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When future change matters: modelling future price and diffusion in health technology assessments of medical devices

Abstract

Objectives: Whilst health technology assessments (HTAs) that take account of future price change have been examined in the literature, the important issue of price reductions that are generated by the reimbursement decision has been ignored. Our objective is 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 modelling approach to derive estimates of technology price as a consequence of changes in technology uptake over future periods based on existing theory and supported by empirical studies. We explore the impact on cost-effectiveness and expected value of information analysis in an illustrative example based on a technology used in pre-term birth screening that is in development.

Results: The application of our approach to the case study technology generates smaller incremental cost-effectiveness ratios (ICERs) compared to the commonly used single cohort approach. The extent of this reduction of the ICER depends on the magnitude of the modelled 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: Since modelling future changes in price and uptake has the potential to affect HTA outcomes, modelling techniques that can address such changes should be considered for medical devices that may otherwise be rejected.

Introduction

Health technology assessments (HTAs) rarely take potential future reductions in price caused by increased implementation into account in their modelling of cost-effectiveness (1). Reimbursement bodies such as the UK's National Institute for Health and Care Excellence (NICE) typically make assessments based on 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 cohorts ICERs in order 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, Claxton & Palmer (4) included future cohorts and modelled changes in price, evidence and competition to explore how the decision time horizon in value of information analysis should be set.

However, these analyses remain divorced from the decision making context of all reimbursement bodies. Where 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. Up to 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. However, 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 realised 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 paper, as the number of units of a technology purchased through the health system relating to a specific medical indication, whilst diffusion is defined as the process of uptake growth over time. Both uptake and diffusion can also refer to the presentation of number of adoptions as a proportion of the number of attainable or desirable adoptions. The phenomenon of experience curves describes the impact of increasing uptake of technologies on price. We performed a literature review of studies citing the experience

curve literature (6,7) and came to the conclusion that experience curves and diffusion theory have not been merged and applied to a HTA setting.

The aim of this paper is to explore the impact of diffusion and associated price changes on HTA. Because empirical evidence of these price changes exist 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 demonstrate the use of a two-stage modelling approach based on existing theory and empirical evidence that includes future changes in price and uptake. We then explore the impact on cost-effectiveness and value of information 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 a variety of different technologies as well as from a study of twenty medical devices by Brown (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 prior to that through 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). Whilst price reductions that are consistent with an experience curve model could in theory be present for all health care products where the market conditions highlighted above exist, there is no evidence on experience curves in pharmaceuticals. Price changes observed for pharmaceuticals are typically related to patent expiry (5), rather than 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 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.

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 characterised by an s-shaped curve showing how cumulative adoptions increases over time (10). Whilst this generalisation 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 parameterised 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 the coefficient of innovation, and q the coefficient of imitation, with $\frac{q}{p} > 1$ to ensure the s-shape(10), M the total number of attainable adoptions with $M > 0$, N_{t-1} 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 to another. Inferences about costs and benefits of health technologies are commonly based on population means assumed to reflect at least one cohort of patients or mean of future cohorts (1).

$$ICER = \frac{c_i - c_j}{e_i - e_j} \quad (3)$$

Where c_i, c_j and e_i, e_j are the population mean costs and effects of interventions i and j , with $c, e \geq 0$.

Experience curves can be integrated in the cost-effectiveness framework through modelling future periods up to a certain technology-specific time horizon and using the experience curve and uptake models in the dynamic ICER calculation. We assume that, given a positive reimbursement decision, uptake would follow equation (2), and given a negative reimbursement decision, no uptake of the technology would occur. Costs in period t are now dependent on price and cumulative uptake up to period t through the experience curve model. It is important to note that we consider future incident cohorts in the modelling of future periods. The reason we refer to periods instead of cohorts is because price changes will also affect the first incident cohort in future

periods in technologies in which consumption occurs in each period. In some cases, medical devices are associated with one-off costs in the first period– in which case a future period equals a future cohort.

To compare cost-effectiveness in this dynamic setting with cost-effectiveness in a commonly used static setting with only one period or cohort modelled, we propose summarising the average of costs over time up to the technology life horizon and the average of effects over time in the average dynamic ICER (Equation (4)). For this, knowledge of the technology life horizon is needed. This may be the time at which the technology is anticipated to be replaced by another better technology or at which it changes due to further product development. It may also be useful to consider the per-period dynamic ICER in which the costs and effects in one specific period (or cohort) are used for the calculation. Contrary to other studies (1-3), we have refrained from weighting the average dynamic ICER by uptake as weighting would lead to assessing a mix of technologies rather than identifying the most efficient technology based on their costs and health effects. Uptake is therefore reflected in each period's (or cohort's) costs, but not used to provide a weighted average of incremental costs and effects.

$$\emptyset ICER^{dyn} = \frac{\frac{1}{t} \sum_t^{T^j} \Delta c(P_{N_t}) \delta}{\frac{1}{t} \sum_t^{T^j} \Delta e(t) \delta}, \quad (4)$$

where $\Delta c(P_{N_t})$ is the difference in costs between interventions over all incident and prevalent cohorts in period t , as a function of price and uptake and $e(t)$ are effects in each period of time, both summed up over the number of periods up to technology life horizon T^j and discounted at a discount factor of $\delta = \frac{1}{(1+r)^t}$ with r as the discount rate, with $c(P_{N_t}), e(t) \geq 0, r \geq 0$.

The effect of the dynamic model on Value of Information analysis

Value of Information (VOI) analysis provides the value of resolving decision uncertainty, thus indicating the potential value of further research. The expected value of perfect information (EVPI), for instance, quantifies the expected opportunity loss associated with the overall decision uncertainty present in an appraisal. Results of the EVPI analysis, calculated as in Philips et al.(17), will be influenced by Equation (1) through changes in the

expected net monetary benefit that now are dependent on uptake and experience curves as well as the technology life horizon adopted.

$$NB = \lambda \sum_{t=1}^{T^j} e_j(t)\delta - \sum_{t=1}^{T^j} c_j(P_{N_t})\delta \quad (5)$$

where NB is the net monetary benefit, and λ is the willingness-to-pay threshold with $\lambda > 0$.

The EVPI is then:

$$EVPI = \mathbb{E}_\theta \max_j NB(j, \theta) - \max_j \mathbb{E}_\theta NB(j, \theta) \quad (6)$$

Where $NB(j, \theta)$ is the expected net monetary benefit of technology j given the uncertain model input parameters θ .

Furthermore, the value of the EVPI accrued over the affected patient population is commonly used to compare the value of further research to its costs. This value is also affected by our dynamic analysis, when a technology is not fully implemented instantly. The number of patients affected then needs to be adjusted by uptake (18,19). This is not usually done: most VOI studies reporting the EVPI for the population use an estimate of the disease incidence or eligible patient population as the population estimate without adjusting for uptake (18,20). If we have knowledge of diffusion, we are able to calculate the diffusion-adjusted population EVPI (PEVPI) by adjusting the population estimate by time-dependent uptake:

$$diffusion - adjusted\ PEVPI = EVPI * \sum_t^{T^{VOI}} \frac{n_{jt}}{M^*} \delta\pi \quad (7)$$

where n_{jt} is uptake of the recommended technology j in period t as a proportion of the desirable number of adoptions M^* , $\delta\pi$ is the discounted affected patient population and T^{VOI} is the VOI time horizon.

Application in illustrative example

We illustrate future price changes through the experience curve using an illustrative example on a technology in development for pre-term birth screening. A new screening technology (T1) is evaluated against no screening (T0). When tested positive, high risk women will be treated which leads to a reduction in the number of women with premature births. There are three different health outcomes associated with the duration of gestation: full health, life-long disability and death of the baby. These health states are associated with utilities measured in QALYs, and the health states as well as pre-term birth itself and potential hospital treatments for mother and baby have costs linked to them.

We created a simple decision tree model that yields the ICER for one period. It is worth noting that in this case study, because screening and treatment happen within one year, a period coincides with one cohort. In some other technologies, such as drugs, this may not be the case, and for those, costs and effects for all prevalent cohorts that use the technology have to be summed up for each period. The model was populated with data from previous cost-effectiveness analyses (21, 22), and ongoing studies on technology T1 as well as some simplifying assumptions. An extra step of modelling uptake for each period of time and the associated price for the same period according to equations (1) and (2) is necessary. We simulated a number of future periods up to the chosen technology life horizon and included the price changes from the previous step into the calculation of the new cost for each period. To represent decision uncertainty, a probabilistic sensitivity analysis (PSA) with 1,000 iterations was performed and the EVPI and PEVPI calculated (population of 26,000 women screened per annum is used) using a threshold of £30,000 per QALY. We performed partial EVPI analyses using a generalised additive model regression method (23) to present decision uncertainty contributed by the technology life horizon, the uptake and experience curve parameters.

Parameterising the experience curve requires both data on the experience curve parameters and data on diffusion parameters. We obtained diffusion estimates for the new technology T1 by performing an elicitation of expert beliefs about parameters that informed the Bass model of technology growth. Beliefs elicited from three experts were synthesised using linear pooling. The method only required elicitation of three uncertain quantities to generate a multi-period diffusion curve, including the total attainable number of adoptions, the number of adoptions in the first period after technology introduction, and the time to peak number of per period adoptions. From these, the Bass model parameters were approximated by an optimisation procedure within Excel that enabled us to generate the diffusion curve for T1. In the absence of a manufacturer's forecast, the estimate for

the initial production quantity was based on the elicited number of adoptions for the first period with an additional 50% added to it (10 devices adopted in the first year). Alternatively, a wealth of literature has shown the fit of the Bass model with real world diffusion data across industries, with meta-analyses of the main parameters p and q available (14) that may be useful to inform decision models in health. With respect to data on specific health technologies, studies by Gobok et al. (15) and Sillup (16) have demonstrated the value of the Bass model in prospective and retrospective analyses of different technologies including neurological monitoring with biomarkers, CT scans, MRI and others with parameter values available from these reports. We suggest basing the experience curve alpha parameter estimate based on the range reported in the empirical study by Brown et al.(7) (we use $\alpha=90\%$), or perform expert elicitation on this. We explored the effects of different values for diffusion parameters on the shape of the diffusion curve and of the experience curve parameters on the format of price changes.

Results

The price of the new screening technology T1 declines after approximately 15% of the attainable uptake has been achieved after two years (Figure 1). The short time in which price remains stable and the subsequent rather quick price decline is a consequence of the parameter values, that cause the initial production run of the device to end at the same time as uptake increases exponentially. With uptake exhibiting diminishing marginal growth towards the later periods, price converges to an asymptote. More intuitively, when uptake growth becomes slower, the reduction in technology price decreases until the lowest possible level of price is reached. Using different values for the experience curve and diffusion parameters shows that both have a significant effect on technology price (Figure 2). For instance, given that all else remains equal, an experience curve parameter (α in Equation 1) of 80% could reduce future price to less than half of its starting value once 140 adoptions are reached, which in the case study example is at approximately 10 years. An α of 95%, in contrast, would reduce the future price to just more than 80% of its starting value. The effect of different values for diffusion parameters p and q is shown in Figure 3: we used the minimum, maximum and mean values that resulted from 1,000 simulations inverting the elicited quantities to yield parameters p and q , and plotted resulting diffusion curves for parameter p in Figure 3a, holding parameter q constant; and for parameter q in Figure 3b, holding parameter p constant. Both parameters could significantly change the speed of diffusion, which would result in price changes occurring faster or more slowly.

The average dynamic ICER is shown to be lower than the commonly used static ICER (Figure 4). This is explained by uptake and price changes affecting costs associated with T1 in such a way that they decline over time, resulting in decreasing per-period dynamic ICERs in each future period modelled. The technology life horizon chosen crucially determines how much lower the dynamic ICER is compared to the static ICER (Figure 4). Modelling more future periods would increase the number of periods with a low ICER and thus lower the average dynamic ICER further. Choosing a shorter technology life horizon may mean that price changes have not been realised and that the average dynamic ICER remains closer to the static ICER. This negative relationship between the average dynamic ICER and technology life horizon exhibits diminishing marginal returns, which is explained by the per-period dynamic ICER decreasing with diminishing marginal returns (Figure 4).

Adding experience curve and diffusion parameters to the model increases the expected opportunity loss associated with decision uncertainty, as calculated by the EVPI (£175 per person in the dynamic analysis versus £112 in the static analysis). The uncertainty associated with the added parameters relating to uptake, the experience curve and the time horizon has an effect on model outcomes and there is value associated with a reduction in uncertainty, with EVPPIs of, respectively: £7.5, £0.01 and £0.06. Together, the diffusion and experience curve parameters have a grouped EVPPI of £11 and the diffusion and technology life horizon parameters a grouped EVPPI of £11.5. The main contributors to decision uncertainty in this example are the parameters describing the predictive ability of T1 (i.e. the sensitivity and specificity parameters).

We show that the diffusion-adjusted PEVPI is smaller than the unadjusted PEVPI (Figure 5). This relationship has to hold as long as uptake of the recommended technology is smaller than 100%. There is a decrease in the unadjusted PEVPI with the VOI time horizon that exhibits diminishing marginal returns, explained by the effect of discounting (Figure 5). The diffusion-adjusted PEVPI shows a more ambiguous relationship with time. The low initial values for the diffusion-adjusted PEVPI are explained by low values for uptake in the first few periods. The subsequent increase is a consequence of rapidly growing uptake that offsets the negative effect of discounting. When uptake reaches its maximum, the diffusion-adjusted PEVPI decreases. Finally, it is noteworthy that the difference between the two estimation methods for the PEVPI becomes smaller over time, suggesting that we might make a bigger mistake when the VOI time horizon is short than when it is longer.

Discussion

We have shown that future changes in price and uptake affecting medical devices and a varying time horizon for modelling future periods significantly affect cost-effectiveness and EVPI results in an illustrative example.

Technology T1 became more cost-effective when future periods and price declines with time and uptake were modelled. PEVPI results were dependent on uptake and results of the partial EVPI analysis implied that there was value in reducing uncertainty surrounding future change parameters in this example.

These results are in line with findings by Hoyle (3) that taking into account future price changes of drugs could reduce ICERs by up to 46% in the author's case studies. These findings call into question the commonly made assumption of the first cohort being representative of future periods until re-appraisal is undertaken, and the common disregard for changes that are precipitated by the reimbursement decision itself. The proposed model is especially useful in technologies that may be rejected at the common cost-effectiveness threshold but that may exhibit a decline in price with increasing uptake, as cost-effectiveness could potentially fall below the threshold. In such a setting, our framework improves analytic accuracy by explicitly modelling future price changes and therefore enables decision makers to transparently utilise the resulting outcomes in decision-making. Furthermore, decision-makers may want to consider the value of implementation measures to boost uptake and increase the value of the technology to the health system. The experience curve modelling approach could be presented as a scenario analysis in a submission, given that more evidence on these price changes is desirable. If used in the base case, it is important to reflect uncertainty about the experience curve and diffusion parameters. In technologies for which price does not represent a substantial part of its cost to the health care system our approach may not affect model outcomes considerably.

The framework described in this paper ignores some of the operational details related to its use as these will be specific to individual reimbursement systems. However, it should be noted that some of the uncertainties included in our analysis can be reduced or potentially eliminated by reimbursement bodies. For example, NICE Technology Appraisals are usually scheduled to be reviewed every five years. Over this time frame, any price changes due to volume changes may be small and value of these further analyses limited. Likewise,

reimbursement bodies may want to consider reducing the uncertainty around price changes by making reimbursement contingent on the establishment of price and volume contracts.

It is important to recognise that when modelling future cohorts there is a trade-off of present against future welfare. We assumed that discounted future welfare gains of one technology could offset larger present welfare gains of another technology. The key problem with this is the uncertainty surrounding future events. Price changes might never materialise or another more cost-effective technology could become available. Careful consideration of competitor technologies to be launched in the following years is therefore advisable, as was highlighted previously in the context of causes for declining sales volumes in drugs (3). As for the uncertainty surrounding future price changes, we advise treating the price change parameter as any other uncertain parameter including uncertainty.

The strength of this research relates to the use of price changes via experience curve and diffusion theory in health economic modelling. We are not aware of any other study incorporating experience curves in cost-effectiveness and VOI analyses. Hoyle (3) investigated the effect of declining real drug prices on the ICER and developed a life-cycle correction factor to take these into account. Incorporation of these price changes into a cost-effectiveness analysis that supports a reimbursement process is questionable. If the price changes are independent of the decision, then they need not be included; re-appraisal at the appropriate time point would be an alternative approach.

Another strength of the research is that we explored the effects of uncertainty surrounding the time horizon parameter. The choice of a technology-specific time horizon was shown crucial for the value of the dynamic ICER. There is differing literature on the appropriate time horizon. Hoyle (2) estimated the mean drug lifetime to be 57 years (95% confidence interval 39-79 years) and used this as a proxy to a time horizon. In contrast, medical devices seem to have much shorter lifespans, estimated as short as 18 months (24). While the ISPOR Good Research Practices task force (25) recommends a time horizon long enough to capture all relevant outcomes which may result in a lifetime horizon, the interpretation of this refers to the within-cohort time horizon rather than to the number of periods that should be modelled in the future for separate cohorts. No matter what time horizon is chosen, it is appropriate to include this within the PSA due to uncertainty over its estimates.

Some limitations of this approach to modelling future price changes relate to the added complexity and data requirements. The two-stage approach of modelling future uptake and price increases computational time and data requirements. For diffusion and price change parameters, we recommend the use of data from meta-analyses or analogous technologies for simplicity but alternatively and for more context-specific estimates, data gaps can be filled using elicitation of expert opinion. This may improve the accuracy of the estimates but probabilistic sensitivity analysis would still be recommended on uncertain parameters. When a longer technology life horizon is adopted, it may be worth considering changes in discount rates. The complexity of data requirements will also increase if the dynamics of the comparator technologies are considered. This would suggest that a modified elicitation task will be required to estimate the uptake of the comparators.

We see potential in conducting further research to explore whether experience curves hold in an increased number of medical devices, whether experience curves also apply to pharmaceuticals and to further establish ways of obtaining data on uptake and price change. Furthermore, the addition of experience curves has established a more complex link between implementation and value of information analysis via price changes that could further be explored in value of implementation and information analysis studies (26, 27, 28)

In conclusion, we argue that the future price reduction need to be incorporated through modelling future periods in cost-effectiveness analysis when these changes are precipitated by the reimbursement decision, as is the case with experience curves in medical devices. Modelling future cohorts in the presence of changes in price that are dependent on uptake has the potential to alter HTA outcomes and modelling techniques that address such issues should be employed in technologies for which such future change is relevant and that may be rejected otherwise.

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Tables

Table 1: Key parameters used in dynamic cost-effectiveness model

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

Figures

Figure 1: Diffusion and price developments of T1

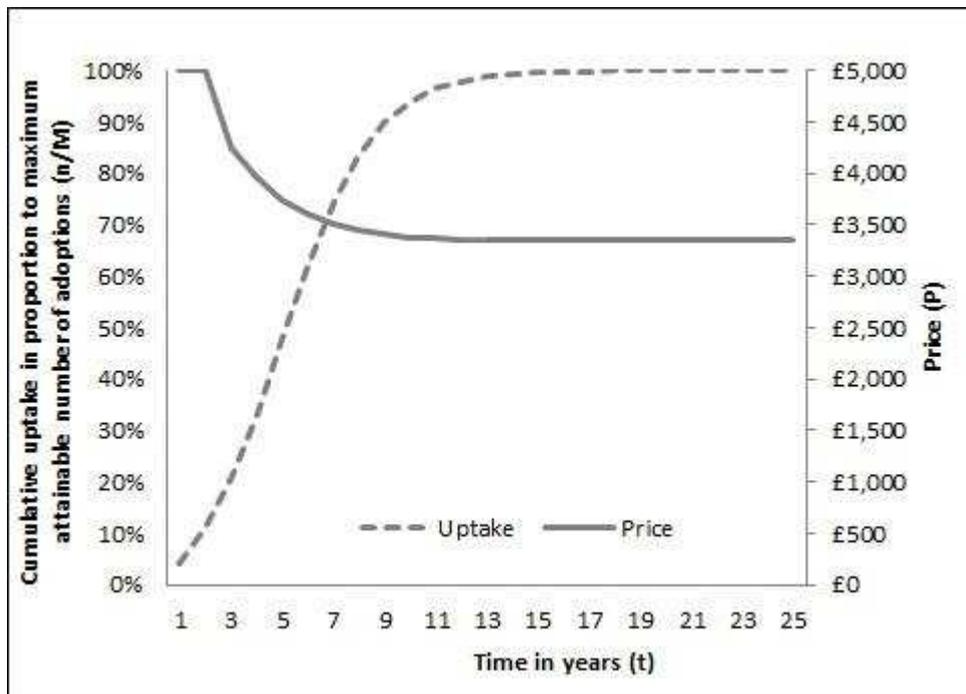


Figure 2: Impact of experience curve parameterisation on price

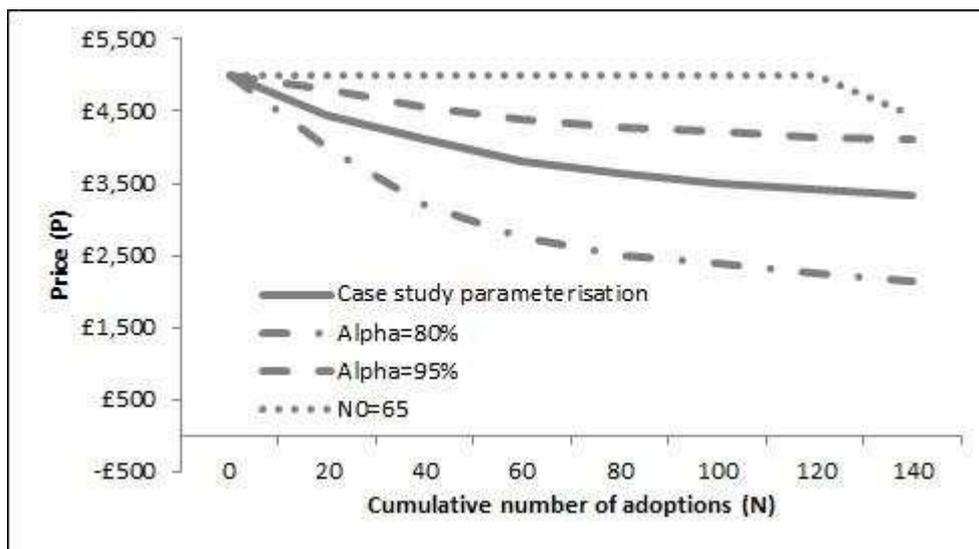


Figure 3: Impact of diffusion curve parameters on diffusion

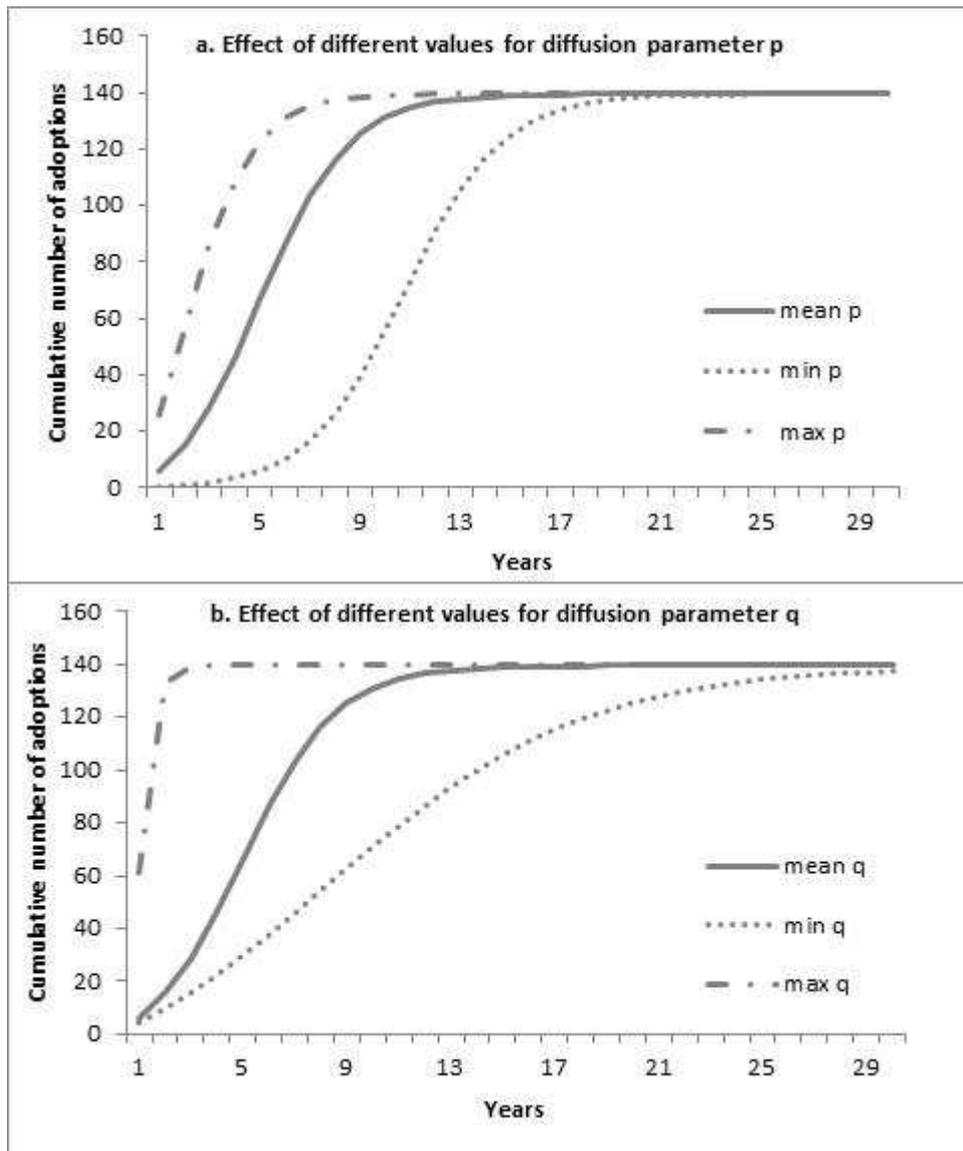


Figure 4: Impact of technology life horizon on dynamic ICER

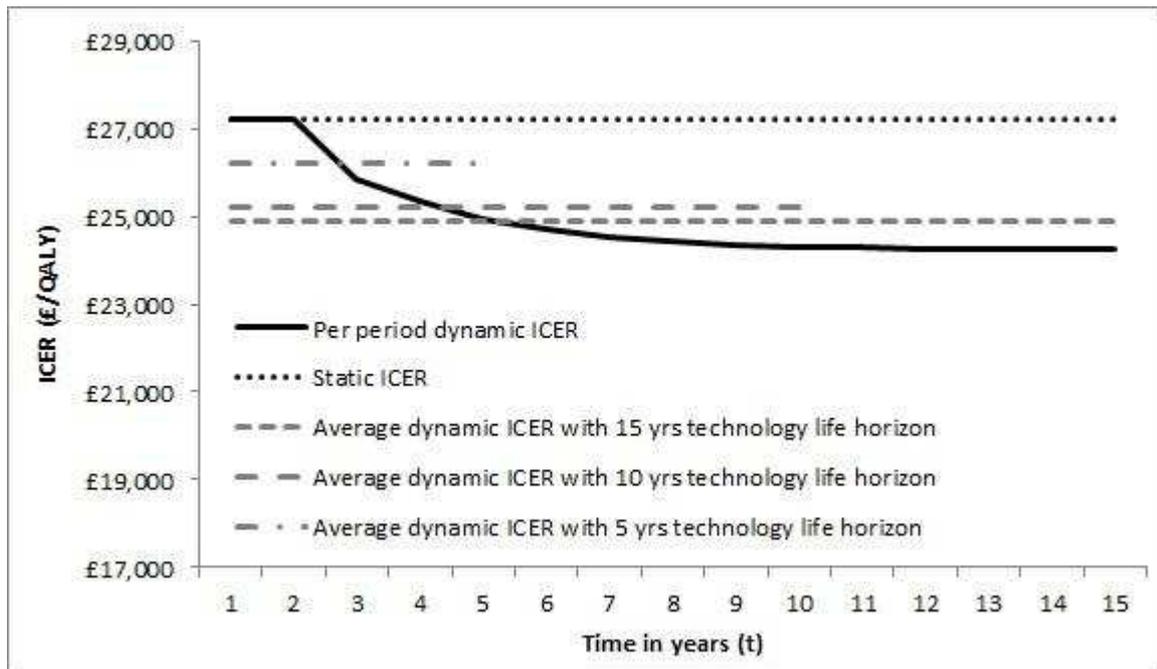


Figure 5: Comparison of diffusion-adjusted and common PEVPI

