INAHTA Brief

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Title Hybrid Closed-Loop Insulin Delivery Systems for People With Type 1 Diabetes

Agency CADTH
Suite 600, 865 Carling Avenue, Ottawa, Ontario, Canada, K1S 5S8
Phone: 1-866-988-1444; www.cadth.ca

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Aim

The objective of this Health Technology Assessment (HTA) was to inform decisions on the appropriate place in care, if any, of hybrid closed-loop insulin delivery (HCL) systems compared with existing technologies for people with type 1 diabetes. The HTA included a review of the clinical effectiveness and safety, a budget impact analysis, a perspectives and experiences review, and an ethics analysis related to the use of HCL systems by people living with type 1 diabetes.

Conclusions and Results

The clinical review concluded that HCL therapy generally increased the proportion of time spent within euglycemic ranges. It also decreased the time spent within hypo- and hyperglycemic ranges compared with sensor-augmented pump therapy and multiple daily insulin injections, or insulin pump therapy informed by self-monitoring of blood glucose. Similarly, HCL therapy demonstrated a general trend in improving glycated hemoglobin, mean glucose concentrations, and glycemic variability. The incidences of adverse events experienced by study participants, such as hypoglycemic events and ketosis-related events, were generally not statistically significantly different between those who were treated with HCL therapy and those who received control interventions.

As all jurisdictions cover insulin pumps to an extent, the reimbursement of HCL systems would require all jurisdictions (apart from Yukon and Ontario) to provide new coverage for continuous glucose monitors. Accordingly, the 3-year budget impact of introducing HCL systems to individuals who are eligible for insulin pumps was estimated to be $823 million from a pan-Canadian perspective. Uncertainty regarding the uptake of HCL systems among current multiple daily insulin injection users significantly influence results. If no current multiple daily insulin injection users are assumed to switch to HCL systems, the estimated budget impact of introducing HCL systems is much lower than the CADTH base case of $97 million over 3 years.

The perspectives and experiences review concluded that people living (or caring for someone) with type 1 diabetes expected (and, to some extent, experienced) HCL systems to take over enough of the day-to-day tasks of self-management that they could be more immersed in the flow of life around them. To work most effectively toward this expectation, however, people will need to trust the control algorithm to adjust things like basal-insulin rates and resist the impulse to do this work themselves. Learning to see HCL systems as partners in care rather than tools providing care may help develop this trust and alleviate frustrations with technical complications. Similarly, providers appreciated the depth of data HCL systems offered but also acknowledged the importance of not confusing this data with the particular needs of the person living with diabetes.

The ethics analysis indicated that HCL systems may promote individual autonomy and agency by relieving the burdens of diabetes management and allowing users to have greater control over their diabetes if they were able to trust the control algorithm. Given evidence of at least short-term clinical and non-clinical benefits to users, the ethics analysis suggested that coverage of HCL systems may fulfill goals to allocate resources to maximize benefits. However, insufficient evidence on the impact of HCL systems limits the understanding of whether HCL systems deliver a balance of long-term benefits over harms compared to other modes of diabetes management.

Recommendations

Considering the evidence, CADTH's Health Technology Expert Review Panel (HTERP) suggests that HCL systems hold promise for the care of people with type 1 diabetes. HTERP considers that, at present, there are insufficient long-term data on clinically relevant and patient-important outcomes to recommend how extensive the role of HCL systems should be in care. In addition, HTERP recommends the collection of robust and comparative data for the consideration of future reassessments that compare

HCL systems to existing insulin delivery and glucose monitoring methods in terms of glycated hemoglobin; time-in-range; time above and below range; glycemic variability; quality of life; patient satisfaction, parent or caregiver satisfaction, and health care provider satisfaction; diabetes-related complications; discontinuation rates; and health system impact. Robust data are defined as that collected in well-designed comparative studies that are, among other considerations, of sufficient duration to ensure a clinically meaningful outcome assessment.

Methods

The review of clinical effectiveness and safety comprised a systematic review of primary studies on the comparative clinical effectiveness and safety of commercialized HCL systems versus other insulin delivery methods in people with type 1 diabetes.

A budget impact analysis was conducted estimating the financial impact of reimbursing HCL systems for the management of type 1 diabetes compared with currently reimbursed technologies over a 3-year time horizon. The budget impact analysis was conducted from the perspective of the Canadian publicly funded health care system (i.e., ministry of health), excluding Quebec; only costs covered by the public health care payer were captured. Market size was derived using an epidemiology-based approach.

The perspectives and experiences review was conducted using an adapted thematic synthesis of primary qualitative research exploring the expectations and experiences of people living (or caring for someone) with type 1 diabetes using HCL systems.

An ethics analysis was conducted to identify the key ethics dimensions of HCL systems using a 2-step approach. The first was a review of the ethics literature, the clinical literature, and the public health literature to identify existing ethical analyses of the technology. The second was a novel ethical analysis based on gaps identified in the ethics literature and the results of concurrent reviews.

Further Research and Reviews Required

Clinical evidence that provides insight into who may benefit the most (i.e., which patient subgroups) from the use of HCL and who may not benefit is lacking. Additionally, clinical evidence that examines the long-term effectiveness and safety (i.e., with follow-up periods longer than 1 year) is required to gain a greater understanding of the optimal role of HCL systems. New or updated HCL systems are anticipated to enter the market in the coming years. It is unclear how the additional evidence associated with these emerging devices could impact the conclusions of this and future reports.

Written by

CADTH, Canada