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CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Safety Needles for Insulin Pens: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to **requests@cadth.ca**

Research Questions

1. What is the clinical effectiveness of insulin pens with safety needles for the management of patients with diabetes?
2. What is the cost-effectiveness of insulin pens with safety needles for the management of patients with diabetes?
3. What are the evidence-based guidelines regarding needle selection for insulin pens for the management of patients with diabetes?

Key Findings

Three evidence-based guidelines were identified regarding needle selection for insulin pens for the management of patients with diabetes.

Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was insulin pen needles. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and October 9, 2019. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with diabetes
Intervention	Q1-2: Insulin pens with safety pen needles (i.e., needles with an automatic safety shield) Q3: All types of needles for insulin pens
Comparator	Q1-2: Insulin pens with other needle types (e.g., non-safety pen needles) Q3: No comparator

Outcomes	Q1: Clinical effectiveness (e.g., glycemic control, safety [e.g., rates of adverse events, number of hypoglycemic events requiring assistance, bruising, bleeding]) Q2: Cost-effectiveness (e.g., incremental cost per quality-adjusted life year or health benefit gained) Q3: Evidence-based guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessments, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

Three evidence-based guidelines were identified regarding needle selection for insulin pens for the management of patients with diabetes.[1-3] No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and non-randomized studies were identified regarding the clinical effectiveness of insulin pens with safety needles for the management of patients with diabetes. Additionally, no economic evaluations were identified regarding the cost-effectiveness of insulin pens with safety needles for the management of patients with diabetes.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Table 2 summarizes the identified guidelines[1-3] with the relevant recommendations regarding needle selection for insulin pens for the management of patients with diabetes.

Table 2: Evidence-Based Guidelines regarding Needle Selection for Insulin Pens for the Management of Patients with Diabetes

Evidence-Based Guidelines	Recommendations
FITTER: New insulin delivery recommendations (Frid et al)[1]	• *"Safety injection devices should be considered first-line choice if injections are given by a third party. Pens and syringes with needles used in this setting should have protective mechanisms for all sharp ends of the delivery device."* • *"The 4-mm needle is long enough to traverse the skin and enter the SC tissue, with little risk of IM (or intradermal) injection. Therefore, it is considered the safest pen needle for adults and children."* • *"After the thumb button is completely pushed in, patients should count slowly to 10 and then withdraw the needle from the skin. This is necessary to prevent medication leakage and to get the full dose."*
NICE Guideline 18: Diabetes (type 1 and type 2) in children and young people[2]	• *"Provide children and young people with type 1 diabetes with insulin injection needles that are of an appropriate length for their body fat." (p.142)* • No recommendation provided regarding the use of safety pen needles
NICE Guideline 17: Type 1 diabetes in adults[3]	• *"Offer needles of different lengths to adults with type 1 diabetes who are having problems such as pain, local skin reactions and injection site leakages." (p.362)* • No recommendation provided regarding the use of safety pen needles

FITTER = Forum for Injection Technique and Therapy: Expert Recommendations; IM = intramuscular; NICE = National Institute for Health and Care Excellence; SC = subcutaneous

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

No literature identified.

Economic Evaluations

No literature identified.

Guidelines and Recommendations

1. Frid AH, Kreugel G, Grassi G, et al. New insulin delivery recommendations. *Mayo Clin Proc*. 2016 Sep;91(9):1231-1255.
PubMed: PM27594187

2. National Institute for Health and Care Excellence. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. *(NICE guideline NG18)* 2015; https://www.nice.org.uk/guidance/ng18/evidence/full-guideline-pdf-435396352. Accessed 2019 Oct 16.
See: 6.1.4 Methods of delivering insulin (page 135)

3. National Institute for Health and Care Excellence. Type 1 diabetes in adults: diagnosis and management. *(NICE guideline NG17)* 2015; https://www.nice.org.uk/guidance/ng17/evidence/full-guideline-pdf-435400241. Accessed 2019 Oct 16.
See: 9.3.7 Recommendations and links to the evidence (page 362)

Appendix — Further Information

Previous CADTH Reports

4. Insulin pens in acute care settings: clinical effectiveness, cost effectiveness, and guidelines. *(CADTH Rapid response report: summary of abstracts)*. Ottawa (ON): CADTH; 2017: https://www.cadth.ca/sites/default/files/pdf/htis/2017/RB1121%20Insulin%20Pens%20Final.pdf. Accessed 2019 Oct 16.

Randomized Controlled Trials – Alternative Intervention

5. Xing Y, Xie X, Xu J, et al. Efficacy and safety of a needle-free injector in Chinese patients with type 2 diabetes mellitus treated with basal insulin: a multicentre, prospective, randomised, crossover study. *Expert Opin Drug Deliv*. 2019 Sep;16(9):995-1002.
PubMed: PM31359813

Non-Randomized Studies – Alternative Comparator

6. Bossi AC, Veronesi G, Poerio CS, et al. A prospective study for introducing insulin pens and safety needles in a hospital setting. The SANITHY study. *Curr Diabetes Rev*. 2016;12(4):460-467.
PubMed: PM26245310

Evidence-Based Guidelines

Unclear Intervention in Abstract

7. Frid A, Hirsch L, Gaspar R, et al. New injection recommendations for patients with diabetes. *Diabetes Metab*. 2010 Sep;36 Suppl 2:S3-S18.
PubMed: PM20933208

Clinical Practice Guidelines

8. Bahendeka S, Kaushik R, Swai AB, et al. EADSG Guidelines: insulin storage and optimisation of injection technique in diabetes management. *Diabetes Ther*. 2019 Apr;10(2):341-366.
PubMed: PM30815830

9. National Institute for Health and Care Excellence. Safer insulin prescribing: key therapeutic topic. *(NICE key therapeutic topic KTT20)* 2017; https://www.nice.org.uk/advice/ktt20/resources/safer-insulin-prescribing-pdf-58758006482629. Accessed 2019 Oct 16.
See p. 5: "Staff, and where appropriate, patients who use pen devices, should be routinely provided with safety needles and access to equipment capable of safely removing and disposing of used insulin pen needles."

10. Haines ST, Miklich MA, Rochester-Eyeguokan C. Best practices for safe use of insulin pen devices in hospitals: recommendations from an expert panel Delphi consensus process. *Am J Health Syst Pharm*. 2016 Oct;73(19 Suppl 5):S4-S16.
PubMed: PM27647099

Review Articles

11. Smallwood C, Lamarche D, Chevrier A. Examining factors that impact inpatient management of diabetes and the role of insulin pen devices. *Can J Diabetes*. 2017 Feb;41(1):102-107.
PubMed: PM27600025

12. Davis EM, Foral PA, Dull RB, Smith AN. Review of insulin therapy and pen use in hospitalized patients. *Hosp Pharm*. 2013 May;48(5):396-405.
PubMed: PM24421496

Additional References

13. Institute for Safe Medication Practices. Severe hyperglycemia in patients incorrectly using insulin pens at home. 2017; https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home. Accessed 2019 Oct 16.
See: "To protect staff from needlestick injuries and guard against the reuse of needles, many hospitals use insulin pen needles that automatically re-cover and lock the pen needle once injection has been completed and the needle has been withdrawn from the skin. Such products include NOVOFINE AUTOCOVER (Novo Nordisk) and BD AUTOSHIELD DUO."