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When Future Change Matters: Modeling Future Price and Diffusion in Health Technology Assessments of Medical Devices

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ABSTRACT

Background: Health technology assessments (HTAs) that take account of future price changes have been examined in the literature, but the important issue of price reductions that are generated by the reimbursement decision has been ignored. **Objectives:** To explore the impact of future price reductions caused by increasing uptake on HTAs and decision making for medical devices. **Methods:** We demonstrate the use of a two-stage modeling approach to derive estimates of technology price as a consequence of changes in technology uptake over future periods on the basis of existing theory and supported by empirical studies. We explore the impact on cost-effectiveness and expected value of information analysis in an illustrative example on the basis of a technology in development for preterm birth screening. **Results:** The application of our approach to the case study technology generates smaller incremental cost-effectiveness ratios compared with the commonly used single cohort approach. The extent of this reduction in the incremental cost-effectiveness ratio depends on the magnitude of the modeled price reduction, the speed of diffusion, and the length of the assumed technology life horizon. Results of value of information analysis are affected through changes in the expected net benefit calculation, the addition of uncertain parameters, and the diffusion-adjusted estimate of the affected patient population. **Conclusions:** Because modeling future changes in price and uptake has the potential to affect HTA outcomes, modeling techniques that can address such changes should be considered for medical devices that may otherwise be rejected.

Keywords: cost-benefit analysis, diffusion of innovation, drug costs, value of information.

Introduction

Health technology assessments (HTAs) rarely take potential future reductions in price caused by increased implementation into account in their modeling of cost-effectiveness [1]. Reimbursement bodies such as UK's National Institute for Health and Care Excellence typically make assessments on the basis of a single patient cohort and follow their costs and effects through patients' lifetimes or through a specific time horizon. Several articles have explored how future cohorts can be incorporated into cost-effectiveness analyses. Hoyle and Anderson [1] and Hoyle [2,3] have established future cohort incremental cost-effectiveness ratios (ICERs) to reflect future drug price reductions and the time-varying mix of prevalent and incident patients, which, conditional on differing parameter values for both groups, affect final model outputs. Philips et al. [4] included future cohorts and modeled changes in price, evidence, and competition to explore how the decision time horizon in value of information (VOI) analysis should be set.

These analyses, however, remain divorced from the decision-making context of all reimbursement bodies. When future changes are independent of the reimbursement decision, such as price reductions following generic entry [5], these can be accommodated by traditional "single cohort models" through re-appraisal at future time points once these price changes occur. Till then, the price parameter can be assumed to be constant and the single cohort model without any price changes would be adequate for decision making. Nevertheless, changes that are dependent on the reimbursement decision, such as price changes produced by increased uptake that have been observed in medical devices [6] and are described as experience curves, must be incorporated into the decision or else these price changes may not be realized if the technology is rejected by the reimbursement body. Consequently, patients will not get access to a technology that, given sufficient uptake, could be cost-effective and provide a positive incremental net benefit.

Central to this issue is a detailed consideration of uptake, diffusion, and associated price changes. *Uptake* is defined, for the purposes of this article, as the number of units of a technology purchased through the health system relating to a specific medical indication, whereas *diffusion* is defined as the process of uptake growth over time. Both uptake and diffusion can also refer to the presentation of the number of adoptions as a proportion of the number of attainable or desirable adoptions.

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The phenomenon of experience curves describes the impact of increasing uptake of technologies on price. We performed a literature review of studies citing experience curve literature [6,7] and came to the conclusion that experience curves and diffusion theory have not been merged and applied to an HTA setting.

The aim of this article was to explore the impact of diffusion and associated price changes on HTA. Because empirical evidence of these price changes exists only for medical devices, the proposed approach will be most relevant in this context, although it could be used in any technology for which such future price reductions are believed to be plausible. We first demonstrate the use of a two-stage modeling approach on the basis of existing theory and empirical evidence that includes future changes in price and uptake. We then explore the impact on cost-effectiveness and VOI analysis results in an illustrative example.

Methods

The Experience Curve Model

There is ample evidence for experience curves that shows how increasing uptake leads to price reductions in several different technologies as well as from a study of 20 medical devices by Brown et al. [6]. Experience curves can be justified through a technology's competitive situation [6]. When the conditions of perfect competition and perfect information are not satisfied, pricing occurs above marginal costs, especially in R&D-intensive industries [8]. The larger a market becomes, the more likely it is for competitors to enter. In the health care industry, this would typically occur after patent expiry but also before that via between-patent competition through close substitutes [8]. With increasing competition, prices are likely to fall. In addition, economies of scale that describe reductions in costs with increasing production volume may also lead to reduced costs and prices [6,7]. Although price reductions that are consistent with an experience curve model could in theory be present for all health care products for which the market conditions highlighted here exist, there is no evidence on experience curves in pharmaceuticals. Price changes observed for pharmaceuticals are typically related to patent expiry [5], rather than to uptake and associated production volumes. Consequently, this work appears to be more applicable to the devices industry.

Experience curves relate technology price to uptake. More specifically, it has been observed that prices of medical devices decline to a percentage of the technology's initial price every time initial production volume doubles [6]:

$$P_{N_t} = \begin{cases} P_{N_0} \text{ for } 0 < N_t < 2N_0 \\ \alpha^{\beta} P_{N_0} \text{ for } N_t \geq 2N_0 \end{cases}, \quad (1)$$

where N_t is the cumulative uptake or sales volume up to period t, with P_{N_t} being the price at N_t; P_{N_0} is the price that was set at initial quantity N_0, which is maintained until $N_t \geq 2N_0$; α is the experience curve parameter or the percentage of the technology's initial price, with $0 < \alpha < 1$; and β is the number of times that the initial quantity doubled, with $\beta = \log_2\left[\frac{N_t}{N_0}\right]$. Table 1 provides a definition of all parameters and the equation is graphed with different parameter values in Figure 2 and explained in the Results section.

Equation 1 implies that prices remain stable until the initial production quantity has doubled for the first time. Furthermore, price is dependent on technology uptake through β, the number of times that the initial quantity had doubled, rather than on time. This highlights the need for another piece of information: technology uptake over time.

Table 1 – Definitions of parameters.

Parameter	Definition
P_{N_t}	Price at cumulative sales volume quantity N_t
α	Experience curve parameter, the proportion of initial price that price is reduced to
β	Number of times that sales volume quantity doubles
n	Number of new per-period adoptions
M	Total number of attainable adoptions
M^*	Number of desirable adoptions
t	Period of time
N_{t-1}	Cumulative number of adoptions up to $t-1$
p	Coefficient of external influence or innovation
q	Coefficient of internal influence or imitation
c_j	Costs of intervention j
e_j	Benefits of intervention j
T^{T1}	Technology life horizon of technology T1
δ	Term for discounting
r	Discounting factor
NB	Net monetary benefit
θ	Vector of uncertain parameters
λ	Willingness-to-pay threshold
T^{VOI}	VOI time horizon

VOI, value of information.

The Uptake Model

Technology uptake is a time-dependent process that has been described in the theory of diffusion of innovations. The theory of diffusion was given prominence by Rogers [9] who, in 1962, gave the impetus for further diffusion research of theoretical and empirical nature. Rogers established a diffusion model that is characterized by an s-shaped curve showing how cumulative adoptions increase over time [10]. Although this generalization may not apply to all technologies, the fact that full uptake does not generally occur instantaneously is supported by studies that highlighted that innovative health technologies, deemed cost-effective in an HTA, were not adopted to their full potential [11,12]. We are not aware of any other empirical evidence on diffusion of medical devices and therefore assume that the s-shape of diffusion holds. We use an established parameterized diffusion model developed by Bass [13], which is a logistic model with parameters reflecting the degree of innovation and imitation as well as the overall attainable number of adoptions to achieve an s-shaped growth.

$$n(t) = p(M - N_{t-1}) + \frac{q}{M} N_{t-1}(M - N_{t-1}), \quad (2)$$

where $n(t)$ is the number of new adoptions in period t, with $n(t) \geq 0$, $t > 0$; p is the coefficient of innovation; q is the coefficient of imitation, with $\frac{q}{p} > 1$ to ensure the s-shape [10]; M is the total number of attainable adoptions with $M > 0$; and N_{t-1} is the cumulative number of adoptions up to $t-1$. To our knowledge, restrictions on p and q are not clearly defined in the diffusion curve literature. We found that the model worked best at values of $0 < p < 0.1$ and $0 < q < 1$. This model is graphed in Figure 3 and explained further in the Results section.

The Dynamic Cost-Effectiveness Model

The standard measure of assessing a technology's value is the ICER, which represents the incremental population mean costs relative to the incremental population mean quality-adjusted life-years (QALYs) of one technology compared with another. Inferences about costs and benefits of health technologies are