Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Inform discussions on new topics received by HTW.
2. Determine the quantity and type of evidence available on a topic.
3. Assess the topic against HTW selection criteria.

Topic:	**Injection ports for the subcutaneous administration of insulin in people with diabetes**
Topic exploration report number:	TER065

Summary of findings

The clinical effectiveness of injection ports as a needle-free method of administering insulin to people with diabetes has been assessed in a small number of randomised trials (three studies, 158 patients in total). Compared to usual care, glycaemic control was improved or similar to usual care in people who used injection ports, but only short-term use of the devices was reported.

We did not identify any evidence analysing the cost impact or cost effectiveness of i-Port or any similar insulin injection systems.

Introduction and aims

i-Port is a disposable, low profile injection port through which prescribed medications, including insulin, can be injected subcutaneously from a syringe or pen without repeated needle punctures of the skin.

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of i-Port or other needle-free injection systems as a method of administering subcutaneous insulin therapy to treat diabetes mellitus.

Evidence

Clinical evidence
Three randomised trials were identified assessing the effectiveness of insulin injection devices. Two of these used i-Port, the remaining trial studied the Insuflon device. Two of the trials studied children/adolescents whilst the third included children and adults. The length of time people used the device varied from three weeks to six months. One trial is available as a conference abstract only from 2014 – we were not able to locate later full publication of this trial.

All three trials report on changes in glycaemic control: in two of three trials, HbA1c was lower at the end of the trial in patients using an injection device compared to patients who received usual care. In the third trial there was no difference in glycaemic control between treatment arms.

Two out of three trials also reported some information on patients' preference for or satisfaction with using an injection device, although these were reported for use of the injection device and not compared to control treatment. In both trials, the majority of patients expressed satisfaction with the device or reported that they found it helpful in managing their diabetes.

Economic evaluations
We did not identify any existing economic evaluations of i-Port or other injection devices for use by people with diabetes to inject insulin.

UK Guidelines and guidance
Relevant NICE Guidelines include NG17: *Type 1 diabetes in adults: diagnosis and management* (https://www.nice.org.uk/guidance/ng17) and NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management (https://www.nice.org.uk/guidance/ng18). These guidelines were both last updated in November 2016.

NG17 contains the following recommendation (1.8.2): "Provide adults with type 1 diabetes who have special visual or psychological needs with injection devices or needle-free systems that they can use independently for accurate dosing." This recommendation was made in the original version of the Guideline, published in 2004. The Full Guideline does not appear to include any evidence that is linked to this recommendation.

NG18 includes a number of recommendations on the use of insulin therapy for children and young people with type 1 diabetes (1.2.18 to 1.2.30). None of these make specific reference to injection devices, although 1.2.25 states "Offer children and young people with type 1 diabetes a choice of insulin delivery systems that takes account of their insulin requirements and personal preferences." The Full Guideline does not appear to include any evidence that is linked to this recommendation.

Areas of uncertainty

The available studies assessed the use of injection devices in people using insulin, but only limited details of their current care and level of glycaemic control are reported. It is therefore unclear what particular groups of patients would most benefit from the use of injection devices to help control their diabetes.

The cost of using the devices in terms of either direct costs, or staff time (either direct or training costs), is not known.

Conclusions

The available evidence suggests needle-free injection devices may be an effective method of administering insulin for people with diabetes. Randomised studies suggest injection devices may improve glycaemic control compared to directly injecting insulin, but the studies identified are all small and only measured the effectiveness of injection devices when used in the short-term (maximum of six months).

We did not identify any existing economic evaluations of i-Port or other injection devices for use by people with diabetes to inject insulin.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland:	We did not identify any relevant advice from this source
Health Technology Assessment Group	We did not identify any relevant advice from this source
Health Information and Quality Authority	We did not identify any relevant advice from this source
UK guidelines and guidance	
SIGN	SIGN Guidelines on diabetes (SIGN 116: management of diabetes and SIGN 154: Pharmacological management of glycaemic control in people with type 2 diabetes) do not make any specific recommendations about the use of injection devices to administer insulin.
NICE	Relevant NICE Guidelines include NG17: *Type 1 diabetes in adults: diagnosis and management* (https://www.nice.org.uk/guidance/ng17) and NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management (https://www.nice.org.uk/guidance/ng18). These guidelines were both last updated in November 2016. We did not identify any other sources of NICE guidance about i-Port or any other insulin injection device.
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant advice from this source
Cochrane library	We did not identify any relevant advice from this source
Medline	We did not identify any relevant advice from this source
Primary studies	
Medline	Randomised trials: • Blevins T, Schwartz SL, Bode B, et al. (2008). A Study Assessing an Injection Port for Administration of Insulin. Diabetes Spectrum. 21(3): 197-202. doi: 10.2337/diaspect.21.3.197 Non-randomised trials: • Khan AM, Alswat KA. (2019). Benefits of Using the i-Port System on Insulin-Treated Patients. Diabetes Spectr. 32(1): 30-5. doi: 10.2337/ds18-0015 • Maltoni G, Zioutas M, Zucchini S, et al. (2018). Using an injection port helps improve metabolic control and compliance to a strict basal-bolus regimen in children and adolescents with type 1 diabetes. J Diabetes. 10(8): 686-8. doi: 10.1111/1753-0407.12665 • Riley D, Raup GH. (2010). Impact of a subcutaneous injection device on improving patient care. Nurs Manage. 41(6): 49-50. doi: 10.1097/01.Numa.0000381743.17905.62
Cochrane library	Randomised trials: • Burdick P, Cooper S, Horner B, et al. (2009). Use of a subcutaneous injection port to improve glycemic control in children with type 1 diabetes. Pediatric diabetes. 10(2): 116-9. doi: 10.1111/j.1399-5448.2008.00449.x

	• Maltoni G, Martini AL, Rollo A, et al. (2014). A randomized, crossover pilot study comparing glycemic control and satisfaction with an indwelling catheter (i-port advance) for insulin administration in children and adolescents with type 1 diabetes on basal-bolus treatment*. Hormone research in paediatrics. 82: 91. doi: 10.1159/000365775

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Concepts used:	i-port, injection port, injection device, diabetes