Hamburg University of Applied Sciences – Faculty of Life Sciences

Master Thesis

Health Technology Assessment of Continuous Glucose Monitors (CGMs) and Continuous Subcutaneous Insulin Infusion (CSIIs)

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Reem El Husseini

[redacted]

[redacted]

Matriculation number: [redacted]

Biomedical Engineering

Reviewer 1: Prof. Dr. Udo van Stevendaal

Reviewer 2: Prof. Dr. Bernd Flick

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Abstract

The emergence of diabetes technologies for glucose monitoring and insulin administration has significantly reshaped the management of type 1 diabetes (T1D). People with diabetes are increasingly choosing to use technologies such as real time continuous glucose monitors (rtCGM), intermittently scanned continuous glucose monitors (isCGM), continuous subcutaneous insulin infusion (CSII), sensor-augmented pumps (SAP), and hybrid closed-loop (HCL) systems to replace the standard care of self-monitoring of blood glucose (SMBG) and multiple daily injections (MDI).

This thesis systematically evaluates the clinical effectiveness, cost-effectiveness, and psychosocial impact of diabetes technologies in individuals with T1D. The goal is to provide an integrated overview of outcomes such as HbA1c, time-in-range (TIR), treatment satisfaction, and cost-effectiveness.

A systematic literature review was conducted of clinical, cost-effectiveness, and patient reported outcomes (PRO) evidence. 63 studies were identified as clinical evidence, 48 as cost-effectiveness evidence, and 20 as PRO or psychosocial evidence across the different technologies. A survey was conducted to complement the findings of the systematic literature review and to collect data directly from adults living with T1D. The survey included various questions covering clinical outcomes, perceived benefits and burdens, device satisfaction, financial cost, and burden of the technologies used by participants. An investigation separate from the systematic review was conducted on the effect of exercise on glycaemic control through integration within the survey and a brief literature search.

SAP technology demonstrated the greatest improvements in glycaemic outcomes, with average HbA1c reduction of 0.83 %, followed by HCL systems with average HbA1c reduction of 0.79 %. Although this could be attributes to SAP technology comparators (SMBG + MDI) being less intensive than HCL comparators (CGM + MDI/CSII). The biggest technology effects were observed in populations with high HbA1c baseline and high risk of hypoglycaemia.

In terms of economic evaluations, HCL vs isCGM showed the highest quality adjusted life years (QALYs) gain at 2.2 ±0.3, with an average incremental cost-effectiveness ratio (ICER) of € 28,886 per QALY. Cost-effectiveness of all technologies was most evident in cohorts with poor glycaemic control in settings using societal perspectives. Furthermore, psychosocial evidence highlighted improved treatment satisfaction, reduced diabetes distress, and better perceived control with technology use.

Survey participants (n=23) were grouped into 3 cohorts: CGM + CSII, CGM + MDI, and SMBG+MDI. The best glycaemic control was noted within the CGM + CSII cohort with 79 % of the cohort achieving HbA1c <7 %, while 50 % of CGM + SMBG cohort achieving HbA1c <7 %. Device

satisfaction was high across cohorts. HbA1c and TIR had a moderate negative correlation. Overall, the survey results aligned with the systematic literature review results.

The evidence supports the clinical and economic value of diabetes technologies, particularly SAP and HCL systems, in T1D management. Cost-effectiveness is favourable in most health system settings across countries. Broad adoption of these technologies, aligned with patient needs and health system capacities, has the potential to improve long-term outcomes for people with T1D.

Keywords: Type 1 Diabetes, Hybrid Closed-Loop, Continuous Glucose Monitors, Continuous subcutaneous insulin infusion, Cost-Effectiveness, HbA1c, TIR, Health Technology Assessment.

Abbreviations

ADA: American Diabetes Association

AHCL: Advanced hybrid closed loop

AID: Automated insulin delivery

CEA: Cost-effectiveness analysis

CGM: Continuous glucose monitor

CSII: Continuous subcutaneous insulin infusion

CUA: Cost-Utility analysis

DAFNE: Dose adjustment for normal eating

DDS: Diabetes distress scale

DIDS: Diabetes impact and device satisfaction

DKA: Diabetic ketoacidosis

FGM: Flash glucose monitoring

FoH: Fear of hypoglycaemia

HbA1c: glycated haemoglobin

HCL: Hybrid closed loop

HFS: Hypoglycaemia Fear Survey

ICER: Incremental cost-effectiveness ratio

INAHTA: International Network of Agencies for Health Technology Assessment

isCGM: Intermittently scanned glucose-monitor

LGS: Low glucose suspend

MDI: Multiple daily injections

MeSH: Medical subject headings

NDSS: National Diabetes Service Scheme

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

NSHE: Nonsevere hypoglycaemia events

POC: Point of Care

PRISMA: Preferred reporting items for systematic reviews and meta-analyses

PRO: Patient reported outcomes

QALY: Quality adjusted life year

QoL: Quality of life

rtCGM: real-time continuous glucose monitoring

SAP: Sensor augmented pump

SHE: Severe hypoglycaemia events

SMBG: self-monitoring of blood glucose

SUS: System usability scale

T1D: Type 1 diabetes mellitus

T2D: Type 2 diabetes mellitus

TAR: Time above range

TBR: Time below range

TIR: Time in range

WHO: World Health Organisation

1 Introduction

Type 1 diabetes (T1D) is an autoimmune disorder in which the insulin producing cells are attacked. The destruction of pancreatic β-cells results in insulin deficiency and elevated blood glucose levels. People living with T1D require lifelong external insulin therapy, with doses adjusted according to food intake, activity levels, stress, and illness as well as frequent monitoring of blood glucose levels. Poor long-term glycaemic control can affect multiple organ systems and is associated with serious illness and a higher risk of premature death [1]. Today, there are approximately 8.5 million individuals living with T1D worldwide [2].

Patients with T1D actively manage their blood glucose levels to maintain values within the recommended range of 3.9-10.0 mmol/L. Persistently elevated glucose levels (hyperglycaemia) can contribute to long-term diabetes-related complications, and low glucose levels (hypoglycaemia) can cause acute and severe events such as loss of consciousness, seizures, or coma [3]. This means that individuals must make frequent decisions throughout the day, every day and must have the knowledge to adapt these decisions to their daily life [4]. In a 2018 study of the T1D Exchange Clinic Registry, it was found that only about 17% of children and adolescents achieved HbA1c (glycated haemoglobin) < 7.5 % and around 21 % of adults achieved HbA1c < 7.0 %. This indicates that people living with T1D tend to struggle to reach the target blood glucose levels [5].

Beyond physiological challenges, individuals living with T1D may face psychosocial and economic burdens. The need for constant blood glucose monitoring and decision-making contributes to diabetes distress, fear of hypoglycaemia (FoH), and treatment fatigue. Financial pressures also arise from the cost of devices, consumables, and clinical care, which can limit access for some individuals. These burdens highlight the importance of assessing not only clinical outcomes, but also patient-reported experiences and affordability when evaluating diabetes technologies.

Advancements in continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems have enhanced the quality of life (QoL) for many individuals living with T1D, although replicating the full physiological function of pancreatic islets and their intricate feedback mechanisms remains difficult. Pancreatic islet transplantation offers a potential functional cure, yet its broader use is limited by scarce donor availability, the need for intensive and ongoing immunosuppression, and variable clinical outcomes [2].

Diabetes treatment was revolutionized in 1921 with Banting and Best's discovery of insulin. Diabetes was effectively a death sentence at the time, prolonged only in certain groups through a strict low-carb diet. It was transformed into a chronic manageable condition [6]. Diabetes technologies have progressed significantly since their invention. Glucose monitoring started in the mid-19th century through basic urine glucose analysis and became widely

available in the 1980s through home testing kits which was another massive step forward in T1D management. Real time continuous glucose monitors (rtCMG) became available in the market in 2004 [7]. Insulin pumps were available earlier with the first implementation occurring in 1970, but widespread adoption took place in the early 2000s [8].

Diabetes technology can be used by individuals living with T1D or type 2 diabetes (T2D). Although research shows that use within T1D patients is more prevalent [9]. For CGM technologies, evidence in T1D shows improvements in HbA1c and reduced hypoglycaemia, whereas findings in T2D are less conclusive [10]. This is likely due to the inherent differences between T1D and T2D. T2D is a heterogeneous disease driven largely by insulin resistance, which affects people differently, and the symptoms, severity, and how it develops can vary from person to person [11]. This could make it challenging to determine whether diabetes technology use is effective. As a result, studies assessing diabetes technologies are typically conducted within distinct diabetes subtypes (T1D, T2D, gestational diabetes, etc.). Although some investigations include mixed populations, combined analyses of T1D and T2D are less common due to the differing clinical profiles and treatment requirements of these groups.

Given these distinctions, this thesis focuses exclusively on T1D to ensure methodological consistency. T1D represents the population for which diabetes technologies are most clinically relevant and most widely studied. Restricting the analysis to T1D therefore improves comparability across studies, avoids the confounding introduced by the different treatment pathways in T2D, and ensures that the findings reflect the group most likely to use, benefit from, and have established access to these technologies.

Despite the major advancements in diabetes management, many individuals with T1D continue to experience suboptimal glycaemic outcomes, high treatment burden, and substantial emotional and financial strain. The rapid expansion of diabetes technologies has created new opportunities for improving clinical and psychosocial outcomes. This thesis provides a comprehensive evaluation to integrate clinical effectiveness, patient experience, and economic considerations into a single assessment to provide a comprehensive understanding of how these technologies perform across multiple outcome domains.

The remainder of this thesis is structured as follows. Chapter 2 provides a brief background on key technologies covered within this research as well as key concepts and terms which will be recurring throughout the results and discussion. The next section outlines the methodology for the systematic literature review and survey design. Chapter 4 presents the results of the systematic review across clinical, economic, and psychosocial domains, and the survey findings. Chapter 5 provides a discussion integrating key insights, strengths, and limitations, and Chapter 6 concludes with implications for future research and practice.

2 Theoretical Background

This chapter provides background on diabetes technologies which will be covered through the systematic literature review and referred to throughout the thesis. It will also define important terms and concepts which will be referred to within the results.

2.1 Glucose Monitoring Technologies

There are multiple devices on the market used to measure blood glucose levels, some more sophisticated than others. This chapter will introduce the types or "families" of glucose monitors available.

2.1.1 Portable Glucose Monitors/Glucometers (SMBG)

Traditionally, point of care (POC) devices, known as portable glucose monitors, blood glucose meter or glucometers, have been used to measure blood glucose at a point in time. It is a handheld device which often comes with test strips and a lancet. The lancet is used to prick the finger and draw a drop of blood, which is then applied to a test strip and inserted into the glucometer. The meter then produces a reading of the blood glucose in units of millimoles per litre (mmol/L) or milligrams per decilitre (mg/dL). Which unit is used usually depends on the region [12–14].

Frequent self-monitoring of blood glucose (SMBG) is linked to lower HbA1c levels, and international guidelines recommend SMBG several times per day for individuals receiving insulin. SMBG, however, presents some disadvantages including only providing limited data at a single point in time, can be inconvenient and painful for the users, and can be costly with frequent use. It is estimated that only 44 % of people with T1D and 24 % of people with T2D routinely perform SMBG as per guidelines [12].

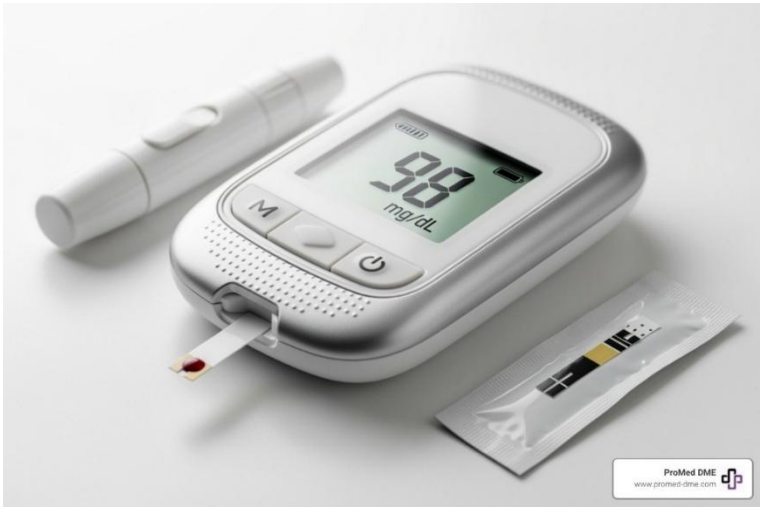

Figure 1 A portable glucose monitor/ Glucometer with lancet and test strip. Adapted from [15]

2.1.2 Intermittently Scanned Continuous Glucose Monitor/Flash Glucose Monitor (isCGM/FGM)

Intermittently scanned continuous glucose monitors (isCGM), also known as flash glucose monitors (FGM), measure blood glucose through an electrochemical sensor electrode that is inserted under the skin, usually in the arm or abdomen area. The sensor is connected to a transmitter for sending the reading to a detector such as a phone device or a pump. The user taps the reader to scan the sensor, and they can see their current glucose reading. Sensor life varies depending on the manufacturer but is often 14-days [16].

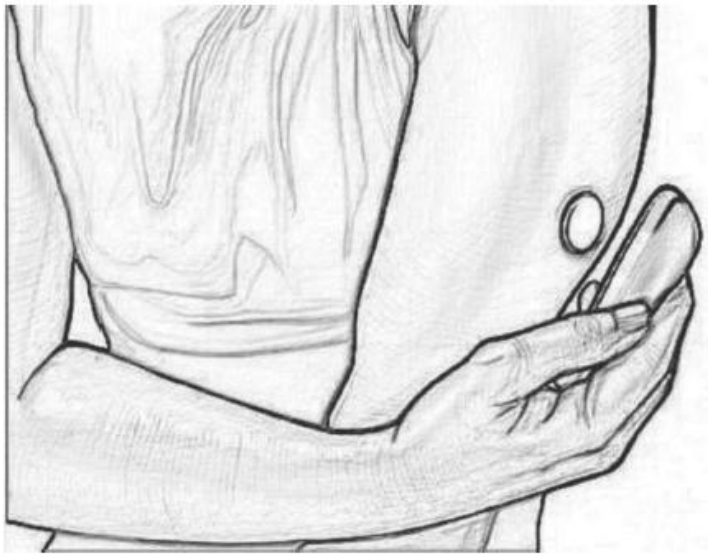

Figure 2 isCGM sensor inserted in arm, scanned by reader. Adapted from [16]

2.1.3 Real-Time Continuous Glucose Monitors (rtCGM)

Real-time continuous glucose monitors (rtCGM), used interchangeably with CGMs work similarly to isCGMs in that a sensor is inserted under the skin and every few minutes (typically 5 minutes), the sensor measures blood glucose levels in the interstitial fluid. The difference is that rtCGM transmits a reading automatically to the display device. It is worth noting that there is a delay between the display and actual readings (roughly 15 minutes) as glucose diffuses from the vascular space to the interstitial fluid. The sensor remains in place for a few days. Certain sensors can provide a range of metrics to help guide diabetes management and can also alarm during dysglycaemia. In comparison to SMBG, CGMs are more expensive [3,12].

2.2 Insulin Administration Methods

Insulin delivery can be done through several methods that range from traditional approaches to more advanced device-based technological systems that provide greater automation and flexibility in diabetes management.

2.2.1 Multiple Daily Injections (MDI)

Standard basal-bolus insulin therapy is defined as three or more insulin bolus injections and at least one basal. Bolus being short acting insulin injected with or before meals, and basal is long-acting insulin typically injected at least once per day. This method is the initial treatment regimen many individuals with T1D start on at diagnosis. It is also often used by individuals with T2D if external insulin is required. Among other available insulin delivery methods, multiple daily injections (MDI) is the least expensive, but it offers less flexibility and feedback [1].

2.2.2 Continuous Subcutaneous Insulin Infusion (CSII)

Continuous subcutaneous insulin infusion (CSII), often referred to as insulin pump therapy, is a pump which is attached to the body with the purpose of delivering insulin subcutaneously. It contains a reservoir where the insulin is stored, and a cannula which is a catheter inserted into the body and secured with adhesive, referred to as infusion set. The insulin is delivered to the body through tubing between the pump and cannula (illustrated in Figure 3). The pump can also be tubeless in which case it is referred to as a "patch pump" where it is a patch that is attached to the skin through the cannula and adhesive, and it contains a reservoir. A patch pump can be controlled wirelessly [8].

Pumps allow for more precise insulin dosing with fewer injections, causing less repeated pain to the users through the infusion set remaining in the body a few days before it must be changed [8].

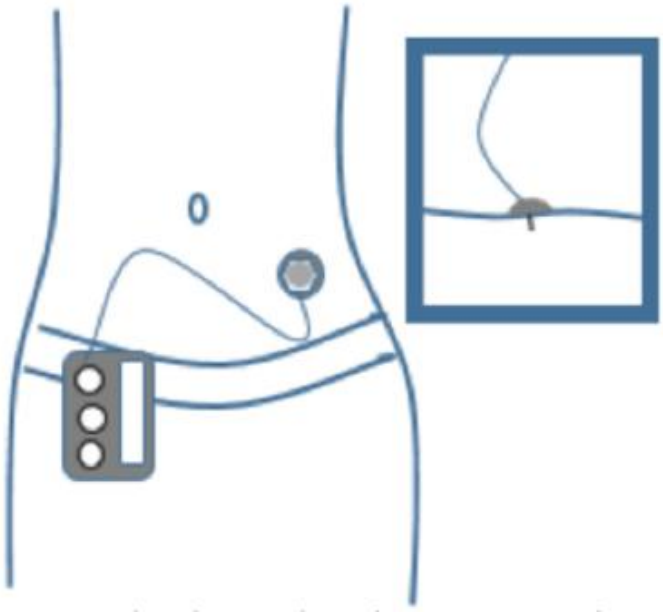

Figure 3 Pump with tubing attached to abdomen through cannula subcutaneously. Adapted from [8].

2.2.3 Sensor Augmented Pump (SAP)/SAP+LGS

The use of CGM together with CSII in a configuration that enables features such as low-glucose suspend, glucose-threshold alerts, or any form of automated insulin-delivery adjustment constitutes an integrated system [1]. A sensor augmented pump (SAP) is a pump which can effectively integrate with a CGM. It also delivers a basal insulin dose specified by the user. Any bolus for meals can only be done through the user; the pump does not automatically deliver insulin. Some SAP devices also have a low glucose suspend (LGS) feature which automatically suspends any insulin delivery when the hypoglycaemia threshold is reached [17].

2.2.4 Hybrid Closed-Loop (HCL) and Advanced Hybrid Closed-Loop (AHCL) Systems

An integrated system, hybrid closed loop (HCL) became commercially available in 2017. It combines a rtCGM, a control algorithm, and an insulin pump. Considered an AID system, the control algorithm adjusts the basal insulin delivery based on the rtCGM readings to assist the user in increasing the time spent in the recommended target range (3.9 - 10.0 mmol/L). The user is still required to bolus for meals [18,19].

Advanced HCL systems offer additional features to HCL systems, including automated correction of bolus insulin up to every 5 minutes when hyperglycaemia threshold is crossed or expected to be crossed by the algorithm [18].

2.3 Relevant Terms and Concepts

Measures of Glycaemic Control

Glycated haemoglobin (HbA1c) measures glycaemic control over 2-3 months. HbA1c is correlated to glucose levels over the preceding 8–12 weeks. The National Institute for Health and Care Excellence (NICE) guidelines on diabetes (T1D and T2D) recommend that people with T1D aim for a target HbA1c level of ≤ 6.5 % (48 mmol/mol) to minimise the risk of long-term complications from diabetes, while the American Diabetes Association (ADA) guidelines recommend an HbA1c goal of < 7 % (53 mmol/mol) [5,18].

HbA1c, however, does not provide detailed information regarding a person's actual experience with diabetes, particularly in terms of frequency and severity of hypoglycaemia and hyperglycaemia episodes. Although HbA1c is the most commonly reported metric in diabetes-related publications, the increasing use of CGM has enabled additional metrics, such as time in range (TIR) and related measures, to be incorporated into research (Table 1) [20].

Table 1 Key glycaemic metrics [18].

Metric	Definition	Interpretation	Unit
Time in Range (TIR)	Time glucose levels were between 3.9–10.0 mmol/L	Higher TIR indicates more time spent in the target glucose range.	%
Time Below Range (TBR)	Time glucose levels were < 3.9 mmol/L	Reflects hypoglycaemia. Lower values in this range are desirable.	%
Time Above Range (TAR)	Time glucose levels were > 10.0 mmol/L	Reflects hyperglycaemia. Lower values in this range are desirable.	%

Cost Analysis Terminology

Incremental cost, incremental cost-effectiveness ratio (ICER), and quality-adjusted life year (QALY) are terms often used in cost-effectiveness analysis (CEA) and cost utility analysis (CUA). Cost evaluation studies usually evaluate a technology (intervention) against another (control) by looking at their costs including device and supplies cost, medical visits, complications, and provided health benefits over time. Many simulation models have been developed to predict how diabetes and its complications progress over time. These often use Markov models, which follow a group of individuals as they move between defined health states, each representing a possible diabetes-related complication. The model uses assumed probability distributions to determine how people transition between states and assigns costs to each complication. The ICER is then calculated by dividing the difference in total costs (Incremental costs) between the intervention and control groups by the difference in their QALYs. In this way, ICERs determine how much the intervention technology costs in comparison to the control and whether it is more effective [21,22].

QALYs were created to provide a measure for comparing improvements in health. They are now widely used as the main outcome in economic evaluations because they capture both how long a person lives and the quality of those years. In simple terms, a QALY reflects years of life adjusted by how good or limited a person's health is during that time [22].

$$ICER = \frac{Cost_{intervention} - Cost_{control}}{QALY_{intervention1} - QALY_{control}}$$

To determine cost-effectiveness of an intervention, ICERs are compared to a willingness-to-pay (WTP) threshold. WTP threshold is defined as "an estimate of what a consumer of health care might be prepared to pay for the health benefit." If an ICER exceeds the WTP threshold, it is considered not cost-effective. Thresholds can be based on national income levels or on values used for previous treatments. The World Health Organisation (WHO) has suggested that an intervention is cost-effective if its cost per QALY is less than three times a country's GDP per capita [21].

3 Methodology

3.1 Literature Review

A systematic literature search was conducted to identify relevant studies assessing the clinical effectiveness, cost-effectiveness, and psychosocial outcomes associated with diabetes technologies in individuals with T1D. This evidence was used to provide a comprehensive and comparative evaluation of diabetes interventions across outcome domains.

3.1.1 Search Strategy

The literature search was conducted using the PubMed database on 26 May 2025. The search string was made to capture key terms across the target domains using free-text terms. It combined three core concept areas: disease (T1D), interventions (glucose monitoring and insulin delivery technologies), and outcomes (clinical, economic, and psychosocial). The following Boolean string was used:

("Type 1 Diabetes" OR "Diabetes Mellitus" OR "T1D") AND ("Continuous Glucose Monitoring" OR "CGM" OR "Flash Glucose Monitoring" OR "Insulin Pump" OR "CSII" OR "MDI" OR "Diabetes technology") AND ("Health Technology Assessment" OR "HTA" OR "Cost effectiveness" OR "Clinical outcomes" OR "Usability" OR "Patient perspective" OR "Patient-reported outcomes").

A keyword-based search strategy was used rather than a MeSH (Medical Subject Headings)-driven approach, as PubMed automatically maps many of the included terms (e.g., Type 1 diabetes, CGM, insulin pump) to their corresponding MeSH headings. This approach also maximised inclusivity. Filters were applied to restrict results to studies published between 2015 and 2025 (within the last 10 years), and only English-language or English translated publications were considered.

In addition to PubMed, a manual search of the International Network of Agencies for Health Technology Assessment (INAHTA) database, ScienceDirect, and reference lists of review studies was conducted to identify additional eligible studies.

3.1.2 Eligibility Criteria

The inclusion criteria were drafted to capture a wide range of relevant evidence while ensuring applicability to T1D technology and desired outcomes. The following inclusion criteria were used:

- Populations within studies include individuals with T1D, either entirely or as a distinct subgroup with separately reported outcomes (e.g. Studies with T1D and T2D populations).
- Studies evaluated a diabetes technology, including:
    - Glucose Monitoring systems: rtCGM or isCGM; and

- Insulin delivery methods: CSII, SAP, or HCL/AHCL systems.

- Studies reported at least one of the following outcomes:
  - Clinical effectiveness: including HbA1c, TIR, or Hypoglycaemia rate; or
  - Cost-effectiveness: including incremental costs, QALYs, or ICER; or
  - Patient-reported outcomes (psychosocial outcomes): including diabetes distress, QoL, sleep quality, treatment satisfaction, burden, or usability.

Systematic reviews, narrative reviews, and observational studies were included if they provided insights into diabetes technology outcomes specifically in T1D populations, even if outcomes were presented as ranges or even qualitatively. These studies however were not considered for quantitative data analysis.

Exclusion criteria applied included:

- Studies exclusively on T2D or gestational diabetes;
- Practitioner perspective or system-level evaluations without direct patient outcomes. (e.g. diabetes technology in in-patient settings); and
- Editorials and commentaries.

3.1.3 Study Screening and Selection

Articles were screened in two stages: first by the title and abstract, then by full-text review based on the inclusion and exclusion criteria outlined above. Identified articles were imported and managed using Zotero reference management software. Although PRISMA (Preferred reporting items for systematic reviews and meta-analyses) guidelines were considered during design, the protocol did not fully align with formal PRISMA requirements and no formal PRISMA checklist was completed. However, a flow diagram of study selection was provided in the results section for transparency (Figure 4).

Data was extracted by first acquiring the full text articles, identifying which diabetes technology is covered and what aspects of the technology were evaluated. The articles were effectively categorised into 3 main categories by evaluation domain: clinical effectiveness, cost-effectiveness, and patient reported outcomes (PRO). The articles were further subdivided by the technology investigated: CGM (isCGM/rtCGM), CSII (CSII,SAP), and HCL (HCL/AHCL). Studies reporting on multiple technologies or multiple evaluation domains (e.g. both clinical and CEA performed) were included in all relevant categories as duplicates.

Currency Conversion for Cost-effectiveness Studies

The systematic review included studies from multiple international countries in various publication, investigation years, and currencies. To facilitate comparison across these studies, all monetary data were converted from the local currency and year to 2024 Euro (€) using the

Campbell and Cochrane Economics Methods Group tool [23]. The conversion tool adjusts for estimates of costs for currency and price year. If cost year was not explicitly stated, it was assumed to be one year prior to the year of publication.

3.2 Survey Development

The survey was developed to collect real-world information from individuals living with T1D focusing on their use of diabetes technologies and associated clinical and psychosocial experiences. Its primary objective was to complement the findings of the systematic literature review by incorporating patient-reported data, with a focus on personal experience, perceived benefits and burdens, and emotional impacts of diabetes technologies.

The target population consisted of adults (≥18 years) diagnosed with T1D, residing in Australia irrespective of their current treatment regimen. Participation was voluntary, with no monetary or material incentives offered.

The survey was developed and conducted using Microsoft Forms which provides an intuitive and accessible interface both for survey creation and respondent completion. The platform supports a range of design features, including multi-section formatting to distinguish thematic areas, several question types (e.g., multiple choice, Likert scales, ranking, and open-ended responses), and conditional branching to tailor the sequence of questions based on participant input. These functionalities enabled the creation of a structured, user-friendly survey with a logical and seamless progression. Microsoft Forms also provides accessibility across devices through the generated link used to access and fill the survey by participants.

Multiple iterations of the survey were developed, refined, and pilot tested before the final instrument was achieved. In addition to internal testing, feedback was obtained from an individual living with T1D who evaluated the survey's clarity, usability, and the ease of recalling relevant personal metrics (e.g. HbA1c). This feedback informed revisions to ensure that the survey was appropriately designed for the target population.

To minimise ethical and privacy risks and to encourage honest participation, the conducted survey was completely anonymous. No names, email addresses, IP addresses, or other identifiable data were collected at any stage. As a result, once a response was submitted, it could not be withdrawn as it could not be linked back to the respondent.

Prior to commencing the survey, participants were presented with an information sheet and consent form, which they were encouraged to read prior to providing informed consent (refer to Appendix A). Only individuals who provided consent were able to proceed to the questionnaire. The information sheet outlined eligibility criteria, the nature of the questions posed within the survey, the purpose and scope of the research, and any potential risks or benefits of participation. Participants were given the option to directly contact the researcher

for any questions or concerns through email communication. It was also emphasised that participation is voluntary, and consent can be revoked at any time before the submission of the entry.

The survey was structured through several thematic sections with branching logic used to ensure relevance. For example, questions related to insulin pumps were shown only to participants who reported current use of pump devices. Respondents were permitted to skip any non-branching or non-pivotal questions they were uncomfortable answering.

Standard demographic questions were collected such as gender, age, and diabetes duration. Participants were asked to disclose their current treatment regimen which dictated the flow of the remaining questions. This ensured that participants only answered questions applicable to their treatment regimen. The survey was designed to be concise and to be completed unhurriedly in under 10 minutes. This was to allow the participants to provide genuine thoughtful answers without getting weary from a large volume of questions. The survey consisted of the components listed in Table 2.

Table 2 Key survey components

Component	Description
General demographics	Information on gender, age, and duration of diabetes.
Device use and treatment characteristics	Current and previous use of diabetes technologies and treatment regimens.
Clinical outcomes	Self-reported HbA1c ranges and time since diagnosis.
Psychosocial outcomes	Concerns and FoH, diabetes distress, and treatment satisfaction.
Cost and affordability	Perceived financial burden associated with diabetes technology use.
Overall treatment satisfaction	Participants' general satisfaction with their current treatment approach.

An additional theme which was not included within the systematic review was covered through the survey was to evaluate the effect of exercise on perceived glycaemic control. Participants were asked about the frequency and nature of exercise they perform, if any, and how they perceived its effect of glycaemic control.

Most clinical questions included multiple choice answers which used categorical ranges for metrics such as HbA1c ranges or TIR ranges to reduce ambiguity, particularly for participants who could recall an approximate range but not a precise value. The ranges included minimal but meaningful bands which capture the full spectrum of clinically relevant values while allowing participants to respond accurately. Other question formats included the 5-point Likert scale ("Strongly Disagree" to "Strongly Agree") which was used to assess psychosocial outcomes across ten statements addressing constructs such as FoH, emotional burden, treatment confidence, device use issues, and device satisfaction. Some questions included multiple answers in which more than one was selectable, and an “other” option was available for manually typed input, e.g. reasons for discontinuing a device.

To maintain a concise format and prevent the formation of excessively small subgroups in the analysis, the survey did not collect information on specific device models or individual technology types. Instead, technologies were categorised into broad types: CGM modalities (rtCGM/isCGM) and insulin delivery methods (CSII, SAP, HCL) and were grouped into a single category each, with a distinction made between automated (HCL) and non-automated systems (CSII, SAP). Ultimately, the participants were split into three cohorts based on treatment regimen:

1. Cohort-1: Continuous Glucose Monitor (CGM) + Continuous Subcutaneous Insulin Infusion (CSII), including any CGM type (e.g. isCGM/rtCGM) and any insulin administration method, regardless of integration (e.g. CSII,SAP,HCL).
2. Cohort-2: Continuous Glucose Monitor (CGM) + Multiple Daily Injections (MDI), including any CGM type (e.g. isCGM/rtCGM) but only using insulin pens for insulin administration.
3. Cohort-3: Self-Monitoring of Blood Glucose (SMBG) + Multiple Daily Injections (MDI),using a finger prick blood glucose monitor in conjunction with insulin pens with no use of any other technology.

This approach was chosen to keep the survey at manageable length and to avoid creating numerous small subgroups within a limited sample size.

3.3 Sampling and Data Collection

Given the online nature of the survey and the limited control over participant verification, efforts were made to restrict distribution to trusted sources to preserve data quality. The survey was not distributed through diabetes online forums or social media groups to minimise the risk of responses from individuals outside the target population. Such platforms contain large audiences, and it is not possible to confirm the respondent's diagnosis or responses authenticity.

Initial plans involved distributing the survey through formal diabetes organisations within Australia such as the National Diabetes Service Scheme (NDSS) or Diabetes Victoria which is an agent of NDSS based in Victoria, Australia. Both entities support people with all types of diabetes and all ages. Both organisations offer online portals through which researchers can apply to recruit participants for studies. Although all required documentation was submitted to the NDSS on 3 July 2025, a response received in mid-August stated that NDSS was not supporting research communication at the time due to an ongoing privacy review by the Commonwealth and no insight to the timeline of that was known. Communications with Diabetes Victoria were more positive, however, further distribution was contingent on ethics approval from an Australian Human Research Ethics Committee (HREC). An application was

submitted in August 2025, but no formal response was received within the required time frame to distribute the survey and analyse the results.

Due to these delays, the survey was ultimately distributed via a T1D support group based in Victoria, Australia. The group consisted of roughly 50 members most of which were older adults who gather for monthly meetups to connect, share experiences and support each other. The survey link was shared with the group facilitator who approved the distribution among the group members. This approach represents a convenience sampling strategy, where participation was based on availability and willingness. This method enabled timely data collection from a relevant and engaged cohort. The survey was conducted entirely online through Microsoft Forms and was accessible starting 9 October 2025. The last response received was on 24 of October 2025. No supervision was provided during survey completion and participants completed the survey in their own time.

3.4 Data Analysis

Systematic Literature Review

After the final set of studies was selected, each article was categorised into an evaluation domain category (clinical effectiveness, cost-effectiveness, PRO) and diabetes technology sub-category. Extraction tables were constructed for each sub-category within each domain. A separate table was created for psychosocial outcomes, which were organised by technology within a single table. Each technology was then analysed within its respective category. Key data extracted from each full text-article are listed in Table 3.

Table 3 Data extracted from full text articles

Data extracted	Description
Bibliographic details	Author(s), publication year, and study country.
Study design	RCT, prospective study, model-based analysis, observational study, or systematic/narrative review.
Population	Age range and confirmation of T1D-focus.
Sample size	Reported size of intervention and comparator groups for clinical effectiveness studies.
Intervention	Type of diabetes technology evaluated.
Comparator	Usual care or alternative technology used for comparison.
Outcomes and key results	HbA1c, TIR, costs, ICERs, QALYs, and patient-reported outcomes.
Other metrics	For economic studies: cost-analysis perspective, time horizon, discount rate, and WTP thresholds.

Common reported outcomes metrics include HbA1c, TIR, QALY, and ICER which were collated where appropriate to enable structured comparison across technologies.

An outlier screening step was done prior to analysis. Extremely high or low values were identified through visual inspection and distributional checks. Outliers were removed when they reflected measurement errors or values which were unlikely to represent the target population. The purpose of excluding these values was to prevent undue distortion of means, correlations, and model estimates. For transparency, all acquired statistics on outcomes were referenced to their respective table added within Appendix B and C which indicates which data was excluded and the reason of exclusion.

Survey Data Analysis

Survey responses were extracted from Microsoft Forms through an automatically generated live-linked Excel file that updated in real time new as responses were submitted. Responses were analysed using descriptive statistics. Categorical data such as treatment regimen, diabetes duration, and responses to Likert-scale items were summarised using frequencies and percentages. For variables reported in ranges (e.g., HbA1c categories, TIR bands), mid-point values were used to approximate continuous values for quantitative investigation (where applicable) for further analysis.

Responses were stratified by technology groups to allow consistent comparison between cohorts (CGM + CSII, CGM + MDI, and SMBG + MDI). This facilitated group-level comparison of key clinical outcomes, including average HbA1c and proportion of participants reporting TIR within target ranges. Group-level summaries were generated for each cohort.

In addition to descriptive summaries, several exploratory analyses were performed to investigate relationships between variables. Including:

- Correlation between HbA1c and TIR
- Association between HbA1c and duration of CGM use
- Differences in HbA1c by insulin delivery method (e.g., pump vs MDI)
- HbA1c differences between cohorts.

All data analysis and visualisations such as tables, charts and figures were created using Microsoft Excel. Missing data were either excluded from relevant analyses or reported explicitly.

4 Results

4.1 Systematic Review

The PubMed search yielded in 523 results, with an additional 7 articles which were identified through manual search. All identified articles were initially screened for eligibility through the title and abstract, and a full text review was performed for the remaining articles. After exclusion of ineligible publications, a total of 115 articles were included in this research, as illustrated in Figure 4.

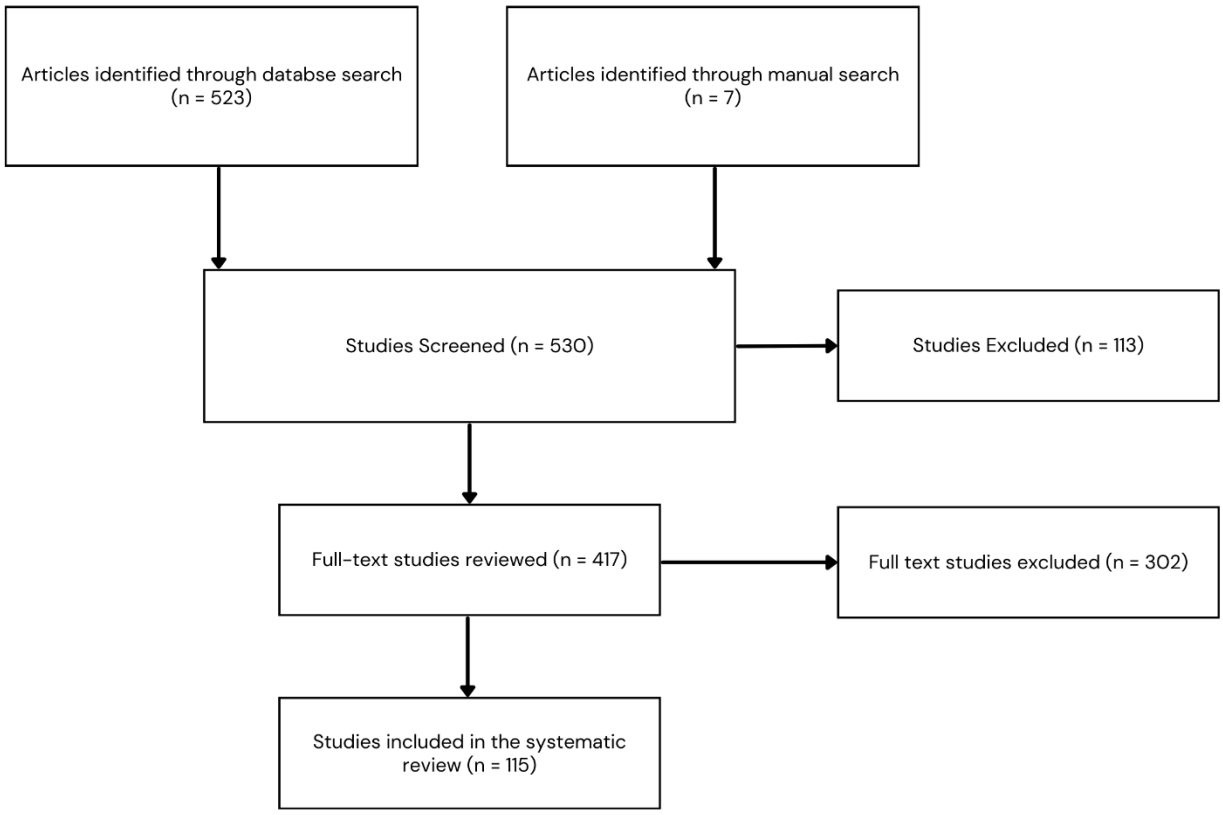

Figure 4 Systematic Review Flow Diagram

In total after sorting each study into its appropriate group(s) and sub-group(s), rtCGM studies included 19 on clinical effectiveness and 15 on cost-effectiveness. For other technologies, isCGM included 9 clinical and 6 cost-effectiveness studies; CSII included 14 clinical and 6 cost-effectiveness studies; SAP included 8 clinical and 9 cost-effectiveness studies; HCL included 13 clinical and 12 cost-effectiveness studies; psychosocial outcomes included 20 which covered different technologies. Together, this resulted in 131 categorised entries, including 16 duplicate papers, of which 10 papers appeared in 2 different categories, while 3 papers appeared in 3 different categories.

4.1.1 Clinical Effectiveness

4.1.1.1 Continuous Glucose Monitors (real time/intermittently scanned)

A total of 28 papers assessed the clinical effectiveness of rtCGMs and isCGMs, detailed in Table 4. Study populations varied, with 14 articles focusing only on adults, 10 on mixed adults and paediatric populations, and 4 papers on youth and adolescents. 19 studies focused on rtCGM, and 9 on isCGM, with a few covering both technologies

The majority of studies demonstrated that CGM use led to reductions in HbA1c, TIR, and fewer episodes of severe or nocturnal hypoglycaemia compared to SMBG. Out of 14 studies reporting baseline and post intervention HbA1c values, the mean reduction reported was 0.63 % ±0.36. When disaggregated by technology type, rtCGM (10 studies) showed a greater reduction (0.74 % ±0.35) than isCGM (4 studies, 0.36 % ±0.26). All 7 papers reported an HbA1c reduction > 0.6 % where the baseline mean HbA1c was ≥ 8.2 % (refer to Table B1 and Table B2 in Appendix B). Figure 5 shows the HbA1c baseline and reduction across different studies.

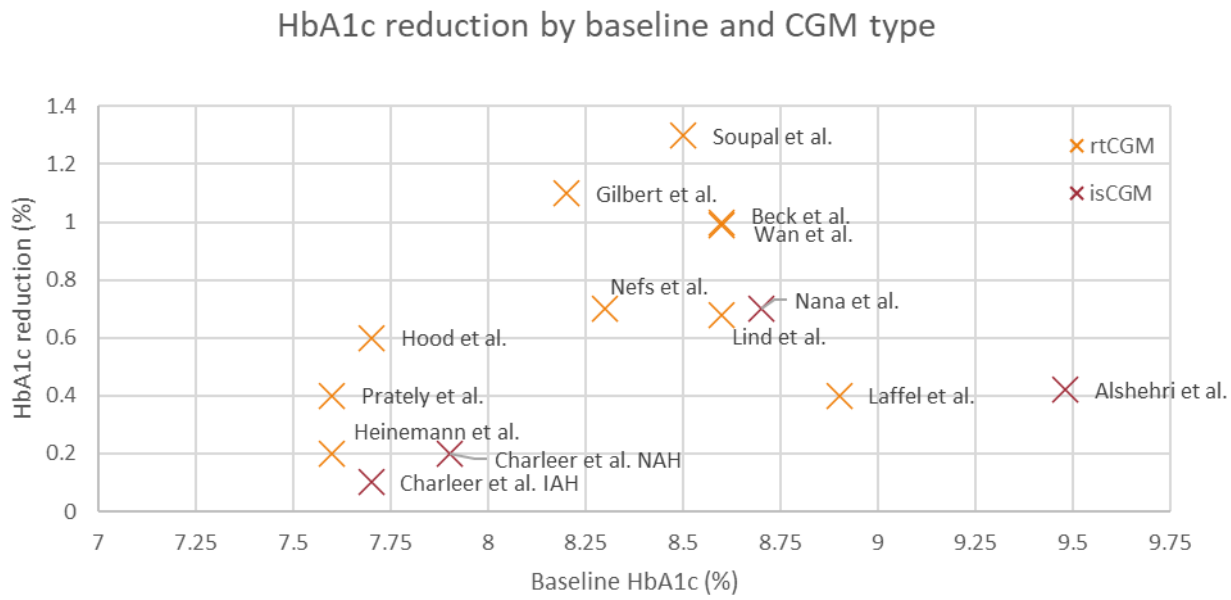

Figure 5 change in HbA1c (%) relative to baseline HbA1c (%) by technology type

Four of the identified studies for isCGM were systematic reviews, and of the remaining 5, only 3 reported baseline HbA1c and post isCGM HbA1c, with one study including two cohorts. An HTA which did not report HbA1c values, reported a minimal increase in TIR by 1 hour per day [24]. Another systematic review noted little to no difference in HbA1c level in comparison to SMBG [25]. Other systematic reviews reported mixed outcomes across paediatric studies, and a 0.23 % average drop across adult and paediatric (mixed) studies [26,27]. In Saudi Arabia, a retrospective publication reported a significant drop of 0.42 %, where the baseline was high for the adolescent cohort [28].

Better outcomes were noted in rtCGM, with more studies reporting on the technology. A systematic review noted HbA1c reduction across studies ranging from 0.3 % to 0.6 %, with a greater benefit in those with a higher baseline, this was also noted in a narrative review which reported the range of 0.3 % to 0.5 % [10,16]. A retrospective study reported that every 10 % rise in TIR, HbA1c decreased by 0.34 %, noting a correlation [29].

Hypoglycaemia outcomes were reported in 18 studies, with 16 showing a reduction in frequency of hypoglycaemic or severe hypoglycaemic episodes (SHEs) either quantitatively or qualitatively. Hypoglycaemia reductions were reported in 7 studies covering isCGM. In a real world prospective study, SHEs dropped from 36.4 % to 16 % of total events by the end of the 24-month study [30]. A Canadian HTA found that TBR decreased by 1.24 hours/day and TAR decreased by 0.37 hours/day. Another study noted a 51.86 % drop in hypoglycaemia episodes [24,31].

Similar outcomes were reported for rtCGM technologies. In the German 2018 HypoDE RCT, hypoglycaemic events dropped from 10.8 to 3.5 per 28 days among rtCGM users versus a smaller reduction in the control group (from 14.4 to 13.7); nocturnal hypoglycaemia also declined [32]. The Swedish 26-week GOLD trial RCT reported a difference in occurrence of hypoglycaemic events during the trial of 5 events occurring with conventional treatment (SMBG) and 1 event occurring with CGM users [33]. A retrospective observational study found a stark contrast in SHEs rates: 256 events/1000 patients among non-CGM users versus 16 events/1000 patients for CGM users [5].

TBR was reported in multiple trials. The 2017 Untied States based DIAMOND RCT reported a median time in hypoglycaemia of 43 minutes/day for CGM users, compared to 80 minutes/day for SMBG users [34]. An RCT with a population of older adults reported a mean drop of 2.4 % in TBR in CGM users vs +0.2 % in SMBG users [35]. Another RCT reported a median drop of 1.0 % in CGM users vs 0.5 % in SMBG users [36]. An observational study on isCGM reported a 51.86 % reduction in hypoglycaemia episodes [31]. In contrast, 2 studies found no significant change in hypoglycaemia rates despite HbA1c improvements [37,38].

TIR was positively influenced by CGM use. An RCT found a 6 % increase in TIR in CGM users vs a 1 % decrease in SMBG users [36]. Similarly, 2018 HTA reported a 9.6–10 % increase in time spent in target glycaemic range with CGM [3].

Some narrative reviews and HTAs also emphasized broader improvements in glycaemic variability, and reduced diabetes-related hospitalizations, especially in those with impaired hypoglycaemia awareness or a history of severe hypoglycaemia [10,16,26].

Table 4 Study Characteristics key clinical outcomes for rtCGMs and isCGMs effectiveness studies

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
Heinemann et al. (2018)[32]	Germany	Multicentre, open-label, parallel-group RCT (26-week)	T1D, Adults, impaired hypoglycaemia awareness	rtCGM 7.6 (±1.0); Control 7.3 (±1.0)	rtCGM	SMBG	75/74	- HbA1c of CGM users dropped to 7.4 (-0.2), while control group dropped to 7.3 (-0.1) - Hypoglycaemic events per 28 days fell from 10.8 to 3.5 with rtCGM vs 14.4 to 13.7 control ([95 % CI 0.20–0.39], p < 0.0001). - Nocturnal events dropped from 2.3 to 1 in CGM group, increased from 2.4 to 2.7 in control group (p < 0.0001). - Mean TIR increased by 0.7 % in CGM group, decreased by 2.4 % in control group
Lind et al. (2017)[33]	Sweden	crossover RCT (26 weeks)	T1D, Adults	8.6	rtCGM	SMBG	69/73	- Mean HbA1c 7.92 % (CGM) vs 8.35 % (SMBG) (-0.43 % absolute; p<0.001) - Severe hypoglycaemia: 5 events in conventional group vs 1 in CGM group
Laffel et al. (2020)[36]	United States	crossover RCT (26 weeks)	T1D, Youth 14-24	8.9 % ± 1.0 % (both arms	rtCGM, with ≥5 days/week use encouraged	SMBG	74/79	- 26 week mean HbA1c 8.5 % (CGM) vs no change in SMBG; adjusted between-group difference −0.37 % (95 % CI −0.66 to −0.08; p=.01) - Mean TIR ↑6.0 % in CGM users, ↓1 % in SMBG users - Mean TAR (>10.0 mmol/L) ↓4 % in CGM users, ↑2 % in SMBG users - Median TBR (<3.9mmol/L) ↓1.0 % (3.2 to 2.2) in CGM users, ↓0.5 % in SMBG users - Median time in severe hypoglycaemia (<2.9mmol/L) ↓0.3 % in CGM users, no change in SMBG users - Severe hypoglycaemia: 3 vs 2 participants; DKA: 3 vs 1 participants; overall adverse-event profile similar between groups
Beck et al. (2017)[34]	United States	Randomised, open-label trial, 24-week follow-up	T1D, Adults, on MDI	8.6 % ± 0.6 % both arms	rtCGM	SMBG	158 randomised (105 CGM, 53 usual care); 155 completed	- Mean HbA1c −1.0 % (baseline 8.6 % → 7.6 %) (CGM); −0.4 % (8.6 % → 8.2 %) (control); adjusted difference −0.6 % (p<.001) - Median time < 70 mg/dL: 43 min/day (CGM) vs 80 min/day (control), p= 0.002
Prately et al. (2020)[39]	United States	Randomised, open-label clinical trial, 6-month follow-up	T1D, Adults ≥60, 52 % on pump	CGM: 7.6 ± 1 SMBG: 7.5 ±0.9	rtCGM	SMBG	203 randomised (103CGM,100 SMBG)	- Mean HbA1c after 26 weeks: 7.2 % (SD, 0.9 %) (CGM) and 7.4 % (SD, 0.9 %) in SMBG group - Mean HbA1c ↓ 0.3 % (adjusted group difference) - TBR (<3.9 mmol/L) for CGM: 5.1 % → 2.7 % vs SMBG (4.7 % →4.9 %) (-1.9 % absolute, −27min/day, p<0.001)
Wan et al. (2018)[40]	United States	Open-label multicentre RCT	T1D, Adults	Intervention: 8.6 ±0.7 Control: 8.6 ± 0.6	rtCGM (Dexcom G4)	SMBG	105/53	- HbA1c reduced -0.74 % (p < 0.01) compared to SMBG cohort - NSHE reduced -0.07 events/day (p = 0.013) - Test-strip use ↓ 0.55 strip/day (p = 0.04)
McQueen et al. (2024)[29]	United States	Retrospective, longitudinal cohort study using linked EMR + CGM data	T1D, Adults	7.5 ± 1.4	CGM(rtCGM/isCGM), some also used insulin pump or HCL	None (within-user analysis)	542 (total sample size)	- Every 10 % rise in TIR ↓ HbA1c by 0.34 % (same visit) and 0.20 % second visit (mean duration between visits 4.9 months)
Gilbert et al. (2021)[41]	United States	Prospective, real-world cohort	T1D & T2D, Adults 25-65, on intensive insulin therapy, no prior CGM	8.2 % ±1.9 %	rtCGM	Within-subject pre-CGM baseline (HbA1c, DDS, HABS) vs. 12-week post-initiation	248 (182 T1D,66 T2D)	- Mean HbA1c↓ to 7.1 %±1.1 % (−1.1 % absolute; p<0.001). - Proportion of HbA1c < 7 % rose from 24.6 % to 50.8 %.
Lin et al. (2021)[16]	Australia	Narrative review of RCTs, meta-analyses and health-technology assessments	T1D (majority) and selected T2D cohorts on insulin, Adults	–	rtCGM, isCGM	SMBG	–	- In T1D, CGM reduced HbA1c by ~0.3–0.6 %, with the greatest benefit in those with higher baseline HbA1c. - CGM use reduced SHEs vs SMBG, especially in high-risk groups. - multiple RCTs reported increase TIR of mean TIR of 1.3–2.4 h/day - CGM improved QoL and treatment satisfaction, particularly in patients experiencing hypoglycaemia fear or high disease burden.-

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
DeSalvo et al. (2023)[5]	United States	Retrospective cohort analysis of electronic-health-record data	T1D, Adults & Paediatric	–	rtCGM	SMBG	11,469; 48 % CGM users	- CGM users median HbA1c: 7.7 % [IQR 6.9-8.6] vs non-users 8.4 % [IQR 7.4-9.5]; difference P <.001 - DKA events: Non-users 230 events/1000 vs CGM users 8.6 events/1000 (significantly higher) - Severe Hypoglycaemia: Non-users 256 events/1000 vs CGM users 16 events/1000
Gomez et al. (2017)[42]	Colombia	Narrative review of CGM technology	T1D & T2D, Adults & Paediatric	Range: 7.3 - 9.7	rtCGM	SMBG	–	- HbA1c reduction of −0.53 % (95 % CI, 0.71 %–0.35 %, p<0.001) and −0.64 % (95 % CI, −0.7 % to −0.4 %, p<0.001) in rtCGM users
Soupal et al. (2016)[37]	Czech Republic	Prospective controlled trial	T1D, Adults	CGM + MDI: 8.5 ± 1.1 MDI + SMBG:8.3 ± 0.8	rtCGM + MDI	SMBG	12/18	- Intervention group reduced HbA1c to 7.2 % - SAP and MDI-RT-CGM subgroups comparable - MDIs alone showed no significant HbA1c change - Hypoglycaemia incidence fell only in sensor augmented insulin regimen (CGM and SAP) (8 % → 6 %, p<0.01)
Ravi et al. (2021)[43]	United States	Retrospective chart review	T1D, children/adolescents	–	rtCGM (some exposure)	SMBG	177/715	Subjects with some exposure to CGM had a significantly lower A1c (median 8.6 %) after CGM exposure compared to those never exposed to CGM (median 9.3 %) (P < .001)
Gavin et al. (2021)[44]	United States	Narrative review of real-world evidence	T1D & T2D, Adults & Paediatric	Range 8.0 -8.8	CGM (rtCGM, isCGM, Flash) across studies	SMBG, MDI, standard care	–	- in one study about CGM, HbA1C had decreased 8.8 % to 7.6 % (P = 0.051) with significant reductions in severe hypoglycaemia (from 9.7 to 2.2 events per 100 patient-years, P = 0.03) - FGM effect on severe hypoglycaemia/DKA: ↓ from 3.3 % → 2.2 % (p=0.031) - HbA1c: ↓ from 8.0 % → 7.4 % (p<0.001) - Hypoglycaemic events: ↓ from 93.1 % → 91.0 % (p<0.05) - Diabetes-related hospitalizations: ↓ from 144 → 22 (p<0.001) - SHE: ↓ from 14.6 % → 7.8 % (p<0.0001)
Nefs et al. (2019)[38]	Netherlands	Single-centre prospective observational study	T1D, Adults mean age 38 ± 11 y	8.3 ± 1.0 %	rtCGM	within-subject comparison of baseline vs. 6-month follow-up	60 (total sample)	- In persons who did not discontinue CGM, HbA1c fell from 8.4 % to 7.7 %; p < 0.001 - No change in hypoglycaemia rate, awareness, general distress, depression or anxiety - RT-CGM was not related to a lower number of SHEs
Baboun et al. (2023)[45]	United States	Cross-sectional study	T1D, Youth (<21 years mean age 12.9 ± 3.25 years)	–	CGM + MDI	SMBG + MDI	48/43	- CGM + MDI users had lower HbA1c (8.53 %) vs non-tech (9.60 %) (p=0.0296); 25 % achieved <7 % HbA1c; inverse correlation HbA1c–TIR (R=-0.52).
Hood et al. (2025)[46]	United States	Prospective single-arm; 6–12 months	T1D & T2D, Adults	7.7 % (T1D)	rtCGM + Virtual care	–	160 (T1D) 74 (T2D)	- HbA1c improved from baseline to 6 months 7.7 to 7.1 (-0.6 %)
Wood et al. (2018)[10]	Australia	Narrative review	T1D & T2D, Adults & Paediatric	–	rtCGM	SMBG	–	rt-CGM consistently lowers HbA1c (≈0.3–0.5 % absolute) and reduces hypoglycaemia in type 1 diabetes (DIAMOND, JDRF trials).
Health Quality Ontario (2018)[3]	Canada	HTA	T1D, Adults and Paediatric	–	rtCGM (Various)	SMBG	–	- CGM increased time in target range by 9.6–10 % - Reduced time in hyperglycaemia and hypoglycaemia Severe hypoglycaemia fewer in CGM groups - A1C modestly reduced, but most remained >7 %
isCGM								
Ang et al. (2020)[47]	United Kingdom	Narrative Review	T1D & T2D, mostly adults, some paediatric	Range 7.4 - 8.5 %	isCGM	SMBG	–	- HbA1c reduced (≈ -0.23 % to -0.9 %) Higher reduction in cohorts with higher HbA1c - ↓time < 70 mg/dL - QoL and treatment-satisfaction improved
Nana et al. (2019)[31]	United Kingdom	Retrospective observational	T1D, Adults mean age 45	8.7 %	isCGM for ≥4 months	Baseline (pre-isCGM) values	90 (total sample)	- Mean HbA1c reduction of 0.7 % (p < 0.001) - Hypoglycaemia episodes ↓ 51.86 % (p < 0.001) - A longer duration of diabetes diagnosis was significantly associated with better HbA1c
Alshehri et al. (2025)[28]	Saudi Arabia	Retrospective observational, pre–post	T1D, Adolescents 12–19 yrs,	9.48 ± 2.22 %	isCGM	SMBG	73 (total sample size)	- Mean HbA1c was significantly reduced to 9.06 ± 1.91 %, average decrease of −0.42 ± 1.37 %, p = 0.011
Charleer et al. (2023)[30]	Belgium	Real-world prospective observational cohort study, 24 months	T1D, Adults Cohort 1: Impaired awareness of hypoglycaemia (IAH)	IAH: 7.7 ±1.1 % NAH: 7.9 ±1.2 %	isCGM	None (pre- vs post-implementation)	1905 (total sample)	- HbA1c after 24 months: IAH: 7:8; NAH: 7:7 - Treatment-satisfaction improved in both cohorts; severe hypoglycaemia fell from 36.4 % to 16.0 % of events (p < 0.001)

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
			Cohort 2: normal awareness of hypoglycaemia (NAH)					
Aggarwal et al. (2022)[48]	India	Systematic literature review (26 clinical & 12 economic studies)	T1D & T2D, Adults & Paediatric	–	rtCGM, isCGM	SMBG	–	- HbA1c ↓ 0.5-0.7 % (MILLENNIAL study, others) - Hypoglycaemia events ↓53 % - Lower ER/hospitalisation rates
Castellana et al. (2020)[27]	Italy	Systematic review & meta-analysis	T1D & T2D, Adults & Paediatric	Type 1 studies range: 7.4 -8.5 ± 1.0 % Mean ~ 7.82 %	isCGM	SMBG	–	- Mean HbA1c ↓ 0.23 % across T1D studies - Overall↓ 0.60 h/day TBR (<3.9 mmol/L)
Health Quality Ontario (2019)[24]	Canada	HTA	T1D & T2D, Adults & Paediatric	–	isCGM	SMBG	–	- +1.0 h/day in target glucose range (95 % CI 0.41–1.59) - –0.37 h/day in hyperglycaemia (95 % CI –0.69 to –0.05) - –1.24 h/day in hypoglycaemia (95 % CI –1.71 to –0.77) - HbA1c change: minimal overall; some studies showed –1.29 % in MDI subgroup
CADTH Health Technology Review (2021)[26]	Canada	HTA	T1D & T2D, Adults	Range 8.2 -10.8 %	isCGM	SMBG	–	- Some studies showed significant HbA1c reductions; others showed no change. - In one study, TBR (< 3.9 mmol/L) reduced by -0.72 h/day on average (statistically significant), another study found no significant reduction - QoL and treatment-satisfaction scores improved significantly
Bidonde (2017)[25]	Norway	Systematic review	T1D & T2D, Adults & Paediatric, insulin dependent	–	isCGM	Any other glucose-monitoring system or conventional SMBG	–	- Little or no difference in HbA1c level in comparison to SMBG - Little or no difference in QoL - Little or no difference in serious adverse events - may slightly improve treatment satisfaction, TIR (3.9 to 10 mmol/L), number of nocturnal events with glucose levels <3.1 mmol/L within 7h, and time spent with glucose levels >13.0 mmol/L in comparison to SMBG

4.1.1.2 Continuous Subcutaneous Insulin Infusion and Sensor Augmented Pump

Across the 19 included studies evaluating clinical outcomes of insulin delivery technologies, both CSII and SAP therapy were associated with improvements in glycaemic control. Although, the magnitude and consistency of these effects varied by population, study design, and technology configuration (Table 5).

CSII was examined in 14 studies, including RCTs, prospective comparative studies, and real-world cohorts. HbA1c reductions with CSII ranged from modest to substantial, with the effect size often proportional to baseline glycaemic control. The largest HbA1c improvements were reported in high-risk or underserved paediatric populations. In an observational study on paediatric population over 24-months in China, a large decrease in HbA1c from 12.68 % to 7.79 % (Δ = –4.9 %) was observed in the first year, although the mean difference between the CSII and MDI cohort was 0.73 %. During the second year, a rise in both cohorts was noted but there remained an even larger difference of 0.87 % between cohorts [49]. In a retrospective audit in underprivileged rural children in India, a reduction from 10.42 % to 7.5 % (Δ = –2.9 %) within 12 months was reported [50]. The 2018 UK based SCIPI RCT reported an approximate 4 % reduction in HbA1c in both the CSII and MDI groups, with no significant difference between them at 12 months among newly diagnosed children [51]. These three studies showed the most dramatic drop in mean HbA1c from baseline to post intervention. A multi country observational study found a difference of 0.5 % between the CSII users and MDI users in paediatric cohorts, while another reported a low difference of 0.18 % between the cohorts [52,53]. Furthermore, a study with a population of young adults noted a median difference of 1.5 % [54].

There were five studies on T1D Adult populations which reported a baseline and a post-CSII HbA1c (Paediatric studies were left out as high HbA1c drops were reported due to newly diagnosed cohorts; and to provide a clearer insight on adult HbA1c outcomes). The mean HbA1c reduction was 0.35 % ±0.27 %, with the highest reduction noted being 0.76 % by the 2017 UK REPOSE trial which had a relatively high baseline of 9.3 % (Table B3 in Appendix B). The RCT duration was 2 years, with HbA1c reported at the 6-, 12-, and 24-month mark, and all participants received structured dose adjustment for normal eating (DAFNE) education. While there was a drop in both the intervention and control cohorts, the CSII group showed modestly lower HbA1c scores. The study noted that CSII was not superior to MDI when both were combined with structured education based on the based on the 2 year mean HbA1c difference of 0.43 % between the groups [55]. A cross-sectional comparison study in China found that adults using CSII had a lower mean HbA1c compared with matched MDI users (7.19 % ± 1.33 % vs. 7.71 ± 1.93 %, ,p = 0.045), indicating a modest but statistically significant improvement with CSII [56]. A retrospective study in the UK reported a median HbA1c reduction of 0.5 % (from 8.5 % to 8.0 %) within the first year of CSII use [57]. Although a 3-arm RCT showed a modest 0.2 % drop in HbA1c among CSII users, it also noted a greater proportion of CSII users achieving HbA1c ≤7.5 % [58].

In paediatric populations, CSII was generally associated with a reduction in both overall hypoglycaemia and SHEs. A matched cohort study reported significantly lower rates of SHEs in children using CSII compared to MDI (9.6 vs 13.9 events per 100 patient-years, Δ −4.42), and diabetic ketoacidosis (DKA) (3.6 vs 4.3 per 100 patient-years, Δ −0.63) [53]. A retrospective study of children from low-income rural settings observed a significant drop in overall hypoglycaemia episodes from 282 to 76, and in severe hypoglycaemia from 28 to 2 over 12-months. DKA episodes were reduced from 18 to 1 during the same period [50]. Another study using matched cohorts over a 2-year period found that SHEs decreased from 9.6 to 1.5 events per 100 patient-years in the CSII group, while it increased from 9.1 to 18.7 in the MDI group [49]. In contrast, an RCT involving newly diagnosed children and adolescents reported no statistically significant differences between CSII and MDI in rates of severe hypoglycaemia or DKA over 12 months [51].

In adult populations, the drop was less prominent. A 3-arm RCT noted a slightly lower occurrence of hypoglycaemia in the cohort using CSII than MDI. However, it was found that the likelihood of experiencing hyperglycaemia was significantly higher when using CSII than when using MDI [58]. Another study reported no change in CSII group but an increase in incidence in MDI group [59]. An RCT and Prospective controlled trial study both reported no change in hypoglycaemia incidence when using CSII, the RCT also noted a slightly higher DKA incidence in the CSII arm (17 vs 5 episodes) [37,55]. The Diamond RCT, which compared CSII and MDI in CGM users, reported a decrease in hyperglycaemia but an increase in hypoglycaemic events [34].

Studies on SAP showed larger reductions in HbA1c. 5 studies reported an average difference in HbA1c in the control group, with an average reduction of 0.83 % ±0.4 (Table B4 in Appendix B). There were two studies which covered both CSII and SAP technologies. A prospective controlled trial reported a drop of 1.1 % (8.2 % to 7.1 %) in SAP users compared to a drop of 0.5 % in CSII users [37]. Another cross-sectional study on T1D youth reported a difference of 1.54 % between SAP and MDI compared to a difference of 0.47 % between CSII and MDI [45]. Two retrospective studies reported a drop in mean HbA1c of 1.3 %, and a median drop of 1.35 % [60,61]. Figure 6 shows the HbA1c reduction relative to baseline for CSII and SAP technologies.

Three studies reported a drop in hypoglycaemic events in SAP users. A Colombia based observational study observed a reduction in severe hypoglycaemia from 32 % to 7.1 %, while another reported a decline in Nonsevere hypoglycaemia events (NSHE) from 20 to 4 episodes per patient-year, alongside significantly reduced hospitalizations and emergency room visits [60,61]. A study comparing CSII and SAP reported improvement in hypoglycaemia incidence only in SAP users (8 % → 6 %) [37]. A systematic review and meta-analysis reported no significant differences in severe hypoglycaemia among SAP users [1].

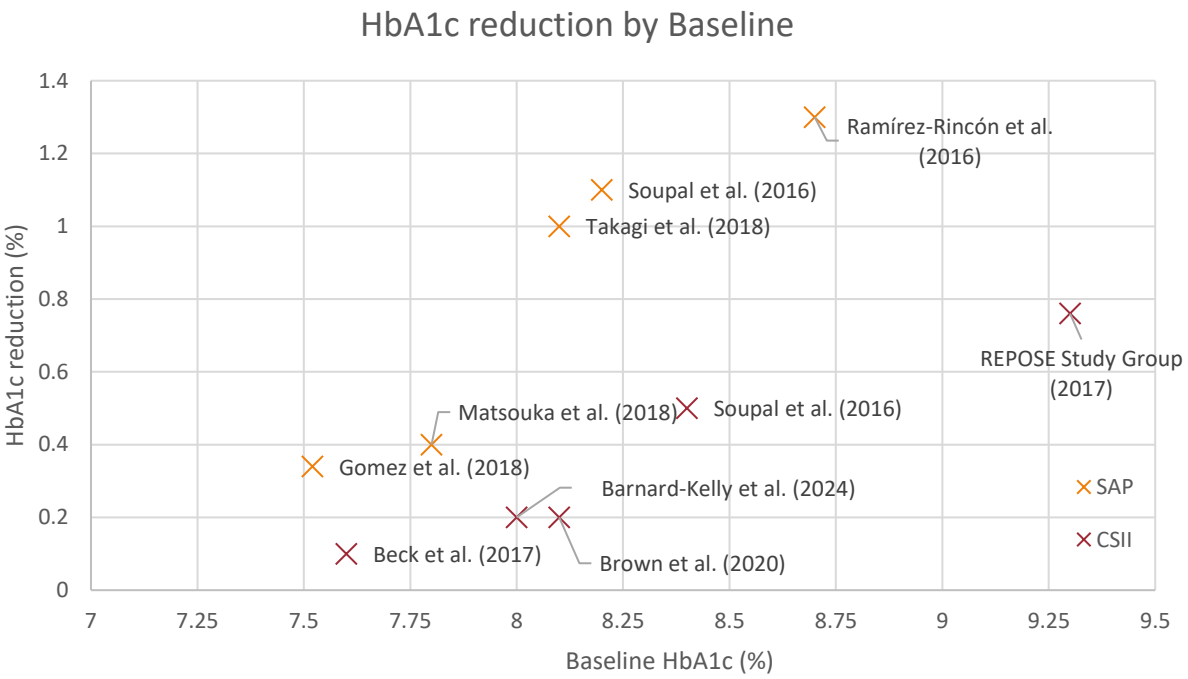

Figure 6 Change in HbA1c (%) relative to baseline HbA1c (%) for CSII and SAP studies

Table 5 Study characteristics and key clinical outcomes for CSII and SAP effectiveness studies

Author (Year)	Country	Study Design/Duration	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
Barnard-Kelly et al. (2024)[58]	Austria, Germany, Poland, UK	Prospective 3-arm randomized trial with partial cross-over	T1D, Adults, on MDI	MDI: 8.0 ± 0.5 CSII: 8.0 ± 0.6	CSII (Accu-Chek Solo; Omnipod)	MDI (then cross-over to Solo at week 26 to 39)	181 randomized: 61 MDI, 62 Solo, 58 Omnipod; 142 completed	- HbA1c: +0.2 % MDI vs −0.2 % Solo (P=.009) and −0.1 % Omnipod (Omnipod vs Solo NS) - More participants met HbA1c ≤7.5 % with pumps (36 % Solo, 33 % Omnipod) vs MDI (21 %) - number of hypoglycaemia events (serious events) was 22.6 (0.03) per year of use for MDI, 23.1 (0.07) for Solo, and 7.1 (0.08) for Omnipod - Probability of hyperglycaemia was significantly higher when using Solo but did not differ significantly with Omnipod
Karges et al. (2017)[53]	Germany, Austria, Luxembourg (DPV registry)	Population-based cohort with propensity score matching	T1D, children/adolescents	–	CSII	MDI (≥4/day)	Matched 9,814/9,814	- HbA1c 8.04 % vs 8.22 % (Δ −0.18 %) - Severe hypoglycaemia 9.55 vs 13.97/100 patient-years (Δ −4.42) (pump 1000 events vs MDI 1371) - Hypoglycaemia coma 2.30 vs 2.96 (Δ −0.66) (233 vs 287 events) - DKA 3.64 vs 4.26 (Δ −0.63) (389 vs 453 events) - Severe DKA 2.29 vs 2.80 (Δ −0.50) (246 vs 296 events)
Brown et al. (2021)[62]	Canada	Retrospective observational cohort with propensity-score matching (Omnipod vs. MDI)	T1D, Adults	Omnipod: 8.1 MDI: 8.2	CSII (Omnipod tubeless)	MDI	179 Omnipod initiators; 1482 MDI users; matched analysis: 143 per arm	- Mean HbA1C reduction–3 ±10mmol/mol (-0.2 %) vs. no change with MDI; - drop (-1.4 %) only in participants with baseline HbA1c ≥ 9 % -Weekly hypoglycaemia incidence unchanged in Omnipod (1.2 ± 1.6 vs 1.1 ± 1.6 events); increased in MDI (1.5 ± 1.7 vs 1.1 ± 1.4, p = 0.04)
Hu et al. (2021)[49]	China	Retrospective matched cohort + model-based CUA (CORE)	T1D, children/adolescents	CSII: 12.68 % ± 3.03 MDI: 12.97 % ± 2.81	CSII	MDI	104/104	- Mean HbA1c after 1 year: CSII: 7.79 ± 1.87 % n=70 MDI: 8.52 ± 2.03 % n=53 - Mean HbA1c after 2 years: CSII: 8.1 ± 0.7 % n=59 MDI: 8.97 ± 2.4 % n=33 - 47.14 % of the CSII patients achieved HbA1c <7.5 % - Severe hypoglycaemia decreased from 9.6 events/100-patient-years at baseline to 1.5 events/100 in CSII - increased from 9.1 events/100-patient-years at baseline to 18.7 events/100 in MDI
Blair et al. (2018)[51]	United Kingdom	Pragmatic multicentre open-label RCT with economic evaluation	T1D, Paediatric; Newly diagnosed, 7 months–15 years	CSII: 11.7 % MDI: 11.5 %	CSII	MDI	144/149 143/144 completed	- HbA1c at 12 months: 7.7 (CSII) vs 7.5 (MDI) - Achievement of HbA1c >7.5 % was low among the two groups (66/143 (46 %) CSII participants 78/142 (55 %) MDI participants - Incidence of severe hypoglycaemia and DKA were low in both groups. - QoL was slightly higher for those randomised to CSII
Paisley et al. (2019)[57]	United Kingdom	Retrospective multi-centre cohort	T1D, Adults, on CSII, median age 39 years	Median 8.5 %	CSII	Pre-CSII status (no parallel control)	693 (total sample)	- Post-CSII HbA1c median 8.0 %. Δ −0.5 % within first year of CSII - higher pre-CSII HbA1c was significantly associated with higher social deprivation (P = 0.036)
Yu et al. (2024)[56]	China	Propensity-score matched cross-sectional comparison	T1D, Adults, on same regimen ≥12 months	–	CSII	MDI	102/102 Matched	- HbA1c 7.19 %±1.33 (CSII) vs 7.71 %±1.93 (MDI), p=0.045 - total score of ITR-QOL-CV scale in CSII group was higher than MDI group (87.08 ± 13.53 vs. 80.66 ± 19.25, P = 0.006) - FoH lower with CSII (8.33±3.49 vs 11.77±5.27, P=0.003)
Swaminathan (2023)[50]	India	Retrospective audit, pre–post	T1D, Paediatric from below-poverty-line families	10.42 % (after ≥6 months on MDI)	CSII + isCGM (Medtronic pump; Libre)	Pre-CSII period on MDI (self-controlled)	50 (total sample)	- HbA1c at 3 months: 8.2 %, at 6 months: 7.9, and at 12 months 7.5 % - DKA episodes reduced 18→1 after 1 year - Hypoglycaemia episodes reduced 282→76 - Severe hypoglycaemia 28→2 (all $p \leq 0.01$)

Author (Year)	Country	Study Design/Duration	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
McKee et al. (2021)[54]	United States	Retrospective electronic Health record (HER) cohort (Medicaid)	T1D, Young adults, 18–30 y	–	CSII	MDI or fixed-dose insulin (FDI)	105/700	- At 19–24 months: median HbA1c CSII 8.0 % (IQR 7.3–10.1) vs MDI/FDI 9.5 % (8.0–11.6), P=0.021 - DKA hospitalization 31.4 % CSII vs 25.1 % MDI/FDI, NS - non-White patients lower odds of CSII; endocrinology follow-up higher odds of CSII and DKA admissions
REPOSE Study Group (2017)[55]	United Kingdom	Cluster randomized trial (parallel group, Pragmatic RCT) 2-year duration	T1D, Adults mean age 39 y; all received structured DAFNE education	Pump treatment: 9.3 % ±1.9 % CSII treatment: 9 % ±1.4 %	CSII + DAFNE	MDI + DAFNE	128/120 (24 month follow up)	- **Mean HbA1c change at 6 months for participants with Baseline ≥7.5:** Pump: -0.76 ; MDI: -0.36 - **Mean HbA1c change at 12 months:** Pump: -0.70 ; MDI:-0.4 - **Mean HbA1c change at 24 months:** Pump: -0.85 ; MDI: -0.42; Adjusted Difference in HbA1c Change at 24 Months: -0.24 % (favouring pump, P=0.10) - **Proportion reaching HbA1c ≤7.5 % at 24 Months:** Pump: 25.0 % MDI: 23.3 % - Severe hypoglycaemia rate reduced across both groups, but no statistically significant difference between groups over 24 months - DKA incidence greater in the pump group (17 vs. 5 episodes)
Sherr et al. (2016)[52]	USA, Germany/Austria, UK	Registry-based observational comparison (DPV, T1D Exchange, NPDA)	T1D, Paediatric	DPV: 8.0±1.6; T1DX: 8.3±1.4; NPDA: 8.9±1.6	CSII	Multiple daily injections	~18,000 pump users ~36,000 MDI users	Pump use associated with significantly lower HbA1c (8.0±1.2 vs 8.5±1.7, p<0.001)
Baboun et al. (2023)[45]	United States	Cross-sectional study	T1D, youth (<21 years; 79 % Hispanic, 17 % Black; mean age 12.9 ± 3.25 years)	–	CSII + SMBG	SMBG + MDI	11/43	- HbA1c 9.13 % vs 9.60 % (p=0.6014) - 27 % achieved <7 % HbA1c
Soupal et al. (2016)[37]	Czech Republic	Prospective controlled trial	T1D, Adults	8.4 ± 0.8	CSII	MDI	20/18	- At 12 months, Intervention group reduced HbA1c from 8.4 % to 7.9 % - MDIs alone showed no significant HbA1c change - Hypoglycaemia incidence unchanged
Beck et al. (2017)[34]	United States	Randomised controlled trial, 28-weeks	T1D, Adults	CSII + CGM: 7.6 ±0.7 MDI + CGM: 7.6 ±0.9	CSII + CGM	CGM + MDI	36/35	- Among participants with baseline hbA1c ≥ 7.5, mean difference was -0.1 % in CGM + CSII group (n=22), and +0.1 % in CGM + MDI group (n=18) - Mean TIR was 791 min per day (SD 157) in the CGM + CSII group and 741 min per day (225) in the CGM + MDI group (adjusted mean treatment group difference: 83 min, 95 % CI 17–149; p=0·01) - Participants in the CGM + CSII group had a greater reduction in mean glucose (p=0·005) and hyperglycaemia, but also an increase in hypoglycaemia
SAP								
Ramírez-Rincón et al. (2016)[60]	Colombia	Observational retrospective cohort (real-world)	T1D majority (94.5 %), Adults & Youth mean age 32 ± 15 y	8.7 % ± 1.7	SAP	Pre-CSII care (mixed; no concurrent control arm)	183 (total sample)	- HbA1c 7.4 % ± 0.8 at 12 months (−1.3 %) - severe hypoglycaemia 32 %→7.1 % - Hospital admission 16.5 %→6.0 %
O'Meara et al. (2023)[61]	Colombia	Retrospective cohort; median 4-year follow-up	T1D majority (95 %), Adults median age 36	median 8.35 (IQR 7.3–9.8)	SAP (Medtronic Paradigm Veo/640G/670 G with CGM)	Prior SMBG+MDI	74 (total sample)	- Median HbA1c decreased from 8.35 % to 7.0 % (p<0.001) - Nonsevere hypoglycaemia reduced (20→4 events/patient-year, p<0.001) - Hospitalizations reduced (50 %→14 %, p<0.001) - ER visits reduced (58 %→6 %, p<0.001)
Pease et al. (2020)[1]	Multinational (Europe, US, Canada, UK, Australia)	Systematic review and network meta-analysis (52 RCTs; ≥6 weeks)	T1D, Adults	8.4 ± 0.8	SAP	MDI + SMBG; CSII + SMBG; MDI + FGM	3,975 total participants across 52 studies	- Integrated systems (SAP with LGS or HCL) reduced HbA1c by –0.96 % vs MDI + FGM and –0.87 % vs MDI + SMBG - QoL improvements modest - Severe hypoglycaemia differences not significant.
Soupal et al. (2016)[37]	Czech Republic	Prospective controlled trial	T1D, Adults	8.2 ± 0.9	SAP	SMBG + MDI SMBG + CSII	15/18 15/20	- At 12 months, Intervention group reduced HbA1c from 8.2 % to 7.1 % (p < 0.0001); SAP and MDI + rtCGM subgroups comparable - MDIs alone showed no significant HbA1c change - Hypoglycaemia incidence fell only in SAP cohort (8 % → 6 %, p<0.01)

Author (Year)	Country	Study Design/Duration	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
Baboun et al. (2023)[43]	United States	Cross-sectional study	T1D, youth (<21 years; 79 % Hispanic, 17 % Black; mean age 12.9 years)	–	SAP	SMBG + MDI	38 / 43	- HbA1c 8.06 % vs 9.60 % (p=0.0016) - 13 % achieved <7 % HbA1c - TIR inversely correlated with HbA1c (R=-0.81).
Gomez et al. (2018)[17]	Colombia	Prospective before–after; 3 months	T1D, Mostly Adults mean age 37.9 (IQR 6–79)	7.52 ± 1.11	SAP (MiniMed 640G SmartGuard)	pre-SAP care	55 / –	- HbA1c was 7.18 % ± 0.91 % at 3 months follow-up after initiation of SAP (mean difference: –0.34) - Severe Hypoglycaemia rate decreased from 2.47 (CI 0.44, 4.90) to0.87 (CI 0.22, 1.52) events/patient-year - 15 patients (27.8 %) achieved A1c less than 7 %
Matsouka et al. (2018)[63]	Japan	Observational before–after; 12 months	T1D, adults; mean age 41.2 ± 16.9	7.8 ± 1.0	SAP (MiniMed 620G)	CSII	18 / –	- HbA1c dropped from 7.7 ± 0.9 % at 6 months and 7.4 ± 0.9 % at 12 months
Takagi et al. (2022)[64]	Japan	Observational before–after; 24 weeks	T1D, adults mean age 42	8.1 ± 0.3	SAP (MiniMed 640G)	Pre-SAP therapy (CSII or MDI + SMBG)	20 (total sample)	- HbA1c dropped from 8.1 ± 0.3 to 7.4 ± 0.3 at 3 months and to 7.1 ± 0.3 at 6 months - TBR increased from 5.0 ± 1.2 to 6.8 ± 1.2 at 3 months and 6.3 ± 1.3 at 6 months - TIR increased from 62.7 ± 3.3 to 67.2 ± 3.3 at 3 months and 68.5 ± 3.3 at 6 months

4.1.1.3 Advanced/Hybrid-Closed Loop System

Across nearly all included studies, the use of HCL and AHCL systems resulted in improvements in HbA1c and TIR, regardless of comparator group. Table 6 summarises the characteristics and key results of the 13 studies.

Six studies reported HbA1c reduction values, the mean reduction was 0.79 % ±0.5 %, with a median of 0.6 % (All included studies in Table B5 in Appendix B). The largest effect was observed in the 2022 multi-country ADAPT RCT, where AHCL users experienced a 1.54 % reduction, compared to a reduction of 0.2 % in the MDI + isCGM cohort [65]. The 12-month continuation of the ADAPT trial supported these findings, where individuals who switched from MDI + isCGM to AHCL experienced a further HbA1c reduction of 1.4 % within 6-months, while those continuing AHCL maintained control (change +0.1 %, not significant) [66]. Figure 7 shows the HbA1c baseline and reduction across different studies. In a real-world pre–post cohort study of adults with a mean baseline HbA1c of 7.7 %, AHCL use led to a 0.6 % reduction in HbA1c and a corresponding 13.8 % increase in TIR (from 49.5 % to 63.3 %) [67]. A 12-month observational study compared groups who use 'auto mode'(where the system automatically adjusts insulin) to those who discontinued 'auto mode,' at the 12-months mark, the average HbA1c was 7.6 % ±0.8 % and 8.3 % ±1.2 %, respectively [68]. A prospective study of adults newly initiating AHCL after MDI + SMBG reported a HbA1c reduction of 0.6 % over 12 months, and TIR maintained between 83.2–84.8 %. It was also noted that 83.3 % of participants had HbA1c level in recommended range (< 7 %) [69]. In children aged 2–6 years, a 12-week prospective study found a modest HbA1c reduction of 0.3 %, accompanied by a TIR increase of 8.3 % [70]. Another prospective study found an increase of 7.7 % in TIR over 6-weeks of AHCL use in paediatric patients [71].

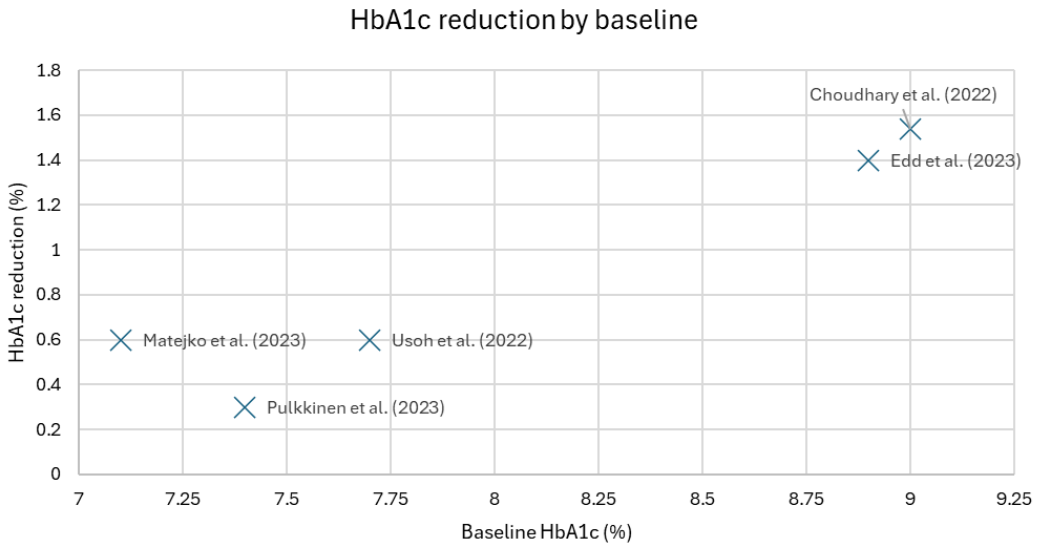

Figure 7 change in HbA1c (%) relative to baseline HbA1c (%) for HCL/AHCL

Some studies did not report on HbA1c but on TIR. In a prospective real-world analysis of over 100,000 users of MiniMed 780G (AHCL system) across Europe, the average TIR was 72.3 %, and

TBR was 2 % [72]. In a large observational study of Control-IQ (AHCL) users, the median TIR in adults was 70.1 %, and severe hypoglycaemia dropped significantly [73]. 7 papers reported baseline and post-intervention TIR, all reported an increase of TIR with a mean of 12.3 % ±10.3 %, shown in Figure 8.

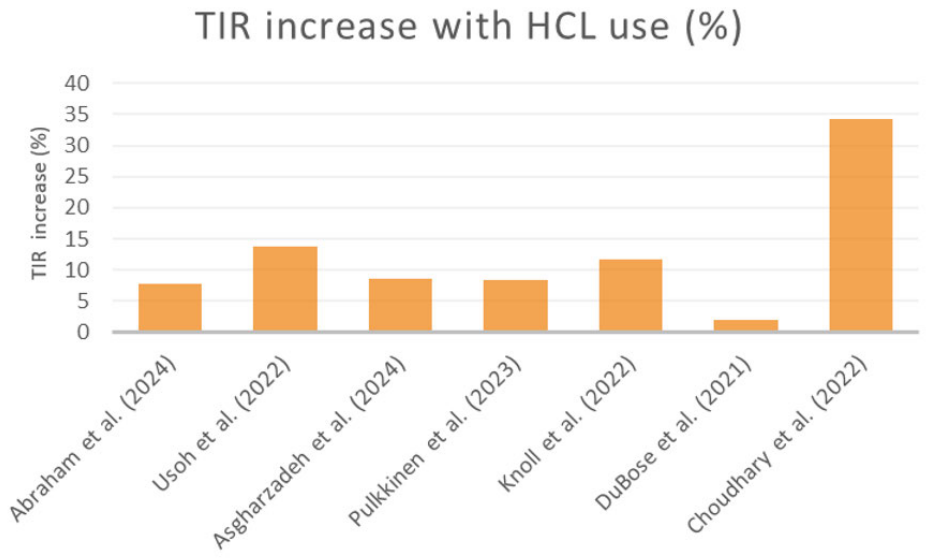

Figure 8 Reported TIR increase by study

Hypoglycaemia (TBR)

Two studies demonstrated a significant decrease in TBR: a real-world cohort reported a reduction from 4.0 % to 1.7 % (Δ 2.3), while a pilot study observed a −0.4 % change after 8-weeks of AHCL use following transition from SAP [67,74]. In a paediatric cohort, TBR of 3.0 %, and severe hypoglycaemia (<3.0 mmol/L) of 0.63 % were reported [71]. The 2024 United States CLIO study reported significantly lower SHEs in adults compared to historical controls (9.77 vs 29.49 per 100 Patient Year) [73]. Two studies reported no significant change in TBR, including a paediatric study and HTA review [18,70]. Only one study reported a marginal increase in TBR (from 2.2 % to 2.6 %) in the AHCL group of the RCT [65].

Hyperglycaemia (TAR)

The largest TAR reduction was observed in an RCT, where it decreased from 61.3 % to 26.7 % (Δ 34.6 %), in AHCL users. A real-world cohort documented a drop from 46.8 % to 34.9 % (Δ 11.9 %), and a paediatric prospective study reported an 8.6 % reduction [67,70]. An HTA review also found a mean TAR reduction of 7.2 % [18].

Table 6 Study characteristics and key clinical outcomes for HCL/AHCL effectiveness studies

Author (Year)	Country	Study Design/Duration	Diagnosis, Age	Mean Baseline HbA1c (%)	Intervention	Control	Sample Size (I/C)	Key Results
Choudhary et al. (2024)[72]	34 EMEA countries	Real-world CareLink analysis; Aug-2020–Aug-2023	T1D, Adults & Paediatric	–	AHCL (MiniMed 780G)	–	101,629 (total sample)	- Mean TIR 72.3 % - Mean TBR (<3.8 mmol/L) 2.0 % - In "optimal settings" (TIR = 78.8 %, and users reaching TIR >70 % = 86.3 %) while safety remained (Time below range (< 3.8 mmol/L) = 2.2 % and TBR (< 2.9 mmol/L) = 0.4 %). - longitudinal cohort TIR ≥73.3 % across 12 months
Abraham et al. (2024)[71]	Australia	Prospective single-arm pilot; 2-week manual mode then 6-week AHCL	T1D, Paediatric	–	AHCL (MiniMed 780G)	Manual-mode baseline (within-subject)	10 (total sample)	- TIR (3.0-10.0 mmol/L) 64.9 % ±10.4→ 72.6 % ±7.4 % - TBR < 3.9 mmol/L = 3.0 % ±1.74 % ; TBR < 2.9 mmol/L = 0.63±0.46 %
Usoh et al. (2023)[67]	United States	Real-world pre–post cohort in endocrine clinic	Majority T1D (92.4 %), Adults, mean age 42	7.70 %	AHCL (t:slim X2 Control-IQ)	Pre-Control-IQ on CSII or MDI	66 (total sample)	- HbA1c 7.7 %→7.1 %P <0.017) (–0.6 %) - TIR 49.5 %→63.3 % ; TBR 4.0 %→1.7 % ; TAR 46.8 %→34.9 %
Asgharzadeh et al. (2024)[18]	United Kingdom	Health Technology Assessment	T1D, Adults & Paediatric	–	HCL/AHCL	CSII + CGM (90 % CSII+isCGM; 10 % CSII+rtCGM)	–	- HCL reduced HbA1c by −0.28 % (95 % CI −0.34, −0.21); - TIR +8.6 % (95 % CI 7.03, 10.22) - TAR -7.2 % (95 % CI -8.89, -5.51) - Did not significantly affect per cent of TBR
Pulkkinen et al. (2023)[70]	Finland	Open-label prospective; 12-week AHCL	T1D, Paediatric	7.4 % ±2.8 % (57.2 mmol/mol)	AHCL (MiniMed 780G)	Historical matched controls (various)	35/35	- From 0→12 weeks: HbA1c mean change −2.7 mmol/mol (~-0.3 %) - TIR +8.3 % (P<0.001) - TAR −8.6 % (P<0.001); - TBR no significant change - PAID-PR (problem areas in diabetes survey) 37.5→27.5 (P=0.006); no DKA/SHE
Lal et al. (2019)[68]	United States	Prospective observational; 12 months	T1D, Adults & Paediatric	Total sample: 7.9 ±1.4 Age < 18: 8.3 ±1.7 Age ≥ 18: 7.8 ±1.2	HCL (Medtronic 670G AutoMode)	Pre-AutoMode	79 (total sample) 56 included in final analysis 30/26	- Baseline TIR improved among active users - Baseline HbA1c vs 12 months for AutoMode user: 7.7 ± 1.1 ; 7.6 ±0.8 vs discontinued: 8.3 ± 1.7 unchanged - By 12 months, 33 % discontinued AutoMode; sensor issues 62 % of discontinuations - Significant correlation HbA1c with AutoMode use; usability factors prominent.
Matejko et al. (2023)[69]	Poland	Prospective 12-months follow-up	T1D, Adults switching from MDI + SMBG	7.1 ± 0.8 %.	AHCL (MiniMed 780G; Guardian 3 → Guardian 4 at Month 6)	Pre-switch baseline (MDI + SMBG)	18 (total sample)	- HbA1c at 3 months: 6.8 ± 0.4 %.; At 6 months: 6.6 ±0.6 %.; At 9 months: 6.2 ±0.4 % (p < 0.001); At 12 months: 6.5 ± 0.5 % (P < 0.001) - 83.3 % (N = 15) of participants have HbA1c level in recommended range (<7 %). - TIR maintained 83.2–84.8 % over 12 months.
Knoll et al. (2022)[73]	Germany	Systematic review (21 studies, 2018–2021)	T1D, Adults & Paediatric	–	HCL	Varied pre-HCL (MDI, CSII, SAP)	–	- Mean HbA1c decreased across studies with a mean HbA1c reduction of -0.55 % (-0.2 to -1.5) - Mean TIR (3.9–10.0 mmol/L) rose across studies with a mean of 11.6 % increase (4.4 to 26.5)
Graham et al. (2024)[73]	United States	Single-arm prospective post-market surveillance; 12 months	T1D, Adults & Paediatric starting Control-IQ (t:slim X2)	–	AHCL (Control-IQ)	Historical data	3,157 enrolled; 2,998 completed safety follow-ups	- Severe Hypoglycaemia significantly lower vs historical (adults 9.77 vs 29.49/100 Patient Year; children 9.31 vs 19.31/100 Patient Year). - Median TIR for adults 70.1 % (61.0–78.8); 60.9 % (50.1–71.8) for age 14–17; and 67.3 % (57.4–76.9) overall
DuBose et al. (2021)[76]	United States	Multicenter observational cohort; 12 months	T1D, Adults & Paediatric initiating 670G as usual care	66 % TIR at baseline in CGM subset	HCL (MiniMed 670G Auto Mode)	Pre-initiation usual care	132 initiated Auto Mode; 80 persisted to 12 months	- Among n=27 with full CGM data: TIR 66 % baseline → 74 % at 6 months → 68 % at 12 months - FoH decreased (participants −6; parents −11); - More than half reported issues with sleep interruption at night due to alarms and 40 % did not like frequent exits from Auto Mode.
Bisio et al. (2021)[77]	United States	Pilot crossover study (SAP→AID); 8 weeks	T1D, Older Adults, ≥ 65, mean 68.7	7.0 ± 0.8 TIR: 69.6 % Median TBR: 1.1 %	AHCL	SAP (same participants pre-AID)	15 (total sample)	- TIR ↑ +10 % with AID (79.6 %, p=0.002). - TAR (>180 mg/dL) decreased −6.9 % (p=0.005) ; TBR (< 70 mg/dl) decreased −0.4 %, (P = .053) - HbA1c Distress reduced
Edd et al. (2023)[66]	Multinational	RCT with 6-months main phase + 6-months continuation	T1D, Adults 2 cohorts:. **SWITCH**: crossing from MDI + isCGM to AHCL **SUSTAIN**: continuing AHCL	At 6 months: - SWITCH 8.9 % - SUSTAIN 7.3 %	AHCL (MiniMed 780G)	MDI + isCGM (first 6 months only for SWITCH arm)	SWITCH n=39; SUSTAIN n=36	- SWITCH cohort 6→12 months: HbA1c −1.4 % to 7.5 % ± 0.6 (P<0.001). - SUSTAIN cohort 6→12 months: HbA1c +0.1 % to 7.4 % ± 0.8 (non-inferior). - Main phase showed AID HbA1c 7.3 % vs MDI + isCGM 8.9 % at 6 months - TIR markedly higher with AHCL - Three SHEs in two SWITCH participants.
Choudhary et al. (2022)[65]	France, Germany, UK	Randomised controlled trial / 6 months	T1D, Adults	9.0 (AHCL), 9.07 (Control)	AHCL (MiniMed 780G)	MDI + isCGM	41 / 41	- HbA1c decreased by 1.54 % in AHCL group, and 0.2 % in MDI + isCGM group; Model-based treatment effect: −1·42 (−1·74 to −1·10; p<0·0001) - TIR in AHCL cohort: 36·4 % (13·60) →70·6 % (9·70); TIR in MDI cohort: 42·6 % (11·20)→43·6 % (15·37); Model-based treatment effect: 27·6 % - TBR in AHCL cohort: 2·2 % (2·12) →2·6 % (2·01); TBR in MDI cohort: 3·2 % (3·37)→2·6 % (2·55); Model-based treatment effect: 0.1 % - TAR in AHCL cohort: 61·3 % (14·71)→26·7 % (10·44); TBR in MDI cohort: 54·2 % (12·59)→53·8 % (16·47); Model-based treatment effect: −27·9 %

4.1.2 Cost-effectiveness

4.1.2.1 Continuous Glucose Monitors

A total of 21 studies assessing the cost-effectiveness of rtCGM and isCGM were found, with more studies focusing on rtCGM (12 vs 6), and 3 studies evaluating both technologies. Studies spanned various countries and payer perspectives, with most applying Markov-based models or the IQVIA CORE Diabetes Model. The majority compared CGM or isCGM to SMBG, with some also comparing CGM directly to isCGM. Interventions were evaluated over lifetime horizons in most studies, and discount rates typically ranged from 1.5 % to 5 %. The characteristics and key results of all CGM cost effectiveness studies are summarised in Table 7.

isCGM demonstrated favourable cost-effectiveness in all included studies. ICERs were consistently below national WTP thresholds, with values ranging from €5,839 to €34,025 per QALY and incremental QALY gains from 0.276 to 1.25. A study in Brazil reported an ICER of €9,721/QALY with 0.276 QALYs gained over one year. In Sweden, a study reported an ICER of €34,025/QALY over 50 years with 0.8 QALYs gained [78].

Six studies in total reported ICERs of isCGM vs SMBG, excluding a Canadian economic evaluation which did not report an ICER but found isCGM to be dominant over SMBG with a reported incremental cost of -€21,554, meaning the technology is cost saving [79]. The mean ICER of the six studies was €13,720 ±10,196. Six studies also reported QALYs gained with isCGM, excluding a Canadian based study which did not report on QALYs gained [80]. The mean QALYs reported was 0.8 ±0.4 (Table C1 in Appendix C). Systematic reviews reporting ICERs and QALYs in ranges were also excluded.

rtCGM was found to be cost-effective across multiple settings. Out of 15 studies including rtCGM: 11 studies found rtCGM to be cost-effective, two systematic reviews found that most reviewed studies judged it to be cost-effective. One systematic review and CUA, and a HTA study both found the technology not cost-effective. ICERs ranged from €6,119 to €4,038,805 per QALY, with most falling below national willingness-to-pay (WTP) thresholds. The 2018 DIAMOND RCT in the United States reported an ICER of €99,104/QALY, which dropped significantly to €33,799/QALY when extended sensor use was modelled (from 7 to 10 days), remaining below the reported WTP threshold of €101,015 [40]. In Canada, two economic evaluations yielded ICERs of €13,298 and €28,092 per QALY, with 2.09 and 3.35 QALYs gained respectively, both below the €41,570 WTP threshold [81,82].

10 studies on rtCGM comparing the technology with SMBG reported ICERs. The mean of which was €25,150 ± € 28,581, excluding a Spanish CEA and a Canada based HTA which were considered outliers. The mean QALYs gained was 1.63 ±0.82, excluding outliers and studies in which comparator was not SMBG (Table C2 in Appendix C) [80]. A Spanish economic study from the perspective of the Spanish National Health Service (NHS) reported a ICER per QALY of €3,810,593

with low incremental QALYs of 0.046 [83]. Other studies which were excluded were systematic reviews reporting ranges of ICERs and QALYs, and studies comparing rtCGM with technologies other than SMBG.

A CEA from Australia compared subsidised CGM to user funded CGM from the Australian healthcare system perspective. The reported ICER was €23,674 and Incremental QALYs was 0.46. The study reported subsidised CGM improved health outcomes and is cost-effective both over a 21-year horizon and a lifetime horizon [84]. A Canadian HTA compared rtCGM to SMBG, and rtCGM + CSII to SMBG + CSII, ICERs were € 898,808 and 631,207, respectively. Both were above the WTP threshold of around €40,000. Therefore, rtCGM was not cost-effective in either scenario [3].

Two studies compared rtCGM vs isCGM directly. A CUA in Denmark compared rtCGM to two different isCGM devices. The ICER was lower in both rtCGM vs isCGM analyses than in the rtCGM vs SMBG analysis (€4,818, €4,051, and €6,119 respectively), which were all below the reported WTP threshold. Reported QALYs were also lower in rtCGM vs isCGM than rtCGM vs SMBG, 1.37 vs 0.87. Both isCGM and rtCGM technologies were determined to be cost-effective [85]. Another study in Australia directly compared the two technologies, where ICER of rtCGM vs SMBG was €10,795, and rtCGM vs isCGM was not much higher at €11,655. QALYs were 1.19 and 0.569 for rtCGM vs SMBG, and isCGM respectively [86].

Figure 9 summarises the results of all studies which reported Incremental costs and QALYs comparing isCGM or rtCGM to SMBG, or to other technologies. Points below the €50,000 WTP line are considered cost-effective at this threshold. With the exception of the grey points, all studies compare CGM technologies against SMBG. Some studies appear twice on the graph if they included more than one technology. For example, a Canadian HTA study which compared rtCGM to SMBG and rtCGM + CSII to SMBG+CSII is represented twice as an orange point, and a grey point [3].

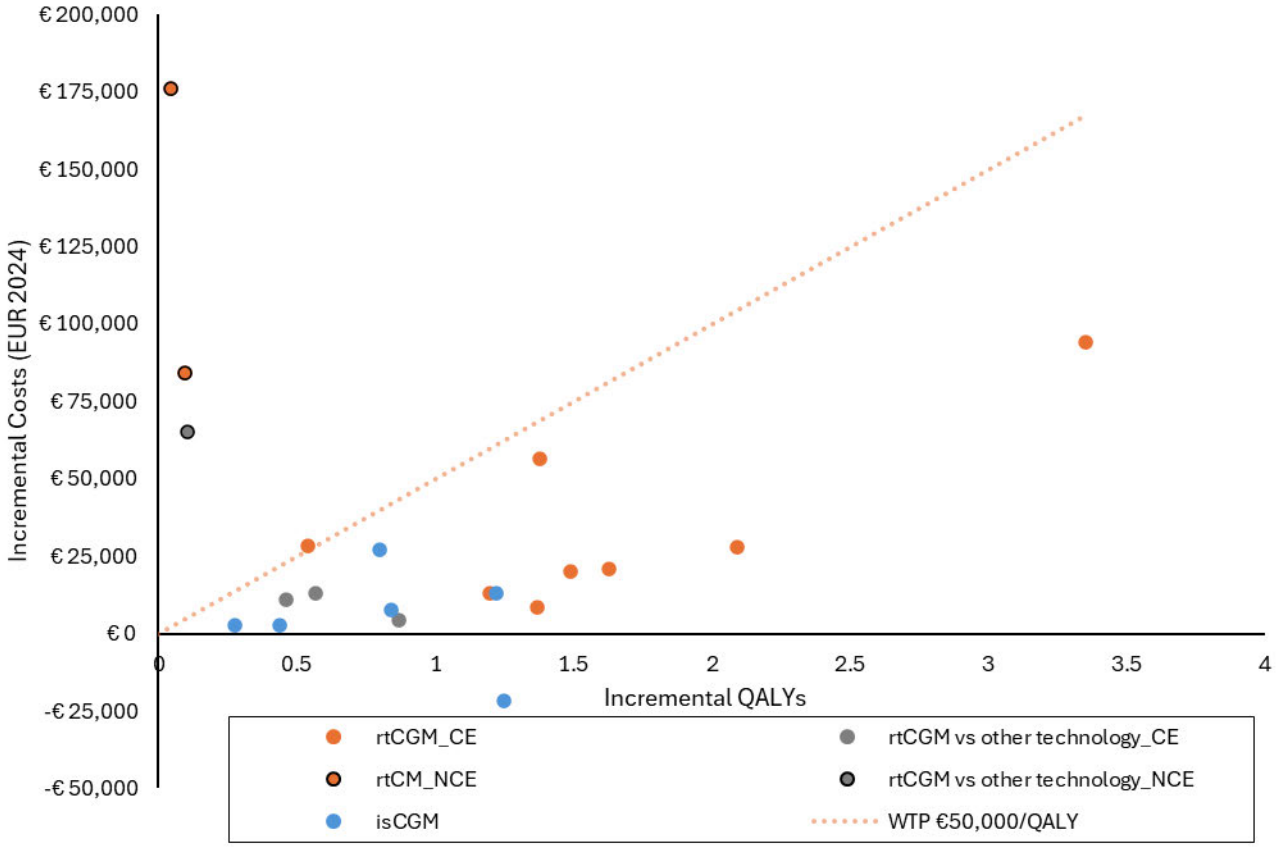

Figure 9 Cost-effectiveness plane presenting incremental Costs vs Incremental QALYs from included economic evaluations of rtCGM and isCGM. Orange markers represent rtCGM studies, blue markers represent isCGM studies, and grey markers represent studies on rtCGM in which the comparator was not SMBG. All costs were converted to 2024 EUR. The dashed line denotes a willingness-to-pay (WTP) threshold of €50,000 per QALY. CE: Cost-effective, NCE: Not Cost-effective

Table 7 Study characteristics and key outcomes for rtCGMs and isCGMs cost-effectiveness studies

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold (EUR)	Is Cost effective?
Jiao et al. (2022)[21]	Australia	Systematic review	T1D, Adults	CGM, SAP, HCL (varied)	SMBG, MDI, CSII (varied)	Healthcare system (varied)	lifetime	Mostly 3 %	–	- studies assessing CGM vs SMBG: €11,958 – €89,641.49	- studies assessing CGM vs SMBG: [0.54–3.35]	€25,161 - €104,837	17 of 19 studies: Yes
Lorenzo (2018)[83]	Spain	Systematic review + meta-analysis with economic modelling	T1D & T2D, Adults	rtCGM	SMBG	Spanish NHS	Lifetime	3 % per annum	€ 176,209.00	€ 3,810,593.00	0.046	€ 29,832 - 37,290	No, ICERs exceed WTP in all scenarios
Wan et al. (2018)[40]	United States	Open-label multicentre RCT	T1D, Adults	rtCGM (Dexcom G6)	SMBG	US healthcare payer	Lifetime	3 % (both costs and benefits)	€ 28,190.00	€ 99,104 - By extending sensor use from7 to 10 days in a real-world scenario, the ICER was reduced to € 33,799 per QALY.	0.54	€ 101,015.00	Yes
Chaugule et al. (2017)[82]	Canada	Health economic model using clinical trial data	T1D, Adults	rtCGM (Dexcom G6)	SMBG	Healthcare system	50 years	1.5 %	€ 94,225.00	€ 28,092.00	3.35	€ 41,570.00	Yes
Alshannaq et al. (2023)[85]	Denmark	Model-based economic evaluation	T1D, Adults & Paediatric, on MDI	rtCGM (Dexcom G6)	SMBG/isCGM (Free Style Libre 1&2)	Healthcare payer	50 years	4 % per annum	rtCGM vs SMBG: € 8,375 rtCGM vs isCGM1: € 4,201 rtCGM vs isCGM2: € 3,532	rt-CGM vs SMBG € 6,119 rt-CGM vs is-CGM1: € 4,818 rt-CGM vs is-CGM2: € 4,051	rt-CGM vs SMBG: ΔQALY = 1.37 rt-CGM vs is-CGM: ΔQALY = 0.87	€ 50,328.00	Yes
De Jong et al. (2024)[87]	Internati-onal	Systematic review of model-based and empirical cost-utility analyses	T1D, Adults & Paediatric	rtCGM/isCGM with various insulin administration devices	SMBG (or next-best alternative)	Various (Societal, Healthcare system, payer)	Various. (most studies included over lifetime horizon)	Various	-€ 18,996 to € 186,761	varying from dominant (cost saving with QALY gains) to € 4,038,805 per QALY. Most of the reported ICERs were either below € 41,562 per QALY (62 %) or below € 83,124 per QALY (75 %)	– 0.01 to 3.81	€ 83,124.00	majority judged cost-effecti ve
Roze et al. (2021)[81]	Canada	Model-based economic evaluation	T1D, Adults, mean age 47.6 years	rtCGM (Dexcom G6)	SMBG	public payer	50 years	1.5 % per annum (costs, outcomes)	€ 27,766.00	€ 13,298.00	2.09	€ 39,270.00	Yes
Molaee et al. (2024)[88]	Iran	Model-based economic evaluation	T1D, Adults, on MDI	CGM	SMBG	Payer	Lifetime	3 %	€ 20,954.00	€ 12,847.00	1.63	€ 14,541.00	Yes
Isitt et al. (2022)[86]	Australia	Model-based economic evaluation	T1D, Adults	rtCGM (Dexcom G6)	SMBG, isCGM	Healthcare Payer	Lifetime	5 %	CGM vs SMBG: €12,938 CGM vs isCGM: €6,628	€ 10,795 (SMBG) € 11,655 (isCGM)	1.199 (SMBG); 0.569 (isCGM)	€ 29,954.00	Yes
Roze et al. (2020)[89]	UK	Model-based economic evaluation	T1D, Adults	rtCGM (Dexcom G6)	SMBG	NHS health care payer	Lifetime	3.50 %	€ 20,083.00	€ 13,485.00	1.49	€ 28,218.00	Yes
Roze et al. (2021)[90]	France	Model-based economic evaluation	T1D, Adults	rtCGM (Dexcom G6)	SMBG	Healthcare payer	Lifetime	4 %	€ 56,703.00	€ 17,334.00	1.38	€ 56,703.00	Yes

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold (EUR)	Is Cost effective?
Pease et al. (2022)[84]	Australia	Model-based economic evaluation	T1D, Youth	CGM (Subsidised)	User-funded CGM	Australian healthcare system	Primary case: < 21 years Secondary case: lifetime extension	5 %	Primary: €10,905 Secondary: NA	Primary: €23,674 Secondary: €20,902	Primary: 0.46 Secondary: NA	€ 29,954.00	Yes
Rotondi et al. (2022)[80]	Canada	Model-based economic evaluation	T1D, Adults	CGM, isCGM	SMBG	single-payer health care system	20 years	1.50 %	–	CGM vs SMBG: € 25,274 isCGM vs SMBG: € 12,622	–	€ 36,088.00	Yes
Lin et al. (2021)[16]	Australia	Systematic review of RCTs, meta-analyses and HTAs	T1D (majority) and selected T2D cohorts on insulin, Adults	rtCGM/isCGM	SMBG	HbA1c, hypoglycaemia, time-in-range (TIR), QoL, cost-effectiveness	Varied	Varied	–	€ 40,991 - 2,634,182	0.05-1.11	Varies	Yes
Health Quality Ontario (2018)[3]	Canada	HTA with economic	T1D, Adults	CGM (rtCGM, SAP)	SMBG + MDI or pump	Ontario health care payer	Lifetime	1.5 % (costs and QALYs)	CGM + MDI vs SMBG + MDI: € 84,162 CGM + Pump vs SMBG + pump: € 65,357	CGM + MDI vs SMBG + MDI: € 898,808 CGM + Pump vs SMBG + pump: € 631,207	CGM + MDI vs SMBG + MDI: 0.094 CGM + Pump vs SMBG + pump: 0.104	€ 40,530.00	No
isCGM													
Bilir et al. (2018)[91]	Sweden	Economic evaluation	T1D, Adults, mean age 43.7 years	isCGM (FreeStyle Libre)	SMBG	Swedish payer (Societal)	50 years	3 %	€ 27,264.00	€ 34,025.00	0.8	€ 46,748.00	Yes
Harris et al. (2024)[79]	Canada	Economic evaluation	T1D and T2D, Adults	isCGM (FreeStyle Libre)	SMBG	Private payer	40 years	1.50 %	-€ 21,554.00	Dominant (Not directly reported)	1.25 (T1D)	€ 10,681.00	Yes
Elliott et al. (2024)[92]	UK	RCT + economic evaluation	T1D, Adults, mean age 44 years	isCGM (FreeStyle Libre 2)	SMBG	NHS healthcare payer	Lifetime	3.50 %	€ 2,549.00	€ 5,839.00	0.436	€ 26,085.00	Yes
Mustonen et al. (2024)[93]	Finland	Real-world economic evaluation	T1D, Adults, mean age 48 years	isCGM (Freestyle Libre 1 and 2)	SMBG	Healthcare payer	Lifetime	3 %	€ 7,722.00	€ 9,230.00	0.84	€ 49,115.00	Yes
Zhao et al. (2021)[94]	China	Health economic model using RCT and real-world data	T1D & T2D, Adults, insulin treated	isCGM	SMBG	Chinese societal perspective	lifetime	–	€ 13,251.00	€ 10,880.00	1.22 (T1D)	€ 51,104.00	Yes
Bahia et al. (2023)[78]	Brazil	Model-based economic evaluation using decision tree	T1D, Adults & Paediatric	isCGM (FreeStyle Libre)	SMBG	Brazilian Public Healthcare System	1 year	None applied	€ 2,685.00	€ 9,721.00	0.276	€ 14,803.00	Yes

4.1.2.2 Continuous Subcutaneous Insulin Infusion

16 studies were included on CSII and SAP including 14 economic evaluations and two systematic reviews of economic evaluations (Table 8). Six studies evaluated CSII against MDIs, including one RCT which evaluated CSII + CGM against MDI + CGM as the comparator, and three studies on a purely paediatric population. CSII was found to be effective in two China based studies and the multi-country systematic review which reported CSII being cost-effective across all included studies. The UK SCIPI RCT (paediatric) and US DIAMOND RCT (adult and paediatric) found the technology not cost-effective [51,95]. An analysis based in Mexico found that CSII can be considered cost-effective with a probability of 43.9 %, although that increased when patients had an HbA1c above 9 % [96]. ICERs ranged from €23,990 to €58,436 per QALY gained, excluding dominated cases and systematic reviews, and QALYs ranged from 0.415 to 0.7 (averages: €40,319 ±17,293 and 0.48 ±0.11, respectively) (Table C3 in Appendix C).

9 studies evaluated SAP or SAP with LGS, with six studies evaluating two separate cohorts: high HbA1c baseline, and increased hypoglycaemia. Most SAP evaluations (n=7) used CSII as a comparator, while two studies compared SAP to MDI. A Canada HTA from a healthcare payer found ICERs significantly higher than WTP threshold for both SAP vs MDI and SAP vs CSII with ICERs of 817,015 and 480,045, respectively, against a 40,530 WTP threshold, making both comparisons non cost-effective [3]. All eight other studies found SAP to be cost-effective across different countries, most from a societal perspective, with discount rates ranging from 1.5 to 5 % and all over a lifetime horizon. Studies were separated into the two cohorts reported in each publication, where relevant. The mean ICER was €26,635 ±13,979 and the QALY 1.79 ±0.48. Although reported average QALY dropped (from 1.95) after the exclusion of a Colombia based cost utility comparing SAP to MDI, where incremental costs were higher than other studies comparing SAP to CSII, and incremental QALYs were also significantly higher at 3.81 QALYs gained at an ICER of €24,321 [97]. Outcomes of the Canadian HTA were also excluded as outliers (Table C4 in Appendix C). In all two cohort studies, the cohort with increased hypoglycaemia risk consistently showed lowers ICERs and higher QALYs gained than the cohort with a high HbA1C baseline. Figure 10 shows the incremental costs vs QALYs of CSII and SAP technologies. Some studies contribute more than one point, reflecting separate cohort analyses.

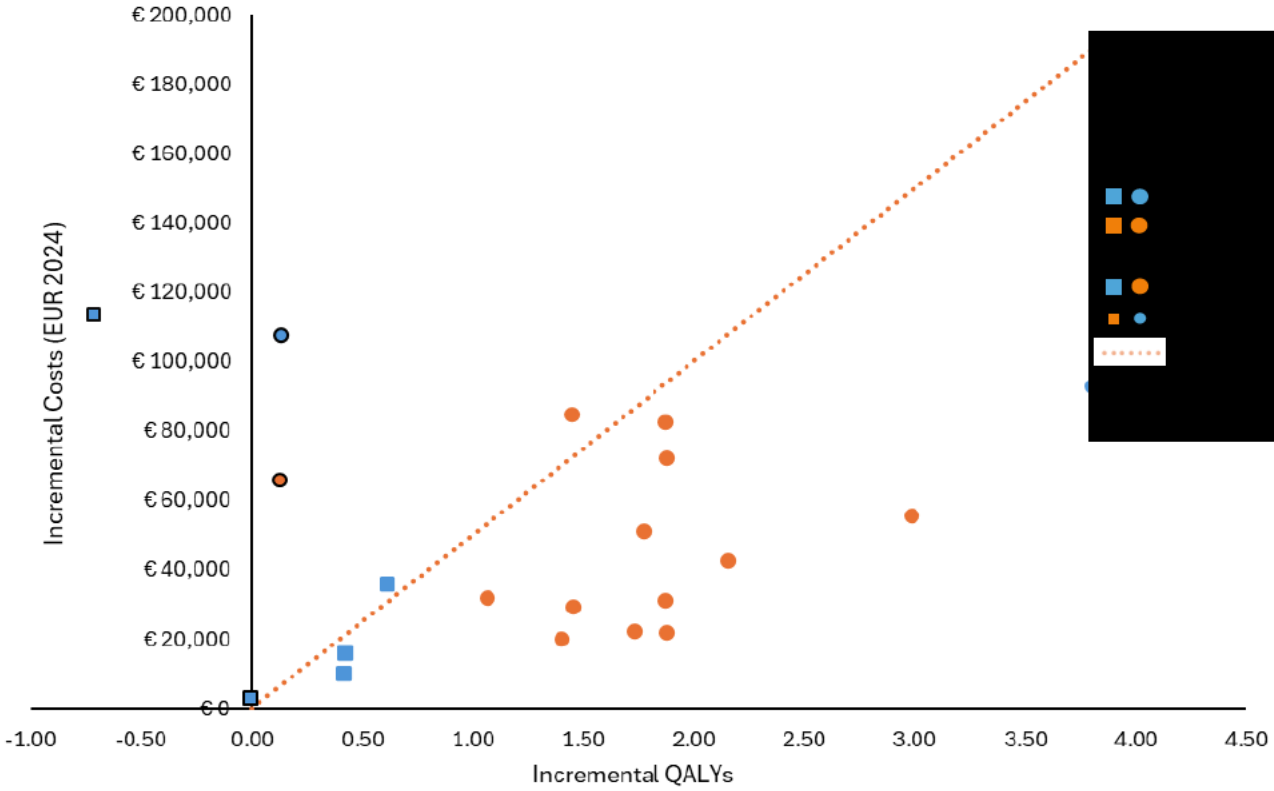

Figure 10 Cost-effectiveness plane presenting incremental costs vs incremental QALYs from included economic evaluations of CSII and SAP. The shape of the data points represents the technology assessed, colour represents the comparator, and border represents cost-effectiveness. Points above the WTP €50,000 line but appear to be cost-effective have ICERs below the WTP threshold reported in the respective study.

CE: Cost-effective, NCE: Nost Cost-effective

Table 8 Study characteristics and key outcomes for CSII and SAP cost-effectiveness studies

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold/QALY (EUR)	Is Cost effective?
Zhang et al. (2022)[98]	China	Model-based economic evaluation	T1D, Children/adolescents	CSII	MDI	Healthcare system	Lifetime (base); 70-year scenario	5 %	€ 9,953.00	€ 23,990.00	0.415	€ 50,641.00	Yes
Roze et al. (2015)[99]	Multi-country	Systematic review of economic evaluations.	T1D, Adults and children	CSII	MDI	–	–	–	–	Mean: € 41,866 (€ 24,413 - € 56,793)	0.7 ± 0.3 QALYs (range 0.4–1.1)	–	Yes, cost effective in all studies included
Wan et al. (2018)[95]	United States	Randomized trial-based CEA (28 weeks) + lifetime modelling	T1D, Adults	CSII + CGM	MDI + CGM	Societal	Within-trial 28 weeks; Lifetime	3 %	€ 113,182.00	CSII dominated	–0.71	–	Not cost-effective; dominated in lifetime CEA
Doubova et al. (2019)[96]	Mexico	Economic evaluation	T1D, Adults mean HbA1c 9.2 %	CSII	MDI	health care system	Lifetime	5 %	€ 35,891.00	€ 58,436.00	0.614	€ 56,111.00	The insulin pump therapy can be considered cost-effective when considering a threshold of three GDPs per capita with 43.9 % probability
Blair et al. (2018)[51]	United Kingdom	Pragmatic multicentre open-label RCT with economic evaluation	T1D, Children & adolescents	CSII	MDI	NHS (UK)	12-months	3.50 %	€ 2,722.00	CSII dominated	–0.006	€ 43,833.00	No
Hu et al. (2021)[49]	China	Retrospective matched cohort + model-based CUA	T1D, Children & adolescents	CSII	MDI	Healthcare system	60-year horizon	5 %	€ 15,986.00	€ 38,530.00	0.42	€ 44,390.00	Yes
SAP													
Jendle et al. (2017)[100]	Sweden	Model-based economic evaluation	T1D, Adults & Paediatric **Cohort 1:** increased hypoglycaemia risk; **Cohort2:** uncontrolled HbA1c	SAP with LGS	CSII	Societal	Lifetime	3 %	Cohort 1: € 31,134 Cohort 2: € 31,906	Cohort 1: € 16,587 Cohort 2: € 29,888	- Cohort 1: 1.877 - Cohort 2: 1.067	€ 35,596.00	Yes
Conget et al. (2018)[101]	Spain	Model-based economic evaluation	T1D, Adults High risk of hypoglycaemia	SAP with LGS	CSII	NHS and societal	Lifetime	5 %	Societal: € 62,003 NHS: € 72,019	Societal: € 38,369 NHS: € 33,032	1.88	€ 45,328.00	Yes
Roze et al. (2019)[102]	Turkey	Model-based economic evaluation	T1D, Adults **Cohort 1:** poor HbA1c control (9.0 %) **Cohort 2:** high hypoglycaemia risk	SAP	CSII	Third-party payer	Lifetime	3.50 %	Cohort 1: € 19,878 Cohort 2: € 22,177	Cohort 1: € 14,178 Cohort 2: € 12,798	Cohort 1: 1.4 Cohort 2: 1.73	€ 14,726.00	Yes
Roze et al. (2019)[103]	Netherlan-ds	Model-based economic evaluation	T1D, Adults **Cohort 1:** suboptimal HbA1c (8.0 %) **Cohort 2:** increased hypoglycaemia risk (7.5 %)	SAP with LGS	CSII	Societal	Lifetime	–	Cohort 1: € 51,098 Cohort 2: € 42,677	Cohort 1: € 28,888 Cohort 2: € 19724	Cohort 1: 1.77 Cohort 2: 2.16	€ 38,819.00	Yes
Nicolucci et al. (2018)[104]	Italy	Model-based economic evaluation	T1D, Adults **Cohort 1:** high baseline HbA1c (9.0 %) **Cohort 2:** high hypoglycaemia risk	SAP with LGS	CSII	Societal	Lifetime	3 %	Cohort 1: € 84,883 Cohort 2: € 82,409	Cohort 1: € 58,617 Cohort 2: € 43,904	Cohort 1: 1.448 Cohort 2: 1.877	€ 65,156.00	Yes

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold/QALY (EUR)	Is Cost effective?
Roze et al. (2017)[105]	Denmark	Model-based economic evaluation	T1D, Adults **Cohort 1:** hyperglycaemia at baseline **Cohort 2:** increased hypoglycaemia risk	SAP with LGS	CSII	Societal	Lifetime	3 %	Cohort 1: € 29,125 Cohort 2: € 21,736	Cohort 1: € 20,113 Cohort 2: € 11,580	Cohort 1: 1.45 Cohort 2: 1.88	€ 28,994.00	Yes
Roze et al. (2016)[106]	United Kingdom	Model-based CEA (CORE)	T1D, Adults, mean age 27 y, mean HbA1c 10 %	SAP with LGS	CSII	UK NHS (payer)	Lifetime	Costs: 3.5 % Outcomes: 1.5 %	€ 55,522.00	€ 18,574.00	2.99	€ 30,367 - 45,550	Yes, under UK NICE thresholds
Gomez et al. (2016)[97]	Colombia	Modelling study	T1D, Adults	SAP	MDI	Healthcare payer	Lifetime (55 years)	5 % (costs and outcomes)	€ 92,813.00	€ 24,321.00	3.81	~ € 27,802	Yes – cost-effective in 99 % of simulations
Health Quality Ontario (2018)[3]	Canada	HTA with economic evaluation	T1D, Adults	SAP, CGM	SMBG + MDI/CSII	Healthcare payer	Lifetime	1.5 % (costs and QALYs)	SAP vs SMBG + MDI: € 107,583 SAP vs SMBG + CSII: € 65,701	SAP vs SMBG + MDI: € 817,015 SAP vs SMBG + CSII: € 480,045	SAP vs SMBG + MDI:0.132 SAP vs SMBG + CSII: 0.137	€ 40,530.00	No

4.1.2.3 Advanced/Hybrid-Closed Loop Systems

12 publications were identified for the cost-effectiveness of HCL systems. Comparators included isCGM + MDI, conventional CSII, and SAP (Table 9). Studies varied in terms of national healthcare perspectives, modelled time horizons (mostly lifetime), and discounting approaches. 7 papers compared HCL to isCGM + CSII or MDI, 2 compared the technology to CSII+MDI, 2 to rtCGM + CSII, and 1 to SAP, excluding the systematic review which included publications comparing it to various technologies. All studies deemed HCL to be cost-effective. A UK based HTA found HCL not cost-effective in their base case analysis, but achieved significantly lower ICER and higher QALY results when higher HbA1c reduction was assumed [18]. Studies were divided into distinct cohort-level analyses resulting in the comparison of 12 cohorts for HCL vs isCGM (Table C5 in Appendix C). Reported ICERs ranged from €3,912 to €50,706, with a mean ICER of €28,886 ±15,114, and a mean QALY gain of 2.2 ±0.3. Although the 6-country CUA found that all countries have a QALY gain of 2.272, removing 5 of them and keeping only one for the average calculation brough down the total average QALY gain to 2.15 ±0.3.

Studies evaluating HCL against CSII+SMBG or CGM had an average ICER per QALY of €15,855 ±11,172 excluding the HTA which found HCL not cost-effective in the base case analysis, reporting an ICER of €209,163 [18]. The mean QALY gain is 1.72 ±0.52. Excluding two results which were considered outliers, the base case of a UK based study which found a very high ICER, and the result of a Sweden based economic evaluation which reported a QALY gain of 13.78 with the use of Control-IQ (CIQ) technology (an AHCL system) in a children and adolescent population. The study determined that this technology cost saving over a 10,20, and 30 year horizon compared to MDI + SMBG and CSII + CGM, shown by the negative incremental costs shown in Figure 11 [107]. The economic evaluation which reported on HCL vs SAP, reported an ICER of -€53,264 and a QALY gain of 0.284 [108]. A multi country evaluation across 6 European countries found an identical QALY gain across the countries at different costs. ICER/QALY was highest in Italy at €50,706 and lowest in Sweden at €3,912, although the publication determined that across the countries, the technology is likely to be cost-effective for people not achieving glycaemic goals [109].

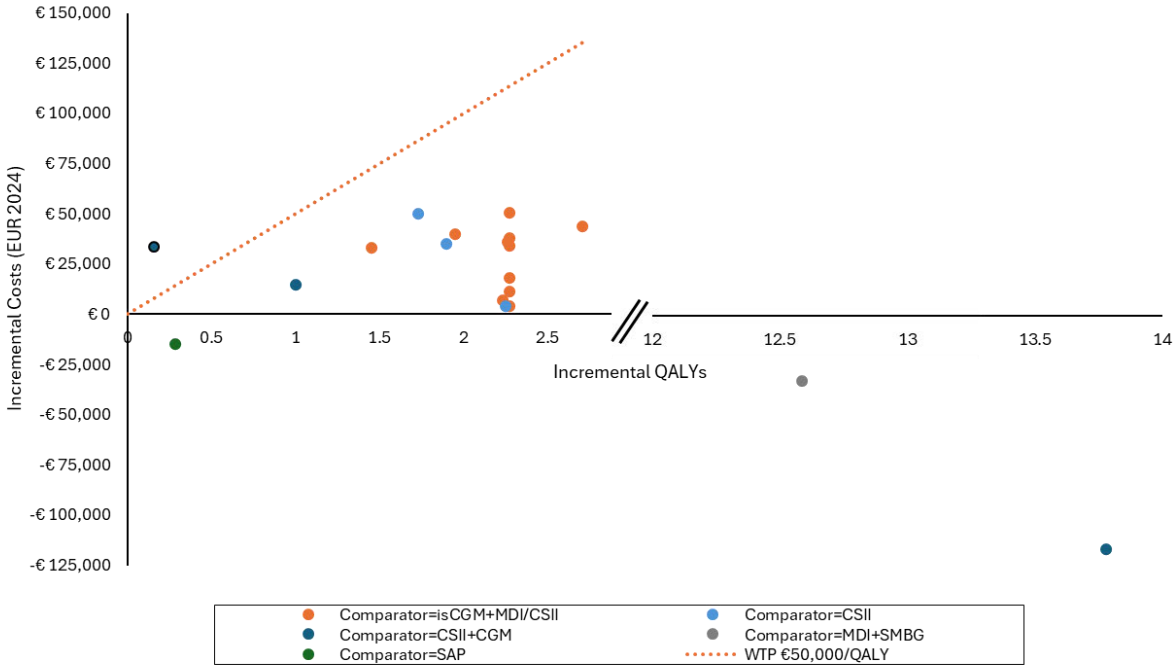

Figure 11 Cost-effectiveness plane presenting incremental costs vs incremental QALYs from included economic evaluations of HCL/AHCL

Table 9 Study characteristics and key outcomes for HCL/AHCL cost-effectiveness studies

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold (EUR)	Is Cost effective?
Jendle et al. (2023)[109]	Europe (6 countries)	Model-based multi-country CUA	T1D, Adults with high baseline (9.04 %)	AHCL (MiniMed 780G)	isCGM + MDI	Payer per country	40 years	3 %	Austria: € 26,048 Greece: € 41,158 Italy: € 115,218 Netherlands: € 77,643 Spain: € 86,061 Sweden: € 8,890	Austria: € 11,463 Greece: € 18,114 Italy: € 50,706 Netherlands: € 34,169 Spain: € 37,874 Sweden: € 3,912	2.272 across all countries	–	likely to be cost-effective relative to isCGM + MDI for people not achieving glycemic goals with is-CGM + MDI
Lambadiari et al. (2022)[108]	Greece	Model-based economic evaluation	T1D, Adults & Paediatric	AHCL (MiniMed 780G)	SAP + LGS isCGM + MDI	Societal	Lifetime	1.5 % costs & outcomes	HCL vs SAP: -€ 14,924 HCL vs MDI+isCGM: € 112,076	-€ 53,264 (HCL vs SAP) € 43,819 (HCL vs isCGM + MDI)	0.284 (HCL vs SAP) 2.708 (HCL vs isCGM + MDI)	€ 49,879.00	Cost-saving vs SAP+PLGM; cost-effective vs MDI + isCGM
Jendle et al. (2019)[110]	Sweden	Model-based economic evaluation	T1D, Adults & Paediatric	HCL (MiniMed 670G)	CSII	Societal	Lifetime	3 %	€ 34,816 Cohort with poor control: € 3,978	€ 18,353 Cohort with poor control: € 1,769	1.90 (overall) 2.25 (poor control)	€ 33,525.00	Yes
Roze et al. (2021)[111]	UK	Model-based economic evaluation	T1D, Adults & Paediatric	HCL (MiniMed 670G)	CSII	UK healthcare payer	Lifetime	3.5 % costs & outcomes	€ 49,981.00	€ 28,812.00	1.73	€ 28,218.00	Likely cost-effective at common UK thresholds
Serné et al. (2022)[112]	Netherlands	Model-based economic evaluation	T1D, Adults	HCL (MiniMed 670G)	isCGM + MDI/CSII	Societal	Lifetime	4 % costs; 1.5 % outcomes	€ 16,056.00	€ 7,196.00	2.231	€ 23,468.00	Cost-effective versus isCGM strategies
Kommareddi & Wherry (2025)[113]	United States	Model-based economic evaluation linked to 6-month RCT	T1D, Adults	AHCL (MiniMed 780G)	isCGM + MDI	US payer	4 years and lifetime (both modelled)	3 %	4-year horizon: € 14,217 lifetime horizon: € 55,328	4-year horizon: € 53,627 lifetime horizon: € 30,452	–	€ 78,400.00	98.1 % chance of theMM780G being cost-effective vs MDI + isCGM
Hanaire et al. (2025)[114]	France	Model-based CUA	T1D, Adults with high baseline (9.04 %)	AHCL (MiniMed 780G)	isCGM + MDI	National payer	40 years	2.5 % costs & outcomes	€ 81,092.00	€ 35,875.00	2.26	€ 206,581.00	Yes
Gardner et al. (2024)[115]	Singapore	Model-based CUA	T1D, Adults; baseline HbA1c 8.4 %	AHCL (MiniMed 780G)	isCGM + MDI	Healthcare payer (Singapore)	Lifetime	3 %	€ 48,088.00	€ 33,119.00	1.45	€ 44,097.00	Yes
Jendle et al. (2021)[116]	Sweden	Model-based CUA	T1D, Adults & Paediatric	AHCL (MiniMed 780G)	isCGM + MDI/CSII	Societal	Lifetime	3 %	€ 77,719.00	€ 39,927.00	1.95	€ 53,422.00	Yes

Author (Year)	Country	Study Design/Method	Diagnosis, Age	Technology Assessed	Comparator	Perspective	Time Horizon	Discount rate	Incremental Cost (EUR)	ICER/QALY (EUR)	Incremental QALYs	WTP threshold (EUR)	Is Cost effective?
Asgharzadeh et al. (2024)[18]	UK	Systematic review + independent economic model	T1D, Adults	HCL	CSII + CGM	NHS payer	50 years (Lifetime)	3.5 %	€ 33,452 (base case) € 14,544 (NHS)	Base case: € 209,163 NHS pilot: assuming higher HbA1c reduction: € 14,487	0.160 (base case) 1.004 (NHS pilot)	€ 23,370 - 35,055	No (base); Yes (NHS pilot scenario)
Jiao et al. (2022)[21]	Australia	Systematic review	T1D, Adults	CGM, SAP, HCL (varied)	SMBG, MDI, CSII (varied)	Healthcare system (varied)	lifetime horizon (all included studies)	Mostly 3 %	NA	Studies assessing HCL vs SMBG+MDI/CSII: €16,612.86 – €22625.14	Studies assessing HCL vs SMBG+MDI/CSII: [1.73–3.72]	€25,161 - €104,837	Yes
Adolfsson et al. (2024)[107]	Sweden	Model-based economic evaluation with trial-linked cohort	T1D, Children & adolescents	Tandem t:slim X2 insulin pump with Control-IQ automated insulin delivery + CGM	(a) MDI + SMBG (b) CSII + CGM	Societal (direct + indirect costs)	10, 20, 30 years	–	10-year: CIQ versus MDI: –€ 37,124 CIQ versus CSII: –€ 47,054 20-year: CIQ versus MDI: –€ 64,160 CIQ versus CSII: –€ 88,082 30-year: CIQ versus MDI: –€ 32,178 CIQ versus CSII: –€ 115,796	10-year: CIQ versus MDI: –€ 8,649 CIQ versus CSII: –€ 9,014 20-year: CIQ versus MDI: –€ 7,085 CIQ versus CSII: –€ 8,619 30-year: CIQ versus MDI: –€ 6,444 CIQ versus CSII: –€ 8,402	10-year: CIQ versus MDI: 4.29 CIQ versus CSII: 5.22 20-year: CIQ versus MDI: 9.06 CIQ versus CSII: 10.22 30-year: CIQ versus MDI: 12.59 CIQ versus CSII: 13.78	€ 49,136.00	Yes, and cost saving

4.1.3 Psychosocial (Patient Reported) Outcomes

A total of 20 studies examined psychosocial outcomes either as a primary or secondary outcome, summarised in Table 10. Key themes which were examined throughout the studies included diabetes distress, FoH, sleep quality, satisfaction, and QoL, using a range of validated instruments, and qualitative approaches. Validated instruments such as various versions of the Diabetes Distress Scale (DDS), Hypoglycaemia Fear Survey (HFS), Diabetes Treatment Satisfaction Questionnaire (DTSQ), and Hypoglycaemia Attitudes and Behaviour Scale (HABS), among others were used. Several studies utilised thematic interviews or literature synthesis.

Multiple studies used the DDS to evaluate diabetes-related distress. In the 2021 United States based Landmark study on rtCGM, DDS improved from 2.39 to 1.86 (Δ 0.53) (evaluated based on a 6-point Likert scale from 1 to 6, 6 indicating high stress) [41]. In users of CGM and virtual care, DDS scores dropped from 1.7 ± 0.6 to 1.5 ± 0.5 (Δ 0.2), and a secondary analysis of rtCGM users in HypoDE also showed a 14.7 % improvement in DDS [46,117]. A study HCL systems observed a reduction of 0.16, while another comparing closed loop technology with SAP reported a small reduction from 1.8 ± 0.6 to 1.7 ± 0.6 (Δ 0.1), although an increase of 0.1 was noted in users of SAP within the study [118,119].

Some studies reported HFS scores to quantify how the technology affected the users FoH (score range of 0–92, higher scores indicate higher fear). A reduction from 39 to 33 (Closed loop users) and 42 to 38 (in SAP users) was observed over six months in a RCT, while another RCT showed a 26 % decrease in HFS score (from 39.1) with rtCGM [117,119]. The 2018 German PUMPKIN trial showed reductions in HFS scores from 30 to 26 in CSII users [120]. Hypoglycaemia confidence also improved with HCL systems, increasing from 3.52 to 3.65 [118].

Treatment satisfaction was generally high across technologies. DTSQ scores (total score range of 0 to 36, with 36 indicating highest satisfaction) of 28.2 ± 5.2 were reported in isCGM users, while an increase was seen in HCL users cohort with an already high DTSQ score (28.4) [118,121]. In the PUMPKIN trial, DTSQ increased from 39.4 to 44.4 (Δ 5.0) in CSII users [120]. Participants in studies involving HCL or Control-IQ also reported improved satisfaction through questionnaires and interviews [31,122].

Studies reporting on System Usability Scale (SUS) (scored from 0–100, higher scores indicate better usability) included two studies on HCL systems where the score increased from 75.9 to 83.8 (Δ 7.9), and a modest 85 to 87 [119,123].

Although most studies have not utilised quantitative analysis to show diabetes related QoL, the consensus was a positive change in QoL that is directly related to the technology used. An observational study reported a Diabetes-specific QoL (EQ-5D-5L) score of 87.9 (high QoL) [121]. Furthermore, multiple studies reported improved sleep quality[46,122,124], and lower perceived

diabetes distress or burden[19,117,124,125], including a study which reported a drop in “feeling overwhelmed” in isCGM users through a modified DDS.

Several burdens of technology use were reported. Cost, alarm fatigue, data fatigue, sensor and adhesion issues were common themes. Body image issues and device-related stigma were also noted [124,126,127]. Alarm fatigue was reported in 9 studies on CGM and HCL, cost burden was reported in 5 included studies, Body issues/stigma and adhesive issues were each reported in 2 studies. Additionally, studies on CGM/HCL reported issues such as perceived sensor inaccuracy and skin irritation [31,128,129].

Table 10 Study characteristics and key outcomes for PRO studies

Author (Year)	Country	Study Design & Population	Technology Evaluated	Experience Domains / PRO Themes	Measurement Approach	Positive Impacts / Benefits	Negative Impacts / Burdens
Artime et al. (2025)[121]	Spain	Observational; n=114 adults with T1D	isCGM	Depression, distress, FoH, satisfaction	DQOL, DTSQ, EQ-5D-5L, work productivity	- DQOL total: 87.9 ± 19.3 - DTSQ total: 28.2 ± 5.2 (high satisfaction) - EQ-5D-5L: 0.88 ± 0.18 (high general QoL) - Higher TIR correlated with a lower number of emergency room visits and better diabetes related QoL	- (higher TIR) has no significant association with general QoL (EQ-5D-5L), treatment satisfaction, or work productivity
Nana et al. (2019)[31]	United Kingdom	Retrospective observational	isCGM (Freestyle Libre)	QoL, diabetes distress, usability	Modified DDS, self-reported questionnaires, inductive qualitative analysis	- "Feeling overwhelmed" scores decreased from 3.38 to 2.04 - Frequent testing scores decreased from 3.34 to 1.37 - 70.6 % reported improved hypoglycaemia awareness - 51.9 % reduction in hypoglycaemia - improved QoL, themes “life-changing,” “positive experience,” “convenient”	- Adhesive issues - Data fatigue - Perceived inaccuracy
Gilbert et al. (2021)[41]	United States	Prospective, real-world cohort	rtCGM	Glycaemic control, treatment satisfaction, device usability	DDS, HABS satisfaction scales	- Significant reductions in DDS score from 2.39 to 1.86 - HABS scores reduced from 2.44 to 1.99 - Improved satisfaction and confidence in glucose management	- Alarm fatigue - Cost
Ehrmann D. et al. (2019)[117]	Germany	RCT secondary analysis; T1D adults with hypoglycaemia unawareness (n= 75/66)	rtCGM vs SMBG	FoH, distress, satisfaction	HFS, GMSS, T1-DDS, EQ-5D validated scales	- rtCGM improved DDS score by 14.7 % (from 2.14) - HFS score improved by 26 % (from 39.1) - Emotional burden score improved by 16.6 % (from 1.79) - GMSS score improved by 13.5 % (from 4.15)	Nonsignificant effects were found for general diabetes distress, hypoglycaemia awareness, and self-reported health status
Holt et al. (2024)[129]	United Kingdom	Cross-sectional survey; n= 605; 83 % T1D, 17 % T2D	CGM	Satisfaction, usability, concerns, trust, alarm fatigue	Registry-based online survey	- 90 % of respondents agreed that the majority of sensors were accurate	- 54 % cited skin irritation using sensors - people who discontinued CGM cited inaccurate readings - Alarm fatigue - Cost
Kubiak et al. (2016)[130]	Germany, UK	Narrative and conceptual review of CGM in adults with T1D	CGM	QoL, psychosocial adjustment, self-management confidence, perceived barriers	Literature synthesis using psychosocial framework	- In one study, 80 % of users reported CGM improved self-management, safety, and hypoglycaemia avoidance - Increased feeling of control - Decrease in FoH	- Alarm fatigue - Data fatigue - Intrafamilial conflict in youth - Children have lower health QoL compared to adults
Liarakos et al. (2024)[19]	United Kingdom	Narrative review of PRO literature in T1D/T2D	CGM (isCGM/rtCGM), CSII, HCL	Treatment Satisfaction, Diabetes Distress, FoH, Anxiety/Depression	Reviewed validated PROMs across >80 studies	- HCL associated with decreased diabetes distress, FoH, and increased diabetes related QoL - CSII associated with fewer and less severe hypoglycaemia episodes - CGM associated with increase in treatment satisfaction and confidence	- PROs often secondary outcomes in research - limited validated tools across studies - CSII insertion issues reported
Hood et al. (2025)[46]	United States	Prospective single-arm; T1D (n=160) and T2D (n=74); 6–12 months	CGM + Virtual Care	Depression, distress, FoH, satisfaction	DDS,FHS,PHQ-8 at baseline/3/6/12 months	- DDS (T1D): 1.7 ± 0.6 → 1.5 ± 0.5 (Δ − 0.2) - FHS (Fear of Hypoglycaemia): 5.0 ± 4.0 → 3.4 ± 3.6 - PHQ-8 (Depression): 2.9 ± 3.1 → 2.5 ± 2.9 - Similar improvements were maintained at 12 months	–

Author (Year)	Country	Study Design & Population	Technology Evaluated	Experience Domains / PRO Themes	Measurement Approach	Positive Impacts / Benefits	Negative Impacts / Burdens
						- TIR had a negative correlation with DDS and FHS, and positive correlation with sleep and wellbeing	
Smith et al. (2019)[131]	United States	Systematic review	CGM/SAP	Usability, adherence, satisfaction, QoL, emotional distress, self-efficacy	PRISMA systematic review	- FoH decreased in adults randomized to SAP vs MDI - Adults using CGM reported significant QoL improvement - Diabetes distress & anxiety lower in adults using CGM/SAP compared with MDI/SMBG - Distress highest in 18–25 yrs group and declined with age	- No change in general health-related QoL - Alarm fatigue - wear-time discomfort - Adhesion issues - Tech issues - Cost
Mueller-Godeffroy E. et al. (2018)[120]	Germany	Randomized controlled trial; children 7–17 y with T1D and parents (n = 211)	MDI/CSII	Family stress, QoL, emotional impact	HFS, DTSQ questionnaires	- HFS dropped in CSII from 30 to 26 and in MDI from 30.2 to 28.5 - DTSQ increased in CSII from 39.4 to 44.4 and in MDI from 36.9 to 40.5 - Significant decline of overall diabetes burden at follow-up compared to the MDI - CSII showed better score for diabetes related QoL - treatment satisfaction increased	- No difference in health-related QoL
Haynes et al. (2021)[127]	Canada	Qualitative interviews; youth ≤25 y with T1D and parents	CSII	Financial stress, social control, worry	Thematic phenomenological interviews (n=23)	- Improved social confidence - control over daily life	- Fear of losing coverage - body image (occasional shame about visibility)
Paisley et al. (2019)[57]	United Kingdom	Retrospective multi-centre cohort	CSII	HbA1c change, influence of demographics	Clinical HbA1c data and deprivation index analysis	People with higher social deprivation had notably higher baseline HbA1c levels.	benefits of CSII therapy were not found to be associated with social deprivation, only with pre-CSII HbA1c
Kudva et al. (2021)[119]	United States	6-month randomized controlled trial; ages 14–71; Close loop (n=112); SAP (n=56)	Closed loop Control (CLC) vs SAP	Diabetes distress, FoH, acceptance, usability	Validated questionnaires: DDS, HFS, INSPIRE, SUS	- HFS decreased in CLC from 39 to 33 and in SAP from 42 to 38 - DDS decreased in CLC from 1.8 ± 0.6 to 1.7 ± 0.6; SAP 1.8 → 1.9 - INSPIRE score in CLC increased from 80 to 87, in SAP increased from 85 to 86 - Slight increase in technology acceptance - Increased system usability score (SUS) from 85 at 13 weeks to 87 at 26 weeks - low perceived burden	- No negative PROs reported for CLC - SAP group reported increased feelings of powerlessness
Pinsker et al. (2021)[122]	United States	Observational registry; 1,435 T1D users (starting Control-IQ)	HCL	Treatment satisfaction, well-being, distress	WHO-5, DIDS scales	- WHO-5 score decreased from 69.8 to 68.2 - DIDS scale: device satisfaction score increased by 0.1 - improved QoL - improved sleep quality	–
Barnard et al., (2017)[124]	UK/Europe	12-wk crossover; 58 participants (32 adults, 26 youth)	HCL & SAP	Perceived control, sleep, burden, reassurance	DTQ + interviews	- Better perceived blood glucose control - improved sleep, less worry about nocturnal lows - Reduced burden of diabetes - 26/32 adults reported feeling safer with Closed Loop, 22/32 would keep using it	- Device bulk - Alarm fatigue - wearing multiple parts - Usability issues included appearance and fashion issue - 16/32 adults reported closed loop requires more time and effort
Polonsky et al. (2022)[118]	United States	Single-arm prospective; n=115 adults (18–70 yrs)	HCL/AID (Omnipod 5)	Diabetes distress, confidence, satisfaction, sleep, usability	T1-DDS, HCS, WHO-5, PSQI, DTSQc, SUS Questionnaires	- DDS score difference of -0.16 ±0.08 - HCS score difference of 0.13 - WHO-5 no significant change	- No changes in general well-being (WHO-5) - 13 % of participants reported alarm fatigue

Author (Year)	Country	Study Design & Population	Technology Evaluated	Experience Domains / PRO Themes	Measurement Approach	Positive Impacts / Benefits	Negative Impacts / Burdens
						- PSQI no significant change - DTSQc score 12.6 ± 7.1 - SUS score difference of 7.9	- 20 % of participants reported connectivity issues
Kubilay et al. (2024)[128]	Australia	Qualitative follow-up after AID trial (n = 21) ≥65 years	SAP/HCL	usability, affordability	Semi-structured interviews with thematic analysis	- Participants preferred HCL over CSII - Increased confidence in diabetes management	- Alarm fatigue - Cost - Sensor inaccuracy
Barnard-Kelly et al. (2025)[123]	United Kingdom	International consensus statement of experts across research, clinical, and patient groups	General Diabetes Technologies (CGM, CSII, HCL)	Depression, distress, treatment satisfaction, QoL, stigma, self-management burden	Expert consensus, literature review	- Most adults report that technology and healthcare are viewed as the biggest drivers of improvements in their lives - Highlights recognition of PROs as crucial for understanding diabetes impact	- Notes current lack of harmonization, overuse of non-validated PROMs, and inconsistent reporting - prevalence of diabetes stress is high - higher diabetes distress is directly correlated to higher HbA1c, lower TIR, and lower QoL
Tanenbaum & Commissariat (2023)[126]	United States	Narrative review (2018–2023 studies)	General Diabetes Technology	Emotional, social, practical burden	Literature synthesis	- Adaptation over time decreases emotional burden - Peer support helps - positive acceptance of diabetes and its treatment is associated with better glycemic control	- Alarm fatigue - Body image - people who consider diabetes management a financial burden, experience more distress - insertion issues - adhesion issues
Alcántara-Aragón (2019)[125]	Spain	Narrative review of technology-related self-care in diabetes	General Diabetes Technology	Burden vs empowerment, distress, adaptability, QoL	Literature and clinical synthesis	- increased feeling of control - Reduced burden - improved QoL	- Cost - Alarm fatigue and inconvenience - Device stigma - Data overload can increase distress

4.1.4 Comparative Analysis

To provide a clearer comparison between technologies, this section summarises and consolidates clinical and cost effectiveness findings from the systematic review. Figure 12 summarises the findings of HbA1c reduction by technology. SAP technology had the highest average reduction at 0.83 % and CSII had the lower average reduction at 0.35 %, comparable with isCGM at 0.36 %. rtCGM and HCL systems were also comparable at 0.74 % and 0.79 % reduction. Other variables like TIR, TBR, and hypoglycaemia events could not be compared between technologies as there was not enough data or standardised reporting across studies and technologies.

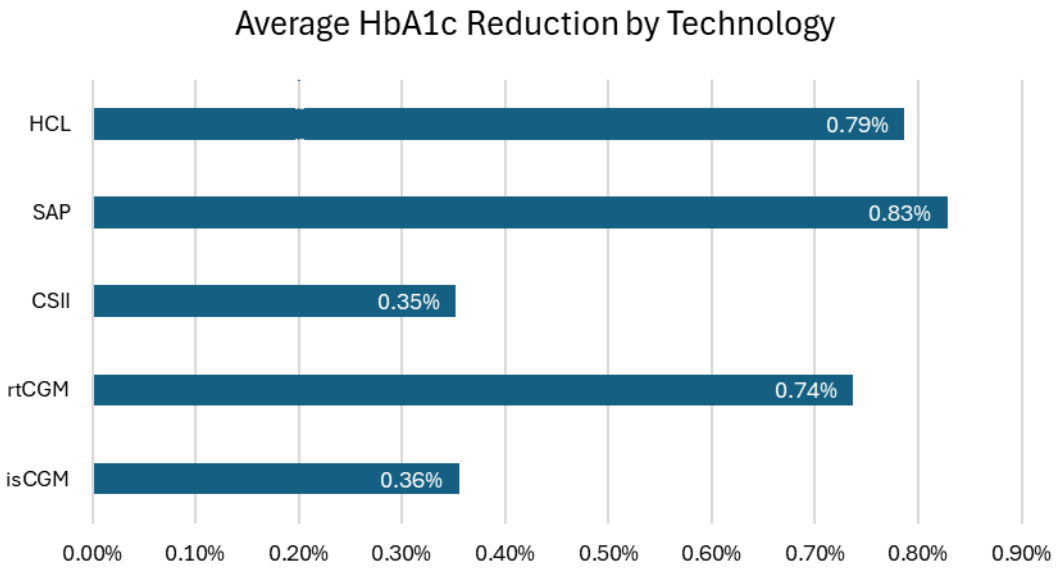

Figure 12 Average HbA1c reduction by technology. Only studies which reported baseline HbA1c and post-intervention HbA1c for the same group were included.

Incremental QALYs and ICERs were the main outcomes for CEAs of each technology. Figure 13 summarises the results of each technology by average QALY and ICER and helps visualise the cost effectiveness of each technology. CSII had the highest averages of ICER and lowest of QALY between the technologies, while HCL vs isCGM had the highest average QALY and isCGM had the lowest average ICER.

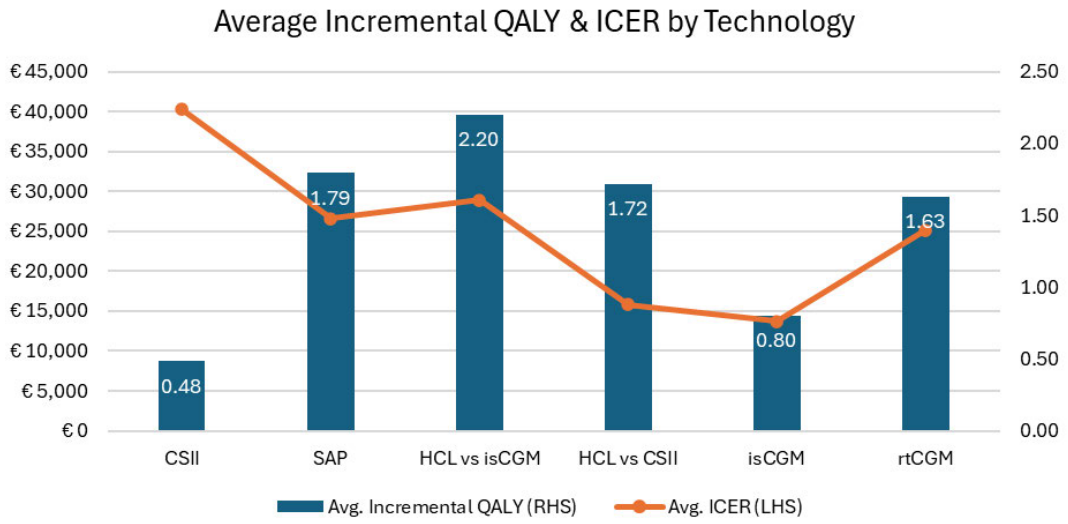

Figure 13 Average incremental QALY and ICER by technology. LHS: Left-hand side; RHS: Right-hand side

4.2 Survey Results

The survey collected a total of 23 responses over the course of 15 days. The rate of completion was 100 % and the rate of unanswered questions was very low. The participants were all residing in Australia and taking part in a T1D support group. The overall cohort was majority female at 69.6 %, older adults with 39.1 % being over 65 years of age and over 50 % diagnosed with T1D for over 30-years. Most participants were on a CGM + CSII regiment (60.9 %) of which 93 % (13/14) reported that their insulin pump automatically adjusts insulin delivery based on glucose which indicates that they use AID systems rather than CSII or SAP. In contrast, 34.8 % used only CGM—whether isCGM or rtCGM was not investigated—with no insulin pump, and only one person reported using only MDI as their current treatment regimen. Table 11 shows the characteristics of the survey participants. The survey included a fourth bucket of treatment regimen which no participant was part of, which was CSII + MDI use.

Table 11 Participants characteristics

Characteristics n (%)	
Male	7 (30.4)
Female	16 (69.6)
Age n (%)	
18 - 25	1 (4.3)
26 - 35	2 (8.7)
36 - 45	2 (8.7)
46 - 55	4 (17.4)
56 - 65	5 (21.7)
> 65	9 (39.1)

Diabetes Duration n (%)	
< 1 year	1 (4.3)
1 -5 years	3 (13.0)
6-10 years	1 (4.3)
11-15 years	3 (13.0)
16-20 years	1 (4.3)
21-25 years	2 (8.7)
26-30 years	0 (0.0)
> 30 years	12 (52)
Diabetes treatment n (%)	
CGM + CSII – Cohort-1	14 (60.9)
CGM + MDI - Cohort-2	8 (34.8)
SMBG + MDI – Cohort-3	1 (4.3)

Participants were asked about their daily frequency of finger prick testing (SMBG). CGM + CSII cohort tested the least per day with 13/14 participants testing 0-1 times per day, while the MDI cohort reported doing over 5 tests per day. Figure 14 shows the frequency of finger prick testing by cohort.

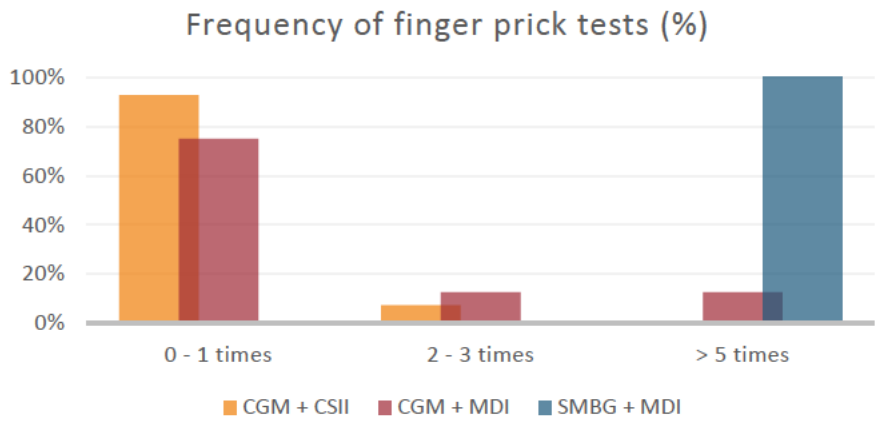

Figure 14 Daily frequency of finger prick tests by cohort

All cohorts were asked about the range of their most recent HbA1c reading. When taking the midpoint of reported HbA1c ranges, cohort-1 has an average HbA1c of 6.4 %, while cohort-2 had an average of 7 %. 78.6 % (11/14) of cohort-1 and 50 % (4/8) of cohort-2 had an HbA1c < 7.0 %. Cohort-1 were asked about their HbA1c reading while they were on MDIs (to recall to the best of their abilities) where applicable. All 14 of the CGM + CSII cohort used MDI for a duration before starting on an insulin pump or integrated pump regimen. Almost all participants reported a drop in HbA1c after starting on an insulin pump. Figure 15 shows the HbA1c readings reported by all

participants by cohort and Figure 16 reports the HbA1c readings of cohort-1 while on MDI and after initiating their current treatment regimen (CSII, SAP, or HCL). Both HbA1c values were taken as ranges, the midpoint was taken of each pre- and post- range, and the percent difference was calculated. A positive correlation (r=0.75) was noted between higher HbA1c baseline values and percent difference between pre- and post-pump initiation. Refer to Table D1,Appendix D.

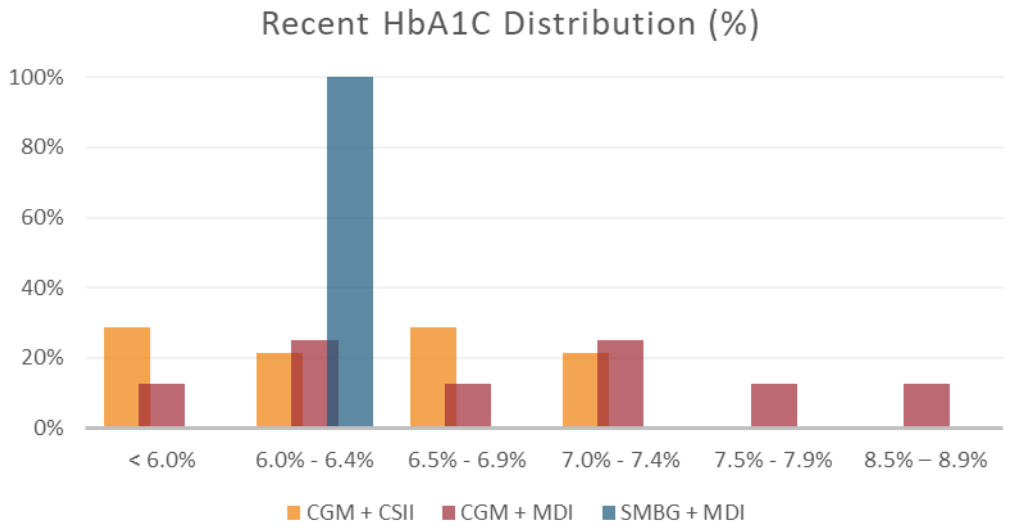

Figure 15 Most recent HbA1c readings from participants of each cohort (in ranges)

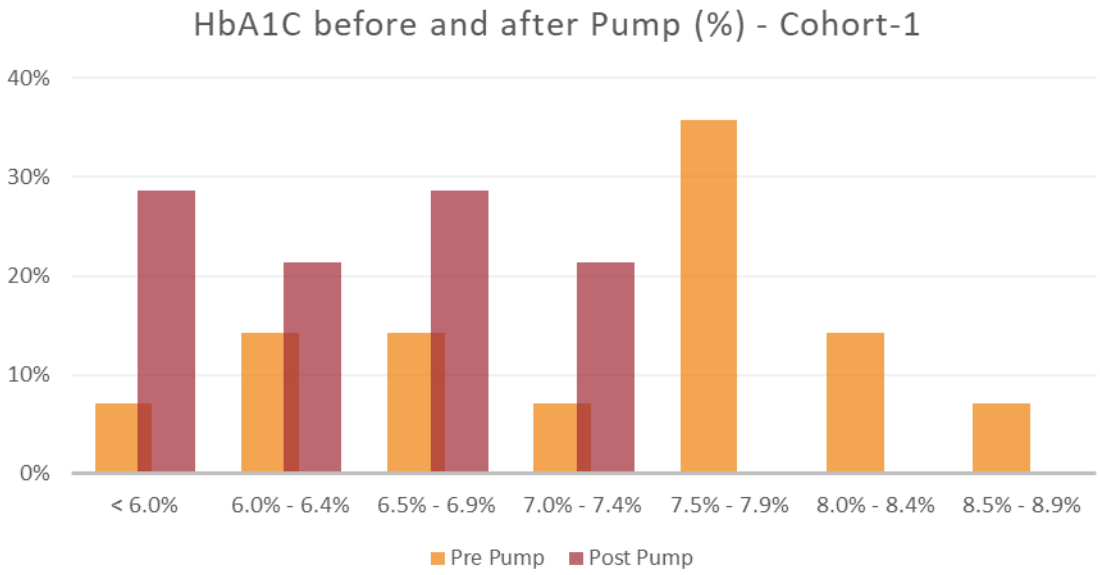

Figure 16 HbA1c ranges of cohort-1 participants pre and post Pump initiation

Cohorts-1 and -2 were asked to report their TIR over the last 30-days based on their CGM data through ranges of 10 steps (30 % - 39 %, ..., 90 % - 100 %). 42.9 % (6/14) of cohort-1 achieved TIR between 90 % - 100 %, 25 % (2/8) of cohort-2 achieved TIR of at least 80 %. 1 person from cohort-1 and 3 persons from cohort-2 had TIR of 50 % and below. Scores by group are shown in Figure 17.

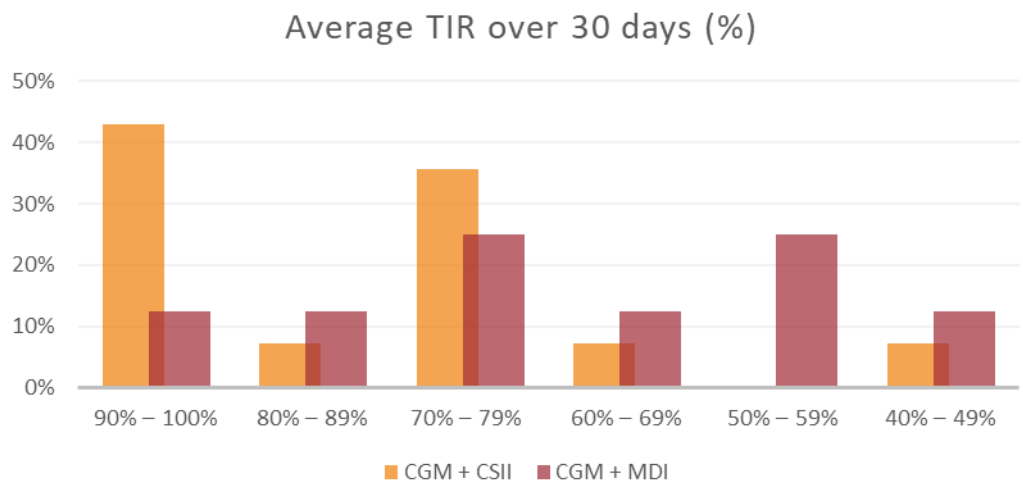

Figure 17 Average TIR of participants using CGM over the last 30 days before survey

Based on the most recent HbA1c and the TIR range values, the midpoint value of each participants TIR range was plotted against the HbA1c midpoint of each participant. To avoid identical data points overlapping on the graph, a jitter was added to the x-axis values. Shown in Figure 18, with a moderate inverse correlation between the two ($R^2 = 0.44$). No correlation was found between CGM duration and HbA1c or diabetes duration and HbA1c.

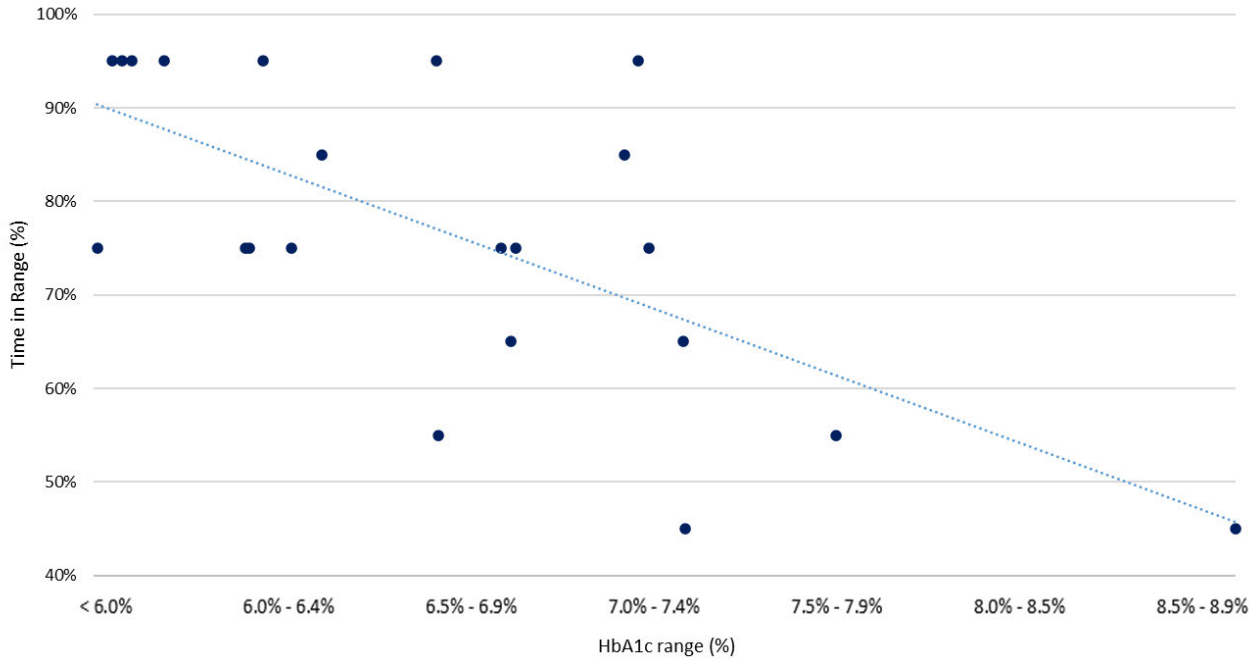

Figure 18 HbA1c range vs TIR of cohort-1 and -2

Participants were asked to disclose their monthly spending on diabetes-related consumables such as insulin, pump consumables such as insulin reservoirs and infusions sets, sensors, test strips, needles, and any other essentials they may require. Costs were reported in AUD and converted to EUR based on the Reserve Bank of Australia rates on November 27, 2025. Costs

reported by CGM + CSII users ranged from 16.8 to 61.7 EUR and by CGM + MDI users from 5.6 to 44.9 EUR per month. This cost (or estimation) did not consider any doctor visits including general practitioners or specialists such as endocrinologists, costs of pump, or treatment for any complications which may have occurred from the diabetes. The majority of the participants (74 % of the total cohort) had both private and public health insurance, with 13 % being only publicly insured and another 13 % having no insurance. No meaningful correlation was observed between insurance type and reported costs based on this sample. 39 % of the total cohort considered the total diabetes cost to be a financial burden for them and 30 % considered it to "sometimes" be a financial burden. A summary of the findings is shown in Table 12.

Table 12 Reported monthly diabetes supply costs, health insurance coverage, and perceived financial burden among participants by treatment modality. Costs were converted from Australian Dollars (AUD) to Euro (EUR) at an exchange rate of 1 AUD to 0.5614 EUR. N/A: Not Applicable

Monthly cost of diabetes supplies AUD (EUR)	**CGM + CSII**	**CGM + MDI**	**SMBG + MDI**
Average	59.2 (33.3)	43.3 (24.3)	70 (39.3)
SD	22.8 (12.8)	25.8 (14.5)	N/A
Health insurance			
Public	2 (14.3)	0 (0.0)	1 (100.0)
Private	0 (0.0)	0 (0.0)	0 (0.0)
Public & Private	12 (85.7)	5 (62.5)	0 (0.0)
No insurance	0 (0.0)	3 (37.5)	0 (0.0)
Perceive as financial burden			
Yes	6 (42.9)	3 (37.5)	0 (0.0)
No	5 (35.7)	2 (25.0)	0 (0.0)
Sometimes	3 (21.4)	3 (37.5)	1 (100.0)

9 participants in total (cohort-2 & -3) stated they have either used and discontinued or have chosen not to use a pump. Participants were allowed to cite multiple reasons for discontinuation or non-initiating. Cited reasons varied but by far the most common was financial reasons with 77.8 % (7/9) of respondents citing it. 44.4 % reported they are satisfied with MDI as a treatment method. Other cited reasons included finding pumps too complicated to use, facing faulty issues, disliking devices permanently attached to body, and disliking the plastic waste generated from pumps through the volume of disposable consumables.

Participants of cohort-1 were asked whether they feel "more comfortable and less stressed" about their diabetes care—referencing perceived diabetes related distress—with the use of a CGM and insulin pump, comparing to when they were using only a CGM or only MDIs. 57.1 % (8/14) of the cohort reported feeling less diabetes distress, the remaining 42.9 % reported

"somewhat" feeling less diabetes distress with the use of the technologies. FoH and other patient outcomes were assessed using the Likert scale. FoH was more prevalent during daily activities than during sleep. 50 % of both cohort-1 and cohort-2 agreed that they get concerned about having hypoglycaemia events during their daily activities; and while it cannot be generalised, the participant on an MDI treatment regimen also agreed to that but remained neutral on having concerns of nocturnal hypoglycaemia. In contrast, 7 % (1/14) of cohort-1 and 50 % (4/8) of cohort-2 agreed or strongly agreed with experiencing concerns of low glucose levels while sleeping, while over 70 % of cohort-1 and 35 % cohort-2 disagreed. 28.6 % (4/14) and 37.5 % (3/8) of each group agreed or strongly agreed that they face occlusion and/or have difficulties finding a suitable site for insulin infusion and insulin injections, respectively. The same problem was lower for sensors where one person from each group either agreed or strongly agreed to facing any issues. 100 % of both groups agreed or strongly agreed that their CGM + CSII or CGM lowers perceived FoH both during daily activities and during sleep. Body image issues were low in all groups where only 1 participant strongly disagreed with feeling confident wearing their CGM or pump out in public, and another participant being neutral towards it. 100 % of participants either agreed or strongly agreed that the technology they use help them feel more confident in caring for their diabetes. 90 % of overall participants believed that they live their daily lives more freely through the help of the technology. Figure 19 and Figure 20 show the overall scores of the Likert scale questions for cohorts 1 and 2, respectively. At the end of the survey, participants were asked to consider their diabetes care routine (now that they had the chance to reflect upon it) to give their rating for their QoL on a scale of 0 to 10. The average rating was 7.6 and 7.1 for each cohort respectively. Figure 21 shows a box and whisker plot of the scores per cohort.

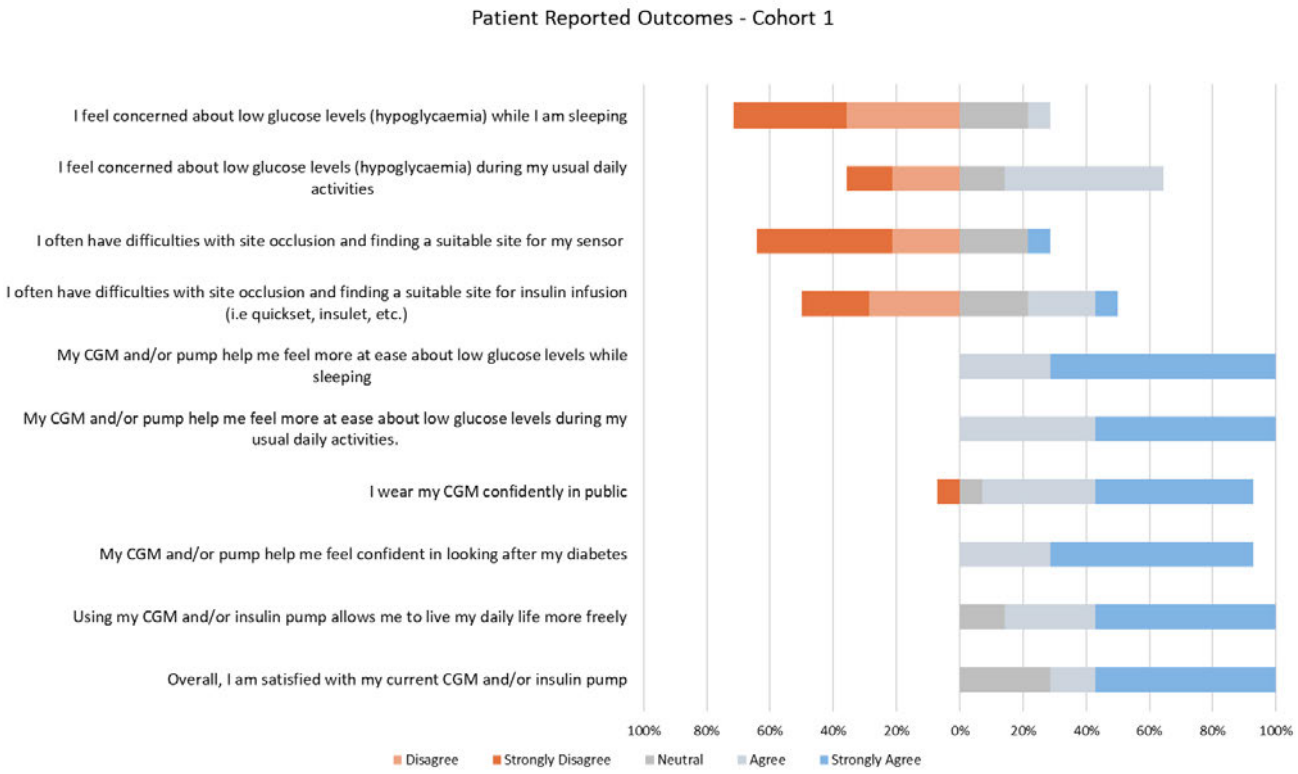

Figure 19 Likert scale scores of patient-reported outcomes statements for cohort-1

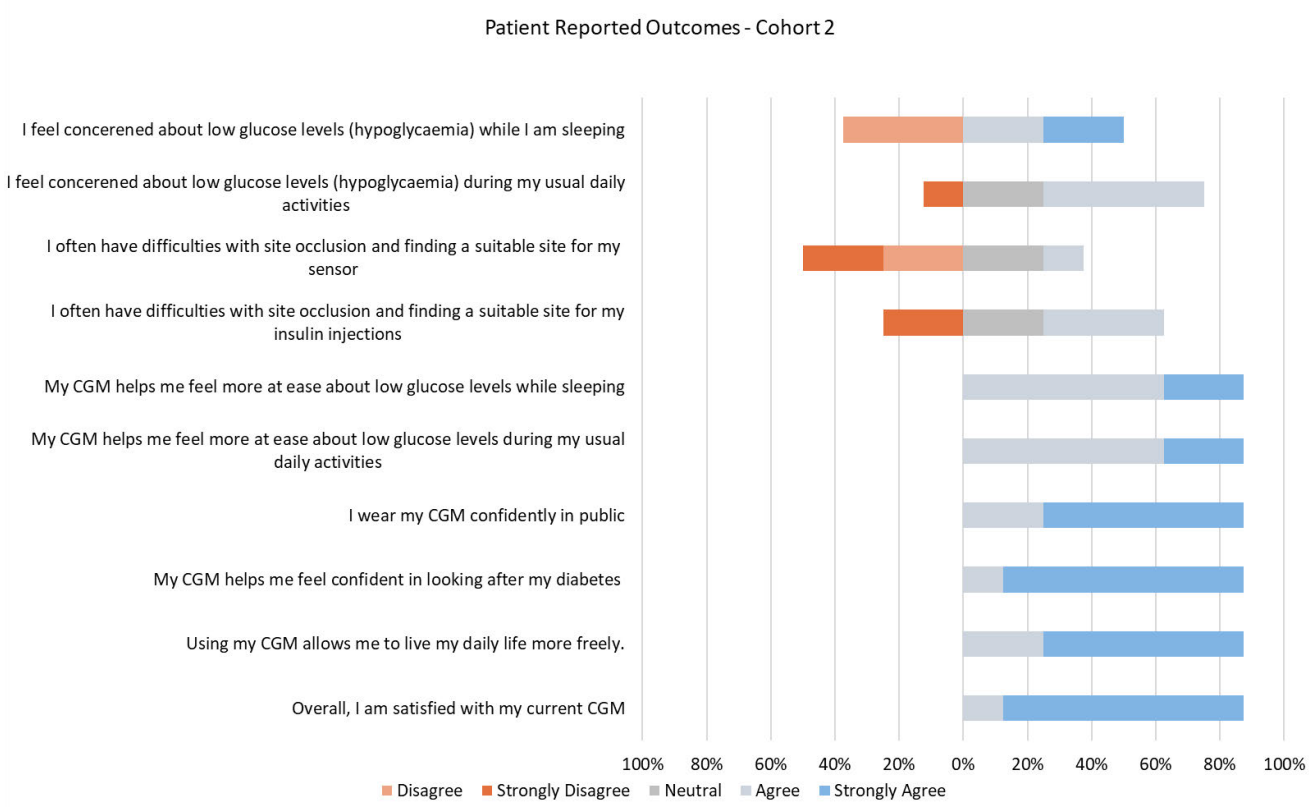

Figure 20 Likert scale scores of patient-reported outcomes statements for cohort-2

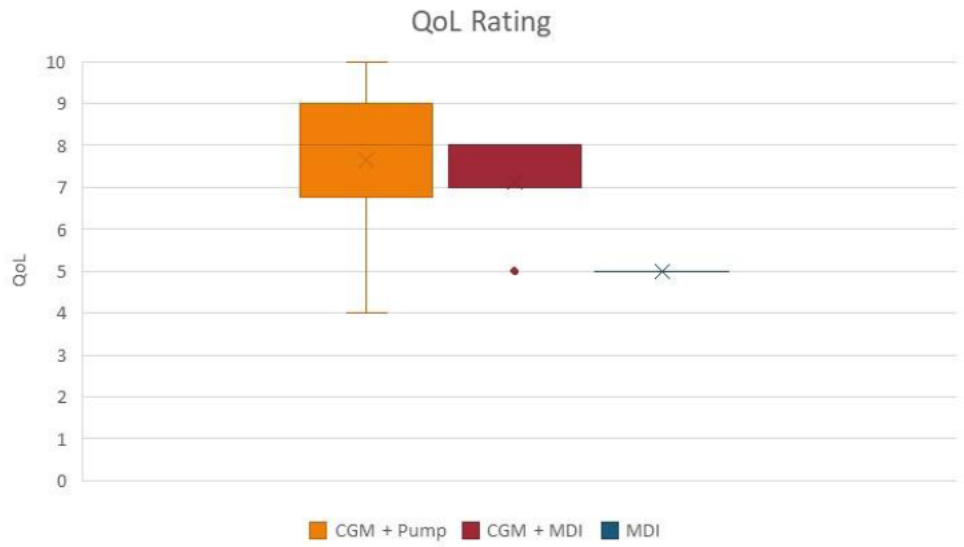

Figure 21 Box and Whisker plot of perceived QoL per cohort

Exercise

91 % of participants said they engaged in aerobic exercise (*Walking, Running, Swimming, Cycling)* at least 1 day a week, with 26 % reporting 5-6 days a week of exercise. 48 % reported engaging in anaerobic exercise (*weightlifting, resistance training, CrossFit, HIIT),* with 17 % exercising ≥ 3 days a week. Overall, 74 % reported having better glycaemic control at least sometimes with exercise (43 % said yes, 30 % said sometimes). 50 % (5/10) of participants who do only aerobic exercise at least once a week note better glycaemic control with exercise. 45 % (5/11) from who do both aerobic and exercise at least one a week reported better glycaemic control. 91 % reported better glycaemic control at least sometimes.

Key survey results are summarised in Table 13.

Table 13 Summary table of results averages

Summary table n (%) - noting averages where applicable	Cohort 1	Cohort 2	Cohort 3	Note
QoL (out of 10)	7.64	7.13	5.00	Avg.
Below 7 % HbA1c	79 %	50 %	100 %	Sum
Below 7 % HbA1c - before CSII	36 %	N/A	N/A	Sum
TIR above 70 %	86 %	50 %	N/A	Sum
Aerobic exercise > 2 times per week	57 %	63 %	0 %	Sum
Anaerobic exercise > 2 times per week	21 %	13 %	0 %	Sum
Notes better glycaemic control with exercise	92 %	63 %	0 %	Sum
Average estimated monthly cost of diabetes supplies AUD (EUR)	59.2 (33.3)	43.3 (24.3)	70 (39.3)	

5 Discussion

Findings from the systematic review indicated that rtCGM was the most researched and clinically effective among CGM technologies, with an average HbA1c reduction of 0.74 %, accompanied by significant reductions in hypoglycaemic episodes. isCGM, though supported by fewer studies, also demonstrated clinical benefits over SMBG in terms of glycaemic outcomes, though significantly smaller than rtCGM.

rtCGM and isCGM showed significant reductions in hypoglycaemia episodes within users. Hypoglycaemia data were less consistently reported than HbA1c across studies, often varying in format and definition across literature and different technologies (e.g. episodes during study duration, time below range, etc). Nevertheless, both rtCGM and isCGM were associated with reductions in hypoglycaemic events compared to SMBG. This is largely due to the practicality of being able to read the glucose levels every few minutes, instead of only at a point in time. SMBG testing can only provide a reading for the moment the test is taken. Although more accurate than CGM at times due to measuring glucose through blood directly and not through interstitial fluid, an individual cannot tell whether their blood glucose levels are on an upward or downward trend. As a result, there becomes a risk of miscalculation in insulin dosage, and which can lead to a higher probability of experiencing hypoglycaemic and hyperglycaemic events.

Studies of CSII showed modest improvements in HbA1c, with larger effects typically seen in paediatric populations. CSII technology (i.e., insulin pump) is the earliest technology that came out for insulin administration before being enhanced to include additional features, and recent studies are limited on this technology as the focus is shifting more towards integrated systems [19]. CSII generally underperformed compared to other technologies, although difference between CSII and isCGM was nonsignificant. Several studies reported no meaningful change in the number of hypoglycaemic events, and one RCT found a nonsignificant difference in HbA1c improvement when comparing CSII to MDI. Though it presents benefits in terms of reducing frequent and painful injections while being more discreet and functional than MDIs.

Integrated systems showed the highest HbA1c improvements at 0.79 % and 0.83 % reduction for HCL systems and SAP, respectively. While both technologies show high reductions and have other reported benefits such as lower number of hypoglycaemic events and increased TIR, it should be considered that the magnitude of HbA1c reduction is strongly influenced by the comparator. SAP was often evaluated against lower-technology regimens (e.g., SMBG + MDI or CSII), where there are potentially larger improvements that can be captured. In contrast, HCL studies typically compared against more advanced technologies (e.g., isCGM/rtCGM + MDI or CSII), creating a ceiling effect that limits further HbA1c reduction. Therefore, the comparator influences the amount of change observed in the intervention group. This is plausible given multiple studies

have showed HCL systems superiority over SAP systems, which do not automate insulin delivery [132,133].

Overall, across technologies, it was evident through results and noted within publications that paediatric and adolescent populations faced the most fluctuation in glycaemic control. Those populations also had poorer glycaemic control than adult populations, which was noted although the number of studies dedicated to adults was larger than studies dedicated to paediatric studies [68]. Given these differences, it is more methodologically appropriate to analyse paediatric and adult populations separately when assessing effectiveness.

The greatest benefiters of all technologies were individuals with poor glycaemic control, either a high baseline HbA1c, or at high risk of experiencing hypoglycaemic events. Technologies were also more likely to be cost-effective when poor glycaemic control is considered. Furthermore, although DKA events were reported less frequently than hypoglycaemic events, all technologies demonstrated a reduction in DKA incidence. While one study reported an increase in the number of hyperglycaemic events among CSII users, this was not a consistent finding across the literature.

Economic evaluation across diabetes technologies demonstrated clear differences between the health benefits and costs. To enable a clear comparison, technologies were further grouped by the most common comparator among studies. For example, studies on rtCGM and isCGM were included if they were compared against SMBG and studies on SAP were included if they compared against CSII. HCL systems had sufficient data for two groups of studies by comparison against CSII, and isCGM (Tables of grouped categories including excluded studies and reason for exclusion are found in Appendix C).

HCL systems compared to isCGM demonstrated the highest average QALY gain of 2.2 among all technologies, with an ICER of €28,886, making it cost-effective under common WTP thresholds. While isCGM had the lowest ICER of €13,720, its corresponding QALY gain was modest (0.8) compared to other technologies, indicating its efficiency but also a lower absolute benefit compared to the other evaluated technologies. HCL vs CSII also showed strong performance, with a QALY gain of 1.7 and a relatively low ICER of €15,855. Compared to HCL vs isCGM, this result reflects smaller additional gains. CSII technology had the lowest average QALY at 0.5 with the highest ICER at €40,319, indicating a high-cost jump when switching from MDI to CSII.

isCGM is more cost effective and produces a higher QALY gain than CSII when examined as standalone technologies, while HCL vs CSII appears more cost-effective than HCL vs isCGM. This is due to the relative cost difference between the baseline technologies. CSII is already a high-cost intervention, so the additional cost to move to HCL is smaller. On the other hand, isCGM is relatively inexpensive, making the jump to HCL more costly in comparison. Thus, even though the health benefit gained from HCL may be higher when compared to isCGM, the large increase

in cost reduces its cost-effectiveness. This highlights the importance of the comparator in economic evaluations.

Given that isCGM is more cost effective and beneficial than CSII, HCL vs isCGM producing higher QALY gains than HCL vs CSII could seem counterintuitive. This may result from studies comparing HCL to isCGM including populations with poorer baseline glycaemic control or simply making varied assumptions about the simulated population. This could also be attributed to a limited number of HCL vs CSII publication where the included studies are not reflective of the real-world situation. Only 3 studies including one study with two different cohorts were used to reach the outcomes presented. Alternatively, it is also possible that CSII provides a greater QALY gain than what was reported in the limited studies available, as there were limited studies reporting ICER and QALY gain on the technology.

SAP systems also produced a relatively high average QALY gain at an ICER not much lower than HCL vs isCGM at €26,635. Overall, all integrated systems produced the highest QALY gains when compared to standalone technologies, with an average ICER below most reported WTP thresholds.

The survey was conducted through a T1D support group which consisted of largely older adults. Although the cohort was relatively small, it is likely representative of the population within Australia which has a high-socioeconomic demographic with broad access to modern diabetes technologies. In this context, people generally have fewer financial and structural barriers in obtaining devices such as CGM and insulin pumps, particularly given the national subsidies that fully or partially fund CGM for Australians with T1D. As a result, individuals may be more familiar with, and more able to adopt, advanced technologies compared with populations in settings where out-of-pocket costs or limited healthcare coverage restrict uptake [134].

The literature review and survey results converged on multiple points which validated the survey results. A large proportion of participants currently using CGM-based technologies reported HbA1c < 7 %. The CGM + Pump cohort achieved a higher percentage of HbA1c below 7 % (79 %) than the CGM + MDI group (50 %), and average HbA1c for each group was 6.45 % and 7 % respectively. This aligns with the literature review of integrated systems users achieving better glycaemic control than a single technology user. Similarly, increases in TIR were commonly reported in the literature, with several studies noting TIR improvements in integrated systems users. These findings correspond to survey results in which a TIR (over the last 30-days) of ≥70 % was achieved by 86 % of cohort-1 users and 50 % of cohort-2 users, with average TIR of 81 %, and 68 %, respectively. Both sources indicate a general trend toward higher TIR among individuals using integrated technologies. Furthermore, cohort-1 exhibited a 12 % decrease in average HbA1c after switching from MDI to pump or integrated system. 93 % of cohort-1 used integrated systems which attributes the decrease to integrated systems. While this result could be considered vague due to no data available on a specified or known duration between HbA1c

measurements, it can still be considered a positive outcome in favour of integrated systems due to the consistent decline in HbA1c among the cohort members and a generally high satisfaction rate with the technology.

Several correlations were established during the systematic review such as TIR and HbA1c have a negative correlation shown quantitatively and qualitatively throughout the studies; diabetes diagnosis duration and CGM use duration both have a negative correlation with HbA1c [29,31]. This is mostly attributed to individuals growing more familiar and comfortable with their technologies and their insulin needs over time, gaining a better understanding of and control over their diabetes. A moderate correlation was also observed between HbA1c and TIR within the survey participants. This shows that HbA1c is a reliable metric that can be used for comparison. However, TIR metrics provide a more accurate representation of glycaemic control than HbA1c. This is specifically problematic for cohorts with high risk of hypoglycaemia where a low HbA1c would indicate good glycaemic control; however, the individual could be facing a lower QoL and side effects of having frequent hypoglycaemic events. Through the survey, no meaningful correlation was found between diabetes duration or CGM use duration with HbA1c. This can be attributed to the limited cohort sizes that can exaggerate the influence of individual outliers. It is also difficult to establish a meaningful relationship between CGM use duration or diabetes duration and HbA1c due to the respondents' demographics. The survey population constitutes largely older adults who have been diagnosed and using technology for a significant period. There were also few varieties of age groups and diabetes durations, thus creating a limitation within the data.

An evaluation which was not a common theme amongst research was the daily frequency of using a glucometer (SMBG). Cohort-3 showed the highest frequency of glucometer use than other cohorts at over 5 times per day which corresponds with the research. When individuals use CGMs, the need for frequent SMBG checks decreases.

Due to the difficulty of evaluating cost-effectiveness through a survey, an alternative evaluation was conducted. Participants were asked to estimate their total monthly costs and to report their health insurance status and perceived financial burden. Insufficient data was available to meaningfully compare between participants with different types of health insurance (e.g., public, private, and uninsured). However, those with public health insurance incur lower out of pocket costs for diabetes consumables than those uninsured. In Australia, CGM sensors and insulin are subsidised under public health schemes; however, insulin pumps are not covered and are funded through private health insurance or self-purchased [135]. Therefore, although no correlation was observed between insurance type and costs, there would likely be a correlation that may be reflected by a larger sample and considering other costs.

Cohort-1 reported a higher average monthly cost than cohort-2. Since the costs reported only cover the consumables and not the pump, any treatments for complications, or regular medical

visits, averages are assumed to be higher than reported. Perceived financial burden was relatively high in cohorts-1 and 2 with 42.8 % and 37.5 % perceiving the costs as a financial burden, respectively. This shows that regardless of treatment regimen, many individuals experience the ongoing cost of diabetes technology as a financial strain, which aligns with the research results. Even though CGM- and pump-related expenses differed between the two cohorts, the proportion of participants reporting financial burden was similarly high. This suggests that the affordability of diabetes technology is a concern across cohorts, and that perceived burden may be influenced not only by absolute cost but also by factors such as income, insurance coverage, and the cumulative nature of recurring consumable expenses.

PRO, although generally positive towards technologies, could not be statistically compared across technologies due to a lack of standardised methods and outcomes. However, evidence from both the literature and survey highlights consistent psychosocial benefits associated with diabetes technologies. Key domains highlighted were diabetes distress, FoH, treatment satisfaction, and overall QoL. Across 20 studies, reductions in FoH were observed, reflecting enhanced sense of control over daily management. Low levels of FoH observed in the survey illustrate the most consistent patient-perceived benefit. Studies using validated PROMs such as the HFS and HCS demonstrated substantial reductions in fear scores.

Most survey respondents agreed nocturnal hypoglycaemia is less of a concern than daily hypoglycaemic events. The slightly greater prevalence of nocturnal concerns among cohort-2 than cohort-1 suggests integrated systems more effectively reduce anxiety around overnight lows (hypoglycaemic events) which is a finding mirrored in RCTs reporting on HCL or SAP. Treatment satisfaction and usability also showed improvement, reflecting greater trust and ease of use, despite recurrent negative themes. Similarly, in the survey, nearly all participants described greater confidence in self-management and a perception of greater lifestyle freedom regardless of technology used. Diabetes distress scores were less prominent across the systematic review in which the decrease in DDS scores were at times nonsignificant. This aligns with systematic reviews reporting on PRO in which research identified that diabetes technologies in general do not seem to affect diabetes distress scores. However, as technology becomes more effective for performing automatic tasks, users report a reduced sense of burden of diabetes and an increase in QoL, suggesting that the technology could positively affect diabetes distress [125]. The survey findings present a more positive trend, with 57.1 % of cohort-1 reporting reduced diabetes-related distress and the remainder noting partial improvement after upgrading their treatment regimen to CGM + CSII (integrated systems), supporting the broader literature consensus that technology mitigates psychological burden through automation and real-time feedback.

Common negative themes reported within the systematic review included cost, alarm fatigue, data fatigue, and site issues, such as occlusion and skin irritation. This was also apparent within

the survey responses, in which 40 % of the respondents reported the technology as a financial burden on them, and 30 % reported a financial burden at least sometimes. 28.6 % of pump users reported site occlusions and difficulty finding suitable sites for insulin infusion sets. Others reported negative feelings towards the technology such as disliking devices semi-permanently attached to the body.

QoL outcomes reported in the literature were generally positive, even though they were measured in different ways across studies. The survey results of participants rating of their QoL was 7.1 and 7.6 out of 10 for cohort-1 and -2, respectively, suggesting good satisfaction. Figure 21 illustrated the results for each cohort's reported QoL. Cohort-1 exhibited the highest average rating but also the greatest variability. Cohort-2 included an outlier, represented by a data point with a rating of 5. Although Cohort-3 showed a lower average rating, this result could not be generalised due to limited data. While issues mentioned above were still common, these drawbacks were overshadowed by the psychosocial and practical benefits that participants associated with using diabetes technology.

Although not included within the systematic review, the theme of exercise was included within the survey in which the frequency and type of exercise were evaluated. This added another layer to the research, showing an additional factor which can influence glycaemic control. Survey responses indicated that most participants engaged in aerobic exercise more frequently than strength training, and a majority reported that exercise improved their glycaemic control. This aligns partially with published evidence showing that aerobic activity leads to a greater immediate reduction in glucose levels compared with resistance exercise. Literature also suggests that resistance exercise may provide more sustained glycaemic benefits, including significantly higher TIR in the 24-hours following activity [136]. Given that many respondents performed resistance exercises infrequently (often 0 to 1 day per week), this may explain why improvements in glycaemic control were often perceived as variable or only 'sometimes' noticeable. The survey results therefore reflect real-world patterns of exercise behaviour but also highlight that individuals may not be regularly engaging in the type or frequency of exercise shown to provide longer-lasting glycaemic benefits.

A theme often underemphasised within studies assessing diabetes technology is patient education. While this was integrated within a few studies, it was absent in most. In certain countries, such as Australia, patients have access to dedicated diabetes educators who provide comprehensive guidance to patients and caregivers on the optimal use of technology. This includes customisation of the technology and accurate calculation of insulin-to-carbohydrate ratios which is important for correct bolus dosing. This education becomes especially critical as technology gets more advanced and incorporates more complex features, which may overwhelm users and contribute to heightened distress or technology fatigue. Furthermore, patients who are well-educated and supported in using their devices are more likely to feel confident in

navigating the technology and report greater satisfaction. However, it can be inferred that existing high diabetes technology costs, combined with the additional expenses of ongoing educational sessions, can limit accessibility, especially among individuals from lower socio-economic backgrounds.

A formal risk of bias or studies quality scoring was not conducted in this thesis due to the heterogeneity of the included studies, which comprised randomised trials, observational studies, model-based economic evaluations, narrative and systematic reviews, among others, for which no single assessment tool would have been methodologically appropriate. Standard reliability tools are primarily designed for specific study types and are not often applicable across diverse methodologies. To capture the reliability of all included studies, multiple tools would have been applied which would not have produced comparable outcomes across the study designs included, thus increasing complexity without adding much value or interpretability.

The reliability of the systematic review is instead supported by a transparent methodology, including a predefined search strategy, explicit inclusion and exclusion criteria, and structured data extraction across all included studies. Study credibility was evaluated qualitatively by considering methodological transparency, appropriateness of comparators and assumptions, and consistency of findings across compared studies. All included studies were published in peer-reviewed journals indexed in major biomedical databases, providing baseline scientific scrutiny. Finally, convergence between findings from the systematic review and the survey further supported the robustness of the conclusions. Nevertheless, the lack of applied reliability assessment tools presented a limitation to this thesis.

Other limitations of the survey include having a relatively small population completing the survey. That was especially apparent by only one respondent comprising cohort-3, limiting the comparison potential between the three cohorts. Although the distribution across cohorts likely reflects treatment preferences among individuals with T1D in Australia, the sample is dominated by older adults living in a single country. As a result, the findings may not represent other age groups, such as younger individuals with shorter diabetes duration, or populations in countries with different healthcare resources or lower socioeconomic conditions. Another limitation was the use of categorical ranges for metrics such as HbA1c and TIR. Although this approach was intended to maintain consistency and accommodate participants who may not recall exact historical values, it also led to instances where individuals with slightly different values were grouped within the same range, appearing identical in the dataset.

6 Conclusion

This thesis examined the clinical effectiveness, cost-effectiveness, and PRO associated with diabetes technologies for the management of T1D, integrating evidence from a systematic literature review with real-world insights from a patient survey. Together, these findings provide a broader understanding of how CGM, CSII, SAP, and HCL systems influence glycaemic outcomes, economic value, and lived experience.

Across clinical studies, all diabetes technologies demonstrated measurable glycaemic benefits, though the magnitude and consistency varied by device and comparator. rtCGM technologies had the strongest evidence base, with reductions in HbA1c, fewer hypoglycaemic events, and improvements in TIR across diverse populations.

Among insulin-delivery devices, integrated systems such as SAP and HCL showed the greatest average HbA1c reductions reflecting the added benefit of sensor-guided insulin suspension or automation. However, this magnitude was strongly influenced by the comparator. SAP was often compared against lower-technology regimens (e.g., SMBG + MDI), where larger improvements were achievable. HCL systems were often compared with advanced baselines (e.g., CGM + MDI or CGM + CSII), leading to a ceiling effect that limited measurable improvement and explained the apparent superiority of SAP in certain studies. Thus, the apparent differences between the two technologies reflect not only technical capability but also the treatment context in which they were evaluated.

A key finding across technologies was that individuals with poor glycaemic control at baseline (HbA1c >8.5 %) experienced the largest benefits in terms of HbA1c reduction and hypoglycaemia prevention. Suggesting that those most at risk stand to gain the most. Furthermore, populations with poor glycaemic control were often paediatric, lower socio-economic status, or racial minorities.

Economic evidence showed notable variation across technologies. CSII demonstrated the lowest cost-effectiveness, with the highest average ICER and the smallest QALY gains, indicating that transitioning from MDI to CSII requires a large increase in cost for a modest health benefit. In contrast, SAP systems showed considerably stronger economic performance, yielding mid-range ICERs alongside relatively high QALY gains. The highest QALY gains were observed in HCL systems.

Furthermore, within the SAP studies, multiple studies had split cohorts into high baseline, and at risk of hypoglycaemia. There was a clear pattern of lower reported ICERs and higher QALYs within cohorts at risk of hypoglycaemia, although all studies reported it to be both beneficial and cost effective for both cohorts.

PRO from both the literature and survey revealed broad psychological and functional benefits. Users reported reduced FoH, greater confidence, and improved day-to-day functioning. Although

formal measures of diabetes distress showed little evidence for benefit within the systematic review. Overall, the use of diabetes technology meaningfully enhanced psychosocial wellbeing, confidence, and daily functioning, despite some usability challenges such as alarm fatigue, skin irritation, and cost. These findings highlight the need for improved device usability, affordability, and a wider inclusion of validated, patient-centred PROMs in future research to capture the experience of diabetes technology users.

Survey results reflected many of the same patterns found in the literature. Integrated system users achieved higher TIR, lower HbA1c, and greater perceived QoL than those using CGM + MDI, aligning with clinical trial evidence. Financial burden was a recurring theme, regardless of treatment regimen, demonstrating that the ongoing costs remain a barrier even in settings with strong technological accessibility such as Australia.

Importantly, the effectiveness of diabetes technologies, both clinical and cost, can heavily depend on the user. Someone who had appropriately managed their diabetes with CMG and MDI may gain little clinical benefit from adopting a more complex AID system, which may instead introduce new burdens such as device bulk or technological overwhelm. This highlights the need for personalised treatment decisions that consider not only clinical indicators, but also cost, lifestyle, and patient preference. Directing future work towards the customisation of diabetes technologies distribution and experience through the current glycaemic control and reported outcomes such as diabetes distress, FoH, and agreeability with technology use would be greatly beneficial.

References

1. Pease A, Lo C, Earnest A, Kiriakova V, Liew D, Zoungas S. The Efficacy of Technology in Type 1 Diabetes: A Systematic Review, Network Meta-analysis, and Narrative Synthesis. Diabetes Technol Ther. 2020 May;22(5):411–21.

2. Grattoni A, Korbutt G, Tomei AA, García AJ, Pepper AR, Stabler C, et al. Harnessing cellular therapeutics for type 1 diabetes mellitus: progress, challenges, and the road ahead. Nat Rev Endocrinol. 2025 Jan;21(1):14–30.

3. Continuous Monitoring of Glucose for Type 1 Diabetes: A Health Technology Assessment. Ont Health Technol Assess Ser. 2018;18(2):1–160.

4. Pérez-Gandía C, García-Sáez G, Subías D, Rodríguez-Herrero A, Gómez EJ, Rigla M, et al. Decision Support in Diabetes Care: The Challenge of Supporting Patients in Their Daily Living Using a Mobile Glucose Predictor. J Diabetes Sci Technol. 2018 Mar;12(2):243–50.

5. DeSalvo DJ, Noor N, Xie C, Corathers SD, Majidi S, McDonough RJ, et al. Patient Demographics and Clinical Outcomes Among Type 1 Diabetes Patients Using Continuous Glucose Monitors: Data From T1D Exchange Real-World Observational Study. J Diabetes Sci Technol. 2023 Mar;17(2):322–8.

6. Sims EK, Carr ALJ, Oram RA, DiMeglio LA, Evans-Molina C. 100 years of insulin: celebrating the past, present and future of diabetes therapy. Nat Med. 2021 July;27(7):1154–64.

7. Reddy M, Oliver N. The role of real-time continuous glucose monitoring in diabetes management and how it should link to integrated personalized diabetes management. Diabetes Obes Metab. 2024 Mar;26 Suppl 1:46–56.

8. Berget C, Messer LH, Forlenza GP. A Clinical Overview of Insulin Pump Therapy for the Management of Diabetes: Past, Present, and Future of Intensive Therapy. Diabetes Spectrum. 2019 Aug 1;32(3):194–204.

9. Wallia A, Agarwal S, Owen AL, Lam EL, Davis K, Bailey SC, et al. Disparities in Continuous Glucose Monitoring Among Patients Receiving Care in Federally Qualified Health Centers. JAMA Netw Open. 2024 Nov 22;7(11):e2445316.

10. Wood A, O'Neal D, Furler J, Ekinci EI. Continuous glucose monitoring: a review of the evidence, opportunities for future use and ongoing challenges. Intern Med J. 2018 May;48(5):499–508.

11. Freckmann G, Buck S, Waldenmaier D, Kulzer B, Schnell O, Gelchsheimer U, et al. Insulin Pump Therapy for Patients With Type 2 Diabetes Mellitus: Evidence, Current Barriers, and New Technologies. J Diabetes Sci Technol. 2021 July;15(4):901–15.

12. Ajjan R, Slattery D, Wright E. Continuous Glucose Monitoring: A Brief Review for Primary Care Practitioners. Adv Ther. 2019 Mar;36(3):579–96.

13. Montagnana M, Caputo M, Giavarina D, Lippi G. Overview on self-monitoring of blood glucose. Clinica Chimica Acta. 2009 Apr;402(1–2):7–13.

14. MIT School of Engineering | » How do glucometers work? [Internet]. Mit Engineering. [cited 2025 Dec 4]. Available from: https://engineering.mit.edu/engage/ask-an-engineer/how-do-glucometers-work/

15. Demystifying Blood Glucose Monitoring: Devices Explained [Internet]. [cited 2025 Dec 4]. Available from: https://www.promed-dme.com/resource/best-blood-glucose-monitors

16. Lin R, Brown F, James S, Jones J, Ekinci E. Continuous glucose monitoring: A review of the evidence in type 1 and 2 diabetes mellitus. Diabet Med. 2021 May;38(5):e14528.

17. Gómez AM, Henao DC, Imitola A, Muñoz OM, Sepúlveda MAR, Kattah L, et al. Efficacy and safety of sensor-augmented pump therapy (SAPT) with predictive low-glucose management in patients diagnosed with type 1 diabetes mellitus previously treated with SAPT and low glucose suspend. Endocrinología, Diabetes y Nutrición (English ed). 2018 Oct;65(8):451–7.

18. Asgharzadeh A, Patel M, Connock M, Damery S, Ghosh I, Jordan M, et al. Hybrid closed-loop systems for managing blood glucose levels in type 1 diabetes: a systematic review and economic modelling. Health Technol Assess. 2024 Dec;28(80):1–190.

19. Liarakos AL, Crabtree TSJ, Wilmot EG. Patient-reported outcomes in studies of diabetes technology: What matters. Diabetes Obes Metab. 2024 Dec;26 Suppl 7(Suppl 7):59–73.

20. Sherr JL, Heinemann L, Fleming GA, Bergenstal RM, Bruttomesso D, Hanaire H, et al. Automated insulin delivery: benefits, challenges, and recommendations. A Consensus Report of the Joint Diabetes Technology Working Group of the European Association for the Study of Diabetes and the American Diabetes Association. Diabetologia. 2023 Jan;66(1):3–22.

21. Jiao Y, Lin R, Hua X, Churilov L, Gaca MJ, James S, et al. A systematic review: Cost-effectiveness of continuous glucose monitoring compared to self-monitoring of blood glucose in type 1 diabetes. Endocrinol Diabetes Metab. 2022 Nov;5(6):e369.

22. Bergmo TS. Using QALYs in telehealth evaluations: a systematic review of methodology and transparency. BMC Health Serv Res. 2014 Dec;14(1):332.

23. Shemilt I, James T, Marcello M. A web-based tool for adjusting costs to a specific target currency and price year. Evidence & Policy. 2010 Jan 1;6(1):51–9.

24. Flash Glucose Monitoring System for People with Type 1 or Type 2 Diabetes: A Health Technology Assessment. Ont Health Technol Assess Ser. 2019;19(8):1–108.

25. Bidonde J, Fagerlund BC, Frønsdal KB, Lund UH, Robberstad B. FreeStyle Libre Flash Glucose Self-Monitoring System: A Single-Technology Assessment. Oslo, Norway; 2017.

26. Young C, Grobelna A. Flash Glucose Monitoring Systems in Pediatric Populations With Diabetes. Ottawa (ON); 2021.

27. Castellana M, Parisi C, Di Molfetta S, Di Gioia L, Natalicchio A, Perrini S, et al. Efficacy and safety of flash glucose monitoring in patients with type 1 and type 2 diabetes: a systematic review and meta-analysis. BMJ Open Diabetes Res Care. 2020 June;8(1).

28. Alshehri NA, Alessa MS, Alrasheed AA, Alyousefi N, Alwatban L, AlSaif HI, et al. Role of Continuous Glucose Monitoring in Supporting Glycemic Control Among Adolescents with Type 1 Diabetes in Saudi Arabia: A Retrospective Study. Healthcare (Basel). 2025 Feb 25;13(5).

29. Brett McQueen R, Perez-Nieves M, Todd Alonso G, Fan L, Hankosky ER, Shah VN, et al. Association between continuous glucose monitoring metrics and clinical outcomes in adults with type 1 diabetes in a real-world setting. Diabetes Res Clin Pract. 2024 June;212:111690.

30. Charleer S, De Block C, Bolsens N, Van Huffel L, Nobels F, Mathieu C, et al. Sustained Impact of Intermittently Scanned Continuous Glucose Monitoring on Treatment Satisfaction and Severe Hypoglycemia in Adults with Type 1 Diabetes (FUTURE): An Analysis in People with Normal and Impaired Awareness of Hypoglycemia. Diabetes Technol Ther. 2023 Apr;25(4):231–41.

31. Nana M, Moore SL, Ang E, Lee ZX, Bondugulapati LNR. Flash glucose monitoring: Impact on markers of glycaemic control and patient-reported outcomes in individuals with type 1 diabetes mellitus in the real-world setting. Diabetes Research and Clinical Practice. 2019 Nov 1;157:107893.

32. Heinemann L, Freckmann G, Ehrmann D, Faber-Heinemann G, Guerra S, Waldenmaier D, et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. The Lancet. 2018 Apr;391(10128):1367–77.

33. Lind M, Polonsky W, Hirsch IB, Heise T, Bolinder J, Dahlqvist S, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):379–87.

34. Beck RW, Riddlesworth T, Ruedy K, Ahmann A, Bergenstal R, Haller S, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):371–8.

35. Pratley RE, Kanapka LG, Rickels MR, Ahmann A, Aleppo G, Beck R, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. 2020 June 16;323(23):2397–406.

36. Laffel LM, Kanapka LG, Beck RW, Bergamo K, Clements MA, Criego A, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. 2020 June 16;323(23):2388–96.

37. Šoupal J, Petruželková L, Flekač M, Pelcl T, Matoulek M, Daňková M, et al. Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study. Diabetes Technology & Therapeutics. 2016 Sept;18(9):532–8.

38. Nefs G, Bazelmans E, Marsman D, Snellen N, Tack CJ, de Galan BE. RT-CGM in adults with type 1 diabetes improves both glycaemic and patient-reported outcomes, but independent of each other. Diabetes Res Clin Pract. 2019 Dec;158:107910.

39. Pratley RE, Kanapka LG, Rickels MR, Ahmann A, Aleppo G, Beck R, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. 2020 June 16;323(23):2397–406.

40. Wan W, Skandari MR, Minc A, Nathan AG, Winn A, Zarei P, et al. Cost-effectiveness of Continuous Glucose Monitoring for Adults With Type 1 Diabetes Compared With Self-Monitoring of Blood Glucose: The DIAMOND Randomized Trial. Diabetes Care. 2018 June;41(6):1227–34.

41. Gilbert TR, Noar A, Blalock O, Polonsky WH. Change in Hemoglobin A1c and Quality of Life with Real-Time Continuous Glucose Monitoring Use by People with Insulin-Treated Diabetes in the Landmark Study. Diabetes Technol Ther. 2021 Mar;23(S1):S35–9.

42. Gómez AM, Henao Carrillo DC, Muñoz Velandia OM. Devices for continuous monitoring of glucose: update in technology. Med Devices (Auckl). 2017;10:215–24.

43. Ravi SJ, Coakley A, Vigers T, Pyle L, Forlenza GP, Alonso T. Pediatric Medicaid Patients With Type 1 Diabetes Benefit From Continuous Glucose Monitor Technology. J Diabetes Sci Technol. 2021 May;15(3):630–5.

44. Gavin JR, Bailey CJ. Real-World Studies Support Use of Continuous Glucose Monitoring in Type 1 and Type 2 Diabetes Independently of Treatment Regimen. Diabetes Technol Ther. 2021 Sept;23(S3):S19–27.

45. Baboun D, Solano N, Del Toro V, Alvarez-Salvat R, Granados A, Carrillo-Iregui A. Technology use and clinical outcomes in a racial-ethnic minority cohort of children and adolescents with type 1 diabetes. J Pediatr Endocrinol Metab. 2023 Dec 15;36(12):1128–32.

46. Hood KK, Bergenstal RM, Cushman T, Gal RL, Raghinaru D, Kruger D, et al. Patient-Reported Outcomes Improve with a Virtual Diabetes Care Model that Includes Continuous Glucose Monitoring. Telemed J E Health. 2025 Jan;31(1):75–84.

47. Ang E, Lee ZX, Moore S, Nana M. Flash glucose monitoring (FGM): A clinical review on glycaemic outcomes and impact on quality of life. Journal of Diabetes and its Complications. 2020 June 1;34(6):107559.

48. Aggarwal A, Pathak S, Goyal R. Clinical and economic outcomes of continuous glucose monitoring system (CGMS) in patients with diabetes mellitus: A systematic literature review. Diabetes Res Clin Pract. 2022 Apr;186:109825.

49. Hu S, Yang H, Chen Z, Leng X, Li C, Qiao L, et al. Clinical Outcome and Cost-Effectiveness Analysis of CSII Versus MDI in Children and Adolescent With Type 1 Diabetes Mellitus in a Public Health Care System of China. Front Endocrinol (Lausanne). 2021;12:604028.

50. Swaminathan K. One-Year follow-up of 50 Rural Underprivileged Type 1 Diabetes Children on Insulin Pump Therapy: Breaking Socio-Economic Barriers in Diabetes Technologies. Indian J Endocrinol Metab. 2023 June;27(3):213–5.

51. Blair J, McKay A, Ridyard C, Thornborough K, Bedson E, Peak M, et al. Continuous subcutaneous insulin infusion versus multiple daily injections in children and young people at diagnosis of type 1 diabetes: the SCIPI RCT. Health Technol Assess. 2018 Aug;22(42):1–112.

52. Sherr JL, Hermann JM, Campbell F, Foster NC, Hofer SE, Allgrove J, et al. Use of insulin pump therapy in children and adolescents with type 1 diabetes and its impact on metabolic control: comparison of results from three large, transatlantic paediatric registries. Diabetologia. 2016 Jan;59(1):87–91.

53. Karges B, Schwandt A, Heidtmann B, Kordonouri O, Binder E, Schierloh U, et al. Association of Insulin Pump Therapy vs Insulin Injection Therapy With Severe Hypoglycemia, Ketoacidosis, and Glycemic Control Among Children, Adolescents, and Young Adults With Type 1 Diabetes. JAMA. 2017 Oct 10;318(14):1358–66.

54. McKee AM, Albert SG, Al-Hammadi N, Hinyard LJ. Outcomes for continuous subcutaneous insulin infusion users in young adults from lower socioeconomic backgrounds. Endocrinol Diabetes Metab. 2021 July;4(3):e00252.

55. Relative effectiveness of insulin pump treatment over multiple daily injections and structured education during flexible intensive insulin treatment for type 1 diabetes: cluster randomised trial (REPOSE). BMJ. 2017 Mar 30;356:j1285.

56. Yu J, Wang H, Zhu M, Xu J. MDI versus CSII in Chinese adults with type 1 diabetes in a real-world situation: based on propensity score matching method. Health Qual Life Outcomes. 2024 June 13;22(1):47.

57. Paisley AN, Beynon J, Fullwood C, Hindle A, Alam T, Urwin A, et al. Impact of social deprivation, demographics and centre on HbA(1c) outcomes with continuous subcutaneous insulin infusion. Diabet Med. 2019 Mar;36(3):383–7.

58. Barnard-Kelly K, Thienel F, Mader JK, Oliver N, Franek E, Vesper I, et al. A Three-Arm Randomized Controlled Study Comparing Patient-Reported Outcomes in People With Type 1 Diabetes Using Continuous Subcutaneous Insulin Infusion or Multiple Daily Injections. J Diabetes Sci Technol. 2024 Mar 8;19322968241234055.

59. Brown JVE, Ajjan R, Alderson S, Böhnke JR, Carswell C, Doherty P, et al. The DIAMONDS intervention to support self-management of type 2 diabetes in people with severe mental illness: Study protocol for a single-group feasibility study. SSM - Mental Health. 2022 Dec 1;2:100086.

60. Ramirez-Rincon A, Hincapie-García J, Arango CM, Aristizabal N, Castillo E, Hincapie G, et al. Clinical Outcomes After 1 Year of Augmented Insulin Pump Therapy in Patients with Diabetes in a Specialized Diabetes Center in Medellín, Colombia. Diabetes Technol Ther. 2016 Nov;18(11):713–8.

61. O'Meara M, Mateus Acuña JC, Uribe A. Long-Term Benefits of an Integrated Continuous Glucose Monitoring and Insulin Pump System for Emergency Admissions, Hospitalization, and Metabolic Control in a Cohort of People With Diabetes: Retrospective Cohort Study. JMIR Diabetes [Internet]. 2023 Jan 1;8. Available from: https://www.sciencedirect.com/science/article/pii/S2371437923000204

62. Brown RE, Vienneau T, Aronson R. Canadian Real-World Outcomes of Omnipod Initiation in People with Type 1 Diabetes (COPPER study): Evidence from the LMC Diabetes Registry. Diabet Med. 2021 June;38(6):e14420.

63. Matsuoka A, Hirota Y, Urai S, Hamaguchi T, Takeuchi T, Miura H, et al. Effect of switching from conventional continuous subcutaneous insulin infusion to sensor augmented pump therapy on glycemic profile in Japanese patients with type 1 diabetes. Diabetol Int. 2018 July;9(3):201–7.

64. Takagi S, Miura J, Shimura K, Hoshina S, Tsuchida Y, Takita M, et al. A sensor augmented pump may improve awareness of hypoglycemia and quality of life in Japanese patients with type 1 diabetes mellitus. Diabetol Int. 2022 Jan;13(1):280–7.

65. Choudhary P, Kolassa R, Keuthage W, Kroeger J, Thivolet C, Evans M, et al. Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study. The Lancet Diabetes & Endocrinology. 2022 Oct;10(10):720–31.

66. Edd SN, Castañeda J, Choudhary P, Kolassa R, Keuthage W, Kroeger J, et al. Twelve-month results of the ADAPT randomized controlled trial: Reproducibility and sustainability of advanced hybrid closed-loop therapy outcomes versus conventional therapy in adults with type 1 diabetes. Diabetes Obes Metab. 2023 Nov;25(11):3212–22.

67. Usoh CO, Price C, Johnson CP, Speiser JL, Aloi JA. Efficacy of Control-IQ Technology in a General Endocrine Clinic. Endocr Pract. 2023 Jan;29(1):29–32.

68. Lal RA, Basina M, Maahs DM, Hood K, Buckingham B, Wilson DM. One Year Clinical Experience of the First Commercial Hybrid Closed-Loop System. Diabetes Care. 2019 Dec;42(12):2190–6.

69. Matejko B, Juza A, Kieć-Wilk B, Cyranka K, Krzyżowska S, Cohen O, et al. One-Year Follow-Up of Advanced Hybrid Closed-Loop System in Adults with Type 1 Diabetes Previously Naive to Diabetes Technology: The Effect of Switching to a Calibration-Free Sensor. Diabetes Technol Ther. 2023 Aug;25(8):554–8.

70. Pulkkinen MA, Varimo TJ, Hakonen ET, Harsunen MH, Hyvönen ME, Janér JN, et al. MiniMed 780G™ in 2- to 6-Year-Old Children: Safety and Clinical Outcomes After the First 12 Weeks. Diabetes Technol Ther. 2023 Feb;25(2):100–7.

71. Abraham MB, Smith GJ, Dart J, Davis EA, Jones TW. Clinical Outcomes with MiniMed(TM) 780G Advanced Hybrid Closed-Loop Therapy in 2- to 6-Year-Old Children with Type 1 Diabetes. Diabetes Technol Ther. 2024 May;26(5):341–5.

72. Choudhary P, Arrieta A, van den Heuvel T, Castañeda J, Smaniotto V, Cohen O. Celebrating the Data from 100,000 Real-World Users of the MiniMed™ 780G System in Europe, Middle East, and Africa Collected Over 3 Years: From Data to Clinical Evidence. Diabetes Technol Ther. 2024 Mar;26(S3):32–7.

73. Graham R, Mueller L, Manning M, Habif S, Messer LH, Pinsker JE, et al. Real-World Use of Control-IQ Technology Is Associated with a Lower Rate of Severe Hypoglycemia and Diabetic Ketoacidosis Than Historical Data: Results of the Control-IQ Observational (CLIO) Prospective Study. Diabetes Technol Ther. 2024 Jan;26(1):24–32.

74. Bisio A, Anderson S, Norlander L, O'Malley G, Robic J, Ogyaadu S, et al. Impact of a Novel Diabetes Support System on a Cohort of Individuals With Type 1 Diabetes Treated With Multiple Daily Injections: A Multicenter Randomized Study. Diabetes Care. 2022 Jan 1;45(1):186–93.

75. Knoll C, Peacock S, Wäldchen M, Cooper D, Aulakh SK, Raile K, et al. Real-world evidence on clinical outcomes of people with type 1 diabetes using open-source and commercial automated insulin dosing systems: A systematic review. Diabet Med. 2022 May;39(5):e14741.

76. DuBose SN, Bauza C, Verdejo A, Beck RW, Bergenstal RM, Sherr J. Real-World, Patient-Reported and Clinic Data from Individuals with Type 1 Diabetes Using the MiniMed 670G Hybrid Closed-Loop System. Diabetes Technol Ther. 2021 Dec;23(12):791–8.

77. Bisio A, Gonder-Frederick L, McFadden R, Cherñavvsky D, Voelmle M, Pajewski M, et al. The Impact of a Recently Approved Automated Insulin Delivery System on Glycemic, Sleep, and Psychosocial Outcomes in Older Adults With Type 1 Diabetes: A Pilot Study. J Diabetes Sci Technol. 2022 May;16(3):663–9.

78. Bahia L, Mello KF, Lemos LLP, Costa NL, Mulinari E, Malerbi DA. Cost-effectiveness of continuous glucose monitoring with FreeStyle Libre(®) in Brazilian insulin-treated patients with types 1 and 2 diabetes mellitus. Diabetol Metab Syndr. 2023 Nov 25;15(1):242.

79. Harris S, Cimino S, Nguyen Y, Szafranski K, Poon Y. Cost-Effectiveness of FreeStyle Libre for Glucose Self-Management Among People with Diabetes Mellitus: A Canadian Private Payer Perspective. Diabetes Ther. 2025 Feb;16(2):169–86.

80. Rotondi MA, Wong O, Riddell M, Perkins B. Population-Level Impact and Cost-effectiveness of Continuous Glucose Monitoring and Intermittently Scanned Continuous Glucose Monitoring Technologies for Adults With Type 1 Diabetes in Canada: A Modeling Study. Diabetes Care. 2022 Sept 1;45(9):2012–9.

81. Roze S, Isitt JJ, Smith-Palmer J, Lynch P. Evaluation of the Long-Term Cost-Effectiveness of the Dexcom G6 Continuous Glucose Monitor versus Self-Monitoring of Blood Glucose in People with Type 1 Diabetes in Canada. Clinicoecon Outcomes Res. 2021;13:717–25.

82. Chaugule S, Graham C. Cost-effectiveness of G5 Mobile continuous glucose monitoring device compared to self-monitoring of blood glucose alone for people with type 1 diabetes from the Canadian societal perspective. J Med Econ. 2017 Nov;20(11):1128–35.

83. García-Lorenzo B, Rivero-Santana A, Vallejo-Torres L, Castilla-Rodríguez I, García-Pérez S, García-Pérez L, et al. Cost-effectiveness analysis of real-time continuous monitoring glucose compared to self-monitoring of blood glucose for diabetes mellitus in Spain. J Eval Clin Pract. 2018 Aug;24(4):772–81.

84. Pease AJ, Zoungas S, Callander E, Jones TW, Johnson SR, Holmes-Walker DJ, et al. Nationally Subsidized Continuous Glucose Monitoring: A Cost-effectiveness Analysis. Diabetes Care. 2022 Nov 1;45(11):2611–9.

85. Alshannaq H, Cogswell G, Pollock RF, Ahmed W, Norman GJ, Lynch PM, et al. Cost-utility of real-time continuous glucose monitoring versus self-monitoring of blood glucose and intermittently scanned continuous glucose monitoring in people with type 1 diabetes receiving multiple daily insulin injections in Denmark. Diabetes Obes Metab. 2023 Sept;25(9):2704–13.

86. Isitt JJ, Roze S, Tilden D, Arora N, Palmer AJ, Jones T, et al. Long-term cost-effectiveness of Dexcom G6 real-time continuous glucose monitoring system in people with type 1 diabetes in Australia. Diabet Med. 2022 July;39(7):e14831.

87. de Jong LA, Li X, Emamipour S, van der Werf S, Postma MJ, van Dijk PR, et al. Evaluating the Cost-Utility of Continuous Glucose Monitoring in Individuals with Type 1 Diabetes: A Systematic Review of the Methods and Quality of Studies Using Decision Models or Empirical Data. Pharmacoeconomics. 2024 Sept;42(9):929–53.

88. Molaee MC, Naseri ZG, Karami MA. Long-Term Cost-Effectiveness of Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Adults With Type 1 Diabetes in Iran. Value in Health Regional Issues. 2024 Sept 1;43:101002.

89. Roze S, Isitt J, Smith-Palmer J, Javanbakht M, Lynch P. Long-term Cost-Effectiveness of Dexcom G6 Real-time Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Patients With Type 1 Diabetes in the U.K. Diabetes Care. 2020 Oct;43(10):2411–7.

90. Roze S, Isitt JJ, Smith-Palmer J, Lynch P, Klinkenbijl B, Zammit G, et al. Long-Term Cost-Effectiveness the Dexcom G6 Real-Time Continuous Glucose Monitoring System Compared with Self-Monitoring of Blood Glucose in People with Type 1 Diabetes in France. Diabetes Ther. 2021 Jan;12(1):235–46.

91. Bilir SP, Hellmund R, Wehler B, Li H, Munakata J, Lamotte M. Cost-effectiveness Analysis of a Flash Glucose Monitoring System for Patients with Type 1 Diabetes Receiving Intensive Insulin Treatment in Sweden. Eur Endocrinol. 2018 Sept;14(2):73–9.

92. Elliott RA, Rogers G, Evans ML, Neupane S, Rayman G, Lumley S, et al. Estimating the cost-effectiveness of intermittently scanned continuous glucose monitoring in adults with type 1 diabetes in England. Diabet Med. 2024 Mar;41(3):e15232.

93. Mustonen J, Rautiainen P, Lamidi ML, Lavikainen P, Martikainen J, Laatikainen T. Long-Term Health Economic Evaluation of Intermittently Scanned Glucose Monitoring Compared with Self-Monitoring Blood Glucose in a Real-World Setting in Finnish Adult Individuals with Type 1 Diabetes. Diabetes Technol Ther. 2024 Dec;26(12):918–24.

94. Zhao X, Ming J, Qu S, Li HJ, Wu J, Ji L, et al. Cost-Effectiveness of Flash Glucose Monitoring for the Management of Patients with Type 1 and Patients with Type 2 Diabetes in China. Diabetes Ther. 2021 Dec;12(12):3079–92.

95. Wan W, Skandari MR, Minc A, Nathan AG, Zarei P, Winn AN, et al. Cost-effectiveness of Initiating an Insulin Pump in T1D Adults Using Continuous Glucose Monitoring Compared with Multiple Daily Insulin Injections: The DIAMOND Randomized Trial. Med Decis Making. 2018 Nov;38(8):942–53.

96. Doubova SV, Roze S, Ferreira-Hermosillo A, Pérez-Cuevas R, Gasca-Pineda R, Barsoe C, et al. Cost-effectiveness of the use of the continuous subcutaneous insulin infusion pump versus daily multiple injections in type 1 diabetes adult patients at the Mexican Institute of Social Security. Cost Eff Resour Alloc. 2019;17:19.

97. Gomez AM, Alfonso-Cristancho R, Orozco JJ, Lynch PM, Prieto D, Saunders R, et al. Clinical and economic benefits of integrated pump/CGM technology therapy in patients with type 1 diabetes in Colombia. Endocrinología y Nutrición (English Edition). 2016 Nov 1;63(9):466–74.

98. Zhang L, Leng X, Tian F, Xiao D, Xuan J, Yang H, et al. Cost-effectiveness analysis of continuous subcutaneous insulin infusion versus multiple daily insulin for treatment of children with type 1 diabetes. Postgrad Med. 2022 Aug;134(6):627–34.

99. Roze S, Smith-Palmer J, Valentine W, de Portu S, Nørgaard K, Pickup JC. Cost-effectiveness of continuous subcutaneous insulin infusion versus multiple daily injections of insulin in Type 1 diabetes: a systematic review. Diabet Med. 2015 Nov;32(11):1415–24.

100. Jendle J, Smith-Palmer J, Delbaere A, de Portu S, Papo N, Valentine W, et al. Cost-Effectiveness Analysis of Sensor-Augmented Insulin Pump Therapy with Automated Insulin Suspension Versus Standard Insulin Pump Therapy in Patients with Type 1 Diabetes in Sweden. Diabetes Ther. 2017 Oct;8(5):1015–30.

101. Conget I, Martín-Vaquero P, Roze S, Elías I, Pineda C, Álvarez M, et al. Cost-effectiveness analysis of sensor-augmented pump therapy with low glucose-suspend in patients with type 1 diabetes mellitus and high risk of hypoglycemia in Spain. Endocrinología, Diabetes y Nutrición. 2018 Aug 1;65(7):380–6.

102. Roze S, Smith-Palmer J, de Portu S, Özdemir Saltik AZ, Akgül T, Deyneli O. Cost-Effectiveness of Sensor-Augmented Insulin Pump Therapy Versus Continuous Insulin Infusion in Patients with Type 1 Diabetes in Turkey. Diabetes Technol Ther. 2019 Dec;21(12):727–35.

103. Roze S, Smith-Palmer J, de Portu S, Delbaere A, de Brouwer B, de Valk HW. Cost-effectiveness of sensor-augmented insulin pump therapy vs continuous subcutaneous insulin infusion in patients with type 1 diabetes in the Netherlands. Clinicoecon Outcomes Res. 2019;11:73–82.

104. Nicolucci A, Rossi MC, D'Ostilio D, Delbaere A, de Portu S, Roze S. Cost-effectiveness of sensor-augmented pump therapy in two different patient populations with type 1 diabetes in Italy. Nutrition, Metabolism and Cardiovascular Diseases. 2018 July 1;28(7):707–15.

105. Roze S, de Portu S, Smith-Palmer J, Delbaere A, Valentine W, Ridderstråle M. Cost-effectiveness of sensor-augmented pump therapy versus standard insulin pump therapy in patients with type 1 diabetes in Denmark. Diabetes Research and Clinical Practice. 2017 June 1;128:6–14.

106. Roze S, Smith-Palmer J, Valentine WJ, Cook M, Jethwa M, de Portu S, et al. Long-term health economic benefits of sensor-augmented pump therapy vs continuous subcutaneous insulin infusion alone in type 1 diabetes: a U.K. perspective. J Med Econ. 2016;19(3):236–42.

107. Adolfsson P, Heringhaus A, Sjunnesson K, Mehkri L, Bolin K. Cost-effectiveness of the tandem t: Slim X2 with control-IQ technology automated insulin delivery system in children and adolescents with type 1 diabetes in Sweden. Diabet Med. 2024 Nov;41(11):e15432.

108. Lambadiari V, Ozdemir Saltik AZ, de Portu S, Buompensiere MI, Kountouri A, Korakas E, et al. Cost-Effectiveness Analysis of an Advanced Hybrid Closed-Loop Insulin Delivery System in People with Type 1 Diabetes in Greece. Diabetes Technol Ther. 2022 May;24(5):316–23.

109. Jendle J, Buompensiere MI, Ozdemir Saltik AZ, de Portu S, Smith-Palmer J, Pollock RF, et al. A European Cost-Utility Analysis of the MiniMed™ 780G Advanced Hybrid Closed-Loop System Versus Intermittently Scanned Continuous Glucose Monitoring with Multiple Daily Insulin Injections in People Living with Type 1 Diabetes. Diabetes Technol Ther. 2023 Dec;25(12):864–76.

110. Jendle J, Pöhlmann J, de Portu S, Smith-Palmer J, Roze S. Cost-Effectiveness Analysis of the MiniMed 670G Hybrid Closed-Loop System Versus Continuous Subcutaneous Insulin Infusion for Treatment of Type 1 Diabetes. Diabetes Technol Ther. 2019 Mar;21(3):110–8.

111. Roze S, Buompensiere MI, Ozdemir Z, de Portu S, Cohen O. Cost-effectiveness of a novel hybrid closed-loop system compared with continuous subcutaneous insulin infusion in people with type 1 diabetes in the UK. J Med Econ. 2021 Dec;24(1):883–90.

112. Serné EH, Roze S, Buompensiere MI, Valentine WJ, De Portu S, de Valk HW. Cost-Effectiveness of Hybrid Closed Loop Insulin Pumps Versus Multiple Daily Injections Plus Intermittently Scanned Glucose Monitoring in People With Type 1 Diabetes in The Netherlands. Adv Ther. 2022 Apr;39(4):1844–56.

113. Kommareddi M, Wherry K. Cost-effectiveness of the MiniMed 780G system for type 1 diabetes. Am J Manag Care. 2025 Apr 1;31(4):e79–86.

114. Hanaire H, Ozdemir Saltik AZ, Pollock RF, Nanu N, Sambuc C, Grangeon A, et al. Cost-Utility Analysis of the MiniMed ™ 780G Advanced Hybrid Closed-Loop System Versus Intermittently Scanned Continuous Glucose Monitoring with Multiple Daily Insulin Injections in People with Type 1 Diabetes in France. Diabetes Technology & Therapeutics. 2025 July 2;dia.2025.0100.

115. Gardner D, Lakkad M, Qiu Z, Inoue Y, Rama Chandran S, Wherry K. The Cost-Effectiveness of an Advanced Hybrid Closed-Loop System Compared to Standard Management of Type 1 Diabetes in a Singapore Setting. Diabetes Technol Ther. 2024 May;26(5):324–34.

116. Jendle J, Buompensiere MI, Holm AL, de Portu S, Malkin SJP, Cohen O. The Cost-Effectiveness of an Advanced Hybrid Closed-Loop System in People with Type 1 Diabetes: a Health Economic Analysis in Sweden. Diabetes Ther. 2021 Nov;12(11):2977–91.

117. Ehrmann D, Heinemann L, Freckmann G, Waldenmaier D, Faber-Heinemann G, Hermanns N. The Effects and Effect Sizes of Real-Time Continuous Glucose Monitoring on Patient-Reported Outcomes: A Secondary Analysis of the HypoDE Study. Diabetes Technol Ther. 2019 Feb;21(2):86–93.

118. Polonsky WH, Hood KK, Levy CJ, MacLeish SA, Hirsch IB, Brown SA, et al. How introduction of automated insulin delivery systems may influence psychosocial outcomes in adults with type 1 diabetes: Findings from the first investigation with the Omnipod® 5 System. Diabetes Res Clin Pract. 2022 Aug;190:109998.

119. Kudva YC, Laffel LM, Brown SA, Raghinaru D, Pinsker JE, Ekhlaspour L, et al. Patient-Reported Outcomes in a Randomized Trial of Closed-Loop Control: The Pivotal International Diabetes Closed-Loop Trial. Diabetes Technol Ther. 2021 Oct;23(10):673–83.

120. Mueller-Godeffroy E, Vonthein R, Ludwig-Seibold C, Heidtmann B, Boettcher C, Kramer M, et al. Psychosocial benefits of insulin pump therapy in children with diabetes type 1 and their families: The pumpkin multicenter randomized controlled trial. Pediatr Diabetes. 2018 Dec;19(8):1471–80.

121. Artime E, Hillman N, Tinahones FJ, Pérez A, Giménez M, Duque N, et al. Glucometrics and Patient-Reported Outcomes in Individuals With Type 1 Diabetes Mellitus: Insights From the Correlation of Time in Range (CorrelaTIR) Study in Real-World Settings. Cureus. 2025 Feb;17(2):e79134.

122. Pinsker JE, Müller L, Constantin A, Leas S, Manning M, McElwee Malloy M, et al. Real-World Patient-Reported Outcomes and Glycemic Results with Initiation of Control-IQ Technology. Diabetes Technol Ther. 2021 Feb;23(2):120–7.

123. Barnard-Kelly K, Marrero D, de Wit M, Pouwer F, Khunti K, Hermans N, et al. Towards standardization of person-reported outcomes (PROs) in pediatric diabetes research: A consensus report. Diabet Med. 2025 Mar;42(3):e15484.

124. Barnard KD, Wysocki T, Ully V, Mader JK, Pieber TR, Thabit H, et al. Closing the Loop in Adults, Children and Adolescents With Suboptimally Controlled Type 1 Diabetes Under Free Living Conditions: A Psychosocial Substudy. J Diabetes Sci Technol. 2017 Nov;11(6):1080–8.

125. Alcántara-Aragón V. Improving patient self-care using diabetes technologies. Ther Adv Endocrinol Metab. 2019;10:2042018818824215.

126. Tanenbaum ML, Commissariat PV. Experience with burdens of diabetes device use that affect uptake and optimal use in people with type 1 diabetes. Endocr Connect. 2023 Oct 1;12(10):e230193.

127. Haynes E, Ley M, Talbot P, Dunbar M, Cummings E. Insulin Pump Therapy Improves Quality of Life of Young Patients With Type 1 Diabetes Enrolled in a Government-Funded Insulin Pump Program: A Qualitative Study. Can J Diabetes. 2021 July;45(5):395–402.

128. Kubilay E, Trawley S, Ward GM, Fourlanos S, Colman PG, McAuley SA. Real-world lived experience of older adults with type 1 diabetes after an automated insulin delivery trial. Diabet Med. 2024 Apr;41(4):e15264.

129. Holt E, Nguyen H, Bispham J, Liu J, Chapman K, Grady M. Perceptions of Continuous Glucose Monitoring Systems in the T1D Exchange Diabetes Registry: Satisfaction, Concerns, and Areas for Future Improvement. Clin Diabetes. 2024 Winter;42(1):104–15.

130. Kubiak T, Mann CG, Barnard KC, Heinemann L. Psychosocial Aspects of Continuous Glucose Monitoring: Connecting to the Patients' Experience. J Diabetes Sci Technol. 2016 July;10(4):859–63.

131. Smith MB, Albanese-O'Neill A, Macieira TGR, Yao Y, Abbatematteo JM, Lyon D, et al. Human Factors Associated with Continuous Glucose Monitor Use in Patients with Diabetes: A Systematic Review. Diabetes Technol Ther. 2019 Oct;21(10):589–601.

132. Mesa A, Roca D, Granados M, Pueyo I, Cabré C, Amor AJ, et al. Massive switch to an automated insulin delivery system in adults with type 1 diabetes previously treated with sensor-augmented pump due to high risk for hypoglycemia. Endocrinología, Diabetes y Nutrición (English ed). 2024 Nov;71(9):390–6.

133. Akturk HK, Giordano D, Champakanath A, Brackett S, Garg S, Snell-Bergeon J. Long-term real-life glycaemic outcomes with a hybrid closed-loop system compared with sensor-augmented pump therapy in patients with type 1 diabetes. Diabetes Obesity Metabolism. 2020 Apr;22(4):583–9.

134. Acerini C. The rise of technology in diabetes care. Not all that is new is necessarily better. Pediatr Diabetes. 2016 May;17(3):168–73.

135. Access Continuous Glucose Monitoring | NDSS [Internet]. 2022 [cited 2025 Dec 14]. Available from: https://www.ndss.com.au/about-the-ndss/cgm-access/

136. Reddy R, Wittenberg A, Castle JR, El Youssef J, Winters-Stone K, Gillingham M, et al. Effect of Aerobic and Resistance Exercise on Glycemic Control in Adults With Type 1 Diabetes. Canadian Journal of Diabetes. 2019 Aug;43(6):406-414.e1.

Appendix A

Survey Instrument

Provided as supplemental material. Attached at the end of the document as Attachment A.

Consent Form

Details and Consent form

Thank you for considering contributing to this Master's research project. Before you fill the survey, please take a minute to read the following information to provide informed consent. You may contact the lead researcher if you have any questions.
Objectives: This Survey is investigating the clinical effectiveness, cost effectiveness, and patient outcomes of different management methods of Type 1 Diabetes.
Criteria for inclusion: Participants must be adults (> 18) who have been diagnosed with Type 1 diabetes.
Potential benefits and risks related to participation: Your participation in this research survey will contribute to better understanding the benefits of general Type 1 Diabetes management methods and current market trends. By sharing your experiences with diabetes management methods and/or devices such as continuous glucose monitors (CGMs) and insulin pumps, you will contribute to better understanding of how these methods and technologies impact daily life, technology satisfaction, and costs for adults with Type 1 Diabetes. Many participants may also find that reflecting on their own diabetes management through this survey may be informative and useful for discussing their care with their healthcare team. There are no potential risks to participation.
Data protection and confidentiality: Participation in this research survey is completely voluntary and anonymous. It involves the collection of data such as demographic data (e.g., age or gender), subjective evaluations (e.g., perceived user experience or usability), or CGM metrics (e.g., time in range). The data collected from you will only be saved and evaluated for the purpose of carrying out the intended objective of this research study. Only data that is necessary and relevant for the evaluation of the research is asked for. You may choose to skip any question that is not vital to the flow of the survey. You may choose to withdraw at any point during completing the survey. After completion, the submission cannot be withdrawn individually because it cannot be linked back to you.
In case you are interested in the research outcomes, please contact the researcher via the contact email address: wcm591@haw-hamburg.de
Identifiable data: There is no identifiable data. Once submitted, your responses will be stored anonymously.

1. Do you agree that we collect non-identifiable data from you via this survey for academic research purposes? *

- ◯ Yes
- ◯ No

Appendix B

Clinical effectiveness comparative tables:

Table B1 isCGM studies reporting HbA1c baseline/difference

Author (Year)	Country	Mean Baseline HbA1c (%)	Intervention	Control	HbA1c reduction
Nana et al. (2019)	United Kingdom	8.7	isCGM	Baseline (pre-isCGM) values	0.7
Alshehri et al. (2025)	Saudi Arabia	9.48	isCGM	SMBG	0.42
Charleer et al. (2023)	Belgium	Impaired awareness of Hypoglycaemia(IAH): 7.7 ±1.1 %	isCGM	None (pre- vs post-implementation)	0.1
Charleer et al. (2023)	Belgium	Normal awareness of Hypoglycaemia (NAH): 7.9 ±1.2 %	isCGM	None (pre- vs post-implementation)	0.2
Average					**0.36**
Standard Deviation					0.27

Table B2 rtCGM studies reporting HbA1c baseline/difference

Author (Year)	Country	Mean Baseline HbA1c (%)	Intervention	Control	HbA1c reduction
Heinemann et al. (2018)	Germany	7.6	rtCGM	SMBG	0.2
Lind et al. (2017)	Sweden	8.6	rtCGM	SMBG	0.68
Laffel et al. (2020)	United States	8.9	rtCGM	SMBG	0.4
Beck et al. (2017)	United States	8.6	rtCGM	SMBG	1.0
Prately et al. (2020)	United States	7.6	rtCGM	SMBG	0.4
Wan et al. (2018)	United States	8.6	rtCGM	SMBG	0.99
Gilbert et al. (2021)	United States	8.2	rtCGM	Within-subject pre-CGM baseline	1.1
Soupal et al. (2016)	Czech Republic	8.5	rtCGM	SMBG	1.3
Nefs et al. (2019)	Netherlands	8.3	rtCGM	within-subject comparison	0.7
Hood et al. (2025)	United States	7.7	rtCGM	–	0.6
Average					**0.74**
Standard Deviation					0.35

Table B3 CSII studies reporting HbA1c baseline/difference

Author (Year)	Country	Mean Baseline HbA1c (%)	Intervention	Control	HbA1c reduction
Barnard-Kelly et al. (2024)	EU (multi country)	8.0	CSII	MDI	0.2
Brown et al. (2020)	Canada	8.1	CSII	MDI	0.2
REPOSE Study Group (2017)	United Kingdom	9.3	CSII + DAFNE	MDI	0.76
Soupal et al. (2016)	Czech Republic	8.4	CSII + SMBG	MDI	0.5
Beck et al. (2017)	United States	7.6	CSII + CGM	CGM + MDI	0.1
Average					**0.35**
Standard Deviation					0.27

Table B4 SAP studies reporting HbA1c baseline/difference

Author (Year)	Country	Mean Baseline HbA1c (%)	Intervention	Control	HbA1c reduction
Ramírez-Rincón et al. (2016)	Colombia	8.7	SAP	Pre-CSII care	1.3
Soupal et al. (2016)	Czech Republic	8.2	SAP	SMBG + MDI SMBG + CSII	1.1
Gomez et al. (2018)	Colombia	7.5	SAP	pre-SAP care	0.34
Matsouka et al. (2018)	Japan	7.8	SAP	CSII	0.4
Takagi et al. (2022)	Japan	8.1	SAP	Pre-SAP therapy (CSII or MDI + SMBG)	1.0
Average					**0.83**
Standard Deviation					0.43

Table B5 HCL studies reporting HbA1c baseline/difference

Author (Year)	Country	Mean Baseline HbA1c (%)	Intervention	Control	HbA1c reduction
Asgharzadeh et al. (2024)	United Kingdom	-	HCL/AHCL	CSII+CGM	0.28
Edd et al. (2023)	Multinational	8.9	AHCL (MiniMed 780G)	MDI + isCGM	1.4
Choudhary et al. (2022)	France, Germany, UK	9.0	AHCL (MiniMed 780G)	MDI + isCGM	1.54
Usoh et al. (2022)	United States	7.7	AHCL	MDI + isCGM	0.6
Pulkkinen et al. (2023)	Finland	7.4	AHCL	MDI + isCGM	0.3
Matejko et al. (2023)	Poland	7.1	AHCL	MDI + isCGM	0.6
Average					**0.79**
Standard Deviation					0.55

Appendix C

Cost-effectiveness comparative tables:

Table C1 isCGM studies reporting ICER and QALY

Author (Year)	Country	Incremental costs	Incremental QALY	ICER	WTP Threshold	Technology Assessed	Control	Cost-effective
Bilir et al. (2018)	Sweden	€ 27,264	0.8	€ 34,025	€ 46,748	isCGM	SMBG	Yes
Harris et al. (2024)	Canada	-€ 21,554	1.25	Dominant (Not directly reported)	€ 10,681	isCGM	SMBG	Yes
Elliott et. Al (2024)	UK	€ 2,549	0.44	€ 5,839	€ 26,085	isCGM	SMBG	Yes
Mustonen et al. (2024)	Finland	€ 7,722	0.84	€ 9,230	€ 49,115	isCGM	SMBG	Yes
Zhao et al. (2021)	China	€ 13,251	1.22	€ 10,880	€ 51,104	isCGM	SMBG	Yes
Bahia et al. (2023)	Brazil	€ 2,685	0.28	€ 9,721	€ 14,803	isCGM	SMBG	Yes
Rotondi et al. (2022)	Canada	–	–	€ 12,622	€ 36,088	isCGM	SMBG	Yes
Average			**0.80**	**€ 13,719.50**				
Standard Deviation			0.39	€ 10,196.3				

Table C2 rtCGM studies reporting ICER and QALY

Author (Year)	Country	Incremental costs	Incremental QALY	ICER	WTP Threshold	Technology Assessed	Comparator	Cost effective
Wan et al. (2018)	United States	€ 28,190	0.54	€ 99,104	€ 101,015	rtCGM	SMBG	Yes
Chaugule et al. (2017)	Canada	€ 94,225	3.35	€ 28,092	€ 41,570	rtCGM	SMBG	Yes
Alshannaq et al. (2023)	Denmark	€ 8,375	1.37	€ 6,119	€ 50,328	rtCGM	SMBG	Yes
Roze et al. (2021)	Canada	€ 27,766	2.09	€ 13,298	€ 39,270	rtCGM	SMBG	Yes
Molaee et al. (2024)	Iran	€ 20,954	1.63	€ 12,847	€ 14,541	rtCGM	SMBG	Yes
Isitt et al. (2022)	Australia	€ 12,938	1.199	€ 10,795	€ 29,954	rtCGM	SMBG	Yes

Author (Year)	Country	Incremental costs	Incremental QALY	ICER	WTP Threshold	Technology Assessed	Comparator	Cost effective	
Roze et al. (2020)	UK	€ 20,083	1.49	€ 13,485	€ 28,218	rtCGM	SMBG	Yes	
Roze et al. (2021)	France	€ 56,703	1.38	€ 17,334	€ 56,703	rtCGM	SMBG	Yes	
Rotondi et al. (2022)	Canada	–	–	€ 25,274	€ 36,088	rtCGM	SMBG	Yes	
Average			**1.63**	**€ 25,149.8**					
Standard Deviation			0.82	€ 28,581.3					
Excluded from Average									**Reason for exclusion**
Health Quality Ontario (2018)	Canada	€ 84,162	0.094	**€ 898,808**	€ 40,530	rtCGM	SMBG	No	outlier
Lorenzo (2018)	Spain	€ 176,209	0.046	**€ 3,810,593**	€ 37,290	rtCGM	SMBG	No	outlier
Alshannaq et al. (2023)	Denmark	€ 4,201	**0.87**	€ 4,051	€ 50,328	rtCGM	**isCGM**	Yes	comparator not SMBG
Health Quality Ontario (2018)	Canada	€ 65,357	0.104	€ 631,207	€ 40,530	CGM + CSII	**SMBG+CSII**	No	comparator not SMBG
Pease et al. (2022)	Australia	€ 10,905	0.46	€ 23,674	€ 29,954	subsidised CGM	**User funded CGM**	Yes	comparator not SMBG
Isitt et al. (2022)	Australia	€ 12,938	0.569	€ 11,655	€ 29,954	rtCGM	**isCGM**	Yes	comparator not SMBG

Table C3 CSII studies reporting ICER and QALY

Author (Year)	Country	Incremental costs	Incremental QALY	ICER	WTP Threshold	Technology Assessed	Comparator	Cost effective
Zhang et al. (2022)	China	€ 9,953.00	0.415	€ 23,990.00	€ 50,641	CSII	MDI	Yes
Doubova et al. (2019)	Mexico	€ 35,891.00	0.614	€ 58,436.00	€ 56,111	CSII	MDI	43.9 % probability of being cost-effective
Hu et al. (2021)	China	€ 15,986.00	0.42	€ 38,530.00	€ 44,390	CSII	MDI	Yes
Average			**0.483**	**€ 40,318.7**				
Standard Deviation			0.113	€ 17,292.5				

Author (Year)	Country	Incremental costs	Incremental QALY	ICER	WTP Threshold	Technology Assessed	Comparator	Cost effective	
Excluded from Average									**Reason for exclusion**
Roze et al. (2015)	Multi-country	–	0.7 ± 0.3 QALYs (range 0.4–1.1)	**Mean: € 41,866 (€ 24,413 - € 56,793)**	CSII	MDI	–	Yes	ICER in range (systematic review)
Wan et al. (2018)	United States	€ 113,182.00	-0.71	**CSII dominated**	CSII + CGM	MDI + CGM	–	No	No ICER reported
Blair et al. (2018)	United Kingdom	€ 2,722.00	-0.006	**CSII dominated**	CSII	MDI	€ 43,833.00	No	No ICER reported

Table C4 SAP studies reporting ICER and QALY

Author (Year)	Country	Cohorts	Incremental costs	Incremental QALY	ICER/QALY (EUR)	WTP threshold (EUR)	Technology Assessed	Comparator	Cost-effective
Jendle et al. (2017)	Sweden	poor HbA1c control	€ 31,906	1.07	€ 29,888	€ 35,596	SAP with LGS	CSII	Yes
Jendle et al. (2017)	Sweden	high hypoglycaemia risk	€ 31,134	1.88	€ 16,587	€ 35,596	SAP with LGS	CSII	Yes
Conget et al. (2018)	Spain	high hypoglycaemia risk, Societal perspective	€ 62,003	-	€ 38,369	€ 45,328	SAP with LGS	CSII	Yes
Conget et al. (2018)	Spain	high hypoglycaemia risk, NHS perspective	€ 72,019	1.88	€ 33,032	€ 45,328	SAP with LGS	CSII	Yes
Roze et al. (2019)	Turkey	poor HbA1c control (9.0 %)	€ 19,878	1.40	€ 14,178	€ 14,726	SAP	CSII	Yes
Roze et al. (2019)	Turkey	high hypoglycaemia risk	€ 22,177	1.73	€ 12,798	€ 14,726	SAP	CSII	Yes
Roze et al. (2019)	Netherlands	poor HbA1c control (8.0 %)	€ 51,098	1.77	€ 28,888	€ 38,819	SAP with LGS	CSII	Yes
Roze et al. (2019)	Netherlands	High hypoglycaemia risk (7.5 %)	€ 42,677	2.16	€ 19,724	€ 38,819	SAP with LGS	CSII	Yes
Nicolucci et al. (2018)	Italy	poor HbA1c control	€ 84,883	1.45	€ 58,617	€ 65,156	SAP with LGS	CSII	Yes

Author (Year)	Country	Cohorts	Incremental costs	Incremental QALY	ICER/QALY (EUR)	WTP threshold (EUR)	Technology Assessed	Comparator	Cost-effective	
Nicolucci et al. (2018)	Italy	high hypoglycaemia risk	€ 82,409	1.88	€ 43,904	€ 65,156	SAP with LGS	CSII	Yes	
Roze et al. (2017)	Denmark	poor HbA1c control	€ 29,125	1.45	€ 20,113	€ 28,994	SAP with LGS	CSII	Yes	
Roze et al. (2017)	Denmark	high hypoglycaemia risk	€ 21,736	1.88	€ 11,580	€ 28,994	SAP with LGS	CSII	Yes	
Roze et al. (2016)	United Kingdom	poor HbA1c control (10 %)	€ 55,522	2.99	€ 18,574	€ 30,367 - 45,550	SAP with LGS	CSII	Yes	
Average		-		**1.79**	**€ 26,634.8**					
Standard Deviation				0.48	€ 13,978.8					
Excluded from Average										**Reason for exclusion**
Gomez et al. (2016)	Colombia	-	€ 92,813	3.81	€ 24,321	~ € 27,802	SAP	**MDI**	Yes	Comparator not CSII
Health Quality Ontario (2018)	Canada	-	€ 107,583	0.13	**€ 817,015**	€ 40,530	SAP, CGM	SMBG + MDI	No	Outlier
Health Quality Ontario (2018)	Canada	-	€ 65,701	0.14	**€ 480,045**	€ 40,530	SAP, CGM	SMBG + CSII	No	Outlier

Table C5 HCL/AHCL studies reporting ICER and QALY

Author (Year)	Country	Incremental Cost (EUR)	Incremental QALYs	ICER/QALY (EUR)	WTP threshold (EUR)	Technology Assessed	Comparator	Cost-effective	Cohort
Jendle et al. (2023)	Europe (6 countries)	€ 26,048.00	2.272	€ 11,463.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Austria
Jendle et al. (2023)	Europe (6 countries)	€ 41,158.00	2.272	€ 18,114.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Greece
Jendle et al. (2023)	Europe (6 countries)	€ 115,218.00	2.272	€ 50,706.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Italy
Jendle et al. (2023)	Europe (6 countries)	€ 77,643.00	2.272	€ 34,169.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Netherlands

Author (Year)	Country	Incremental Cost (EUR)	Incremental QALYs	ICER/QALY (EUR)	WTP threshold (EUR)	Technology Assessed	Comparator	Cost-effective	Cohort
Jendle et al. (2023)	Europe (6 countries)	€ 86,061.00	2.272	€ 37,874.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Spain
Jendle et al. (2023)	Europe (6 countries)	€ 8,890.00	2.272	€ 3,912.00	–	AHCL (MiniMed 780G)	isCGM + MDI	likely	Sweden
Serné et al. (2022)	Netherlands	€ 16,056.00	2.231	€ 7,196.00	€ 23,468.00	HCL (MiniMed 670G)	isCGM + MDI/CSII	Yes	
Kommareddi & Wherry (2025)	United States	$55,328.00	–	€ 30,452.00	€ 78,400.00	AHCL (MiniMed 780G)	isCGM + MDI	98.1 % chance of being cost-effective	
Hanaire et al. (2025)	France	€ 81,092.00	2.26	€ 35,875.00	€ 206,581.00	AHCL (MiniMed 780G)	isCGM + MDI	Yes	
Gardner et al. (2024)	Singapore	€ 48,088.00	1.45	€ 33,119.00	€ 44,097.00	AHCL (MiniMed 780G)	isCGM + MDI	Yes	
Jendle et al. (2021)	Sweden	€ 77,719.00	1.95	€ 39,927.00	€ 53,422.00	AHCL (MiniMed 780G)	isCGM + MDI/CSII	Yes	
Lambadiari et al. (2022)	Greece	€ 112,076.00	2.708	€ 43,819.00	€ 49,879.00	AHCL (MiniMed 780G)	isCGM + MDI	Yes	
Average		**€ 62,114.75**	**2.20**	**€ 28,885.5**					
Standard Deviation			0.30	€ 15,113.7					
Different comparators -HCL vs CSII									
Jendle et al. (2019)	Sweden	€ 34,816.00	**1.90**	€ 18,353.00	€ 33,525.00	HCL (MiniMed 670G)	CSII	Yes	Base case
Jendle et al. (2019)	Sweden	€ 3,978.00	**2.25**	€ 1,769.00	€ 33,525.00	HCL (MiniMed 670G)	CSII	Yes	Poor control
Roze et al. (2021)	UK	€ 49,981.00	**1.73**	€ 28,812.00	€ 28,218.00	HCL (MiniMed 670G)	CSII	likely	
Asgharzadeh et al. (2024)	UK	€ 14,544	**1.00**	€ 14,487.00	€ 23,370 - 35,055	HCL	CSII + CGM	Yes	NHS Pilot
Average		**€ 25,829.75**	**1.72**	**€ 15,855.25**					

Author (Year)	Country	Incremental Cost (EUR)	Incremental QALYs	ICER/QALY (EUR)	WTP threshold (EUR)	Technology Assessed	Comparator	Cost-effective	Cohort	
Standard Deviation			0.52	€ 11,171.55						
Excluded from Averages										**Reason for exclusion**
Adolfsson et al. (2024)	Sweden	-€ 115,796	**13.78**	€ 8,402	€ 49,136	CIQ automated insulin delivery + CGM	CSII+CGM	Yes, and cost saving		outlier
Asgharzadeh et al. (2024)	UK	€ 33,452.00	0.16	**€ 209,163**	€ 23,370 - 35,055	HCL	CSII + CGM	No	Base case	outlier
Adolfsson et al. (2024)	Sweden	-€ 32,178	12.59	–€ 6,444	€ 49,136	CIQ automated insulin delivery + CGM	**MDI + SMBG**	Yes, and cost saving		different comparator
Lambadiari et al. (2022)	Greece	-€ 14,924	0.28	-€ 53,264	€ 49,879	AHCL (MiniMed 780G)	**SAP + LGS**	Cost-saving vs SAP+PLGM; cost-effective vs MDI + isCGM		different comparator

Appendix D

Survey results tables

Table D1 pre- and post- pump HbA1c values from cohort-1, presented as mid-point values of reported ranges

Pre-pump [A]	Post-pump [B]	% difference [(A-B)/A]
5.8 %	6.2 %	-6.9 %
6.2 %	5.8 %	6.5 %
6.2 %	5.8 %	6.5 %
6.7 %	5.8 %	13.4 %
6.7 %	6.2 %	7.5 %
7.2 %	6.7 %	6.9 %
7.7 %	6.7 %	13.0 %
7.7 %	6.7 %	13.0 %
7.7 %	7.2 %	6.5 %
7.7 %	6.2 %	19.5 %
7.7 %	7.2 %	6.5 %
8.2 %	5.8 %	29.3 %
8.2 %	7.2 %	12.2 %
8.7 %	6.7 %	23.0 %

Branching options

Details and Consent form

Thank you for considering contributing to this Master's research project. Before you fill the survey, please take a minute to read the following information to provide informed consent. You may contact the lead researcher if you have any questions.

Objectives: This Survey is investigating the clinical effectiveness, cost effectiveness, and patient outcomes of different management methods of Type 1 Diabetes.

Criteria for inclusion: Participants must be adults (> 18) who have been diagnosed with Type 1 diabetes.

Potential benefits and risks related to participation: Your participation in this research survey will contribute to better understanding the benefits of general Type 1 Diabetes management methods and current market trends. By sharing your experiences with diabetes management methods and/or devices such as continuous glucose monitors (CGMs) and insulin pumps, you will contribute to better understanding of how these methods and technologies impact daily life, technology satisfaction, and costs for adults with Type 1 Diabetes. Many participants may also find that reflecting on their own diabetes management through this survey may be informative and useful for discussing their care with their healthcare team. There are no potential risks to participation.

Data protection and confidentiality: Participation in this research survey is completely voluntary and anonymous. It involves the collection of data such as demographic data (e.g., age or gender), subjective evaluations (e.g., perceived user experience or usability), or CGM metrics (e.g., time in range). The data collected from you will only be saved and evaluated for the purpose of carrying out the intended objective of this research study. Only data that is necessary and relevant for the evaluation of the research is asked for. You may choose to skip any question that is not vital to the flow of the survey. You may choose to withdraw at any point during completing the survey. After completion, the submission cannot be withdrawn individually because it cannot be linked back to you.

In case you are interested in the research outcomes, please contact the researcher via the contact email address: wcm591@haw-hamburg.de

Identifiable data: There is no identifiable data. Once submitted, your responses will be stored anonymously.

---

1. Do you agree that we collect non identifiable data from you via this survey for academic research purposes? *

Yes — Go to Next

No — Go to End of the form

Go to Next

Demographics

2. What gender do you identify as?

- Male
- Female
- Other

3. What is your age?

- < 18
- 18 - 25
- 26 - 35
- 36 - 45
- 46 - 55
- 56 - 65
- > 65

4. How many years have you been living with Type 1 diabetes?

- ◯ < 1 year
- ◯ 1 -5 years
- ◯ 6-10 years
- ◯ 11-15 years
- ◯ 16-20 years
- ◯ 21-25 years
- ◯ 26-30 years
- ◯ > 30 years

Go to Next

Diabetes care methods

5. Which of the following best describes your current approach to diabetes care? *

◯ Continuous glucose monitor (CGM)+ Insulin Pump	
◯ Continuous glucose monitor (CGM) + Multiple Daily Injections (MDI)	Go to 5. CGM + MDI
◯ Self-monitoring of blood glucose (SMBG) + Multiple Daily Injections (MDI)	Go to 6. MDI
◯ Self-monitoring of blood glucose (SMBG) + Insulin Pump	Go to 7. SMBG + Insulin Pump

Go to Next

CGM + Insulin Pump

6. How long have you used any Continuous glucose monitor (CGM) and/or insulin pump (not just your current one)?

- ◯ < 1 year
- ◯ 1 5 years
- ◯ 6 10 years
- ◯ 11 15 years
- ◯ 16 20 years
- ◯ 21 25 years
- ◯ 26 30 years
- ◯ > 30 years

7. Does your pump automatically adjust insulin based on your glucose readings?

- ◯ Yes
- ◯ No
- ◯ Not sure

8. How often do you check your blood glucose using a finger prick (capillary) method daily?

- ◯ 0 - 1 times
- ◯ 2 - 3 times
- ◯ 4 - 5 times
- ◯ > 5 times

9. What is your most recent HbA1c measurement?

- ◯ < 6.0%
- ◯ 6.0% – 6.4%
- ◯ 6.5% – 6.9%
- ◯ 7.0% – 7.4%
- ◯ 7.5% – 7.9%
- ◯ 8.0% – 8.4%
- ◯ 8.5% – 8.9%
- ◯ 9.0% – 9.4%
- ◯ 9.5% – 9.9%
- ◯ 10.0% – 10.4%
- ◯ 10.5% – 10.9%
- ◯ 11.0% – 11.4%
- ◯ 11.5% – 11.9%
- ◯ ≥ 12.0%

10. Over the past 30 days, what has your average Time in Range (3.9–10.0 mmol/L or 70–180 mg/dL) been according to your CGM data?

- ◯ Less than 30%
- ◯ 30% – 39%
- ◯ 40% – 49%
- ◯ 50% – 59%
- ◯ 60% – 69%
- ◯ 70% – 79%
- ◯ 80% – 89%
- ◯ 90% – 100%

11. Have you previously used multiple daily injections before starting on an insulin pump? *

- ◯ Yes
- ◯ No Go to 14. Indicate the level of your ...

12. What was your HbA1c range while using MDIs (before the insulin pump)?

Give an approximate of the last measurement you recall to the best of your ability

- ◯ < 6.0%
- ◯ 6.0% – 6.4%
- ◯ 6.5% – 6.9%
- ◯ 7.0% – 7.4%
- ◯ 7.5% – 7.9%
- ◯ 8.0% – 8.4%
- ◯ 8.5% – 8.9%
- ◯ 9.0% – 9.4%
- ◯ 9.5% – 9.9%
- ◯ 10.0% – 10.4%
- ◯ 10.5% – 10.9%
- ◯ 11.0% – 11.4%
- ◯ 11.5% – 11.9%
- ◯ ≥ 12.0%

13. Please indicate whether the below statement is true:

Compared to when I was using only multiple daily injections, I feel more comfortable and less stressed about my diabetes care now that I use a CGM and an insulin pump

- ◯ True
- ◯ Somewhat true
- ◯ False

14. Indicate the level of your agreement with each of the below statements

	Strongly Disagree	Disagree	Neutral	Agree
I feel concerned about low glucose levels (hypoglycaemia) while I am sleeping	○	○	○	○
I feel concerned about low glucose levels (hypoglycaemia) during my usual daily activities	○	○	○	○
I often have difficulties with site occlusion a nd finding a suitable site for my sensor	○	○	○	○
I often have difficulties with site occlusion and finding a suitable site for insulin infusion (i.e quickset, insulet, etc.)	○	○	○	○
My CGM and/or pump help me feel more at ease about low glucose levels while sleeping	○	○	○	○
My CGM and/or pump help me feel more at ease about low glucose levels during my usual daily activities.	○	○	○	○
I wear my CGM confidently in public	○	○	○	○

My CGM and/or pump help me feel confident in looking after my diabetes	○	○	○	○
Using my CGM and/or insulin pump allows me to live my daily life more freely	○	○	○	○
Overall, I am satisfied with my current CGM and/or insulin pump	○	○	○	○

Go to 8. Lifestyle

CGM + MDI

15. How long have you used any Continuous glucose monitor (not just your current one)?

- ◯ < 1 year
- ◯ 1 - 5 years
- ◯ 6 - 10 years
- ◯ 11 - 15 years
- ◯ 16 - 20 years
- ◯ 21 - 25 years
- ◯ 26 - 30 years
- ◯ > 30 years

16. How often do you check your blood glucose using a finger-prick (capillary) method daily?

- ◯ 0 1 times
- ◯ 2 3 times
- ◯ 4 5 times
- ◯ > 5 times

17. Why have you chosen not to use a pump?

- [ ] Financial Reasons
- [ ] Distrust of Technology
- [ ] I don't think I need it / I'm satisfied with multiple daily injections (MDIs)
- [ ] Too complicated to use
- [ ] Doctor did not recommend
- [ ] Other

18. What is your most recent HbA1c measurement?

- ◯ < 6.0%
- ◯ 6.0% – 6.4%
- ◯ 6.5% – 6.9%
- ◯ 7.0% – 7.4%
- ◯ 7.5% – 7.9%
- ◯ 8.0% – 8.4%
- ◯ 8.5% – 8.9%
- ◯ 9.0% – 9.4%
- ◯ 9.5% – 9.9%
- ◯ 10.0% – 10.4%
- ◯ 10.5% – 10.9%
- ◯ 11.0% – 11.4%
- ◯ 11.5% – 11.9%
- ◯ ≥ 12.0%

19. Over the past 30 days, what has your average Time in Range (3.9–10.0 mmol/L or 70–180 mg/dL) been according to your CGM data?

- ◯ Less than 30%
- ◯ 30% – 49%
- ◯ 50% – 59%
- ◯ 60% – 69%
- ◯ 70% – 79%
- ◯ 80% – 89%
- ◯ 90% – 100%

20. Indicate the level of your agreement with each of the below statements

	Strongly Disagree	Disagree	Neutral	Agree
I feel concerened about low glucose levels (hypoglycaemia) while I am sleeping	◯	◯	◯	◯
I feel concerened about low glucose levels (hypoglycaemia) during my usual daily activities	◯	◯	◯	◯
I often have difficulties with site occlusion and finding a suitable site for my sensor	◯	◯	◯	◯
I often have difficulties with site occlusion and finding a suitable site for my insulin injections	◯	◯	◯	◯
My CGM helps me feel more at ease about low glucose levels while sleeping	◯	◯	◯	◯
My CGM helps me feel more at ease about low glucose levels during my usual daily activities	◯	◯	◯	◯
I wear my CGM confidently in public	◯	◯	◯	◯

My CGM helps me feel confident in looking after my diabetes	◯	◯	◯	◯
Using my CGM allows me to live my daily life more freely.	◯	◯	◯	◯
Overall, I am satisfied with my current CGM	◯	◯	◯	◯

Go to 8. Lifestyle

MDI

Multiple Daily Injections (MDIs)

21. How often do you check your blood glucose using a finger prick (capillary) method daily?

- ◯ 0 - 1 times
- ◯ 2 - 3 times
- ◯ 4 - 5 times
- ◯ > 5 times

22. Have you previously used a Continuous glucose monitor and/or insulin pump before? *

◯ Yes, I have used only CGM before	Go to 23. Why have you chosen to ...
◯ Yes, I have used only an insulin pump before	Go to 25. Why have you chosen to ...
◯ Yes, I have used a CGM and insulin pump before	Go to 24. Why have you chosen to ...
◯ No, I have not used a CGM or insulin pump before	Go to 26. Why have you chosen not...

23. Why have you chosen to discontinue the use of Continuous glucose monitor?

- [ ] Financial Reasons
- [ ] Distrust of Technology
- [ ] Inaccuracy of blood sugar readings from CGM
- [ ] Complications relating to sensor site (i.e., rash, bruising, bleeding, etc.)
- [ ] Doctor's recommendation
- [ ] Other

Go to 27. What is your most recent ...

24. Why have you chosen to discontinue the use of Continuous glucose monitor?

- [ ] Financial Reasons
- [ ] Distrust of Technology
- [ ] Inaccuracy of blood sugar readings from CGM
- [ ] Complications relating to sensor site (i.e., rash, bruising, bleeding, etc.)
- [ ] Doctor's recommendation
- [ ] Alarm fatigue
- [ ] Other

25. Why have you chosen to discontinue the use of an insulin pump?

- [ ] Financial Reasons
- [ ] Distrust of Technology
- [ ] Ease of use of Multiple Daily Injections (MDIs)
- [ ] Complications relating to infusion sets (i.e., occlusions, bubbles in tubing, etc.)
- [ ] Doctor's recommendation
- [ ] Other

Go to 27. What is your most recent ...

26. Why have you chosen not to use a Continuous Glucose Monitor (CGM) or insulin pump?

- [ ] Financial Reasons
- [ ] Distrust of Technology
- [ ] Too difficult or complicated to switch
- [ ] I don't think I need it / I'm satisfied with multiple daily injections and self monitoring of blood glucose
- [ ] Doctor did not recommend
- [ ] Other

27. What is your most recent HbA1c measurement?

- ◯ < 6.0%
- ◯ 6.0% – 6.4%
- ◯ 6.5% – 6.9%
- ◯ 7.0% – 7.4%
- ◯ 7.5% – 7.9%
- ◯ 8.0% – 8.4%
- ◯ 8.5% – 8.9%
- ◯ 9.0% – 9.4%
- ◯ 9.5% – 9.9%
- ◯ 10.0% – 10.4%
- ◯ 10.5% – 10.9%
- ◯ 11.0% – 11.4%
- ◯ 11.5% – 11.9%
- ◯ ≥ 12.0%

28. Indicate the level of your agreement with each of the below statements

	Strongly Disagree	Disagree	Neutral	Agree
I feel concerned about low glucose levels (hypoglycaemia) while I am sleeping	○	○	○	○
I feel concerned about low glucose levels (hypoglycaemia) during my usual daily activities	○	○	○	○
I often have difficulties with occlusions and finding a suitable site for my insulin injections	○	○	○	○
Using MDIs, I feel confident in looking after my diabetes	○	○	○	○
Using MDIs, I am able to live my daily life freely	○	○	○	○
I am overall satisfied with MDIs and do not consider using a pump	○	○	○	○

Go to 8. Lifestyle

SMBG + Insulin Pump

29. How often do you check your blood glucose using a finger prick (capillary) method daily?

- ◯ 0 - 1 times
- ◯ 2 - 3 times
- ◯ 4 - 5 times
- ◯ > 5 times

30. Have you previously used a Continuous glucose monitor before? *

- ◯ Yes
- ◯ No — Go to 32. What is your most recent ...

31. Why have you chosen to discontinue the use of Continuous glucose monitor?

- ☐ Financial Reasons
- ☐ Distrust of Technology
- ☐ Inaccuracy of blood sugar readings from CGM
- ☐ Complications relating to sensor site (i.e., rash, bruising, bleeding, etc.)
- ☐ Doctor's recommendation
- ☐ Other

32. What is your most recent HbA1c measurement?

- ◯ < 6.0%
- ◯ 6.0% – 6.4%
- ◯ 6.5% – 6.9%
- ◯ 7.0% – 7.4%
- ◯ 7.5% – 7.9%
- ◯ 8.0% – 8.4%
- ◯ 8.5% – 8.9%
- ◯ 9.0% – 9.4%
- ◯ 9.5% – 9.9%
- ◯ 10.0% – 10.4%
- ◯ 10.5% – 10.9%
- ◯ 11.0% – 11.4%
- ◯ 11.5% – 11.9%
- ◯ ≥ 12.0%

33. Indicate the level of your agreement with each of the below statements

	Strongly Disagree	Disagree	Neutral	Agree
I feel concerned about low glucose levels (hypoglycaemia) while I am sleeping	◯	◯	◯	◯
I feel concerned about low glucose levels (hypoglycaemia) during my usual daily activities	◯	◯	◯	◯
I often have difficulties with occlusions and finding a suitable site for insulin infusion (i.e quickset, insulet, etc.)	◯	◯	◯	◯
Using my insulin pump, I feel confident in looking after my diabetes	◯	◯	◯	◯
Using my insulin pump, I am able to live my daily life freely	◯	◯	◯	◯
I am overall satisfied with my insulin pump and do not consider using a CGM	◯	◯	◯	◯

Go to Next

Lifestyle

34. How many days per week do you typically engage in aerobic (cardio) exercise? *(e.g. Walking, Running, Swimming, Cycling)*

- ◯ 0 days
- ◯ 1-2 days
- ◯ 3-4 days
- ◯ 5-6 days

35. How many days per week do you typically engage in strength or anaerobic exercise? *(e.g weightlifting, resistance training, CrossFit, HIIT)*

- ◯ 0 days
- ◯ 1 2 days
- ◯ 3 4 days
- ◯ 5 6 days

36. Do you notice better glyemic control with exercise?

- ◯ Yes
- ◯ No
- ◯ Sometimes
- ◯ Not applicable

Go to Next

Management Cost

37. What is the approximate cost of a month supply of diabetes related consumables (insulin, pump consumables, sensors,...). Please indicate currency within your answer.

38. Select the statement that applies to you in regards of health insurance

- ◯ I have public health insurance
- ◯ I have public and private health insurance
- ◯ I have no health insurance

39. Do you consider the overall cost of managing your diabetes (including medication, monitoring devices, supplies, and healthcare visits) to be a financial burden for you?

- ◯ Yes
- ◯ No
- ◯ Sometimes

Go to Next

Quality of Life & Satisfaction

40. Thinking about your diabetes care routine, how would you describe your overall day to day wellbeing?
(1 = Poor, 10 = Excellent)

Please consider your daily comfort, freedom, stress levels, and confidence in your diabetes care when giving your rating

1	2	3	4	5	6	7	8	9	10

Go to Next