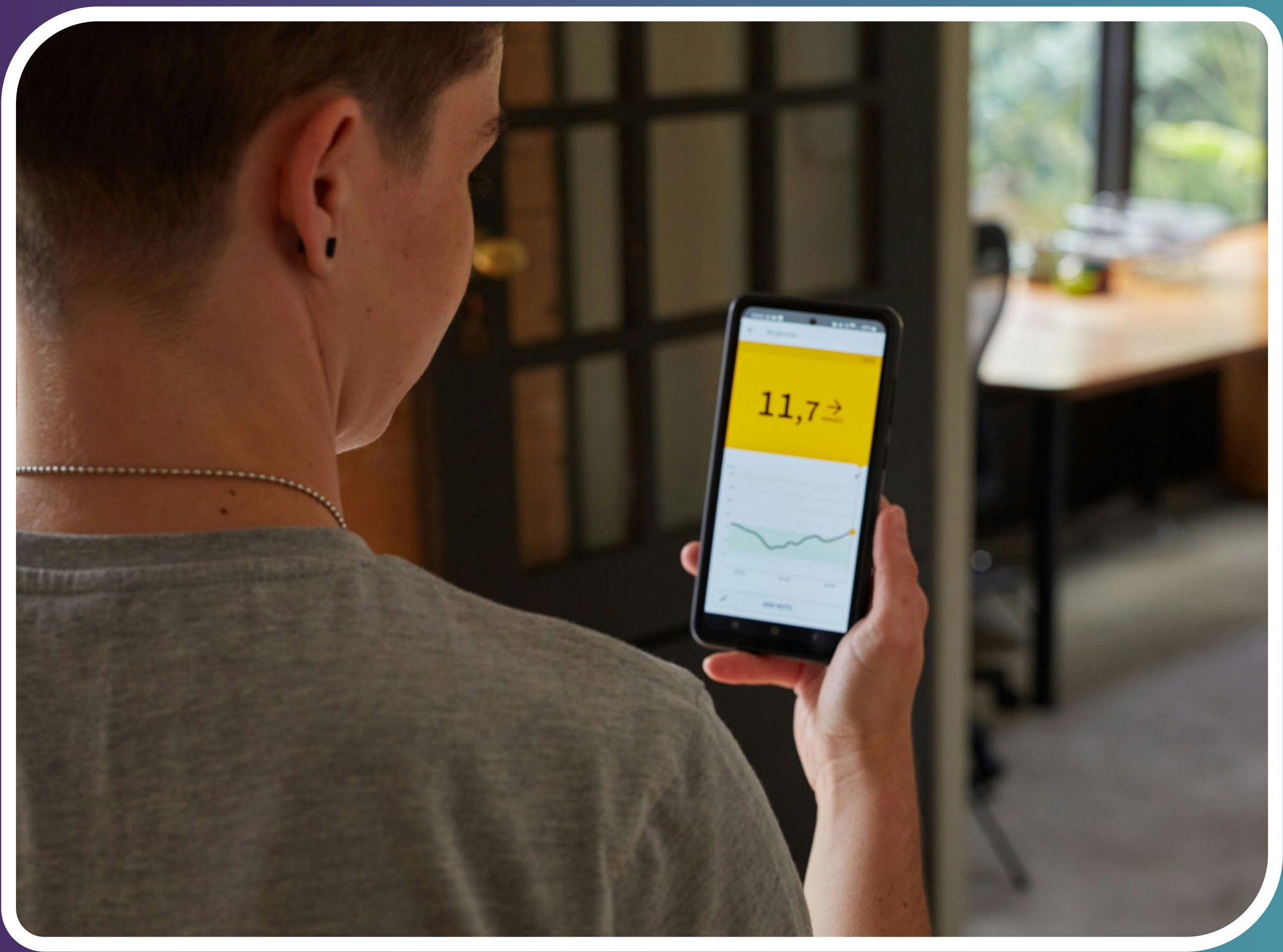

Contents

1. Executive summary **5**

2. Background **7**

3. Objective and scope **9**

4. Patient, Caregiver and Community Perspectives **11**

5. CGM Technology Landscape **13**

6. Clinical Effectiveness of CGM in People Living with Type 1 Diabetes **15**

A. International 15

B. Local Evidence 17

C. Interpretation and Implications 17

7. Local Evidence on Perceptions, Acceptability and Quality of Life **19**

8. Economic Evaluation – the ACCEDE trial and model **20**

A. Within-trial cost-effectiveness analysis 20

B. Modelled lifetime cost-effectiveness analysis 20

9. Implementation and Feasibility Considerations for Public-Sector Rollout **22**

10. Financing and Sustainability **23**

A. Budget Impact Analysis 23

B. Willingness to Pay findings 25

C. Conclusion and financing pathway 26

11. Conclusion and Recommendations **27**

12. Recommended additional reading **28**

13. References **29**

Abbreviations

ACCEDE	Access to CGMs for Equity in Diabetes Management
BIA	Budget Impact Analysis
CEA	Cost-Effectiveness Analysis
CGM	Continuous Glucose Monitoring
CI	Confidence Interval
CV	Coefficient of Variation
CVD	Cardiovascular Disease
DALY	Disability-Adjusted Life Year
DCCT	Diabetes Control and Complications Trial
DIAMOND	Dexcom CGM vs SMBG Trial in Type 1 Diabetes
DKA	Diabetic Ketoacidosis
EQ-5D	EuroQol 5-Dimension Questionnaire
HbA1c	Glycated Haemoglobin
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
ISPAD	International Society for Pediatric and Adolescent Diabetes
isCGM	Intermittently Scanned Continuous Glucose Monitoring
ITT	Intention-To-Treat
JAMA	Journal of the American Medical Association
LMIC	Low- and Middle-Income Country
MARD	Mean Absolute Relative Difference
MDI	Multiple Daily Injections
NCD	Non-Communicable Disease
NHI	National Health Insurance
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PICOST	Population, Intervention, Comparator, Outcomes, Study Design, Time Horizon
QALY	Quality-Adjusted Life Year
RCT	Randomised Controlled Trial
ROI	Return on Investment
rtCGM	Real-Time Continuous Glucose Monitoring
SAHPRA	South African Health Products Regulatory Authority
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
SHE	Severe Hypoglycaemic Episode
SMBG	Self-Monitoring of Blood Glucose
STG	Standard Treatment Guidelines
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
TAR	Time Above Range
TBR	Time Below Range
TIR	Time In Range
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization
WTP	Willingness-To-Pay
ZAR	South African Rand

1. Executive Summary

Type 1 diabetes (T1D) affects a relatively small but highly vulnerable population in South Africa, with approximately 35,000 children and adults living with the condition, most of whom rely on the public health sector for lifelong insulin therapy and glucose monitoring. Despite clear clinical guidelines, glycaemic management remains poor, driving high rates of acute complications, long-term disability, and disproportionately high healthcare costs, with people living with T1D incurring up to 14 times the per-capita health expenditure of the general population.

Continuous glucose monitoring (CGM) has transformed T1D care globally, improving glycaemic control, reducing hypoglycaemia, and enhancing quality of life relative to self-monitoring of blood glucose (SMBG) and is standard of care in many high-income countries. In comparison, access in South Africa's public sector remains extremely limited due to high device costs and a lack of locally generated evidence to inform policy and procurement decisions. This investment case responds directly to that gap by synthesising evidence from the ACCEDE trial (the first pragmatic randomised evaluation of both continuous and periodic CGM use in South Africa) alongside international evidence, economic modelling, and a budget impact analysis.

Clinical findings from ACCEDE suggest that the effects of CGM on HbA1c in a younger population with high baseline HbA1c may be more uncertain and variable than those reported in international trials. At 6 months, periodic CGM use demonstrated statistically significant and clinically meaningful HbA1c reductions (>1 percentage point) compared with SMBG. However, by the 9-month endpoint, neither continuous nor periodic CGM showed statistically significant differences, with smaller effect sizes observed. Across analyses, periodic CGM (defined, in this study, as two weeks of sensor use every three months) performed similarly to continuous use, despite requiring fewer sensors.

Importantly, CGM benefits extend beyond HbA1c. Evidence from ACCEDE suggests improvements in monitoring satisfaction, diabetes confidence in day-to-day self-management, and reduced distress and anxiety - particularly among children, adolescents, and caregivers. These patient-centred gains align strongly with national Health Technology Assessment priorities and international clinical guidelines.

While no significant differences were observed within the 9-month trial period, lifetime modelling suggests that periodic CGM use may be cost-effective in the youth cohort under certain conditions, highlighting the importance of evaluating long-term value in chronic disease management. CGMs used continuously may provide additional health gains but are unlikely to be cost-effective at current prices (requiring discounts of > 50% discounts).

Budget impact analysis indicates that providing CGMs on a periodic use basis to children and adolescents with T1D in the public sector would require an additional R4 million per year above the current SMBG budget. Although CGM is costly per user, the eligible T1D population is small, and periodic use requires only 4 sensors per year. The emergence of lower-cost sensors already represents a ~50% price reduction relative to earlier benchmarks for periodic use, substantially improving affordability. At this price point, periodic CGM becomes fiscally manageable (an additional R1m), and modelling suggests that at ~65% price reductions, the intervention becomes cost-neutral for government for both youth and adults in the medium term. Willingness-to-pay data further suggests strong latent demand and support for tiered subsidy models.

These findings suggest that targeted introduction of periodic CGMs could be considered within a public-sector diabetes programme in South Africa. Realising their value as well as broader adoption and equitable access will likely require manufacturer-led price reductions aligned with public-sector affordability constraints, as well as sustained patient engagement and education, and delivery within a well-functioning diabetes care ecosystem.

Recommendations

- **Adopt periodic CGM for paediatric and adolescent T1D, and continuous CGM for pregnant women with T1D, as an initial public-sector policy option that is a fiscally light, high-benefit entry point. This staged approach allows South Africa to realise the clinical benefits of CGM rapidly and equitably.**
- **Pursue national procurement and price negotiation strategies to bring sensor prices closer to public-sector affordability thresholds identified in WTP and cost-effectiveness analyses.**
- **Expand access to adults or to continuous use as procurement efficiencies, price reductions, and co-financing mechanisms mature.**
- **Add CGM to South Africa's STGs for people with T1D, with clear guidance on eligibility criteria, monitoring schedules, and clinical follow-up.**
- **Strengthen system readiness, including appointment of specialist diabetes nurse educators, nurse educator training, and patient education, to ensure high-quality implementation.**

2. Background

In South Africa, diabetes has become one of the leading causes of death and disability accounting for more than 33,000 deaths in 2022[1] and 1.2m disability-adjusted life years (DALYs) in 2023[2]. Current estimates indicate that between 2.3 million and 5.6 million adults in South Africa are living with diabetes, and approximately 27% of these individuals are insulin-using adults with Type 2 diabetes (T2D)[3,4,5] paucity of reliable epidemiological data for different regions on diabetes and treatment outcomes may further widen the inequalities of access and quality of healthcare services across the country. This study examines the sociodemographic and clinical determinants of uncontrolled type 2 diabetes mellitus (T2DM). Within this national context, Type 1 diabetes (T1D) remains a smaller but critical population in South Africa: with 30,629 adults and 4,718 children currently living with T1D, the majority of whom rely on the public health sector for lifelong glucose monitoring and insulin therapy. Although this represents a relatively small proportion of the total population, people living with T1D use a disproportionately large share of health-care resources - with recent South African estimates showing that they incur up to *14 times* the per-capita health budget of the general population[6].

South Africa's National Strategic Plan for NCDs (2022–2027) identifies diabetes as one of the five major priority non-communicable diseases (NCD) within its national 5×5 strategy and introduces a diabetes '90-60-50' cascade aimed at improving early detection, treatment uptake, and effective control. Achieving the final cascade target - ensuring at least 50% of individuals receiving treatment achieve glycaemic targets - is critical to preventing both acute and long-term complications and enabling a long and healthy life for those living with diabetes. The South African Standard Treatment Guidelines (STGs) for Primary Health Care have defined good control as maintaining HbA1c level below 7%[7]. However, achieving glycaemic targets remains a challenge with a recent study estimating that less than 10% of people with T1D in the public sector manage to achieve target blood glucose levels within 24 months of diagnosis[8] yet access to insulin, specialized care, and education is limited in low- and middle-income countries (LMICs). Achieving glycaemic targets is not only clinically important but also financially consequential: South African evidence shows that adults with uncontrolled T1D incur *nearly double* the healthcare expenditure of those who do meet glycaemic targets, underscoring the substantial cost savings associated with effective glucose management[6].

While improving glycaemic management depends on a multipronged approach, including appropriate insulin therapy, structured education, dietary support, psychosocial care, and regular clinical follow-up, glucose monitoring remains a foundational tool within this package. It enables people living with diabetes to understand their glucose patterns and make informed adjustments to diet, activity, and medication. Current national guidelines therefore recommend self-monitoring of blood glucose (SMBG) via capillary fingerstick as standard practice: adults living with T1D should test at least three times per day, and children four times per day, to support safe and effective insulin management[7]. However, SMBG via fingerstick in South Africa remains sub-optimal due to a combination of factors including limited patient education, low self-awareness of its importance, stock-outs of key supplies (lancets, test strips) at public health facilities and "test fatigue" or discomfort associated with finger-prick testing[9].

In recent years, Continuous Glucose Monitoring (CGM) technology has emerged as a transformative tool in diabetes care. CGMs offer real-time glucose readings, trend information, and alarms for hypo- or hyperglycemia, providing patients and healthcare providers with far more comprehensive insights into glycemic patterns. Numerous studies have demonstrated that CGMs improve HbA1c, reduce the time spent in hypo- or hyperglycemia, and enhance quality of life by minimizing reliance on fingerstick testing and reducing the fear of hypoglycemia[10,11]. CGMs have shown particular benefit in people with insulin-treated T1D and T2D, both clinically and economically, with multiple evaluations supporting their cost-effectiveness[12].

In high-income countries, CGMs are now widely accessible and reimbursed, resulting in widespread uptake among people living with T1D[13,14]. However, in most low- and middle-income countries (LMICs), including South Africa, access to CGM remains severely limited with high sensor costs of CGMs remaining a major barrier to adoption, and with uptake further constrained by the scarcity of locally generated evidence to inform policy and reimbursement decisions[15,16]. A number of CGMs are available on the market in South Africa and have been approved for use by the South African Health Products Regulatory Authority (SAHPRA)[17]. It is estimated that approximately 16% of the 31,000 people living with T1D use CGMs at least occasionally[18,19]. Whilst this represents encouraging progress in the adoption of CGMs in South Africa, this is largely limited to the private sector where CGMs are fully or partially covered by private insurance. CGMs remain largely inaccessible to patients relying on public healthcare and are not included in the STGs for diabetes care.

International efforts are increasingly focused on improving access to glucose monitoring and diabetes technologies. The WHO Global Diabetes Compact has set ambitious global targets - such as ensuring *100% of people with T1D have access to affordable insulin and blood-glucose self-monitoring*, and achieving *good glycaemic control in at least 80% of people with diagnosed diabetes* - to drive progress by 2030[20]. WHO guidance also recommends CGM use during pregnancy in women with diabetes to improve maternal and neonatal outcomes[21]. Complementing this, initiatives such as the T1D Community Fund highlight the urgent need to expand access to affordable, life-saving diabetes technologies, including CGM, for people living with T1D in LMICs[22].

The growing burden of diabetes and ongoing difficulties in managing blood sugar levels in South Africa highlight the urgent need to improve access to advanced glucose monitoring technologies in the public sector. Consequently, expanding access to affordable CGM in the South African public sector, beginning with priority groups, could significantly improve glucose monitoring and targets, strengthen equity in care, reduce long-term complications, and lower healthcare costs. Such investments align directly with the country's national health priorities to manage NCDs and promote universal access to essential health technologies.

3. Objective and Scope

The objective of this investment case report is to provide a synthesis of locally generated evidence from the Access to CGMS for Equity in Diabetes Management (ACCEDE) trial, complemented by selected international findings, to inform immediate policy dialogue and investment planning for the adoption of CGMs in South Africa's public healthcare sector.

While this report is not a Health Technology Assessment (HTA) as defined in the National Department of Health's HTA Methods Guide (2022–2027)[23], it is designed to inform, support and accelerate the national assessment and decision-making process, by presenting high-quality, locally relevant evidence in a structured format.

The intent is to equip policy-makers with the information needed for timely, well-informed adoption decisions, rather than to substitute for the formal HTA processes.

To clearly define the scope of this investment case, we applied the Population, Intervention, Comparator, Outcomes, Study Design, Time Horizon (PICOST) framework outlined in the South African HTA Methods Guide. The table below summarises the key elements (population, intervention, comparators, outcomes, study designs, and time horizons) that structure the assessment of CGM versus SMBG in the public sector. It provides an overview of the population, intervention, comparators, outcomes and evidence sources considered, enabling transparent interpretation of the clinical, economic and budget impact findings that follow. The PICOST table is not intended to specify all analyses conducted, but rather to clarify the parameters within which this assessment has been developed.

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Table 1: Population, Intervention, Comparator, Outcomes, Study Design, Time Horizon: PICOST framework

CRITERIA	DETAILS
Population	**Primary population:** People living with T1D in South Africa who rely on the public health sector for glucose monitoring and insulin therapy. **Condition/severity:** people living with T1D requiring lifelong insulin. **Age groups:** Children (>4 years), adolescents, and adults. **Sex:** All. **Comorbidities:** Any. **Clinical history:** may include individuals with suboptimal glycaemic control, recurrent diabetic ketoacidosis (DKA), frequent hypoglycaemia, or high variability in glucose control. **Subgroups for analysis:** Children and adolescents (≤19 years) (youth); Individuals with persistent HbA1c ≥10%; Individuals with recurrent severe hypoglycaemia or DKA; pregnant women; Populations with high expected clinical benefit; engaged user populations in terms of CGM usage (both sensor wear time and scan adherence).
Intervention	**CGM** devices used for real time or intermittently scanned glucose monitoring. **Device and schedule:** Any CGM registered with SAHPRA with sensor wear-time as stipulated by manufacturer (10-21 days). **Place in care pathway:** Adjunctive or non-adjunctive to existing SMBG. Intended to improve glycaemic control, reduce complications, and reduce burden on patients and providers. **Dosage/frequency:** Continuous use (sensor wear ~100%) or periodic use (2 weeks per 3 months), or as defined. **Mode of delivery:** Self-applied sensor; readings accessed via reader or smartphone. Training by diabetes nurse educators required. **Setting:** Outpatient/primary or tertiary diabetes clinics within the public sector. **Prescriber:** Medical officers, endocrinologists, nurse educators as per public sector scope of practice. **Co-interventions:** Insulin therapy, diabetes education, acute care for hypoglycaemia or DKA.
Comparator	**Primary comparator:** Standard of care: SMBG using capillary fingerstick testing. **Components:** Glucometer + test strips + lancets; recommended frequency: 3 tests/day for adults with T1D and 4 tests/day for children (Guidelines). **Reason for selection:** SMBG is the existing, widely used and guideline-recommended method for monitoring glucose in the South African public sector. **Regulatory:** Only SAHPRA-registered glucometers and strips included. **Place in care pathway:** Existing standard; CGM would partially or fully replace SMBG depending on policy scenario. **Additional comparators:** None relevant.

Outcomes	**Critical outcomes:** HbA1c reduction (absolute and relative); Frequency of severe hypoglycaemia; Frequency of DKA episodes; Time-in-range (TIR) 70–180 mg/dL; Adverse events from device use. **Important outcomes:** Glycaemic variability metrics (CV, time below range (TBR), time above range (TAR); Hospitalisations (diabetes-related); Quality-adjusted life years (QALYs); Utility change (EuroQol 5-Dimension Questionnaire (EQ-5D)); Patient/caregiver burden and satisfaction; Engagement and persistence with monitoring method. **Economic outcomes:** Incremental cost-effectiveness ratios (ICER) (ZAR per QALY gained); Direct medical costs (devices, insulin, strips, healthcare providers, hospitalisation, laboratory tests); Indirect costs (productivity losses, caregiver time); Long-term complication costs (retinopathy, nephropathy, neuropathy, cardio-vascular disease (CVD)).
Study designs / data sources	**Clinical efficacy:** Randomised controlled trials (ACCEDE trial; international RCTs); Systematic reviews and meta-analyses of CGM vs SMBG; Observational studies for real-world engagement and complication rates. **Economic / implementation evidence:** Within-trial cost and QALY analyses (partial societal perspective); Model-based economic evaluations (lifetime cost-utility); Costing studies; Qualitative evidence (acceptability, feasibility in public sector); International HTAs, clinical guidelines (SEMDSA, ISPAD, NICE).
Time horizon	**Clinical time horizon:** Short-term: <12 months. **Economic time horizon:** Lifetime horizon preferred (sufficient to capture long-term complication avoidance and cost savings). Rationale: Diabetes complications evolve over decades; short-term analyses underestimate benefit. **Budget Impact time horizon:** 1-year and 5-year scenarios.

Note: This investment report focuses on a relatively small but important population, people living with T1D. CGMs could equally be beneficial for the insulin-using T2D population.

4. Patient, Caregiver and Community Perspectives

In November 2025, a national petition calling for equitable access to CGM for children under 18 living with T1D was formally submitted to the National Department of Health. Led by SA Diabetes Advocacy, the petition garnered just under 10,000 signatures from caregivers, clinicians, adults living with T1D, and members of the public. It was supported by formal letters of endorsement from the following organisations:

- Sweet Life Diabetes Community
- Diabetes Alliance
- SEMDSA (Society for Endocrinology, Metabolism and Diabetes of South Africa)
- Diabetes South Africa
- PAEDS-SA
- FIND, Diagnosis for All
- Inkosi Albert Luthuli Central Hospital (KwaZulu-Natal)
- Universitas Academic Hospital (Free State)
- Chris Hani Baragwanath Academic Hospital (Gauteng)
- Rahima Moosa Mother and Child Hospital (Gauteng)
- Red Cross War Memorial Children's Hospital (Western Cape)
- Groote Schuur Hospital | University of Cape Town (Western Cape)
- Tygerberg Academic Hospital (Western Cape)
- Steve Biko Academic Hospital (Gauteng)

The petition reflects a unified and urgent call from the diabetes community for CGM to be recognised as essential, evidence-based care for children in the public sector, and for implementation pathways to be formally considered within national diabetes policy and guidelines.

Community statement on equitable access to CGM

As organisations representing people living with T1D, caregivers, clinicians, and community stakeholders across South Africa, we affirm that access to CGM is no longer a luxury technology - it is a recognised standard of care for children, adolescents and adults living with T1D globally. In the public sector, people living with T1D continue to rely on outdated fingerstick monitoring, often testing multiple times per day, including during the night. This places a heavy emotional, physical, and financial burden on people living with T1D and caregivers, and contributes to preventable episodes of severe hypoglycaemia, DKA, and long-term complications. CGM provides real-time data, early warning alerts, and improved glycaemic targets, enabling children to attend school safely and consistently, and adults to participate fully in work and other productive activities. By reducing uncertainty, fear of hypoglycaemia, and the constant burden of glucose monitoring, CGM supports greater independence, daily functioning, and overall well-being.

We respectfully call on the National Department of Health to prioritise equitable public-sector access to CGM for all people living with T1D. We recognise the fiscal constraints facing the health system, and we stand ready to work collaboratively with government, clinicians, and policymakers to support phased, targeted, or innovative implementation models where appropriate. Ensuring access to CGM is not only clinically sound and economically justifiable, it is a matter of health equity, dignity, and safeguarding the future of people living with diabetes in South Africa.

While clinical and economic data are critical for policy decisions, they do not fully capture the lived experience of managing T1D in the public sector. The voices below reflect the everyday realities behind the data.

"My CGM sensor has saved my life over and over again. I would not be alive if I didn't have my CGM. I would always go into hypo comas during my sleep (at night) and of course because I have now been a Type 1 diabetic for 32 years, I do not feel my blood glucose going low any more - I'm hypo unaware. Since having my CGM, it wakes me up when my blood glucose is falling or is going into the low bracket I have set (which is anything below 3.1 mmol/l) and I am able to wake up and fix it myself." - Lynn Sewell

"I write to you as both a scientist and a Type 1 diabetic (diagnosed February 2002). My HbA1c was 13.2% in January 2003, with the help of every specialist I could get, it came down to the lowest of 9.3% in February 2019. Purely by adding sensor technology (CGM and then the flash glucose sensor) to my daily diabetes management regimen, my HbA1c dropped to 7.4% in July 2021. My mental health has also improved drastically, particularly due to the fact that I can now run longer distances with peace of Mind. I have also had no incidences of severe hypoglycemic events (I would have at least one a month, to the point where I would sometimes lose consciousness) and have also not since been hospitalised for anything diabetes related (I had been hospitalised three times prior for DKA)" - Nireshni Chellan

"This continuous glucose monitor not only aids in checking glucose levels but has saved my daughter's life on multiple occasions from dangerous glucose events. The warning alarm gives us enough time to act in the midst of being on the road and in our busy lives. Since using CGM, we've been able to bring her HbA1c level down from 14 to six. The sensor has taught my 6-year old how to make meal choices when I am not present and also takes the burden off the educator. The use of the sensor should not be optional - it is mandatory" - Monique Abrahams Brittain

"I am a Social Worker living with diabetes, working in a very stressful setting. The adrenaline and unpredictability of my work environment are added variables in my diabetes management. Sensor technology has made a huge difference in my working environment, helping me to focus on my work. It has also had a huge impact on my physical performance in exercise, as the effect of exercise is measured more effectively." - Melany-Ann Voigt

"As a single mother caring for a child with Type 1 Diabetes in the public healthcare system, I have experienced both the strengths and the gaps within our current diabetic care model. My son relies on manual finger-prick glucose testing and manual insulin administration multiple times a day. This approach is painful, inconsistent, and places him at constant risk of undetected hypoglycemia or hyperglycemia, especially at night, during school, and periods of physical activity. Despite the fact that the public sector serves the largest population of diabetic patients in the country, essential technology such as Continuous Glucose Monitoring (CGM) is not currently accessible. Families like mine are not asking for convenience, we are advocating for basic, modern, and equitable medical care." - Sarah-Jane van Merch

5. CGM Technology Landscape

The analysis presented in this investment case is technology-agnostic, focusing on the value of expanding access to CGM in South Africa's public sector rather than recommending a specific device.

However, procurement and implementation decisions require a clear understanding of the available CGM technologies, as device characteristics influence usability, adherence, service delivery requirements, and overall cost.

Examples of CGM systems currently available on the South African market include products from manufacturers such as Abbott (FreeStyle Libre), Dexcom (G6, G7, One+), Medtronic (Guardian, Simplera), Roche (Accu-Chek SmartGuide), Yuwell (Anytime CT-3), Microtech (Linx), Sibionics (GS-1), Sinocare (iCAN), Syai Health (sYai Nano) and other emerging manufacturers. These represent the main commercially available platforms at present, within a rapidly evolving market with ongoing product entry.

While these systems are broadly similar in their core function - measuring interstitial glucose levels - they differ across several important dimensions that are highly relevant for public-sector adoption decision-making. Key considerations include regulatory status and age indication (particularly whether devices are approved for paediatric and adolescent populations), the strength of the clinical evidence base, and accuracy (typically measured by Mean Absolute Relative Difference, MARD). Practical and cost-related factors are equally important, including sensor duration and replacement requirements (generally 10–14 days), real-time functionality and alert features (such as hypoglycaemia warnings and predictions), and the device ecosystem (including smartphone dependence, reader availability, and transmitter requirements). In addition, sensor insertion and wear characteristics influence patient acceptability, while data sharing and integration are critical for clinical monitoring and follow-up. Finally, price and overall affordability within the public sector remain central to procurement decisions.

The analysis presented in this investment case is technology-agnostic, focusing on the value of expanding access to CGM in South Africa's public sector rather than recommending a specific device.

International comparator frameworks provide useful guidance on how to interpret differences between CGM devices. The ABCD / Diabetes Technology Network UK (DTN-UK) highlights that there are no universally standardised approaches to assessing CGM accuracy, and that regulatory approval alone is insufficient to compare performance across devices[24]it is one of the most challenging long-term conditions to live with. Recent years have seen major progress in the management of T1DM, with minimally invasive glucose monitoring technology and glucose-responsive insulin delivery systems, also called hybrid closed-loop systems. This narrative review focuses on three key areas: continuous glucose monitoring (CGM. Complementing this, the Diabetes Specialist Nurse (DSN) Forum UK CGM comparison charts offer a particularly valuable, up-to-date summary of the key features of technologies currently available on the market[25]. These charts bring together information on clinical accuracy and practical characteristics - such as sensor wear time, alerts, and device requirements - in a clear and accessible format. Importantly, they do not rank devices or make judgements on overall safety, but rather support decision-makers in interpreting the available evidence and comparing products across relevant domains. In addition, the FIND CGM factsheet, co-developed with the Institute for Diabetes Technology and the South African Diabetes Advocacy community, and endorsed by SEMDSA, provides a complementary, globally relevant framework to support decision-makers in assessing CGM technologies[26]. The factsheet is specifically designed to guide interpretation of CGM performance in the absence of formal ISO standards for CGM devices.

For decision-makers, these frameworks highlight that CGM adoption decisions should not be based on a single parameter (such as accuracy or price), but rather on a balanced assessment of evidence, functionality, and system fit. As a result, any policy decision on the type of CGM for adoption in South Africa should be informed by up-to-date comparisons across available devices.

The distinction between intermittently scanned CGM (isCGM) and real-time CGM (rtCGM) was relevant in the context of the ACCEDE trial, but less so now. At the time of trial initiation (2022), the FreeStyle Libre 1, an isCGM device, was used, as it was the most accessible option and the only device registered in South Africa for use in children aged 4 years and older. During the trial, this was replaced by the FreeStyle Libre 2, which offers real-time functionality; however, it continued to be used in an intermittent (scan-based) manner in line with the study design.

Since the start of the trial, the CGM market has evolved rapidly, with newer devices increasingly offering real-time data and alert functionality at substantially lower price points. For example, the FreeStyle Libre 2 14-day sensor is priced at R1,089, the Accu-Chek SmartGuide 14-day sensor at R860, and the Dexcom One+10-day sensor at R540 (including paediatric indication from age 2).

Since the start of the trial, the CGM market has evolved rapidly, with newer devices increasingly offering real-time data and alert functionality at substantially lower price points. For example, the FreeStyle Libre 2 14-day sensor is priced at R1,089, the Accu-Chek SmartGuide 14-day sensor at R860, and the Dexcom One+10-day sensor at R540 (including paediatric indication from age 2).

These price reductions since the start of the trial materially improve the affordability equation and highlight the pace at which this market is evolving, with increasing competition driving down costs and expanding feasible access within the public sector.

6. Clinical Effectiveness of CGM in People Living with Type 1 Diabetes

This section synthesises the international clinical evidence on the effectiveness of CGM compared with SMBG and complements it with locally generated evidence from the ACCEDE pragmatic randomised controlled trial (RCT) in South Africa. Consistent with Stage 1 of the National HTA Methods Guide, the purpose is to summarise high-quality existing evidence rather than perform a full systematic review, drawing on the strongest available trials and meta-analyses.

A. International Evidence

The most robust synthesis of CGM effectiveness is the Maiorino et al. (2020) systematic review and meta-analysis, which pooled 18 randomised controlled comparisons of CGM versus SMBG use in T1D[11]. A key contribution of this review is its subgroup analysis separating real-time CGM (rtCGM) from intermittently scanned CGM (isCGM). Although both technologies improve glucose monitoring, they differ in functionality: rtCGM transmits glucose values automatically via Bluetooth, whereas isCGM requires users to actively scan the sensor to obtain readings. As mentioned in the Technology section, this distinction is no longer relevant as most new devices are rtCGM but it was relevant for the ACCEDE trial. The Maiorino subgroup findings show that the magnitude of HbA1c benefit differs by device type:

- rtCGM: HbA1c reduction –0.23 percentage points (95% CI –0.36 to –0.10), p<0.001
- isCGM: HbA1c effect 0.00 percentage points (95% CI –0.01 to 0.02), p=0.861
- Overall pooled effect: –0.17 percentage points (–0.29 to –0.06), p=0.003

These results are consistent with the more recent Diabetologia meta-analysis by Teo et al. (2022)[10], which synthesised 22 RCTs (n≈2,100) comparing CGM with SMBG in people living with T1D. Teo et al. reported an overall mean HbA1c reduction of –0.23 percentage points with CGM versus SMBG, with larger benefits (≈–0.4 percentage points) among individuals with poorer baseline glucose levels (HbA1c >8%), and no clear effect on DKA or severe hypoglycaemia events. A complementary meta-analysis of isCGM by Evans et al., which included predominantly real-world and short-term studies (rather than only RCTs), reported an HbA1c reduction of around 0.5 percentage points; this larger effect likely reflects differences in study design, higher baseline glycaemia, and shorter follow-up duration rather than a true divergence from RCT evidence[27]. Notably, the subsequent FLASH-UK RCT conducted within the UK National Health Service (NHS) by Leelarathna et al. also demonstrated a statistically significant HbA1c reduction of approximately 0.5 percentage points with isCGM compared with SMBG, alongside improvements in TIR and reduced hypoglycaemia, providing more recent RCT evidence that isCGM can achieve clinically meaningful glycaemic improvements in routine care settings[28].

This section synthesises the international clinical evidence on the effectiveness of CGM compared with SMBG and complements it with locally generated evidence from the ACCEDE pragmatic randomised controlled trial (RCT) in South Africa.

Table 2 below summarises the major RCTs since 2015 that directly compare CGM with SMBG and largely evaluate rtCGM systems. These trials, conducted primarily in Europe and the United States, reinforce the pattern observed in the Maiorino and Teo analysis (GOLD, DIAMOND, HypoDE are included in the Maiorino and Teo meta-analyses) and demonstrate:

- HbA1c reductions of approximately 0.2–0.5 percentage points, with the strongest effects in adults with higher baseline HbA1c.
- Increases in TIR (70–180 mg/dL) of approximately 1–1.5 hours per day, a clinically important improvement associated with fewer long-term complications.
- Substantial reductions in hypoglycaemia among high-risk individuals, particularly in trials focused on impaired awareness or recurrent severe hypoglycaemia (e.g., HypoDE).

Table 2: Randomised Controlled Trials (2015–present) comparing CGM vs SMBG in people living with T1D

Study (Year)	Population & Setting	Insulin Regimen	CGM Device	N	Duration	HbA1c Change (CGM – SMBG)	TIR/Hypo Change (CGM – SMBG)	Key Notes
GOLD Trial – Lind *et al.*, 2017 (JAMA)[29]	Adults with T1D, Sweden	MDI only	Dexcom G4 rtCGM	161	2 × 6-month crossover	−0.43%		Crossover RCT; High adherence; strong evidence for MDI users.
DIAMOND T1D – Beck et al., 2017 (JAMA)[30]	Adults with T1D, US	MDI only	Dexcom G4 rtCGM	158	6 months	−0.6%	+1.0 h/day TIR	Better satisfaction; fewer hypoglycaemia episodes.
HypoDE – Heinemann et al., 2018 (Lancet)[31]	Adults with impaired hypoglycaemia awareness, Germany	MDI only	Dexcom G5 rtCGM	149	6 months	No significant HbA1c difference	↓ hypoglycaemic events by 72% (TIR ↑ mainly from reduced TBR)	Most relevant for high-risk patients.
IMPACT Trial – Bolinder et al., 2016 (Lancet)[32]	Adults with well-controlled T1D, Europe	MDI only	FreeStyle Libre (isCGM)	241	6 months	No significant HbA1c change	↓ time in hypoglycaemia by 38% (~1.0 h/day)	Key flash/ isCGM RCT; improved satisfaction
Laffel et al., 2020 (JAMA)[33]	Adolescents & young adults (14–24 yrs), US	MDI & pumps	Dexcom G5 rtCGM	153	26 weeks	−0.37%	+1.7 h/day	Stronger benefits among adherent users.
Helmi et al., 2021 (Malaysia, paediatrics) (**RoSEC**)[34]	Children with T1D, Malaysia	Mixed	Medtronic CGM	22	3 months	No HbA1c difference	↓ hypoglycaemic events	LMIC evidence (small sample). Periodic use of CGM
FLASH UK Trial – Leelarathna et al., 2022 (N Engl J Med)[28]	Adults with T1D, UK (NHS setting)	MDI & pumps	FreeStyle Libre (isCGM)	156	6 months	-0.5%	↑ TIR (~+1h/ day); ↓ time <3.9 mmol/L	Key isCGM RCT.

This table includes only the large RCTs published since 2015 where CGM was directly compared with SMBG, regardless of whether participants used Multiple Daily Injections (MDI) or pumps. Trials of sensor-augmented pumps or hybrid closed-loop systems are excluded because they reflect different technologies not under consideration in this investment case. MDI = multiple daily injections; TIR = Time in Range; TBR = Time

While this evidence base is extensive, it is drawn predominantly from high-income countries. A recent scoping review by Bernabe-Ortiz et al.[16] (2023) mapped the use of CGMs in LMICs and found that empirical evidence is limited in both quantity and scope, with most studies being small, single-centre observational designs and very few RCTs. As a result, there is limited strong (trial-based) evidence from LMICs, and most robust RCT data on CGM effectiveness still comes from high-income settings.

Further, there is no systematic review or meta-analysis specifically evaluating periodic CGM use in T1D. "Periodic use" refers to a structured regimen in which a CGM sensor is worn only for short, predefined intervals, such as 1–2 weeks every 1–3 months, while individuals rely on SMBG between these cycles. Existing syntheses focus almost entirely on continuous CGM wear, reflecting the structure of the underlying evidence base. Trials that involve periodic sensor use (such as blinded professional CGM worn for short diagnostic periods) are typically performed in T2D and for treatment adjustment, rather than as an ongoing monitoring strategy. As a result, robust trial evidence for periodic CGM use in T1D is extremely limited, and the ACCEDE trial represents one of the first randomised evaluations of a structured periodic-use regimen (2 weeks every 3 months).

B. Local Evidence

The ACCEDE trial provides the first locally generated randomised evidence on continuous and periodic isCGM effectiveness for people living with T1D in South Africa. Conducted across three major public sector hospitals and enrolling 248 children, adolescents and adults with baseline HbA1c ≥10%, the trial compared continuous isCGM, periodic isCGM (2 weeks wear-time every 3 months), to standard SMBG-based care over a period of 9 months.

At 6 months in the intention-to-treat (ITT) population, only the periodic use CGM demonstrated statistically significant and clinically meaningful improvements in HbA1c (> 1 percentage point reductions) compared with SMBG (Table 3). At month 9 (the trial endpoint), neither continuous nor periodic CGM showed statistically significant differences, where the effect sizes were smaller (ranging from −0.21% to −0.36%). Similarly, among children and adolescents in the ITT population, effect sizes were attenuated (approximately -0.12% to -0.24%) and did not reach statistical significance at the 9-month time point (periodic use was significant at the 6-month time point). These non-significant results likely reflect the complexity of the study population (including younger patients and those with a very high baseline HbA1c) as well as broader challenges to sustained engagement within a resource-constrained care ecosystem.

Table 3: Adjusted between-arm differences in HbA1c (%) for CGM versus SMBG at 6 and 9 months in the intention-to-treat populations: ACCEDE trial, South Africa

	Intention to treat population	
	6 months	9 months
Continuous isCGM vs SMBG	-0.53 (SE 0.32, p=0.228)	-0.21 (SE 0.31, p=0.766)
Periodic isCGM vs SMBG	**-1.13** (SE 0.32, p=0.001)	-0.36 (SE 0.3, p=0.470)

Although the trial was not powered to detect statistically significant differences in hospitalisation outcomes, a trend towards higher diabetes-related hospitalization rates was observed in the standard of care arm compared with the intervention arms. TIR outcomes were assessed only among CGM users; therefore, direct between-arm comparisons with standard care were not possible, although periodic CGM users generally demonstrated higher TIR than continuous CGM users (30-33% for periodic CGM users vs. 24-25% for continuous). Measures of glucose variability showed that the coefficient of variation of glucose concentrations was consistently lower among continuous CGM users than periodic CGM users across both ITT, reaching statistical significance at month 3 suggesting more stable glucose control with continuous use.

C. Interpretation and Implications

International meta-analyses typically report small but statistically significant CGM–SMBG differences, in the order of −0.17% to −0.23%. In contrast, ACCEDE observed numerically larger HbA1c reductions (ranging from −0.2% to −1.13%) in a younger and more clinically complex real-world cohort. Unlike the more stable populations typically enrolled in high-income country trials, ACCEDE participants exhibited substantial glycaemic variability, with standard deviations higher than those reported internationally. This higher variability may have limited the ability to detect smaller effect sizes of the magnitude observed elsewhere.

In addition, the magnitudes of within-arm HbA1c reductions seen at 6 and 9 months in the ACCEDE trial, whilst not statistically significant, may still be of clinical interest. Even modest reductions in HbA1c (≈0.3–0.5%) have been associated with reductions in microvascular risk, given the continuous relationship between glycaemia and complications demonstrated in the Diabetes Control and Complications Trial (DCCT)/ United Kingdom Prospective Diabetes Study (UKPDS), which may provide context for interpreting these findings[35–37]. Further, evidence from paediatric cohorts indicates a metabolic memory effect, whereby glycaemic control in the first months after T1D diagnosis predicts long-term HbA1c trajectories and complication risk[38–42]1983–1993. This suggests that CGM introduced early in the disease course could have longer-term implications, even where short-term trial effects (as observed in ACCEDE) in children and adolescents are not significant. This is consistent with ISPAD guidelines, which recommend intensive monitoring and individualized targets to support optimal long-term outcomes in children and adolescents with T1D[43].

In summary, international evidence strongly supports CGM effectiveness. South Africa now has high-quality local evidence indicating modest average reductions in HbA1c relative to SMBG, although these did not reach statistical significance, with findings that suggest that the impact of CGM in this setting may depend on both patient characteristics and consistent sensor use and scanning behaviour. Targeting CGM access to individuals likely to engage with their CGM, supported by structured education, behavioural reinforcement, and follow-up, may help to optimise benefits within the South African public sector.

Across analyses, periodic CGM use appeared to perform similarly to, and in some cases better than, continuous use. At 6 months, the periodic arm achieved the largest observed HbA1c reduction. This suggests that periodic CGM may represent a lower-intensity approach to CGM use, delivering some glycaemic benefit even at lower levels of sensor utilisation. For a resource-constrained public health system, periodic use could therefore represent a potentially feasible early implementation strategy.

The HbA1c reductions observed in ACCEDE are particularly notable given that ACCEDE evaluated isCGM, not rtCGM, which has shown larger effects in high-income settings. With technological improvements, newer rtCGM devices such as the FreeStyle Libre 2 are now available at no additional cost relative to isCGM. This means that future implementation in South Africa could potentially incorporate more advanced rtCGM technologies at the same price (or lower), although the extent of any additional benefit in this context remains uncertain.

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7. Local Evidence on Perceptions, Acceptability and Quality of Life

A qualitative sub-study conducted within ACCEDE explored participants', caregivers' and healthcare providers' perceptions and experiences with continuous and periodic CGM in the South African public sector. Using semi-structured interviews and focus group discussions, the study engaged 75 participants across the three trial arms, 17 caregivers, and 15 healthcare providers involved in diabetes care. Discussions focused on usability and acceptability of the devices, perceived benefits and challenges, impact on daily self-management and wellbeing, and practical issues related to training, clinic workflow, and integrating CGM into routine public-sector care. This qualitative evidence provides important context for interpreting the trial findings and understanding real-world uptake.

Qualitative findings from the ACCEDE study suggest that CGM use was highly acceptable to participants, caregivers, and healthcare providers, with perceived benefits extending well beyond clinical outcomes. Participants frequently reported that CGM devices provided a sense of security, reduced anxiety about nocturnal hypoglycaemia, and enabled more confident self-management. Many participants described CGM as "*life-changing*", indicating greater visibility into glucose fluctuations, reduced fingerstick burden, and the ability to detect dangerous highs and lows they previously never knew were happening. For caregivers of children and adolescents, CGM was reported to provide reassurance, improved sleep, and reduced the emotional and logistical strain associated with constant monitoring. Users also valued the device's ability to support better conversations with clinicians and to motivate behaviour change, particularly when supported by structured education from nurse educators. Barriers identified were practical rather than attitudinal: concerns about affordability, early challenges with sensor adhesion, concerns about device visibility, and fear of stigma in public spaces.

These perceived gains in autonomy, safety and day-to-day functioning are consistent with quality-of-life domains highlighted in the national HTA Methods Guide[23]. They are partly reflected by ACCEDE's quantitative findings. At 6 months, participants in both CGM arms reported significantly higher Glucose Monitoring Satisfaction Survey scores than those in the standard-of-care SMBG arm. A complementary acceptability survey, completed only by participants in the CGM arms, also indicated very high user acceptance. At six months, acceptability scores were slightly higher among periodic CGM users in the ITT population; however, among engaged CGM users, scores were marginally higher for continuous CGM, suggesting that sustained device use may be associated with higher perceived value and satisfaction. Diabetes-related distress, as captured by the Diabetes Distress Scale, declined over time across all arms, with no significant between-arm differences in participant-reported distress. Likewise, EQ-5D utility values were broadly similar across arms at 6 and 9 months, with no consistent statistically significant between-arm differences across populations.

Taken together, the quantitative findings suggest that CGM may be associated with improved treatment satisfaction and high acceptability while broader generic quality-of-life gains were less clearly captured by the trial instruments.

Additional South African evidence outside of ACCEDE further is broadly consistent with these findings. A study conducted with adolescents and young adults using CGM in local settings showed increased self-confidence, better integration of diabetes tasks into daily life, and an improved sense of control over their health44. A small qualitative study of young adults using CGM similarly found that real-time glucose feedback was associated with strengthened self-regulation behaviours, enabling participants to adapt daily decisions around diet, insulin use, and physical activity45. By fostering responsibility and greater disease awareness from an early age, CGM may empower adolescents and young adults to manage their diabetes well, and in turn improve long-term health outcomes. Collectively, these insights underscore that CGM aligns with patient preferences and is seen not just as a monitoring tool, but as a technology that can enhance wellbeing, confidence, and engagement in diabetes care - factors critical for real-world adoption and sustainable scale-up in the public health system.

8. Economic Evaluation – the ACCEDE Trial and Model

International economic evaluations consistently demonstrate that CGM is cost-effective for people living with T1D, particularly in high-income settings. A recent systematic review by Jiao et al. found that most published CGM evaluations report favourable ICERs, often well below commonly used willingness to pay (WTP) thresholds12. In addition, the UK FLASH study, which evaluated isCGM in routine NHS care, found that isCGM was cost-effective and even cost-saving for the sub-group with high HbA1c (>9-11%)[46]. However, this evidence is almost exclusively based on high-income country cost structures, healthcare utilisation patterns, and reimbursement arrangements, which are not directly transferable to the South African public sector.

Given the large differences in health systems, device prices, service delivery costs, and baseline glycaemic levels in South Africa, a de novo economic evaluation using local data was essential. We therefore conducted two complementary analyses: (i) a within-trial cost-effectiveness analysis (CEA) alongside the ACCEDE RCT, and (ii) a modelled lifetime cost-utility analysis to capture longer-term costs and health outcomes not observable within the trial period. The device used in the trial was the Abbott Freestyle Libre II priced at R1060/reader and R1089/sensor (14-day wear-time).

A. Within-trial cost-effectiveness analysis

The within-trial CEA, conducted over the 9-month trial horizon from a partial societal perspective, found no statistically significant differences in QALYs, utilities or HbA1c outcomes between trial arms at 9 months. As expected, given the short time horizon and upfront device costs, both continuous and periodic isCGM strategies were dominated by standard care in the trial-based analysis. These findings are consistent with international evidence, including trials such as DIAMOND and the FLASH-UK study, where short-term analyses similarly failed to demonstrate cost-effectiveness despite clear longer-term benefits[46,47].

Findings indicate that periodic CGM use, 4 sensors per year, may offer a relatively favourable value-for-money profile, particularly in younger populations; however, this is highly dependent on reductions in acute complications (DKA and severe hypoglycaemia) associated with CGM use.

Importantly, the within-trial results should not be interpreted as evidence against CGM value, but rather as a reflection of the structural limitation of short-term CEAs for chronic conditions such as T1D, where the major health and cost benefits accrue through reduced long-term complications.

B. Modelled lifetime cost-effectiveness analysis

To address this limitation, a lifetime cost-utility analysis was conducted using a validated diabetes microsimulation model populated with ACCEDE trial data and South African cost inputs. Overall, the long-term modelling suggests that CGM could represent a cost-effective intervention in South Africa under certain conditions, although results remain sensitive to assumptions around device prices, treatment effects, event rates, and long-term risk trajectories.

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In the youth cohort (<20 years), periodic CGM was associated with modest QALY gains at relatively low incremental cost, suggesting it may be cost-effective under a plausible South African cost-effectiveness threshold[1]. However, in the overall

1. As South Africa does not have an explicitly adopted cost-effectiveness threshold for decision-making, results were interpreted against published estimates of opportunity cost-based thresholds for the South African health system. We used the upper-bound estimate proposed by Pichon-Rivière *et al*., corresponding to approximately USD 4,600 (R82,000) per QALY, as the primary reference.[48]

T1D population, cost-effectiveness for periodic use is less certain. Continuous CGM generated larger health gains, but at substantially higher cost. As a result, its cost-effectiveness is more uncertain and appears to depend more strongly on underlying assumptions, including price, treatment effect and complication rates.

Price threshold analyses suggest that affordability remains a key determinant of value. Across the full T1D population, price reductions in the range of ~65–70% may be required for CGM strategies to be considered cost-effective, while lower reductions (around ~50%) may be sufficient for continuous CGM in younger populations (<20 years). Although substantial, these price reductions are approaching levels seen among emerging CGM technologies.

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From an investment-case perspective, periodic CGM in the youth sub-population delivers health gains alongside partial cost offsets. While the intervention is not cost-saving, reductions in acute events (DKA and severe hypoglycaemia) result in average lifetime savings which partially offset average lifetime sensor costs. This results in a favourable cost-effectiveness profile, indicating that the additional investment translates into measurable health gains at a cost that may be considered acceptable within the South African context.

Taken together, these findings suggest that periodic CGM represents a lower-risk, more immediately implementable policy option, while broader scale-up, particularly of continuous CGM, would likely depend on further price reductions and additional real-world evidence to reduce uncertainty in treatment efficacy and acute event rates.

9. Implementation and Feasibility Considerations for Public-Sector Rollout

Findings from ACCEDE highlight several practical, system-level considerations that could shape implementation of CGM in South Africa's public sector.

Healthcare providers consistently emphasised that structured, ongoing training is essential for both clinicians and patients to ensure correct sensor use, interpretation of glucose data, and sustained engagement over time.

As one clinician noted, "*training programs both for healthcare providers as well as for patients… will have to go together*" and require continuous evaluation of patient involvement. Training for the ACCEDE trial entailed four hours of CGM-specific training provided to professional nurses to enable device rollout and participant education. A practical lesson from ACCEDE was the need to proactively address sensor detachment - particularly in hot climates or during physical activity - by routinely applying a medical-grade adhesive plaster over the sensor. Introducing this as part of standard training and supply packs can substantially reduce device loss and prevent data gaps, thereby supporting sensor engagement and sustained benefit.

FIND in collaboration with the International Diabetes Federation (IDF), local experts and lived experience representatives developed an online course for both people living with T1D and healthcare professionals on the use of CGMs. To date, over 11 000 people with T1D and healthcare professionals have completed the courses online, and three in-person training workshops have been conducted in South Africa with 150+ attendees and one workshop in Kenya with 46 healthcare professionals. Scaling CGM adoption in the public sector could therefore be supported by embedding a similar structured training and education framework within national implementation plans.

Providers also raised the need to integrate CGM into existing clinic workflows - ensuring staff capacity for device initiation, troubleshooting, and follow-up - while acknowledging gaps such as the absence of **diabetes specialist nurses, who are key to sustained support and education across visits**. At the health-system level, the qualitative data identified broader structural barriers, including affordability concerns, limited resources, and competing patient needs, which constrain adoption and must be addressed through supportive policy and workforce strengthening measures. Overall, ACCEDE underscores that successful scale-up requires a coordinated implementation strategy that couples device access with training, adequate staffing, and integration into routine care pathways to ensure sustainable and equitable CGM use in the public sector.

Targeting early CGM rollout to groups most likely to use the device consistently is a practical and evidence-based implementation strategy for the South African public sector. In the ACCEDE trial, only 40% of participants were defined as Engaged Users (≥70% wear-time), with this subgroup achieving the greatest glycaemic benefit: at six months, engaged users in both CGM arms demonstrated statistically significant and clinically meaningful HbA1c reductions of more than 1 percentage point, exceeding outcomes seen among less engaged users and those relying on SMBG.

Given that CGM effectiveness and downstream cost savings depend on sustained device use, prioritising early access for pregnant individuals or individuals with demonstrated adherence, such as those with regular clinic attendance, stable engagement with diabetes education, or adequate literacy to interpret CGM data, may maximise clinical returns while supporting a phased, affordable implementation pathway.

Clinicians involved in ACCEDE also noted that they can reliably identify patients most likely to benefit based on behavioural patterns and prior diabetes management. While such prioritisation may raise equity considerations, phased introduction of new health technologies commonly requires initial targeting to maximise impact and ensure efficient use of limited public resources. Over time, as workforce capacity, patient education and support structures strengthen, eligibility could be broadened to include groups who may derive even greater long-term benefit. This targeted approach ensures early programme success while building the foundation for equitable scale-up.

10. Financing and Sustainability

A. Budget Impact Analysis

A budget impact analysis (BIA) was undertaken to estimate the financial implications for the South African public health sector of introducing CGM technologies for people living with T1D. The analysis complements the cost-effectiveness results by quantifying affordability and fiscal feasibility under national budget constraints.

Consistent with the HTA Methods Guide (2023), the analysis was conducted from the government payer perspective, reflecting both direct device and consumable procurement and the broader health-system budget, which includes potential cost offsets from avoided acute events such as DKA and severe hypoglycaemic episodes (SHE)[23].

Intervention, comparator, and scope

The analysis compares three scenarios:

- *Status quo*: SMBG only, using strips, lancets and glucometers aligned with testing frequency stipulated in the national guidelines (3 x per day for adults, 4 x per day for children).
- *Periodic isCGM:* 4 sensors per year (one per quarter) used in combination with continued SMBG.
- *Continuous isCGM*: full-time wear, equivalent to 26 sensors per year (14-day sensors), also with reduced SMBG use.

The intervention package includes sensors, readers (annualised over two years), adhesive plasters, and training (per user per year). Prices were drawn from the ACCEDE trial procurement data (2025 ZAR), with alternative scenarios reflecting possible price reductions for CGM sensors of 25%-75% through price negotiations or the adoption of new market entrants.

Eligible and user population

The total population of people living with T1D in South Africa was estimated at 30,629, of whom approximately 4,728 are children and adolescents (< 20 years of age)[4]. Based on national estimates, 80% of individuals with T1D are assumed to use public-sector services[23]. Within this population, 40% were considered active CGM users ('Engaged Users') and therefore eligible for CGM, reflecting engagement with sensor use observed in the ACCEDE trial. The BIA focuses on this engaged subgroup (defined as ≥70% wear-time) because clinical benefits and downstream cost savings from CGM depend strongly on sustained device use. Clinicians involved in ACCEDE reported that they can generally identify individuals most likely to engage and benefit, and early implementation is expected to prioritise such users. To reflect uncertainty in programme rollout, uptake among eligible users was varied between 80% and 100%, representing different implementation scenarios (Table 1).

The BIA considered two sequential phases for population coverage:

- **Phase 1**: paediatric and adolescent T1D population ("youth" < 20 years of age);
- **Phase 2**: full T1D population (youth and eligible adults).

Table 4: Input parameters for Budget impact analysis

Parameter	Parameter	Source/Note
Total T1D population	30,629	Diabetes Atlas[4]
Total YouthT1D population	4,728	Diabetes Atlas (< 20 years of age)[4]
Share using public services	80%	HTA Methods Guide 2023[23]
Engaged CGM users	40%	ACCEDE trial[49]
Uptake	80-100%	Assumption

Time horizon

The BIA was conducted over one-year and five-year, undiscounted time horizons, consistent with national HTA guidance recommending presentation of both 1- and 5-year scenarios[23]. No population growth was assumed over the five-year analytic horizon.

Costs and resource use

All direct health-sector expenditures were included:

- Pharmaceutical budget: sensors (R1,089/sensor) 14-day wear-time, plasters, readers, and training for the CGM scenario, and SMBG supplies (lancets, test strips and glucometers) for the SMBG scenario[49].
- Event-related offsets: expected reductions in DKA and SHE, valued using public-sector cost estimates and micro-costing (R35,990 per DKA; R26,753 per SHE). Event rates were drawn from the ACCEDE trial.

No discounting or productivity costs were applied, consistent with BIA conventions. All parameters and calculations are available in the BIA workbook (BIA workbook available upon request).

Results

At current prices, the total annual cost of introducing CGM across the public-sector T1D population would vary substantially by user group and device schedule. **Periodic CGM** - where patients use one sensor every three months while continuing standard SMBG (requiring just 4 sensors a year) - represents the most financially feasible option for phased adoption. Among paediatric and adolescent T1D users, the additional annual cost is estimated at R4 million above the current SMBG expenditure of about R3 million, corresponding to a 143% increase in spending for this group. For all T1D users combined (youth + adults), total incremental expenditure rises to approximately R29 million above a baseline SMBG budget of R16 million, a 182% increase (Table 5).

In contrast, **continuous CGM** - where sensors are worn continuously (requiring about 26 per year) - would entail much higher annual outlays and may only be feasible for targeted sub-groups. For children and adolescents, expenditure would increase by approximately R27 million over the current R3 million SMBG budget (~898% increase), while adoption across all T1D users would require an additional R181 million per year (~1140% increase) over the current R16 million budget. Even when accounting for modest cost offsets from reduced DKA and SHEs (estimated savings of R7 to R43 million per year), continuous CGM remains a large fiscal commitment at current sensor prices.

At a 50% discounted sensor price (a likely scenario given newer technology on the market), the incremental budget impact of periodic CGM is lower: R1m for the youth and an additional R8m for adults and children. At a 50% discount, continuous CGM becomes more affordable but still requires an additional R10 million and R66 million for youth and all people with T1D, respectively.

While CGM may appear expensive on a per user basis, the eligible T1D population is small. **Periodic** CGM for all users at baseline prices would cost ~R45 million annually, only 0.02% of the national health budget (R296.1 billion)[50], making it highly affordable from a macro-budget perspective. Universal provision of **continuous** CGM to the same population at baseline prices would be equivalent to 0.07% of the national health budget - still a very small share in macro-budget terms, despite higher per-patient costs.

Table 5: Budget Impact Analysis: One and five-year results

	No. of users	Status quo annual cost (R)	Additional budget required (R)	% increase	Additional budget required (R)	% increase
1 year BIA						
80% uptake, Baseline sensor price			**Periodic CGM**		**Continuous CGM**	
T1D Youth	1,210	3m	+4m	143%	+27m	898%
T1D All	7,841	16m	+29m	182%	+181m	1140%
80% uptake, 50% sensor price discount						
T1D Youth	1,210	3m	+1m	35%	+10m	314%
T1D All	7,841	16m	+8m	48%	+66m	414%
5 year BIA						
80% uptake, 65% sensor price discount			**Periodic CGM**		**Continuous CGM**	
T1D Youth	1,210	15m	-0.4m	-3%	+20m	140%
T1D All	7,841	75m	0.2m	0.3%	+150m	201%

Minimal variation was observed between the Year 1 and Year 5 budgets, as most cost components remain stable over time. The only elements that varied were the replacement of glucometers and readers, which occur on a multi-year cycle. Importantly, if large discounts on the sensor price are achieved (65%) (which may be achievable given ongoing price reductions and market evolution), the budget trajectory for **periodic** CGM becomes cost-saving for both the youth subpopulation and for all eligible individuals. This is driven by the discounted sensor price and the bumpy, non-annual reader replacement cycle (with costs incurred only every second year). As a result, total programme expenditure for periodic CGM falls below the status quo over the medium term, further strengthening its affordability and fiscal feasibility when really large discounts are realised.

Interpretation and affordability

This BIA shows that introducing CGM for periodic use into the public sector could be considered fiscally feasible. A phased roll-out starting with paediatric and adolescent T1D would require an additional R4 million per year at baseline prices and even less, R1 million, with new, lower cost CGMs entering the market. Although CGM is costly per user, the eligible T1D population is small, and periodic use requires only 4 sensors per year, meaning the overall system impact is minimal.

Providing periodic CGM to *all users* costs roughly R45 million per year—only 0.02% of the national health budget. Even universal continuous CGM represents just 0.07% of national health spending.

Periodic CGM in the youth population thus represents the most practical, affordable entry point for public-sector adoption, with expansion to adults or continuous use contingent on achieving meaningful price reductions. Importantly, these estimates are highly conservative: unlike a BIA in the UK by Blissett et al[51]., which incorporated longer-term savings from improved glycaemic levels, our analysis includes only the most certain, short-term cost offsets - reductions in DKA and SHE[52].

B. Willingness to Pay Findings

The WTP analysis, conducted among 167 participants living with T1D enrolled in the ACCEDE trial at three South African public hospitals, provides important evidence on perceived value and affordability of CGM devices within public-sector populations[53]. Using the Van Westendorp Price Sensitivity Meter, the study estimated acceptable price ranges for both continuous and periodic (ad-hoc) CGM use, reflecting how much individuals might reasonably contribute out of pocket if the devices were made available through public facilities.

Participants reported an acceptable monthly price range for continuous CGM of R379–R543, with an optimal price[1] point of **R314 per month**, corresponding to approximately 14% of current market prices (≈ R2 000 per month: 2 sensors at ~R1,000). For periodic use, the acceptable range was similar (R302–R545), with a slightly higher optimal price of R350 per month - suggesting that short-term or cyclical CGM access may be more feasible for households in this setting.

Price perceptions were highly elastic: 83% of respondents said they would be likely or very likely to buy at a "good deal"[2] price (R514 per month), while only 23% would consider purchasing when the price was perceived as expensive. WTP values were somewhat higher among adults, frequent glucose testers, and higher-income households, while lower-income groups and caregivers of children reported much lower affordability, underscoring the need for targeted subsidies or cost-sharing models. Importantly, a monthly WTP of R514 is equivalent to approximately 95% of the cost of a lower-priced sensor (R540), used periodically (10 days per month).

Overall, the findings indicate strong latent demand for CGMs, with most participants expressing a desire to use a device for at least six months per year if affordable.

This supports the notion that people with T1D in the public sector value CGMs sufficiently to contribute modest amounts toward their cost, even where care is normally free at the point of service. These insights provide an empirical foundation for co-payment or tiered subsidy models, in which user contributions of roughly R300–R500 per month (equivalent to 15-25% of the current CGM price of R2000/month) could meaningfully reduce the fiscal burden on the health system while maintaining affordability for patients. At a sensor price of R540 for periodic use, this range corresponds to approximately 55–93% of the cost of a single sensor.

C. Conclusion and Financing Pathway

The combined BIA and WTP findings point to a clear and actionable pathway for CGM scale-up in South Africa. The emergence of lower-cost sensors (R540 per sensor with 10 days wear-time) already represents a ~50% price reduction relative to earlier benchmarks for periodic use, substantially improving affordability. At this price point, periodic CGM becomes close to fiscally manageable, and modelling suggests that at ~65% price reductions, the intervention becomes cost-neutral for government in the medium term.
Given this rapidly evolving price landscape, the most pragmatic near-term strategy is targeted public-sector subsidisation of periodic CGM for eligible users. This allows immediate access while maintaining fiscal control and leveraging ongoing market price declines. A phased financing approach could include:

- *Subsidy tiers*: Full subsidy for children and adolescents; partial subsidy for adults
- *Earmarked fund or donor bridge*: External or philanthropic support to enable early roll-out while local cost-effectiveness evidence matures
- *Integration with National Health Insurance (NHI):* Gradual inclusion of CGM within chronic disease benefit packages, with co-financing during transition years

This approach prioritises and enables immediate access for high-need groups, aligns with equity goals, and avoids delaying implementation while waiting for further price reductions or evidence. It also creates a credible demand signal to manufacturers, strengthening the case for additional price negotiations and smooths the transition toward eventual full public reimbursement.

Overall, periodic CGM represents a low-cost, high-impact entry point that is already within reach of the public health system. As prices continue to decline toward cost-neutral thresholds, this strategy provides a clear pathway to broader coverage and eventual full public reimbursement. Importantly, CGM provision for all engaged public-sector users represents only a very small fraction of total national health spending, underscoring that future expansion is achievable as prices fall.

1 The optimal price point is the balanced point where perceptions of 'too cheap' and 'too expensive' meet. It indicates a price that feels reasonable and sustainable.

2 A good deal price is higher than the optimal price point. This is the point where people still see CGM as a fair deal, but any higher and it starts to feel expensive.

11. Conclusion and Recommendations

Demand for CGMs in the public sector is clear and compelling. Beyond the WTP results in ACCEDE, which reveal that public-sector users value CGMs to the extent that they are willing to pay out of pocket for them, national advocacy has intensified: a public petition calling for CGM access in South Africa's public sector recently gathered just under 10,000 signatures, signalling broad social support and unmet need.

The ACCEDE evidence package provides the strongest South African dataset to date on the clinical, economic and operational implications of CGM use in the public sector. While within-trial differences in HbA1c, QALYs and acute events were not statistically significant over nine months, the qualitative, acceptability, and feasibility evidence suggest that CGM improves the lived experience of people living with T1D - reducing anxiety, increasing confidence in self-management, and supporting better engagement in glucose management among users and caregivers. These findings are aligned with robust international evidence demonstrating that CGM improves glycaemic control, increases TIR, reduces severe hypoglycaemia, and is cost-effective across multiple high-income settings.

The ACCEDE experience however shows that device provision alone is insufficient for sustained glycaemic improvement; real-world effectiveness will depend on integrating CGM into strengthened diabetes education pathways, routine clinical review, and ongoing support for interpretation and behavioural change.

It should be noted that this investment case does not incorporate evidence from South Africa's private sector, where a substantial body of clinical and implementation experience with CGM has been generated, and which may provide additional relevant insights for adoption and scale-up decisions.

The BIA indicates that periodic CGM is fiscally feasible, with an estimated additional annual cost of approximately R1–4 million, with lower costs driven by emerging lower-priced market entrants.

Taken together, this evidence supports a phased and targeted expansion of CGM access grounded in affordability, equity, and health system readiness, and provides a strong foundation for a formal national HTA process, laying the groundwork for eventual inclusion of CGM in medium-term budget planning and future NHI benefit design.

Recommendations

- **Adopt periodic CGM for paediatric and adolescent T1D, as well as continuous CGM for pregnant women with T1D, as an initial public-sector policy option that is a fiscally light, high-benefit entry point. This staged approach allows South Africa to realise the clinical benefits of CGM rapidly and equitably.**
- **Pursue national procurement and price negotiation strategies to bring sensor prices closer to public-sector affordability thresholds identified in WTP and cost-effectiveness analyses.**
- **Expand access to adults or to continuous use as procurement efficiencies, price reductions, and co-financing mechanisms mature.**
- **Add CGM to South Africa's STGs for people with T1D, with clear guidance on eligibility criteria, monitoring schedules, and clinical follow-up.**
- **Strengthen system readiness, including appointment of specialist diabetes nurse educators, nurse educator training, and patient education, to ensure high-quality implementation.**

12. Recommended Additional Reading

1. ACCEDE publications:

- Protocol paper
- Willingness to pay Report
- Please check the ACCEDE website for upcoming publications:
  - Qualitative acceptability
  - Clinical outcomes
  - Accessibility and feasibility
  - Cost-effectiveness

2. NdoH petition

3. FIND CGM training:

- People living with diabetes
- Healthcare professionals

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FIND Diagnosis for all

ACCEDE Access to CGMs for Equity in Diabetes Management

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