

Project scope: closed loop systems and the artificial pancreas for type I diabetes mellitus (T1DM)

14 June 2021

Research question

What is the clinical effectiveness, cost effectiveness and safety of closed loop insulin systems and the artificial pancreas in the management of type I diabetes mellitus (T1DM)?

Inclusion criteria

The selection of studies for inclusion in the literature review element of the project will be based on the following criteria:

Population	Patients with type I diabetes mellitus (T1DM) Adults and children (normal cut-off for paediatrics is 16)
Intervention	Artificial pancreas or closed loop systems (excluding DIY pancreas/CLS) Synonyms: artificial pancreas; closed loop system; closed loop pancreas; closed loop insulin system; closed loop therapy
Comparator	Multiple daily insulin injections (MDI) + fingerprick testing (standard care) MDI + flash glucose monitoring (FGM) Continuous subcutaneous insulin infusion (CSII) pumps + fingerprick testing CSII + FGM CSII + continuous glucose monitoring (CGM)
Outcomes	Glycaemic control *Time in range (glucose 3.9-20.0mmol/l) Time in hypoglycaemia *HbA1c *Microvascular complications (eyes, feet, and kidney) *Macrovascular complications (myocardial infarction and stroke) *Quality of life/PROMS Safety/adverse effects/complications Patient uptake *Cost effectiveness

	Equality of access/impact on inequalities Patient experience
Limits	English language Study designs: systematic review/meta-analysis, RCTs, economic evaluations, qualitative studies Published 2011-2021

Planned activities

SHTG have agreed on the following activities to support the development of SHTG

Recommendations on closed-loop insulin systems and the artificial pancreas for treatment of T1DM:

1. Evidence review of the published literature on clinical effectiveness, cost effectiveness, safety and patient aspects
2. Patient organisation submission (to be confirmed)
3. *de novo* economic modelling of closed loop insulin systems and the artificial pancreas in the Scottish context
4. Engagement of clinical experts through peer review and consultation on draft recommendations

End products

At the end of the project, SHTG will publish:

- SHTG Recommendations (with economic modelling incorporated)
- Peer-review and consultation comments
- Patient organisation submission (to be confirmed)
- Plain language summary

Timescales (approximate)

Publication in January 2022