Norwegian Medical Products Agency

Project Plan for Health Technology Assessment

Continuous glucose monitoring in type 2 diabetes treated with insulin

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Summary

In this health technology assessment (HTA) project plan, we outline the methods for evaluating the clinical effectiveness, safety, cost-effectiveness, organisational implications, and patient experiences of continuous glucose monitoring (CGM) compared to self-monitoring of blood glucose (SMBG) in individuals with insulin-treated type 2 diabetes (T2D). An expert group, comprising clinical experts and end-users, will provide input on the HTA report.

We will conduct a systematic review to evaluate the clinical effectiveness and safety of CGM compared to SMBG in individuals with insulin-treated T2D. The review will follow guidelines from the Norwegian Institute of Public Health and the Cochrane Handbook. Where feasible, subgroup analyses will be conducted for populations identified by clinical experts as particularly suitable for CGM use.

To evaluate the health economic impact of CGM compared with SMBG in individuals with T2D treated with insulin, we will conduct a model-based cost-effectiveness analysis. The model will estimate costs and quality-adjusted life years over a lifetime horizon from an extended healthcare sector perspective, using Norwegian unit prices and following national treatment guidelines. The analysis will incorporate data from systematic literature reviews, registry data, and expert input. Additionally, a budget impact analysis will estimate the five-year financial impact of CGM implementation.

We will also address the organisational aspects and potential implications of introducing CGM for individuals with insulin-treated T2D in Norway. This includes examining the impact on the healthcare system and exploring how resources can be organised and mobilised if the technology is implemented. The assessment will draw on input from the expert group, relevant guidelines and literature, as well as current practices for the distribution of CGM in Norway.

Furthermore, we aim to explore the challenges of living with insulin-treated T2D, experiences with SMBG, as well as experiences with SMBG and expectations for CGM within this group. Our assessment will be informed by input from the Norwegian Diabetes Association and literature on patients' experiences with CGM.

Title:
Continuous glucose monitoring in type 2 diabetes treated with insulin: project plan for a health technology assessment

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The Ordering Forum for New Methods (the national system for managed introduction of health technologies in the specialist health care service in Norway)

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Sammendrag

Denne prosjektplanen beskriver fremgangsmåtene for å vurdere klinisk effekt, sikkerhet, kostnadseffektivitet, organisatoriske konsekvenser og brukeropplevelser ved bruk av kontinuerlig vevsglukosemålere (CGM) sammenlignet med egenmåling av blodglukose (SMBG) hos personer med insulinavhengig diabetes type 2 (T2D). En ekspertgruppe bestående av kliniske eksperter og brukere vil bidra med innspill i arbeidet med metodevurderingen.

Vi vil utarbeide en systematisk oversikt om CGMs kliniske effekt og sikkerhet sammenlignet med SMBG hos personer med insulinavhengig T2D, i tråd med metodeboken fra Folkehelseinstituttet og Cochrane-håndboken. Hvis mulig, vil vi utføre subgruppeanalyser for populasjoner som kan ha særlig nytte av CGM. Disse gruppene ble identifisert av de kliniske ekspertene i et forarbeid utført ved Folkehelseinstituttet.

For å evaluere de helseøkonomiske konsekvensene av CGM sammenlignet med SMBG hos personer med T2D som behandles med insulin, vil vi gjennomføre en modellbasert kostnadseffektivitetsanalyse. Modellen vil estimere kostnader og kvalitetsjusterte leveår over et livstidsperspektiv fra et utvidet helsetjenesteperspektiv, basert på norske enhetspriser og i tråd med nasjonale behandlingsretningslinjer. Analysen vil inkludere data fra systematiske oversikter, registerdata og ekspertinnspill. I tillegg vil en budsjettkonsekvensanalyse estimere de økonomiske implikasjonene av å implementere CGM over en femårsperiode.

Vi vil også diskutere de organisatoriske konsekvensene ved å introdusere CGM til personer med insulinavhengig T2D i Norge. Vi vil belyse konsekvensene for helsesystemet, samt hvordan ressurser kan organiseres og mobiliseres hvis teknologien tas i bruk. Vurderingen vil hovedsakelig basere seg på innspill fra ekspertgruppen og gjennomgang av retningslinjer, samt dagens praksis for utdeling av CGM i Norge.

Vi vil i også kartlegge utfordringer med å leve med insulinavhengig T2D, erfaringer med SMBG og forventninger til CGM i denne gruppen. Vurderingen vil hovedsakelig baseres på innspill fra Diabetesforbundet og litteratur om brukeres erfaring med CGM.

Tittel:
Kontinuerlig vevsglukosemåling ved diabetes type 2 som behandles med insulin: prosjektplan for en fullstendig metodevurdering.

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Commission

The Division of Health Economics and Analysis at the Norwegian Medical Products Agency (NOMA) was commissioned on October 21, 2024, to conduct a full health technology assessment (HTA) on continuous and flash glucose monitoring for individuals with type 2 diabetes treated with insulin (1). For the HTA, we have chosen only to use the term "continuous glucose monitoring" (CGM) to encompass both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM), often referred to as flash glucose monitoring.

The HTA was commissioned within the National System for Managed Introduction of New Methods in the Specialist Health Care Service in Norway (called “Nye metoder” in Norwegian). The HTA will be used as a tool for informed decision-making by the regional health authorities in the Decision Forum in the national system.

The Division of Health Economics and Analysis follows an established framework when conducting HTAs, described in the Norwegian Institute of Public Health’s methods manual (called «Slik oppsummerer vi forskning» (2)). This framework enables the use of standardised formulations when describing methods, presenting results, and discussing findings.

Collaborators:

Project leader at NOMA: Ida-Kristin Ørjasæter Elvsaas (IKØE), clinical effectiveness and safety (responsible), organisational aspects (responsible), and patient experiences (responsible)

Internal team members at NOMA:

- Julia Bidonde (JB), clinical effectiveness and safety
- Vida Hamidi (VH), health economics (responsible)
- Fawaz Tariq Chaudhry (FTC), health economics
- Gunn Eva Næss (GEN), information retrieval (responsible)

External expert group:
Clinical experts recruited via the national system (“Nye metoder”), other external clinical experts, and patient representatives.

Declared conflicts of interest
All project members, experts, and reviewers have completed a declaration of interest according to NOMA policies. No conflicts of interest were reported.

NOMA is solely responsible for the content of this project plan.

Acknowledgement of AI tool usage in this HTA project plan
As part of NOMA’s commitment to innovation and efficiency in preparing HTAs, we have utilised AI tools to support our work. In this HTA project plan, we employed ChatDMP, an AI-powered language model, to enhance the clarity, consistency, and readability of several sections of the document. However, all suggestions from ChatDMP were approved by our team.

Abbreviations

Term/abbreviation	Explanation
CGM	Continuous glucose monitoring
CI	Confidence interval
DMP	Direktoratet for medisinske produkter (NOMA in English)
EQ-5D	EuroQol-5 Dimension
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HbA1c	Glycated haemoglobin
HTA	Health Technology Assessment
HTAi	Health Technology Assessment international
ICER	Incremental cost-effectiveness ratio
isCGM	Intermittently scanned continuous glucose monitor
MD	Mean differences
MDI	Multiple daily (insulin) injections
NOMA	Norwegian Medical Products Agency
NOK	Norwegian kroner
RCT	Randomised controlled trial
Non-RCT	Non-randomised controlled trial (also known as an observational study)
OGTT	Oral glucose tolerance test
PICO	Population, Intervention, Comparison, Outcome
SMBG	Self-monitoring of blood glucose
SMD	Standardised mean difference
QALYs	Quality-adjusted life years
RoB	Risk of Bias
rtCGM	Real-time continuous glucose monitoring
RR	Risk ratio
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TAR	Time above the glucose target range
TBR	Time below the glucose target range
TIR	Time within the glucose target range

1. Introduction

1.1 Diabetes

Diabetes is a metabolic disease characterised by abnormally high blood glucose levels (3), resulting from the body's reduced ability to either produce or respond to the hormone insulin (4). If left untreated or poorly managed, diabetes can result in severe acute complications, long-term vascular conditions, and an increased risk of death (3). Diabetes includes several subtypes. However, the three primary forms are type 1 (T1D), type 2 (T2D), and gestational diabetes, with T2D accounting for 90–95% of all diabetes cases (4).

The prevalence of diabetes in Norway has increased in recent years, with an estimated 316,000 to 345,000 people affected in 2020 (5), along with an additional 11% undiagnosed cases (6). The rise in diabetes cases is primarily driven by the growing prevalence of T2D, which is largely attributed to increasing obesity rates (7) and an ageing population.

1.1.1 Diabetes diagnostic standards

The primary diagnostic marker for diabetes is haemoglobin A1c (HbA1c) (8), which measures the blood glucose bound to haemoglobin. HbA1c reflects an individual's average plasma glucose levels over the past eight to 12 weeks (9). In contrast, blood glucose or plasma glucose concentrations provide a measure of current blood glucose status.

The Norwegian Directorate of Health's diabetes guideline (8) outlines the following criteria for diagnosing diabetes:

- HbA1c ≥48 mmol/mol (≥6.5%), or
- fasting plasma glucose ≥7.0 mmol/L, and/or
- plasma glucose ≥11.1 mmol/L two hours after an oral glucose tolerance test (OGTT)

Before a diagnosis can be confirmed, a follow-up test must verify a value that exceeds the diagnostic threshold (8). However, according to the diabetes guideline, no further testing is required if the patient has random plasma glucose levels of ≥ 11.1 mmol/L along with symptoms of diabetes (8).

HbA1c cannot be used to diagnose gestational diabetes (10). Instead, the diagnosis is based on plasma glucose concentrations. The diagnosis can be confirmed at any point during pregnancy if, during an OGTT, fasting plasma glucose is between 5.3–6.9 mmol/L and/or if the 2-hour plasma glucose level is between 9.0–11.0 mmol/L (10).

1.1.2 Type 2 diabetes

T2D is a metabolic and progressive condition. In its early stages, it is characterised by insulin resistance, where the body's tissues fail to respond properly to the hormone insulin (4). The body initially produces more insulin to compensate for the reduced insulin effectiveness. However, as the condition progresses, the pancreas gradually loses its ability to produce sufficient insulin due to β-cell dysfunction, leading to an inability to regulate blood glucose levels and resulting in abnormally high blood glucose levels (hyperglycaemia) (11).

Both environmental and genetic factors contribute to the development of T2D (10). The most significant risk factors include a sedentary lifestyle, ethnicity, genetic predisposition, and obesity, with obesity being the most critical risk factor (11). Smoking is also a recognised risk factor for developing T2D (10). The incidence of T2D increases with age (the mean age in Norway is approximately 65 years) and is higher among individuals in lower socioeconomic groups (10). Certain ethnic groups, particularly those of Asian and African descent, are at greater risk of developing T2D (10;11).

Each year, approximately 14,000 to 18,000 new cases of T2D are diagnosed in Norway, averaging about 40 new cases per day (12). A Norwegian study conducted by Bakke and colleagues in 2017 (13), using data from 2005 to 2014, found that approximately 14.7% of individuals with T2D were treated with insulin. However, the prevalence of individuals with T2D receiving insulin treatment is expected to decline as the use of blood glucose-lowering agents rises.

1.1.3 Type 2 diabetes management

Diabetes is primarily a self-managed condition, with healthcare professionals encouraging individuals to actively participate in managing their diabetes (14). The management of T2D typically begins with lifestyle modifications and may progress to oral medications (12). In some cases, insulin therapy may eventually become necessary if other glucose control methods prove inadequate (12). Insulin therapy in T2D can be categorised into two main types that require injection: long-acting insulin analogues and rapid-acting insulin analogues. For most individuals, long-acting insulin is sufficient (15) and is usually administered once or twice daily. However, some individuals may also require rapid-acting insulin (15), which is taken at mealtimes to manage post-meal blood glucose levels.

When insulin therapy is initiated in T2D, regular blood glucose monitoring aids in identifying when therapeutic action is needed to minimise the risk of hypoglycaemia or hyperglycaemia (16;17). However, achieving glucose control should not come at the expense of addressing other critical treatment and management strategies, such as hypertension, dyslipidemia, and obesity.

While a holistic approach is vital for managing T2D, capillary blood glucose monitoring—performed through self-monitoring of blood glucose (SMBG) levels two or more times a day—remains a cornerstone of diabetes management for individuals receiving insulin treatment (18). SMBG involves pricking the skin to obtain a capillary blood sample, which, for some individuals, may cause needle-stick anxiety, pain, and inconvenience (19;20). Additionally, SMBG has limitations due to insufficient data, often resulting from infrequent testing and the lack of nocturnal readings (21). As a result, manufacturers are increasingly focusing on developing glucose monitoring methods that are less painful and more data-rich, such as personal continuous glucose monitoring (CGM) devices (see Table 1 for examples), to support individuals with diabetes in better self-managing their condition (16).

1.2 Description of the technology

Sensor-based CGM systems usually consist of a subcutaneous glucose sensor connected to a transmitter and an external interface for data visualisation (16;22). The visualisation interface can be a dedicated receiver or a mobile application (16;22). There are two primary types of personal CGM systems: real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) (16;22), also known as flash glucose monitors (22). rtCGM devices continuously measure glucose levels and transmit the data at regular intervals, usually every 1-5 minutes, to a receiver or a smartphone application (16;22;23). In contrast, isCGM systems require users to actively scan the sensor throughout the day using a device reader or a smartphone application to access glucose measurements and related data (16).

Unlike traditional capillary blood glucose testing, CGM devices with electrochemical sensors measure glucose levels in the interstitial fluid of the subcutaneous tissue (23). When the electrochemical sensor is inserted subcutaneously, glucose concentrations in the interstitial fluid can be measured and wirelessly transmitted to a receiver or smartphone. Under steady-state conditions, there is an average lag time of 8 to 10 minutes between blood and interstitial glucose concentrations (24). This delay occurs because glucose must diffuse from the capillaries into the interstitial fluid before being measured (24). Software algorithms are designed to account for the lag under stable conditions, but the delay can become clinically significant when glucose levels fluctuate abruptly (24). Advanced CGM systems with enhanced calibration algorithms are increasingly capable of predicting critical events, such as hypoglycaemia and hyperglycaemia, in advance, thereby improving patient safety (23). Modern rtCGM devices can also issue alerts and alarms in response to rising or falling glucose levels

(25). However, when symptoms or expectations do not align with CGM readings, users are advised to confirm their glucose levels using capillary glucose monitoring (finger-prick SMBG), which reflects the actual circulating glucose, such as in the brain (24;26-28). Additionally, many CGM devices allow users to share their data remotely with family members, caregivers, and healthcare providers. This data-sharing feature offers reassurance to all parties involved and supports individuals in sharing the responsibilities of managing diabetes (25).

In Norway, three manufacturers supply the four CGM models included in the current public framework agreement (29) for use among individuals with T1D and, in certain cases, individuals with insulin-treated T2D who have been prescribed a device following evaluation by a specialist healthcare provider. The models are: Freestyle Libre 3+ and 2+ (Abbott) (26), Simplera (Medtronic) (28), and Dexcom G7 (Nordic Infucare) (27). Table 1 summarises key features of these devices, based on the manufacturer's publicly available information (26-28). A more detailed description of the CGM devices, provided by the Norwegian Endocrinology Association, can be found in Appendix 1. However, it is available only in Norwegian and contains information about the Freestyle Libre 3 and 2, the precursors to the 3+ and 2+ models (26).

Table 1. Comparison of the CGM devices included in the current Norwegian public framework agreement

	Freestyle Libre 3+ (26)	**Freestyle Libre 2+ (26)**	**Simplera (28)**	**Dexcom G7 (27)**
Type of system	rtCGM	isCGM with some rtCGM functions	rtCGM	rtCGM
Frequency of glucose testing	Every 1 minute	Every 1 minute	Every 5 minutes	Every 5 minutes
Calibration with SMBG is required	No	No	No	No
Allows optional calibrations	-	-	-	Yes
Warm-up time†	60 minutes	60 minutes	120 minutes	30 minutes
Sensor wear time‡	15 days	15 days	6 days (and a 24-hour grace period#)	10 days (and a 12-hour grace period#)
Provides trend arrows*	Yes	Yes	Yes	Yes
Provides alarms for hyper- and hypoglycaemia	Yes	Yes	Yes	Yes
Connects with insulin pumps	Yes	NA	No	Yes
Compatibility with mobile devices	Yes	Yes	Yes	Yes
Real-time remote data sharing	Yes	Yes	Yes	Yes
Indicated for use in pregnancy	Yes	Yes	No	Yes
Minimum age for use	2 years	2 years	2 years	2 years

NA: not assessable, meaning no information easily available; rtCGM: real-time continuous glucose monitoring; isCGM: intermittently scanned continuous glucose monitoring.

† The period required for calibration after placement under the skin. During this time, users must rely on finger-prick blood glucose checks for treatment decisions (30).

‡ The maximum duration a sensor can be worn before it needs to be replaced (30).

The grace period gives users extra time and flexibility to change their CGM sensor (27).

* Trend arrows show the direction of glucose levels, enabling proactive adjustments to prevent hyper- or hypoglycaemia (30).

1.3 Why is it important to conduct this health technology assessment?

The use of CGM in place of routine SMBG has been shown to improve glycaemic control in systematic reviews involving individuals with T1D (31-33). Several randomised trials have also compared CGM to SMBG in individuals with T2D treated with insulin (34-38). Some of these trials have been synthesised in systematic reviews that also include trials evaluating CGM use in the broader T2D population (39;40), with one review conducting a subgroup analysis on individuals with insulin-treated T2D (41). However, to our knowledge, no systematic reviews have exclusively compared CGM and SMBG among individuals with insulin-treated T2D.

Furthermore, a comprehensive analysis of the cost-effectiveness of CGM compared to SMBG for individuals with insulin-treated T2D in the Norwegian context has not yet been conducted. Additionally, the organisational implications of introducing CGM for individuals with insulin-treated T2D within the Norwegian healthcare system have not been evaluated. Finally, no published overview of the experiences of individuals with T2D in Norway using CGM devices appears to be available.

1.3.1 Group exemption until the HTA is finalised

The medical directors of the regional health authorities have decided on a group exemption until the HTA is finalised. At the Interregional Medical Directors' Meeting on June 19, 2023 (42), the following group exemption for T2D was approved (directly translated from Norwegian):

> CGM devices may be allocated in the following cases:
>
> 1. **Patients with insulin-requiring diabetes** who, despite long-term follow-up and significant self-management efforts, still experience highly challenging blood sugar regulation and recurrent episodes of hypoglycaemia. The Norwegian Directorate of Health's recommendation of a target HbA1c of 53–64 mmol/mol (7.0–8.0%) should not, on its own, serve as a criterion for allocating CGM devices to this patient group.
> 2. **Pregnant persons with known diabetes** where there is a medical indication to use a CGM device instead of the nationally recommended practice of SMBG. This also applies to women with gestational diabetes, where a medical indication for CGM use is identified.
> 3. **Patients with severe chronic kidney failure** who are on multiple daily insulin injections and have an increased risk of hypoglycaemia due to impaired glucose production in the kidneys could be considered under a slightly more liberal indication.

According to the group exemption, the allocation of CGM devices to patients with T2D must be approved by an established expert group or the medical director at the responsible healthcare institution (42).

1.4 Objectives and research question

In the HTA, we aim to evaluate the clinical effectiveness, safety, cost-effectiveness and organisational implications, as well as patient experiences, of CGM versus SMBG in individuals with T2D treated with insulin.

Additionally, the commissioner has tasked NOMA with conducting subgroup analyses for insulin-treated T2D populations identified as particularly well-suited for CGM use (1). These subpopulations were described in a preliminary research project conducted at the Norwegian Institute of Public Health in 2023 (43) and include the following:

- Individuals with T2D on multiple daily injections (MDI) with rapid-acting insulin who continue to experience persistent challenges with hypoglycaemia despite attempts to adjust insulin doses.

- Individuals with T2D on insulin therapy who have experienced more than one episode of severe hypoglycaemia in the past year.
- Individuals with T2D on insulin therapy whose profession involves significant risks if hypoglycaemia occurs.
- Younger individuals with T2D on insulin therapy with intellectual disabilities.
- Women with T2D using MDI of insulin, during preconception planning and throughout pregnancy. Continuous use may also be considered during the postpartum period if the MDI regimen is maintained and there is a risk of hypoglycaemia.

These groups align with the indications for CGM use as outlined in the Norwegian Endocrinology Guideline (44). To facilitate the assessment of these broadly defined subgroups in our HTA, we will refine the inclusion criteria for each subgroup as part of the development of the HTA project plan.

1.5 Expert group and patient representatives

At the start of the project, clinical experts with expertise in endocrinology, general practice, and diabetes care were recruited as contributors to the project. The expert group will help define the inclusion criteria in the PICO framework (Population, Intervention, Comparator, and Outcome). The experts will also provide input on the technologies to be included, relevant publications, organisational aspects, and input to the health economic evaluation based on Norwegian clinical practice. Additionally, the expert group will contribute to the interpretation of results and provide input to the report's discussion section.

NOMA also engaged patient representatives, specifically Central Board leaders of the Norwegian Diabetes Association, to provide input on the experiences of association members living with T2D, their perspectives on current practices for managing the condition, and their expectations for the CGM technology being considered. They will also be invited to review the HTA report before its finalisation.

2. Clinical effectiveness and safety – method

In this chapter, we outline the plan for conducting a systematic review to evaluate the clinical effectiveness and safety of CGM in individuals with T2D treated with insulin, compared to SMBG. The review will follow the recommendations outlined in the Norwegian Institute of Public Health's methodology manual "Slik oppsummerer vi forskning" (2) and the Cochrane Handbook (45).

2.1 Inclusion criteria

The inclusion criteria are described in Table 2.

Table 2. Inclusion criteria

Population	Individuals 18 years and older with T2D treated with insulin
	
	Subgroups (delimited from the broad definitions provided in the preliminary work (43) described in chapter 1.4):
	• Individuals with T2D on MDI therapy with rapid-acting insulin.
	  ○ Condition: documented persistent hypoglycaemia, defined as ≥2 episodes of symptomatic hypoglycaemia per week despite insulin dose adjustments for optimisation.
	• Individuals with T2D on any form of insulin therapy.
	  ○ Condition: history of ≥2 severe hypoglycaemic episodes in the past 12 months, where "severe hypoglycaemia" is defined as requiring third-party assistance in the specialist healthcare service (hospital).
	• Individuals with T2D on insulin therapy whose profession involves safety-critical roles (e.g., drivers, machine operators, pilots, healthcare professionals).
	  ○ Condition: evidence of hypoglycaemia-related risks in the workplace, such as documented hypoglycaemia episodes during work hours or professions where hypoglycaemia might endanger themselves or others.
	• Individuals aged <60 years with T2D on insulin therapy and diagnosed with intellectual disabilities, defined by standardised criteria (e.g., IQ <70 or adaptive functioning limitations).
	  ○ Condition: documented challenges in managing diabetes due to cognitive or functional impairments.
	• Women with T2D using MDI therapy who are planning pregnancy, currently pregnant, or in the postpartum period.
	  ○ Condition: risk of hypoglycaemia during pregnancy or postpartum due to MDI therapy.

Intervention	Personal continuous glucose monitoring (CGM); real-time (rtCGM) and intermittently scanned CGM (isCGM)
Comparator	Self-monitoring of blood glucose (SMBG)
Outcomes	• HbA1c • Total hypoglycaemia incidence (i.e., including both severe and nocturnal hypoglycaemia) • Severe hypoglycaemia incidence (i.e., blood glucose level below 3.1 mmol/L and requiring third-party assistance) • Nocturnal hypoglycaemia incidence (i.e., blood glucose level below 3.9 mmol/L during sleep)

	• Time within the glucose target range (time in range, TIR, 3.9-10.0 mmol/L (46)) • Time below glucose target range (time below range, TBR, 3.0-3.8 mmol/L (46)) • Time above glucose target range (time above range, TAR, 10.1-13.9 mmol/L (46)) • Glycaemic variation (fluctuations in blood glucose levels, %CV, target ≤36% (46)) • Quality of life (overall and psychological subdomain(s)), both disease-specific PROMS and general measures (e.g., EQ-5D) • Vascular complications (nephropathy, retinopathy, neuropathy, coronary heart disease, peripheral vascular disease, stroke) • Mortality • Adverse events associated with the CGM device (e.g., contact dermatitis, hypersensitivity reactions, scarring, lipodystrophy, false low glucose readings) • Mental health outcomes associated with the use of the CGM device (e.g., anxiety, depression, distress)
Study design	Randomised controlled trials (RCTs) Non-randomised studies (prospective and retrospective) with a control group and a follow-up period of 12 months or more Trial registry records
Publication year	No limit
Country/context	No limit
Language	English, Spanish, Norwegian, Swedish, Danish

The inclusion of randomised controlled trials (RCTs) will allow us to infer causality, depending on the risk of bias present in the studies. Additionally, we will include non-randomised studies (also known as observational studies) to obtain long-term data on the intervention, beyond what we expect to find in RCTs. However, we will exercise caution when inferring causality from non-randomised studies due to their inherently higher risk of bias.

2.1.1 Exclusion criteria

Studies that do not meet the inclusion criteria will be excluded from the systematic review. However, some studies excluded from the systematic review may still be relevant to other sections of the HTA, such as the health economics chapter, the organisational aspects chapter, or the chapter on patient experiences.

For the systematic review, we will exclude the following types of studies and publications:

- Cross-sectional studies, non-controlled studies and non-RCT studies with less than 12 months of follow-up.
- Editorials, commentaries, letters, brief reports, and conference abstracts.
- Systematic reviews, review articles and HTAs (although they may be used or screened for relevant primary studies related to any section of this HTA).
- Guidelines, position papers, and recommendations (however, guidelines and recommendations may be relevant to the organisational aspects chapter).
- Studies including both type 1 and 2 diabetes, where data is reported in aggregate form and not provided separately for T2D.
- Head-to-head comparisons of one CGM versus another CGM.
- Professional CGM devices, meaning that the involvement of a healthcare professional is required.
- Continuous glucose monitors for use only in a hospital setting.

2.2 Literature search

2.2.1 Search in databases

The information retrieval specialist (GEN) will develop a search strategy in collaboration with the team and, following best practices in the field (47;48), conduct the literature searches. Search tactics will be tailored to suit the unique interface of each electronic bibliographic database. For the population and intervention concepts, the search strategy will include both keywords and controlled vocabulary, such as MeSH (Medical Subject Headings) from the National Library of Medicine. Boolean operators "OR" and "AND" will be used to combine search terms and concepts, respectively. We will not limit the search by language, publication year, study design, or publication type. A second information retrieval specialist (EH) will proofread the search strategies before the literature searches are conducted. Documentation of the search process and results will be included in the HTA report

The main literature search will be conducted in the following sources:

- Medline (Ovid)
- Embase (Ovid)
- Epistemonikos
- The international HTA database
- ClinicalTrials.gov (National Institutes of Health)
- International Clinical Trial Registry Platform (World Health Organization)

The search results from bibliographic databases and study registries will be exported to the reference management tool EndNote. Duplicates will be removed using a standardised, semi-automated method (49). The unique records will then be uploaded to EPPI-Reviewer (50) for relevance assessment against the inclusion and exclusion criteria.

2.2.2 Literature search in other sources

Reviewing the reference lists of systematic reviews and HTAs, as well as consulting the clinical experts involved in this HTA for any relevant publications, may be relevant.

2.3 Selection of studies

Two reviewers (IKØE and JB) will independently screen titles and abstracts from the literature search against the inclusion criteria using EPPI Reviewer 6 (50). We will retrieve the relevant studies in full text, and the same reviewers will independently assess the full-text articles against the inclusion criteria. Disagreements regarding inclusion and exclusion will be addressed through discussions after a new review of the studies. If the disagreement persists, a third project team member will be consulted to help reach a consensus.

A list of publications excluded after full-text review will be included in the report’s appendix.

2.4 Risk of bias

We will assess the risk of bias in the included studies. For RCTs, we will use Cochrane's Risk of Bias 2 (RoB v2) (51;52). We will use Cochrane’s web-based Review Manager (RevMan) software to summarise and visualise the assessments (53). For non-randomised controlled studies, we will use the Risk of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool (54). These assessments can be visualised using the Robvis tool, a web application designed to display risk-of-bias assessments in systematic reviews (55).

The assessments will be conducted at the study outcome level. The five domains included in RoB v2 (51) are: 1) bias arising from the randomisation process; 2) bias due to deviations from intended interventions; 3) bias due to missing outcome data; 4) bias in the measurement of the outcome; and 5) bias in the selection of the reported result.

In ROBINS-I, seven domains of bias are addressed (54). These are: 1) bias due to confounding; 2) bias in the selection of participants into the study; 3) bias in classification of interventions; 4) bias due to deviations from intended interventions; 5) bias due to missing data; 6) bias in measurement outcomes; and 7) bias in the selection of the reported results.

Two reviewers will independently conduct the risk of bias assessments. Disagreements regarding the assessments will be resolved through discussion following a re-evaluation of the studies. If the disagreement persists, a third team member will be consulted to help reach a consensus.

2.5 Data extraction

We plan to use a custom-made Excel sheet for the data extraction process. Additionally, we intend to utilise an AI tool called Google NotebookLM (56) to support this process. Google NotebookLM is an online AI tool based on Gemini 2.0, designed to assist users in interacting with documents (56). One reviewer will extract data from the included studies, while a second reviewer will cross-check the extracted data against the relevant publications to identify any potential errors. Any disagreements will be resolved by consensus.

If needed, for example, if the data are unclear or missing, we will contact the authors to request additional information for use in our HTA. Furthermore, if multiple publications are linked to the same study, they will be treated as a single study and reported together with all associated references. Table 3 presents an overview of the data to be extracted from the included studies.

Table 3. Data to be extracted from the included studies

Concerning	Information to be extracted
The study	Authors, publication year, study design, total duration of study, details of any ‘run-in’ period, number of study centres and locations, setting, funding, clinical identification number
The participants	Number of participants in each group, age range, sex, duration of T2D, ethnicity
The intervention	Type of CGM device, CGM usage patterns
The comparator	Type of glucose measurement, measurement frequency, measurement time (mealtime, bedtime, etc.)
The outcomes	Definitions of outcomes, means, medians, standard deviations, or confidence intervals at baseline and post-intervention and follow-up assessment(s), contextual information if provided, and variables adjusted for in the analyses related to all outcomes (see Table 2 for details)

2.6 Analysis

We will group the studies and results according to the outcome measures and study designs. Most analyses and calculations will be performed using the web-based RevMan software (53).

2.6.1 Effect estimates

We will use group post-test means and standard deviations to calculate effect sizes.

Dichotomous outcomes

We will calculate the relative risk (RR) along with 95% confidence intervals (CI) for dichotomous outcomes, such as adverse events. The RR, also known as the risk ratio, quantifies the likelihood of an event occurring in the exposed group compared to the likelihood of the same event in the unexposed group (57).

Continuous outcomes

For continuous outcomes measured with similar measurement methods, such as HbA1c, we will calculate the mean difference (MD) with 95% CI. For outcomes measured by different measurement methods, we will calculate the standardised mean difference (SMD) with 95 % CI. The SMD corresponds to Hedges' *g*, which is often interpreted as follows: small effect size = 0.2-0.5, medium effect size = 0.5-0.8, and large effect size > 0.8 (58).

Where possible, we will also calculate RR, MD, or SMD with 95% CI for studies that have not provided these themselves, using RevMan (53). We will calculate effect estimates for relevant outcomes reported in the included studies, even if meta-analyses are not possible.

When conducting meta-analyses, we will use relative effect estimates directly from the included studies. If the studies report data in other ways, e.g., in figures or graphs, we will extract the available data either manually or using software tools, such as PlotDigitizer (59), a free, web-based tool for extracting data from 2D plots, bar graphs, scatter plots, and other types of visualisations. Where possible, we will use the standard methods available in RevMan (53) to impute relative effect estimates for inclusion in meta-analyses.

Unit of analysis

Although many randomised trials involve only two parallel arms (i.e., groups), some include three or four parallel arms. As a result, a single randomised trial can provide multiple relevant comparisons. This review will consider any comparison that enables the evaluation of the effects of CGM. For example, a three-arm trial might compare different versions of CGM to SMBG. If a control group is used as a comparator in two analyses, its sample size will be halved to avoid duplication. In cases where two arms of the same trial are included in a comparison, we plan to aggregate and present the data as one.

Statistically adjusted effect estimates are preferable to unadjusted effect estimates (such as the number of events). Adjustments are needed to deal with both precision and systematic bias. In RCTs, adjustment related to precision adjustment for baseline values includes clustering effects (e.g., if the unit of randomisation is different from the unit used to randomise), and other design-based adjustments (e.g., adjustment for a variable used in the randomisation process). In non-randomised studies, adjustment related to bias is essential. We expect the studies to adjust for a minimum of confounding factors: age, sex, duration of diabetes, comorbidities, body mass index, and baseline HbA1c level. Studies that have not adjusted for these confounding factors will be downgraded in the risk of bias evaluation.

2.6.2 Meta-analysis

RCTs and non-RCTs will be analysed separately. Where possible, we will compile the results of the included studies in meta-analyses. This requires that the studies are sufficiently homogeneous in terms of study design, participants, intervention, comparator(s), outcome measures, and any confounding factors adjusted for in the analyses. When meta-analyses are not feasible or appropriate, we will present the results narratively.

As we cannot anticipate identical populations, interventions and outcomes across the included studies, we will use a random effects model in the meta-analyses. The random effects model assumes that each study's sample is drawn from different populations. In other words, we assume that there is not one absolute effect, but rather that each study can present slightly varying effects, from which we calculate an average effect. Generally, this gives somewhat wider confidence intervals compared to the fixed effect model. If the studies report both adjusted and unadjusted effect estimates, we will use the adjusted estimates. We will conduct pairwise meta-analyses and present forest plots and pooled effect estimates for each meta-analysis.

We will assess potential sources of statistical heterogeneity in study outcomes by examining the confidence intervals (CIs) and calculating Chi^2 and I^2 using RevMan (53). Wide CIs may indicate variability in effect estimates across studies, with poor overlap of CIs generally suggesting

heterogeneity (60). The Chi^2 test evaluates whether observed differences in results are greater than would be expected by chance (60). A significant p-value (<0.05) suggests heterogeneity, but this test is sensitive to the number or size of studies (60). The I^2 statistic quantifies the percentage of variability in effect estimates attributable to heterogeneity rather than chance. I^2 values between 0–40% are unlikely to be important, 30–60% may indicate moderate heterogeneity, 50–90% may indicate substantial heterogeneity, and 75–100% suggest considerable heterogeneity (60). If a high degree of heterogeneity is identified, we may conduct subgroup analyses based on population type or setting. Additionally, we may perform sensitivity analyses by excluding studies with a high risk of bias, as well as small or underpowered studies. Finally, we will report CIs, Chi^2, p-values, and I^2 for heterogeneity and discuss how heterogeneity affects the interpretation of our findings.

Subgroup analyses will be conducted for populations identified as particularly relevant for CGM use (see Section 1.4 for details), provided such data are available. Forest plots and pooled effect estimates will be presented for each subgroup.

2.6.3 Narrative analysis

We will calculate and present effect estimates for relevant outcomes reported in the included studies, even if meta-analyses cannot be performed. In such cases, we will summarise and explain the effect estimates, for example, using forest plots without an 'overall effect estimate' and providing additional context in the supporting text.

2.7 Certainty of evidence

By 'certainty of the evidence,' we refer to the extent to which the research results reflect the 'true' or 'real' effect of the intervention(s). We will assess the certainty of the evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (61) and the digital tool GRADEpro (62). While the degree of confidence is continuous, it is divided into four categories in GRADE for practical purposes: high, medium, low, and very low certainty, as shown in Table 4.

Table 4. The GRADE categories of the degree of confidence in the evidence

Certainty	Symbol	Definition
High	⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	⊕⊕⊕◯	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	⊕⊕◯◯	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low	⊕◯◯◯	We have very low confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

To determine the level of confidence in the evidence, we will first consider the study design and then consider five criteria: 1) risk of systematic bias (risk of bias); 2) degree of consistency of the results between studies (consistency); 3) directness; 4) sparse data/precision of data (precision); and 5) publication bias.

For non-randomised studies, it is possible to consider upgrading the evidence. This is accomplished by considering the following three criteria: 1) strong or very strong associations between intervention and outcome (that is, the estimated effect is so large that it is unlikely to be due to chance); 2) large or very large dose-response effects; and 3) opposing plausible residual confounding or bias.

Two reviewers will assess the certainty of the evidence for the following outcomes: HbA1c, TIR, TAR, TBR, severe hypoglycaemic episodes, quality of life, vascular complications, and mortality. We will resolve differing assessments by discussion.

2.8 Minimal clinically important differences

When interpreting the results and drawing conclusions, we will use the same thresholds for minimal clinically important differences (MIDs) as those specified in the NICE guideline, “Type 2 diabetes in adults: diagnosis and management” (63), Table 5.

Table 5. Thresholds for MIDs

Outcome	**MID**
HbA1c (presented as a percentage or mmol/l)	0.5 percentage points or 5.5 mmol/mol
TIR (%)	5% change in TIR

In the NICE guideline (63), when no other MID was available, a MID of 0.5 of the median standard deviation of the comparison arms was used. For dichotomous outcomes, such as relative risk, the default MIDs of 0.8 and 1.25 were applied when no other MID was available. We will adopt the same MIDs in our HTA.

3. Health economics – method

Priority setting in the Norwegian healthcare system is based on three principles: health benefit, resource use, and severity (64). Health technology assessments, and particularly health economic evaluations, are essential for quantifying these criteria.

To evaluate the health economic impact of CGM compared with SMBG in individuals with T2D treated with insulin, we will conduct a model-based cost-utility analysis. This analysis will be implemented in TreeAge Pro 2025 to estimate and compare the relevant costs and health outcomes associated with these alternative glucose-measuring methods within the Norwegian context. The model will adopt a lifetime time horizon with health effects expressed in terms of quality-adjusted life years (QALYs).

We will use Norwegian treatment guidelines and expert advice to inform model assumptions and structure, where appropriate. Efficacy estimates and data on adverse events will be derived from the results of the systematic literature review. When available, we will use Norwegian epidemiological data; in the absence of such data, we will rely on the best available transferable data. A separate search will be conducted to identify utility weights required for calculating quality-adjusted life years in the model. Utility weights, preferably measured by EQ-5D, will be collected to represent quality of life across different disease stages and for related complications.

We will calculate costs in Norwegian kroner (NOK) from an extended healthcare sector perspective. This approach includes all relevant healthcare costs across both specialist and primary healthcare services in the Norwegian setting but excludes broader societal costs, such as productivity losses. This perspective aligns with priorities established within a fixed healthcare budget, as outlined in the Priority-setting White Paper (64). Norwegian unit prices will be applied to estimate these costs. Both costs and health outcomes will be discounted at 4% per year as recommended by the Norwegian guidelines (65).

The results of the model will be expressed as incremental cost-effectiveness ratios (ICERs), where the numerator captures the difference in costs between the intervention and its comparator, and the denominator reflects the difference in effects between the intervention and its comparator. All uncertain input parameters will be included in the model as probability distributions to reflect the degree of uncertainty associated with them. Sensitivity and scenario analyses will be performed to assess the robustness of the results. In addition, in order to quantify the severity principle, we will calculate the absolute shortfall for individuals with T2D treated with insulin.

Final decisions regarding the appropriate health economic methods for evaluating the implementation of CGM compared with SMBG in the relevant subpopulations will be made once efficacy data for the subpopulations become available.

In addition to the cost-effectiveness analysis, we will conduct a budget impact analysis to estimate costs to the healthcare sector over the next five years of implementing the glucose-measuring alternatives for individuals with T2D treated with insulin, and the relevant subpopulations that may benefit particularly from CGM. The estimated number of patients in the target population, as well as the number of eligible patients in the relevant subpopulations, will be based on Norwegian registry data and/or expert opinions.

4. Organisational aspects – method

We will describe the organisational aspects and consequences of the potential introduction of CGM for individuals with insulin-treated T2D in Norway. When assessing these aspects, we will describe the implications for the healthcare system and how various resources need to be organised and mobilised to implement the technology (66). The health economic evaluation will also rely on data generated from this process.

Our approach to assessing organisational aspects will follow the procedure outlined in the handbook of the Norwegian Institute of Public Health (2). Primarily, we will consult the expert group to explore organisational considerations. Input from clinical experts regarding patient flow will also be essential for integration into the health economic analysis. NOMA will prepare a questionnaire to collect relevant information, which will be used during the information-gathering process. Additionally, relevant publications, guidelines, and recommendations identified during the screening process described in Section 2.3 will serve as supporting literature and discussion points in this chapter. However, we will not restrict ourselves to literature identified in the systematic search; literature from targeted searches will also be used to supplement the information, if necessary. The current practice, in which hospitals approve and fund CGM for individuals with T1D and, in certain cases, individuals with insulin-treated T2D through the Treatment Aid (Behandlingshjelpemidler), will also be considered.

It is important to recognise the limitations of our approach, as we will not conduct a systematic literature review, and the information primarily relies on feedback from the clinical experts recruited for this project. Nevertheless, given that the clinical experts represent the health trusts, we assume they have a sufficient overview of the organisational aspects within the health service to provide relevant insights into the problem area. These insights, supported by existing guidelines, recommendations and current practice in Norway, are expected to provide a solid foundation for the Decision Forum's decision-making process regarding the organisational aspects of the potential introduction of CGM for individuals with insulin-treated T2D.

One team member (IKØE) will oversee the information-gathering process and draft the chapter, with input from other team members and the expert group.

5. Patient experiences – method

Patients, caregivers, family members, and friends can provide unique perspectives on their experiences, attitudes, preferences, beliefs, and expectations regarding health, illness, service delivery, and therapies (66). These insights can help inform our HTA.

We aim to shed light on the challenges of managing insulin-treated T2D, the experiences with SMBG, and expectations for CGM. Specifically, we will explore what individuals with insulin-treated T2D value most about the technology, any challenges associated with its management, and potential negative effects.

We will use the HTA Core Model, version 3.0, for the domain “Patients and Social aspects” (66) as a starting point for our work. Additionally, we will employ our Norwegian adaptation of the HTAi questionnaire for patient input (67) to collect information (Appendix 2). The questionnaire will be distributed to the Central Board of the Norwegian Diabetes Association for completion on behalf of its members.

Relevant systematic reviews and qualitative studies identified during the screening process described in Section 2.3 will be used to discuss and compare the results of our questionnaire responses with findings from the published literature. However, it is important to acknowledge the limitations of this approach in capturing patient experiences. Specifically, it does not involve conducting a systematic review of patient experiences or constitute primary research. As such, the results of this analysis will be limited to insights provided by the diabetes association, which will be discussed in relation to the published literature.

One team member (IKØE) will be responsible for the information-gathering process and drafting the chapter, with input from the other team members, the expert group, and patient representatives.

6. Deliverables and publication

6.1 Delivery

The approved project plan will be published on www.dmp.no, along with a description of the commission. It will also be made available in the INAHTA database.

The primary deliverable from this work will be an HTA report prepared following the methods outlined in the Norwegian Institute of Public Health's methodology manual "Slik oppsummerer vi forskning" (2) and using NOMA's template for full HTAs. The report is primarily intended for the Ordering Forum and Decision Forum for "Nye Metoder", but it should also be accessible to a broader audience. The report will be written in English and published on www.dmp.no. Additionally, we are open to publishing the entire report or parts of its content as one or more articles in scientific journals.

6.2 Peer review of the project plan and the HTA report

Project plan
The project plan will be reviewed internally and by the external expert group before receiving final approval from the Head of Unit.

Report
After the final HTA report has been reviewed and approved by the external expert group and internal reviewers, we will consider submitting it for external peer review. Following this process, the HTA report will be submitted to the Head of Unit for final approval.

6.3 Time frame

Start date:	In the first meeting with the clinical experts on 04.12.2024, we determined the research question and inclusion criteria.
End date:	04.12.2025, proposed date for submission to the Ordering Forum

6.3.1 Delays and unforeseen project developments

If circumstances arise that pose a risk that the delivery deadline cannot be met, such as unforeseen long-term absences among project members or other circumstances, one or more of the following will be appropriate:

- Increased staffing within the agreed framework of man-months.
- Replacing project employees in the event of absence or illness.
- Restrictions on inclusion criteria (by agreement with the commissioner).
- Extension of the delivery deadline (by agreement with the commissioner).
- Adjustments to the Economic model (by agreement with NOMA's management).

7. Related projects, publications and studies

Giske L, Stoinska-Schneider A, Flatby AV, Næss GE. Notat - forarbeid til oppdraget fra Bestillerforum om kontinuerlig / flash glukosemåling til pasienter med diabetes type 2 [Memo - preparatory work for the commission from Ordering Forum on continuous/flash glucose monitoring for patients with type 2 diabetes]. Oslo: Norwegian Institute of Public Health/ Norwegian Medical Products Agency, 2023, updated 2024.

Brurberg KG, Sverre JM. Sensorbaserte glukosemålere ved diabetes type I: forenklet metodevurdering. [Sensor based glucose monitoring in type I diabetes: rapid HTA]. Oslo: Norwegian Institute of Public Health, 2023.

Bidonde J, Fagerlund BC, Frønsdal KB, Lund UH, Robberstad B. FreeStyle Libre flash glucose self-monitoring system: a single-technology assessment. Norwegian Institute of Public Health (Folkehelseinstitutttet). Oslo: Norwegian Institute of Public Health, 2017.

8. References

1. Nye metoder. ID2023_075 Kontinuerlig glukosemåling og flash glukosemåling - Indikasjon II [Internet]. Oslo: Nye metoder [updated 2023-06-19; cited 2025-04-08]. Available from: https://www.nyemetoder.no/metoder/kontinuerlig-glukosemaling-og-flash-glukosemaling-indikasjon-ii/
2. Norwegian Institute of Public Health. Metodeboka - "Slik oppsummerer vi forskning" [Internet]. Oslo: Norwegian Institute of Public Health [cited 2025-04-08]. Available from: https://www.fhi.no/ku/kunnskaps-og-beslutningsstotte/metodeboka/
3. World Health Organization. Diabetes [Internet]. Geneva: World Health Organization [cited 2025-04-08]. Available from: https://www.who.int/health-topics/diabetes
4. Ojo OA, Ibrahim HS, Rotimi DE, Ogunlakin AD, Ojo AB. Diabetes mellitus: From molecular mechanism to pathophysiology and pharmacology. Medicine in Novel Technology and Devices 2023;19:100247. DOI: 10.1016/j.medntd.2023.100247
5. Stene LC, Ruiz PL, Åsvold BO, Bjarkø VV, Sørgjerd EP, Njølstad I, et al. [How many people have diabetes in Norway in 2020?]. Tidsskr Nor Laegeforen 2020;140(17). DOI: 10.4045/tidsskr.20.0849
6. Bjarkø VV, Haug EB, Sørgjerd EP, Stene LC, Ruiz PL-D, Birkeland KI, et al. Undiagnosed diabetes: Prevalence and cardiovascular risk profile in a population-based study of 52,856 individuals. The HUNT Study, Norway. Diabetic Medicine 2022;39(6):e14829. DOI: 10.1111/dme.14829
7. Åsvold B. Diabetes [database]. Store norske leksikon [updated 2025-02-25; cited 2025-04-08]. Available from: https://sml.snl.no/diabetes
8. The Norwegian Directorate of Health. Nasjonal faglig retningslinje for diabetes [Internet]. Oslo: The Norwegian Directorate of Health [updated 2024-12-05; cited 2025-04-08]. Available from: https://www.helsedirektoratet.no/retningslinjer/diabetes
9. World Health Organization. 2 Glycated haemoglobin (HbA1c) for the diagnosis of diabetes. In: Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus: Abbreviated Report of a WHO Consultation. Geneva: World Health Organization; 2011. Available from: https://www.who.int/publications/i/item/use-of-glycated-haemoglobin-(-hba1c)-in-diagnosis-of-diabetes-mellitus
10. The Norwegian Directorate of Health. Nasjonal faglig retningslinje for svangerskapsdiabetes [Internet]. Oslo: The Norwegian Directorate of Health [updated 2023-06-06; cited 2025-04-08]. Available from: https://www.helsedirektoratet.no/retningslinjer/svangerskapsdiabetes
11. Galicia-Garcia U, Benito-Vicente A, Jebari S, Larrea-Sebal A, Siddiqi H, Uribe KB, et al. Pathophysiology of Type 2 Diabetes Mellitus. Int J Mol Sci 2020;21(17):6275. DOI: 10.3390/ijms21176275
12. Stene LCM, Berg CL, Ruiz PL-D, Gulseth HL. Diabetes i Norge [Diabetes in Norway]. I: Folkehelserapporten - Helsetilstanden i Norge [Internet]. Oslo: Norwegian Institute of Public Health [updated 2021-05-31; cited 2025-04-08]. Available from: https://www.fhi.no/he/folkehelserapporten/ikke-smittsomme/diabetes/
13. Bakke Å, Cooper JG, Thue G, Skeie S, Carlsen S, Dalen I, et al. Type 2 diabetes in general practice in Norway 2005-2014: moderate improvements in risk factor control but still major gaps in complication screening. BMJ Open Diabetes Res Care 2017;5(1):e000459. DOI: 10.1136/bmjdrc-2017-000459
14. Bujnowska-Fedak MM, Puchala E, Steciwko A. The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in Poland. Telemedicine Journal & E-Health 2011;17(3):153-63. DOI: 10.1089/tmj.2010.0113
15. Rafi E, Tranchito L, Hatipoglu B. Navigating Insulin Options for Diabetes Management. The Journal of Clinical Endocrinology & Metabolism 2025;110(Supplement_2):S159-S64. DOI: 10.1210/clinem/dgae790
16. Reddy N, Verma N, Dungan K. Monitoring technologies-continuous glucose monitoring, mobile technology, biomarkers of glycemic control. In: Endotext [Internet]South Dartmouth (MA): MDText.com [updated 2023-07-08; cited 2025-04-08].
17. Mathew T, Zubair M, Tadi P. Blood Glucose Monitoring. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing [updated 2023-04-23; cited 2025-04-08]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK555976/

18. Weinstock RS, Aleppo G, Bailey TS, Bergenstal RM, Fisher WA, Greenwood DA, et al. The role of blood glucose monitoring in diabetes management. 2020. DOI: 10.2337/db2020-31
19. Ong WM, Chua SS, Ng CJ. Barriers and facilitators to self-monitoring of blood glucose in people with type 2 diabetes using insulin: a qualitative study. Patient Prefer Adherence 2014;8:237-46. DOI: 10.2147/ppa.S57567
20. Shlomowitz A, Feher MD. Anxiety associated with self monitoring of capillary blood glucose. British Journal of Diabetes 2014;14(2):60-3.
21. Bergenstal RM, Mullen DM, Strock E, Johnson ML, Xi MX. Randomized comparison of self-monitored blood glucose (BGM) versus continuous glucose monitoring (CGM) data to optimize glucose control in type 2 diabetes. J Diabetes Complications 2022;36(3):108106. DOI: 10.1016/j.jdiacomp.2021.108106
22. Oriot P, Klipper dit kurz N, Ponchon M, Weber E, Colin IM, Philips JC. Benefits and limitations of hypo/hyperglycemic alarms associated with continuous glucose monitoring in individuals with diabetes. Diabet Epidemiol Manag 2023;9:100125. DOI: 10.1016/j.deman.2022.100125
23. Sun T, Liu J, Chen CJ. Calibration algorithms for continuous glucose monitoring systems based on interstitial fluid sensing. Biosensors and Bioelectronics 2024;260:116450. DOI: 10.1016/j.bios.2024.116450
24. Cengiz E, Tamborlane WV. A tale of two compartments: interstitial versus blood glucose monitoring. Diabetes Technol Ther 2009;11 Suppl 1(Suppl 1):S11-6. DOI: 10.1089/dia.2009.0002
25. Longo R, Sperling S. Personal Versus Professional Continuous Glucose Monitoring: When to Use Which on Whom. Diabetes Spectr 2019;32(3):183-93. DOI: 10.2337/ds18-0093
26. Abbott. FreeStyle Libre systemene - måling av glukose - diabetes [Internet]. Abbott [updated 2024-12; cited 2025-04-08]. Available from: https://www.freestyle.abbott/no-no/home.html
27. Dexcom. Dexcom Continuous Glucose Monitoring [Internet]. Dexcom, Inc. [cited 2025-04-08]. Available from: https://www.dexcom.com/nb-NO
28. Medtronic. Simplera™ CGM System [Internet]. Northridge (CA): Medtronic [cited 2025-04-08]. Available from: https://www.medtronicdiabetes.com/products/simplera-cgm-system
29. Andreassen IE, The Norwegian Hospital Procurement Trust. Nye metoder - CGM (ID2023_074) unntatt offentlighet off. lova § 13.1 og § 23.1. email to: Stoinska-Schneider A, Norwegian Medical Products Agency, 2024-09-03.
30. Danatech. Continuous Glucose Monitor (CGM) Glossary [Internet]. Chicago (IL): Association of Diabetes Care & Education Specialists (ADCES) [cited 2025-04-08]. Available from: https://www.adces.org/education/danatech/glucose-monitoring/continuous-glucose-monitors-(cgm)/cgm-101/cgm-glossary
31. Battelino T, Phillip M, Bratina N, Nimri R, Oskarsson P, Bolinder J. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. Diabetes Care 2011;34(4):795-800. DOI: 10.2337/dc10-1989
32. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. Bmj 2011;343:d3805. DOI: 10.1136/bmj.d3805
33. Teo E, Hassan N, Tam W, Koh S. Effectiveness of continuous glucose monitoring in maintaining glycaemic control among people with type 1 diabetes mellitus: a systematic review of randomised controlled trials and meta-analysis. Diabetologia 2022;65(4):604-19. DOI: 10.1007/s00125-021-05648-4
34. Beck RW, Riddlesworth TD, Ruedy K, Ahmann A, Haller S, Kruger D, et al. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Annals of Internal Medicine 2017;167(6):365-74. DOI: 10.7326/M16-2855
35. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Therapy Research, Treatment and Education of Diabetes and Related Disorders 2017;8(3):573-86. DOI: 10.1007/s13300-017-0255-6
36. Lind N, Christensen MB, Hansen DL, Norgaard K. Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial. Diabetes Care 2024;47(5):881-9. DOI: 10.2337/dc23-2194

37. Yaron M, Roitman E, Aharon-Hananel G, Landau Z, Ganz T, Yanuv I, et al. Effect of Flash Glucose Monitoring Technology on Glycemic Control and Treatment Satisfaction in Patients With Type 2 Diabetes. Diabetes Care 2019;42(7):1178-84. DOI: 10.2337/dc18-0166
38. Martens T, Beck RW, Bailey R, Ruedy KJ, Calhoun P, Peters AL, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA 2021;325(22):2262-72. DOI: 10.1001/jama.2021.7444
39. Janapala RN, Jayaraj JS, Fathima N, Kashif T, Usman N, Dasari A, et al. Continuous glucose monitoring versus self-monitoring of blood glucose in type 2 diabetes mellitus: a systematic review with meta-analysis. Cureus 2019;11(9):e5634. DOI: 10.7759/cureus.5634
40. Seidu S, Kunutsor SK, Ajjan RA, Choudhary P. Efficacy and Safety of Continuous Glucose Monitoring and Intermittently Scanned Continuous Glucose Monitoring in Patients With Type 2 Diabetes: A Systematic Review and Meta-analysis of Interventional Evidence. Diabetes Care 2023;47(1):169-79. DOI: 10.2337/dc23-1520
41. Jancev M, Vissers T, Visseren FLJ, van Bon AC, Serné EH, DeVries JH, et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia 2024;67(5):798-810. DOI: 10.1007/s00125-024-06107-6
42. Vikse B, Fagdirektørene i de regionale helseforetakene. Gruppeunntak for kontinuerlig glukose-måling (CGM) ved diabetes type 2. Oslo: Nye metoder; 2023.
43. Direktoratet for medisinske produkter, Folkehelseinstituttet. Forarbeid til oppdraget fra Bestillerforum om kontinuerlig/flash glukosemåling til pasienter med diabetes type 2: notat. Oslo: Nye metoder; 2023 (updated 2024).
44. Carlsen S, Åsvold BO, Nermoen I, Løvås K, Joakimsen R, Julsrud Berg T. Indikasjoner for bruk av vevsglukosemåler hos pasienter med diabetes type 2 behandlet på en diabetespoliklinikk [database]. metodebok.no [updated 2024-05-07; cited 2025-04-08]. Available from: https://metodebok.no/emne/SnGXd7YC
45. Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. Cochrane Handbook for Systematic Reviews of Interventions [Internet]. Cochrane; [updated August 2024; cited 2025-04-08]. Available from: www.training.cochrane.org/handbook
46. Marcela M, Jimena S, Adrian P, Carla M, Guillermo EU. Glycemic variability and cardiovascular disease in patients with type 2 diabetes. BMJ Open Diabetes Research & Care 2021;9(1):e002032. DOI: 10.1136/bmjdrc-2020-002032
47. Hunter KE, Webster AC, Page MJ, Willson M, McDonald S, Berber S, et al. Searching clinical trials registers: guide for systematic reviewers. BMJ 2022;377:e068791. DOI: 10.1136/bmj-2021-068791
48. Lefebvre C, Glanville J, Briscoe S, Featherstone R, Littlewood A, Metzendorf M-I, et al. Chapter 4: Searching for and selecting studies. In: Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. Cochrane Handbook for Systematic Reviews of Interventions [6.5.1 ed.: Cochrane [updated March 2025; cited 2025-04-08]. Available from: https://training.cochrane.org/handbook/current/chapter-04
49. Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. J Med Libr Assoc 2016;104(3):240-3. DOI: 10.3163/1536-5050.104.3.014
50. Thomas J, Brunton J, Graziosi S. EPPI-Reviewer 4.0: software for research synthesis. EPPI-Centre Software London: Social Science Research Unit, Institute of Education2010.
51. Higgins JP, Savović J, Page MJ, Elbers RG, Sterne JA. Chapter 8: Assessing risk of bias in a randomized trial. In: Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. Cochrane handbook for systematic reviews of interventions [version 65] [Cochrane [updated October 2019; cited 2025-04-08]. Available from: https://training.cochrane.org/handbook/current/chapter-08
52. Sterne JAC, Savovic J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:l4898. DOI: 10.1136/bmj.l4898
53. Review Manager (RevMan Web) [software]. The Cochrane Collaboration [cited]. Available from: https://revman.cochrane.org
54. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. bmj 2016;355:i4919. DOI: 10.1136/bmj.i4919

55. McGuinness LA, Higgins JPT. Risk-of-bias VISualization (robvis): An R package and Shiny web app for visualizing risk-of-bias assessments. Res Synth Methods 2021;12(1):55-61. DOI: 10.1002/jrsm.1411
56. Google NotebookLM: Note Taking and Research Assistant Powered by AI [software]. Google [cited 2025-04-08]. Available from: https://notebooklm.google/
57. Tenny S, Hoffman M. Relative Risk In: StatPearls [Internet]Treasure Island (FL): StatPearls Publishing [updated 2023-03-27; cited 2025-04-08]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430824/
58. Andrade C. Mean Difference, Standardized Mean Difference (SMD), and Their Use in Meta-Analysis: As Simple as It Gets. J Clin Psychiatry 2020;81(5):20f13681. DOI: 10.4088/JCP.20f13681
59. PlotDigitizer [software]: PlotDigitizer [cited 2025-04-08]. Available from: https://plotdigitizer.com/
60. Deeks J, Higgins J, Altman D, McKenzie J, Veroniki A, editors. Chapter 10: Analysing data and undertaking meta-analyses In: Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M, et al., editors. Cochrane Handbook for Systematic Reviews of Interventions [version 65] [Cochrane [updated November 2024; cited 2025-04-08]. Available from: https://training.cochrane.org/handbook/current/chapter-10
61. Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol 2011;64(4):383-94. DOI: 10.1016/j.jclinepi.2010.04.026
62. Evidence Prime. GRADEpro GDT: GRADEpro Guideline Development Tool [software]. Hamilton (ON): McMaster University.
63. National Institute for Health and Care Excellence. Type 2 diabetes in adults: diagnosis and management: (C) Evidence reviews for continuous glucose monitoring in adults with type 2 diabetes. United Kingdom: National Institute for Health and Care Excellence (NICE); 2022. NICE guideline NG28. Available from: https://www.nice.org.uk/guidance/ng28/evidence/c-continuous-glucose-monitoring-in-adults-with-type-2-diabetes-pdf-11013297805
64. Helse- og omsorgsdepartementet. Verdier i pasientens helsetjeneste: Melding om prioritering. Meld. St. 34 (2015 - 2016). Available from: https://www.regjeringen.no/no/dokumenter/meld.-st.-3420152016/id2502758/
65. Norwegian Medical Products Agency. Submission guidelines For Single Technology Assessment of Medical Devices. Oslo: Norwegian Medical Products Agency; 2024. Available from: https://www.dmp.no/en/public-funding-and-pricing/health-technology-assessments/submission-of-documentationtation-for-single-technology-assessment-of-medical-devices/innsending-av-dokumentasjon
66. EUnetHTA Joint Action 2. Work Package 8. HTA Core Model ® version 3.0. 2016. Available from: www.htacoremodel.info/BrowseModel.aspx
67. Health Technology Assessment International. Patient & Citizen Involvement: Resources and Materials [Internet]. Edmonton (AL): Health Technology Assessment International [cited 2025-04-08]. Available from: https://htai.org/interest-group/patient-citizen-involvement/#resources-and-materials

9. Appendices

Appendix 1. Information regarding CGM devices

Details beyond those listed in Table 1 (available only in Norwegian), from the National endocrinology guidelines (available at https://metodebok.no/index.php?action=topic&item=JADy7pjj).

SAMMENLIGNING AV CGM OG PRAKTISERING AV AVTALEN

	Freestyle libre 3	Freestyle libre 2	Simplera	Dexcom G7
Estimert årskostnad	15000 kr	15000 kr	22000 kr	30000 kr
Firmaoppgitt MARD	7,8% (samlet) 7,6% voksne 8,7 % barn 6-17 år 10,1% barn 4-5 år	9,2% voksne 9,7% barn	10,2 % voksne 10,9 % barn (10,2% rumpe) 13,2% 2-6 år (13,6% rumpe)	8,2% voksne (9,1% mage) 8,1% barn (9,0 % mage)
Godkjent plassering i tillegg til bakside arm?	Nei	Nei	Øvre del av rumpe(2-17år)	Øvre del av rumpe (2-7 år) Mage
Alder	Fra 4 år (inkl.gravide)	Fra 4 år(inkl.gravide)	Fra 2 år	Fra 2 år (inkl.gravide)
Oppvarmingstid Oppdateringsfrekvens	1 time Hvert minutt	1 time Hvert minutt	2 timer Hvert 5.min.	½ time Hvert 5.min
Varighet sensor	14 dager	14 dager	7 dager	10 dager + 12 t flex
Størrelse	21 x 2,9 mm	35 x 5 mm	28,64 x 28,65 x 4,77 mm	24 x 27,3 x 4,6 mm
Mulighet for egen monitor	Ja	Ja	Nei	Ja
Mulighet for alarmer utover høy og lav alarm?	Nei	Nei	Ja	Ja
Akutt snart lav og raskt fallende glukose alarm	Nei	Nei	Ja	Ja
Kompatibelt med digitale insulinpenner og mulighet for doseringsråd og oversikt over aktivt insulin i app?	Nei.	Nei Har mulighet for å legge inn novopen Echo Plus og novopen 6 i libre link appen, men ingen doseringsråd	Ja i InPen app	Nei
Nivå grense for fallende og stigende alarm	Nei	Nei	Nei	Ja
Utsatt høy alarm	Nei	Nei	Ja kan utsettes i 1-3 timer.	Ja kan utsettes i for eksempel. 2 t. Kan også ha et 2.varsel via slumre
Alarm for manglende insulindose	Nei	Nei	Ja, hvis InPen app benyttes	Nei
Korriger høy alarm med doseringsanbefaling	Nei	Nei	Ja, hvis InPen app benyttes	Nei
Mulighet for flere alarmprofiler og mulighet for å stille inn ulik alarmgrense på ulik tid av døgnet og for ulike dager?	Nei	Nei	Ja kan ha ulik alarm på dag og natt. Kan IKKE ha ulik alarm på ulike ukedager.	Ja, kan både ha ulik alarm for dag og natt og for ulike ukedager.
Følgerfunksjon i realtid?	Ja	Ja	Ja	Ja
Interaksjoner	Vitamin C (hvis over 500 mg, falsk høy) Aspirin (mulig noe falsk lav)	Vitamin C (hvis over 500 mg, falsk høy) Aspirin(mulig noe falsk lav)	Acetaminofen=Paracetamol Hydroksyurea	Hydroksyurea
Kompatible tilpasninger for synshemming?	Voice over for IOS og TalkBack for Android	Voice over for IOS og TalkBack for Android	Voice over for IOS og TalkBack for Android	Voice over og Siri for IOS og TalkBack for Android.
Hørselshemming	Lydalarm kan innstilles som høy lyd på telefonen. Aktivere vibrasjon.	Lydalarm kan innstilles som høy lyd på telefonen. Aktivere vibrasjon.	Kan innstille alarmer til å ha max volum om natten.	Hypo-repeat alarm med høy lyd
Smartklokker	Kan kun se alarmer med verdi og trendpil	Kan kun se alarmer med verdi og trendpil	Kan se kontinuerlig CGM graf på apple watch. På andre smartklokker kan man kun se alarmer	Kan se kontinuerlig CGM graf også på kompatibel smartklokke

Appendix 2. Patient input questionnaire

This questionnaire is only available in Norwegian.

Spørreskjema for pasient- og brukerorganisasjoner for innsending av innspill til metodevurderinger

(Oversatt og tilpasset versjon av skjemaene utarbeidet av Health Technology Assessment (HTAi) som er tilgjengelig Patient & Citizen Involvement – HTAi)

Direktoratet for medisinske produkter

Metodevurdering av kontinuerlig glukosemåling ved diabetes type 2 som behandles med insulin

1. Formålet med dette skjemaet

Pasienter og pårørende har unik kunnskap om hvordan det er å leve med en bestemt sykdom eller medisinsk tilstand. De kan beskrive fordeler og ulemper ved behandlingstiltak som ikke blir rapportert i publisert forskning, og i tillegg beskrive hva de vil verdsette mest ved metoden under vurdering. Denne erfaringsbaserte kunnskapen er verdifull for de som gjennomfører metodevurderinger (engelsk: health technology assessment, HTA).

Dette skjemaet er utarbeidet for å hjelpe pasient- og brukerorganisasjoner med å gi erfaringsbasert informasjon til vurdering av en bestemt metode. Skjemaet forsøker å fange opp erfaringskunnskap som er til nytte i vurderingsprosessen til de som utfører selve metodevurderingen.
Del 2 gir veiledning om hvordan dere skal fylle inn dette skjemaet.
Del 3 ber dere om å beskrive bakgrunnsinformasjon om pasient- eller brukerorganisasjonen.
Del 4–8 er hoveddelen av skjemaet, hvor vi ber dere om å beskrive synspunkter og erfaringer fra pasienter, brukere og pårørende.

2. Slik fyller dere ut dette skjemaet

I hoveddelen av dette skjemaet blir dere bedt om å beskrive hvilke utfordringer de som lever med den aktuelle tilstanden eller pårørende til de som lever med den aktuelle tilstanden har, erfaringer med eksisterende behandlingstiltak, forventninger til metoden under vurdering, og potensielle fordeler eller ulemper ved den aktuelle metoden, hvis dere kjenner til dette.

Hvert spørsmål har flere hjelpepunkter som skal gjøre det enklere å gi verdifull informasjon. Denne informasjonen skal brukes av dem som gjennomfører metodevurderingen, for bedre å forstå hvordan det er å leve med tilstanden og erfaringer med dagens behandlingstiltak. Dere oppfordres til å tenke over alle aspektene deres pasient- eller brukerorganisasjon synes er viktige, i tillegg til å beskrive andre relevante aspekter som ikke er nevnt.

I alle deler av skjemaet beskriver ordet 'bruker' personer som lever med eller har levd med tilstanden den aktuelle metoden er rettet mot, eller pårørende til disse.
Vi ber dere om å oppgi informasjon og sammendrag av erfaringer som gir en pålitelig og balansert oversikt over pasienters og pårørendes perspektiver. Vi ber dere også om å oppgi eventuelle kilder og referanser til informasjonen.

Dere trenger ikke sende oss publiserte artikler, da vi har tilgang til disse. Men, hvis dere har synspunkter angående tolkningen av en studie, vil vi gjerne høre dette.

Følgende gjelder alle deler i skjemaet: hvis det er grupper som har spesielle behov, vennligst oppgi de aktuelle behovene for denne gruppen (f.eks. barn, kvinner/menn, etniske grupper, personer som bor bestemte steder, personer med andre funksjonshemminger, undertyper av sykdommen).
Vi ber dere om ikke å oppgi informasjon som kan knyttes til eller identifisere enkeltpersoners helsetilstand og erfaringer.

Hvis dere trenger opplæring eller annen støtte kan dere kontakte kontaktpersonen ved Direktoratet for medisinske produkter. Her er det er informasjon om hva metodevurderinger er og hvordan det er å være involvert. Der kan dere også se rutine for brukermedvirkning i metodevurderinger. Dette er på Folkehelseinstituttets nettsider grunnet nylig overføring av ansvar.
Hvis dere har noen spørsmål, kontakt: Ida-Kristin Ø. Elvsaas, ida.elvsaas@dmp.no

3. Informasjon om pasient- eller brukerorganisasjonen

Navn på organisasjon:
Kontaktperson:
Rolle:
Epostadresse:
Telefon:
Postadresse:

Type gruppe (merk alle gjeldende):

☐ Interesseorganisasjon
☐ Uformell selvhjelpsgruppe
☐ Annet, vennligst oppgi: _____

Hensikt med gruppe (merk alle gjeldende):

☐ Støtte ☐
☐ Opplæring ☐
☐ Politisk arbeid ☐
☐ Forskning ☐
☐ Annet, vennligst oppgi: _____

Beskriv organisasjonen (antall og type medlemmer (pasienter, pårørende o.a.), alder, kjønn osv.), finansieringskilder, osv.

[Svar her]

Hvilke informasjonskilder er innspillet i dette skjemaet basert på? Oppgi kilder der det.

[Svar her – f.eks. om informasjonen er innhentet via spørreskjema blant medlemmer, analyse av hjelpetelefon, sosiale nettforum, fokusgrupper, pasientjournaler, en-til-en samtaler med deltakere i kliniske studier, forskning, informasjon fra firma, eller annet. Oppgi referanser til hvor informasjonen er tilgjengelig.]

Dersom du svarer på skjemaet som privatperson: hjalp noen deg med å fylle ut dette spørreskjemaet? JA ☐ / NEI ☐

Hvis ja, vennligst oppgi hvem som hjalp deg og på hvilken måte:

[Svar her]

Vi ønsker å belyse brukerperspektivet i metodevurderingsrapportene. Dette kan gjøres på ulike måter. Hvis aktuelt, godkjenner dere at dette innspillet bli lagt ved metodevurderingsrapporten i sin helhet? JA ☐ / NEI ☐

Merk: I tråd med hvordan vi behandler alle bidragsytere i metodevurderinger skal taushetserklæring og habilitetsskjema fylles ut.

4. Tilstandens påvirkning

Hvordan påvirker tilstanden eller sykdommen pasientenes livskvalitet?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:

- *Aspekter ved tilstanden som er mest utfordrende (f.eks. symptomer, manglende evne til å arbeide, mindre selvtillit til å gå ut, ute av tilstand til å kjøre, sosial ekskludering).*
- *Aktiviteter pasienten syns er vanskelige eller som de ikke kan utføre.*
- *Aspekter ved tilstanden som er viktigst å ivareta (f.eks. symptomer som begrenser sosial interaksjon eller evne til å arbeide).*
- *Støtte og hjelp som er nødvendig i hverdagen (fysisk eller psykisk).*
- *Psykisk påvirkning som f.eks. angst, usikkerhet, redsel, stigma, sjenanse.*
- *Utfordringer ved å håndtere tilstanden hvis pasienten i tillegg har andre medisinske tilstander.*
- *Hva pasienter ville satt mest pris på ved ny behandling (f.eks. forsinkelse av sykdommens fremgang, forbedring av et spesielt symptom).*
- *Økonomiske aspekter som f.eks. kostnader knyttet til hjelpemidler, tap av inntekt.*

Hvordan påvirker tilstanden pårørende?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:

- *Utfordringer for pårørende som støtter pasienter*
- *Press på pårørende i deres hverdag (f.eks. følelsesmessig/psykisk, trøtthet, stress, angst, depresjon, fysiske utfordringer, økonomisk)*

Er det grupper av pasienter som spesielt har vanskeligheter med å håndtere tilstanden?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:

- *F.eks. grupper som kvinner, menn, barn, unge voksne, eldre, personer med funksjonshemming, etniske grupper, vanskeligstilte, minoriteter.*
- *Utfordringer de står overfor som f.eks. ta vare på familie, håndtere tilstanden i tillegg til andre tilstander/sykdommer, tilgang til behandling, sosial stigma.*

5. Erfaringer med eksisterende behandling

Hvor bra håndterer pasientene tilstanden med eksisterende metoder?

(*Metoder* kan være f.eks. legemidler, medisinsk utstyr, prosedyrer, rehabilitering, m.m. Hvis ingen behandlingstiltak er tilgjengelige, bør dette oppgis.)

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:

- *De viktigste eksisterende behandlingstiltakene som brukes av pasienter med denne tilstanden og hvordan det gis (tablett, injeksjon, fysioterapi, sykehusbesøk, om det er hjemme/på sykehus, dosering og tilgjengelighet). Hvis det ikke er noen, oppgi dette.*
- *I hvilken grad eksisterende behandling ivaretar eller reduserer de mest utfordrende aspektene ved tilstanden (f.eks. reduksjon av symptomer, på- og avkledning, arbeid, skole, sosialisering, pustebesvær, bevegelse).*
- *De viktigste fordelene ved eksisterende behandlinger.*
- *Byrde av behandlingen i hverdagen (f.eks. vanskeligheter med å bruke tiltaket/utstyret, avbrytelser i arbeid, besøk hos lege for behandling eller, utfordringer med å komme seg etter behandling, behov for rehabilitering).*
- *Bivirkninger fra behandling som er vanskelige å håndtere.*
- *Økonomiske konsekvenser for pasienter og deres pårørende.*
- *Aspekter for pårørende knyttet til å bruke tiltaket/utstyret, f.eks. redsel for påføre smerte*
- *Områder der eksisterende behandling ikke hjelper på.*
- *Bekymring om langtidsbruk av eksieterende behandling.*
- *Hvis eksisterende behandling er et legemiddel:*
  - *Utfordringer med å ta legemiddelet slik som det er foreskrevet (f.eks. svelge pillen, selv-injeksjon, bruk av utstyr, ta etter mat, ikke mulighet for å ligge 30 minutter etter å ha tatt legemiddelet).*
  - *Måter dosering er tilpasset eller endret fra det er som foreskrevet (f.eks. deling av doser for å unngå uønskede bivirkninger, tapte doser på grunn av det ikke passer i hverdagen).*

Er det grupper av pasienter som spesielt har vanskeligheter med å bruke eksisterende behandling?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:
- *Grupper som har vanskeligheter med å bruke tiltaket/utstyret (f.eks. barn, eldre, personer med funksjonshemming).*
- *Grupper som bruker utstyr som kan være pinlig å bruke på offenlige steder.*
- *Grupper med en spesiell type sykdom som ikke har noen behandlingsmuligheter.*

6. Erfaringer med metoden som er under vurdering

a) For de med erfaring med den nye metoden eller metoden under vurdering: hvilken forskjell utgjorde det i livene deres?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:
- *Hovedgrunner for å bruke denne metoden.*
- *Mål som ble satt da de startet å bruke metoden og om de ble oppnådd.*
- *Grunner for å like eller mislike metoden under vurdering sammenlignet med andre alternativer.*
- *I hvilken grad metoden hjelper på de vanskeligste aspektene ved tilstanden.*
- *Symptomer som har forandret seg og påvirkning av dette på dagliglivet og livskvaliteten.*
- *Metodens begrensninger.*
- *Uønskede hendelser (bivirkninger, skader) som er vanskelig å tolerere, og det som pasienter er villige / stand til å tolerere.*
- *Økonomiske konsekvenser for pasient og pårørende (reisekostnader, kjøp av utstyr, dager borte fra arbeid)*
- *Den nye metodens innvirkning på bruk av helsetjenester (f.eks. færre sykehusbesøk).*
- *Metodens påvirkning på pårørende.*
- *For legemidler: Forklar om den fullstendige dosen som er foreskrevet av det nye legemiddelet vanligvis blir tatt, og hvilke faktorer som eventuelt fører til tapte doser.*
- *I hvilken grad den nye metoden ivaretar pasientenes behov.*

b) For de uten erfaring med den nye metoden eller metoden under behandling, men som er klar over kliniske studier: hva er forventninger og begrensninger med metoden?

Punkter som bør tas i betraktning i svaret:
- *Om kliniske studier har målt utfall som er viktige for pasienter (f.eks. symptomer som begrenser aktivitet).*
- *Minimumsnivå av forbedring på symptomer som er mest viktige for pasienter.*
- *Hva pasienter håper den aktuelle metoden kan ivareta (f.eks. forbedret dagligliv, evne til å arbeide, bedret mobilitet, bedre symptomlindring, enklere å bruke tiltaket/utstyret).*
- *Antatte fordeler og ulemper ved den aktuelle metoden (og hovedgrunner for hvorfor den eventuelt ikke vil bli brukt)*
- *Den nye metodens potensielle innvirkning på bruk av helsetjenester (f.eks. færre sykehusbesøk).*
- *Økonomiske konsekvenser (reisekostnader, utstyr for å ta legemiddelet/bruke metoden, dager borte fra arbeid).*
- *Metodens påvirkning på pårørende.*

Hvilke grupper av pasienter kan ha mest nytte av metoden under vurdering?

[Svar her og slett hjelpepunktene]
Punkter som bør tas i betraktning i svaret:
- *Grupper som på nåværende tidspunkt har få eller ingen behandlingsalternativer, eller som syns det er vanskelig å bruke eksisterende tiltak/utstyr.*

7. Ytterligere informasjon

Vennligst oppgi ekstra informasjon dere tror kan være til hjelp for de som gjennomfører metodevurderingen (f.eks. sosiale eller etiske aspekter).

[Svar her]

8. Hovedbudskap

I maks fem punkter, oppgi de viktigste poengene i skjemaet dere vil fremheve.

[Svar her – for eksempel:]

- *Den største utfordringen ved å leve med denne tilstanden er…*
- *Eksisterende behandling er utilstrekkelig fordi…*
- *Det nye tiltaket er viktig for pasientene fordi…*