Application of Continuous Glucose Monitoring and Automated Insulin Delivery Technologies for Pregnant Women with Type 1 Diabetes, Type 2 Diabetes or Gestational Diabetes Mellitus: An International Consensus Statement

Appendix

Search strategy

Scope

To review the evidence in context for the application of CGM and AID devices in pregnancies complicated by diabetes and to make a series of consensus recommendations on how these diabetes technologies may be applied to optimise glycaemia and minimise risks for complications of pregnancy for women with pregestational diabetes or GDM.

PICO

Population: In pregnant women with type 1 diabetes, type 2 diabetes or GDM

Intervention: Do diabetes technologies (such as CGM and AID)

Comparison: Compared to glycaemic monitoring without CGM and/or use of standard insulin therapy (insulin injections or open-loop insulin pumps)

Outcome: Improve glycaemic outcomes, pregnancy outcomes and participant-reported outcomes?

Search Protocol

Comprehensive literature search on MEDLINE, PubMed and the Cochrane Library, for articles published between Jan 1, 2008 (when the first data on CGM in pregnancy became available), and up to October 25th 2025, by nested use of Boolean operators (AND/OR/NOT) to combine, expand or limit results, selectively. Searching of titles and abstracts – e.g., in PubMed, will be done by adding [title/abstract] as a search operator with any term.

Terms used: "randomised controlled trial", "randomised clinical trial", "real world study", "observational study", "cohort study", "continuous glucose monitoring", "CGM", "CGM metrics", "intermittently scanned continuous glucose monitoring", "isCGM", "flash glucose monitoring", "time in range", "time below range", "time above range", "insulin pumps" , "sensor-augmented pump therapy", "closed-loop therapy", "closed-loop insulin delivery", "CSII", "automated insulin delivery", "HbA_{1c}", "GMI", "glycaemic control", "hypoglycaemia", "glycaemic variability", "predictive low glucose suspend", "pregnancy outcomes", "pregnancy complications" "delivery", "intrapartum", "breastfeeding", "postpartum", "cost-effectiveness", in combination with the term "pregnancy" and "diabetes".

Inclusion criteria: RCT's, real world studies, observational studies and cohort studies. If no other evidence is available, case reports and case series will also be considered. Only studies performed in humans and published in English were considered. Studies published between Jan 1 2008 and October 25th 2025 are included.

Exclusion criteria: Case reports and case series if evidence is available from RCT's, real world studies, observational studies and/or cohort studies. Articles published in other languages than English. Studies in animals. Studies published before 2008.

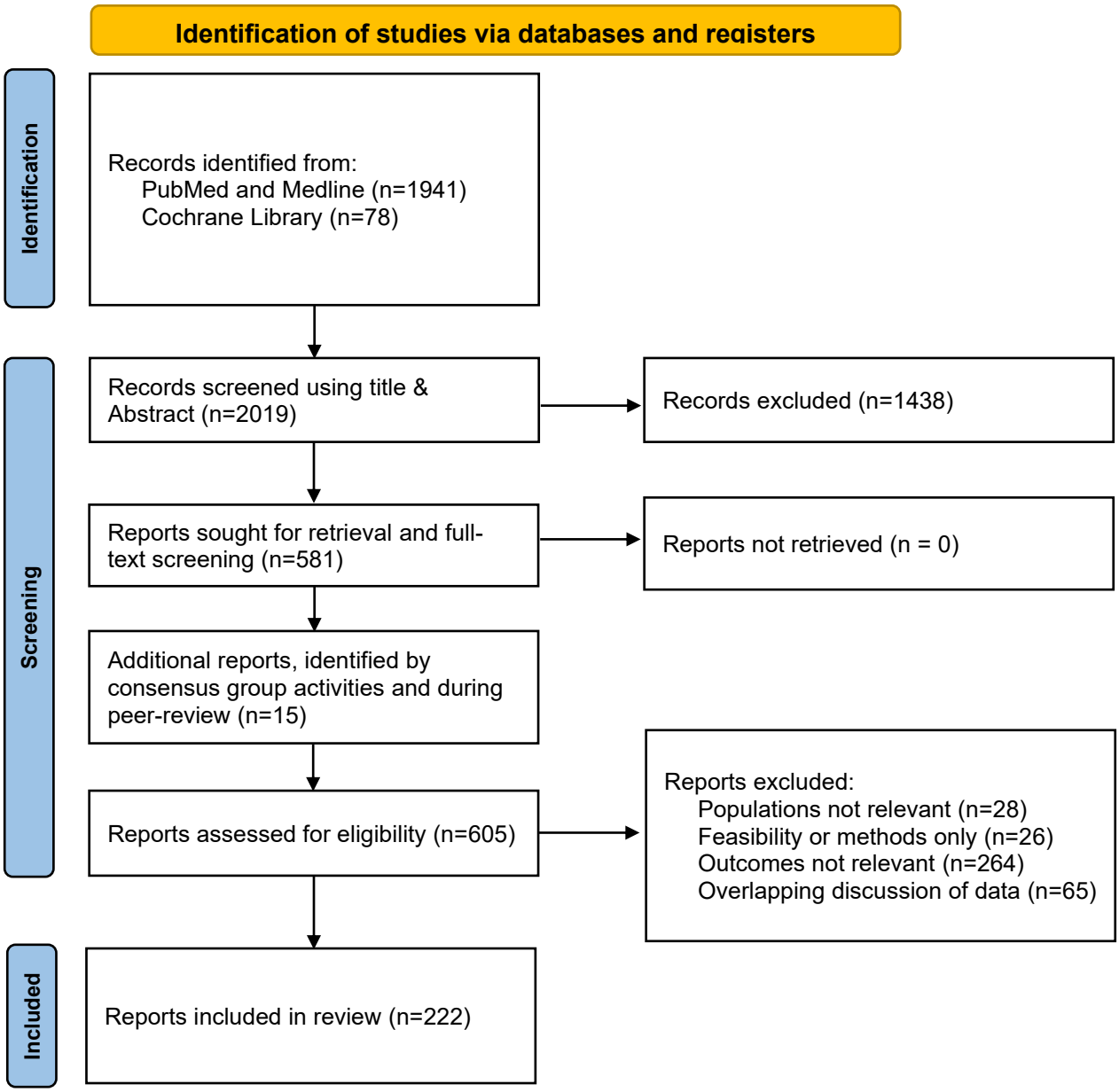
Search Documentation and inclusion in the review: see Prisma Flow chart

- Databases searched: PubMed, Medline and the Cochrane Library
- Date of search: Between November 1st 2024 and October 25th 2025

Quality Assessment: Assess the quality of the included studies and articles for the protocol, study size, risk-of-bias, outcomes.

Articles included in review: the PRISMA flow of literature assessment review and selection for inclusion is outlined on Appendix P4.

PRISMA flow diagram of systematic literature retrieval for review purposes



Databases were searched according to the strategy listed on Appendix P1. All selection was done initially by assessment of titles and abstracts, and subsequently by full-text screening without automation

Evidence appraisal: American Diabetes Association grading system

Level of Evidence	Description
A	Clear evidence from well-conducted, generalizable randomised controlled trials that are adequately powered, including: ● Evidence from a well-conducted multicentre trial ● Evidence from a meta-analysis that incorporated quality ratings in the analysis Supportive evidence from well-conducted randomised controlled trials that are adequately powered, including: ● Evidence from a well-conducted trial at one or more institutions ● Evidence from meta-analysis incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies, including: ● Evidence from a well-conducted prospective study or registry ● Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from well-conducted case control study
C	Supportive evidence from poorly controlled or uncontrolled studies, including: ● Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results ● Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) ● Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience