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Making health technology assessment more dynamic – Temporal trend analysis to capture performance trajectories

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Dynamic HTA;
Meta-regression;
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Technological progress;
Technology cycle analysis

Abstract
Objectives: Health technology assessment (HTA) has an increasing role in evaluating not only drugs, but also medical devices. Assessing medical devices is more challenging as outcomes tend to improve substantially over time. This paper analyzes clinical outcomes over time of insulin pump therapy in adult type 1 diabetes. Meta-regression was used to capture outcome trends while considering innovation theory.
Methods: A systematic review of 4.297 studies was conducted covering a 35 year time period. To meet the need for a more dynamic evaluation method, temporal trend analysis was applied based on meta-regression of three extracted outcome parameters: HbA1c, incidence of severe hypoglycemia and ketoacidosis.
Results: The systematic review included 150 studies. Performance improvement in HbA1c and ketoacidosis was rapid during the 1980 and 90s. Thereafter the improvement trajectory of insulin pumps measured by HbA1c, ketoacidosis or severe hypoglycemia was essentially flat. Meta-regression of several covariates was performed showing publication year to be statistically significant. Retrospective recruitment and the percentage of female patients were also statistically significant. A technology cycle model analysis revealed convergence to a dominant design by the end 1990s, followed by slower progress in outcomes.
Conclusions: Insulin pump technology currently does not offer an improving performance trajectory according to key indicators HbA1c, incidence of severe hypoglycemia and ketoacidosis, but compares well to manual insulin injections in terms of quality of life. Applying

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temporal trend analysis is especially valuable in an early technology cycle stage when uncertainty is high, and when predicted improvements in future performance can influence the choice of technology.

Introduction

Health technology assessment (HTA) of drugs prior to their introduction into national healthcare systems has been a common practice in many jurisdictions over the last 15 years [1], requiring pharmaceutical companies to demonstrate their products´ value [2]. An increase in HTAs for drugs has triggered increasing interest in HTAs for medical devices, which has presented some challenges [3,4]. Drummond, Griffin and Tarricone pointed out some major differences between drugs and medical devices. These include differences in regulatory requirements on evidence prior to commercialization, technical challenges in developing evidence, dependence on user skills causing learning-curve effects, and outcomes dependent on local complementary equipment and setting [5]. Compared to pharma, medical device development times are shorter and there is usually more technological opportunity to circumvent existing patents resulting in heightened competition and faster price erosion. Also, medical devices do not enjoy the public price subsidies of prescription drugs, instead are usually procured through large tenders that reduce prices [5].

HTA methods were primarily developed to evaluate individual prescription drugs that cannot change after being approved. These methods meet with challenges when evaluating medical device classes due to lower regulatory hurdles and several company-individual product life-cycles [3,4]. An HTA of a medical device class may therefore quickly become outdated due to user-learning and ongoing technological development. To capture this rapid change in outcomes over time from several individual studies, it is suggested in this paper that meta-regression techniques could be used [6]. A meta-regression analysis using publication year as a covariate can identify temporal trends in outcomes and thus provide better predictions of the future performance of a technology [7].

Health technology assessments are increasingly used to support decision making concerning medical devices at national, regional and hospital levels early in a product's life-cycle when uncertainty tend to be highest [8,9]. Although current HTA methods include systematic literature reviews and sometimes meta-analysis, they do not address the opportunity to do a meta-regression to capture the dynamic aspects of outcome improvements. As a consequence, HTAs run the risk of drawing the wrong conclusions about a medical technology because they fail to capture dynamic allocative efficiencies in healthcare [9,10].

The primary aim of this paper is to analyze clinical outcomes over time resulting from progress in insulin pump technology (both continuous subcutaneous insulin infusion – CSII and intraperitoneal insulin infusion – IPII) and clinical practice in type 1 diabetes. The paper also aims to evaluate how meta-regression can be used in HTAs of medical devices to capture performance trajectories in outcomes over a full technology cycle.

Central outcome parameters in type 1 diabetes are related to glycemic control, measured by glycated hemoglobin (HbA1c) and the incidence of severe hypoglycemia (too low glucose level) and ketoacidosis (too high glucose level). HbA1c is a core outcome measure in diabetes therapy with treatment guidelines prescribing a target value below 7% according to the National Glycohemoglobin Standardization Program - NGSP (52 mmol/mol) and normal values below 5.7% (38,8 mmol/mol) [11,12]. The HbA1c value reflects the glycaemic level of the past six to eight weeks [13], and an elevated level over a longer time eventually leads to cardiovascular complications [14]. Too low or too high blood glucose levels may also lead to acute coma requiring urgent assistance of the diabetes patient. This paper does not include an analysis of changes in price, or costs, over time of insulin pump therapy, although these changes are relevant from a cost-effectiveness or HTA point of view.

Background

Technological change in a product class usually follows cyclical patterns (Figure 1) that have implications for when to do an HTA [8]. An initial radical innovation causes substantial uncertainty on how to best adapt it to the needs of users and therefore usually creates competition among different designs. The resulting era of design competition often converges to a dominant design that meets the

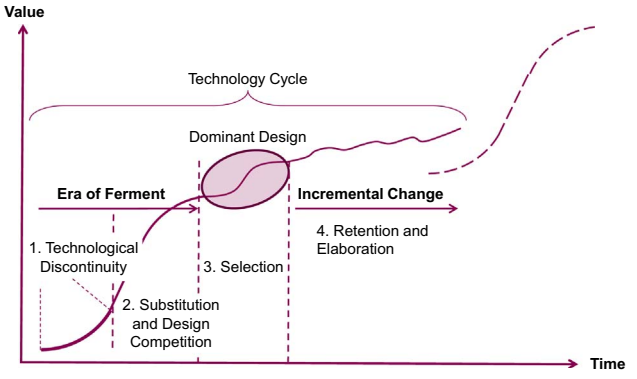

Figure 1 The value of a product technology is increased by successive innovations over time in an industry. Innovations usually follow a pattern starting with 1. Technological discontinuity, 2. Substitution and design competition, 3. Selection of a dominant product design, 4. Retention and elaboration of the dominant design.

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