The Option Value of Delay in Health Technology Assessment

By S. Eckermann and A. Willan
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Summary:

Where decision makers face evidence of positive but uncertain incremental net benefit there is an option value to delaying decisions and waiting for further evidence. This option value represents the expected value to decision makers of additional information in reducing uncertainty of evidence, or expected value of sample of information (EVSI). For irreversible decisions delay is preferred to adopt without trial where the EVSI exceeds expected costs of information including opportunity costs for anticipated and/or planned trials. For reversible decisions, to adopt and trial becomes a potentially viable strategy, but costs of reversal reduce the EVSI of this strategy.

Keywords: economics of information; decision theory; option value of delay; cost of reversal
Introduction - the option value of delay

The option value of delaying an irreversible decision is the expected value under uncertainty of avoiding bad decisions by delaying decision making. This is the case whether investing in a project or choosing between alternative health care strategies in health technology assessment (HTA). However, the nature of uncertainty and expected payoffs over time differ in these two settings.

In the stock market estimating the option value of delaying irreversible investment decisions considers a random walk on a stochastic variable such as price over time, where the payoff (usually profit) cumulates over the time horizon with variation in this stochastic variable [1-2]. In HTA the option value of delaying decisions relates to a walk on cumulated information (evidence from trials), and the payoff of incremental net benefit (INB), while varying with trial information does not vary over the modeled time horizon for given information. Previous modelling of the option value of delaying decisions in HTA have not allowed for these differences, attempting to apply directly option-value methods from investment decisions in the stock-market.

Palmer and Smith [3] modeled the option value of delay of irreversible decisions in HTA, as in Pindyck [1] and Dixit and Pindyck [2], by considering variation in stochastic variables such as the price of a drug varying with a Brownian motion over time, and payoffs reflecting this variation. However, these methods do not model the expected value to decision making of reducing uncertainty with further information. As Palmer and Smith [3:765] admitted in discussing their study applying option value methods
directly from the stock market: “.. all of the analysis described here assume an essentially passive approach towards the emergence of new information. It may well be fruitful, however, to seek to integrate the options approach with decision analytic approaches towards acquisition of effectiveness information.” Value of information methods are more appropriate for estimating the option value of delaying a decision to allow consideration of additional evidence.

**The option value of delay in HTA with irreversible decisions**

In what follows, decision makers are assumed to face evidence of positive but uncertain INB. Where a decision to adopt a new intervention is irreversible, additional information only has value where decisions are delayed. Therefore, for irreversible decisions viable options are to adopt the new intervention or delay the decision and wait for additional evidence. Such information may be from a planned trial undertaken by the decision makers or from the anticipated reporting of an existing trial.

We first consider the case in which decisions are irreversible and information is anticipated from an existing trial of known size and duration. The expected value from delaying a decision to wait for additional evidence, relative to adopting the new intervention now, is the reduction in expected value of losses, associated with lower expected uncertainty of incremental net benefit. This corresponds to the expected value of sample information (EVSI) from new trial evidence [4], given prior evidence of INB (b). The EVSI per patient for a trial of size n is depicted in Figure 1 as the expected value of losses (L(b)) integrated across the prior distribution for incremental net benefit (f₀(b)).
less expected losses integrated across the expected posterior distribution of incremental net benefit \( E(f_i(b) | n) \). Formulations for calculating \( E(f_i(b) | n) \) and EVSI per patient given prior evidence of INB and a trial of known size are provided in Willan and Pinto [5].

Delaying decisions to wait for information from an existing trial has an expected value in reducing uncertainty and has no direct cost to the decision maker of undertaking a trial. However, in delaying the decision rather than adopting the new intervention there is an expected opportunity cost in patients treated with standard intervention until evidence is updated, equal to the prior mean INB. Therefore, for irreversible decisions, whether it is better to adopt now or wait for anticipated information involves trading off the EVSI in patients remaining to be treated at the time anticipated information becomes available (the value of delay) against the expected loss in expected net benefit from waiting for the information (the cost of delay).

There are, however, options other than waiting for anticipated information. These options include commissioning a trial or making a side payment to influence the design (increase the size or length for example) of an anticipated trial. In undertaking a planned trial or making a side payment to increase the size of an existing trial, there will similarly be value (EVSI) and opportunity costs of delaying, but also direct costs of such information to the decision maker. The principle of maximising expected net gain [4], as the expected value of sample information less expected direct and opportunity costs of delay, across potential viable options can be applied to identify the optimal strategy and trial design. Adopt now without a trial is preferred if the expected net gain is not positive for
any delay option., otherwise delay is preferred with the optimal trial design that where expected net gain is maximised. For irreversible decisions adopt and trial is not a viable option.

Since Marshank [6], economists have studied the irreversibility (illiquidity) problem in a number of contexts. Weisbrod [7], Arrow and Fischer [8] and Henry [9] developed the thesis, while examining environmental preservation, that there is an option value associated with avoiding irreversible actions under uncertainty. Because of this option value, irreversible acts will not be justified in some cases, where their reversible counterparts should be undertaken. As Pindyck [1112] noted: “When a firm makes an irreversible investment expenditure, it exercises, or ‘kills’ its option to invest... This lost option value is an opportunity cost that must be included as part of the cost of investment”.

What constitutes an irreversible decision to invest has been clarified in applications outside of environmental settings. Bernanke [10:86] defined individual investment projects as economically irreversible if: “once constructed they cannot be ‘undone’ or made into a radically different project without high costs”. Tirole [11:308] clarifies this further as: “…the cost of being freed from the commitment within the period is sufficiently high that it does not pay to be freed.” Decisions become irreversible where, given the costs of reversal, it is always better to live with the decision rather than reverse it. These definitions clarify that where costs of reversal are high enough decisions become irreversible and there is a 0 value of additional information and hence EVSI of 0 when adopting. However, these definitions also suggest that for cost of reversal below
some threshold level EVSI from trials while adopting have a continuous relationship with costs of reversal, increasing towards the EVSI of an equivalently sized trial while delaying as costs of reversal reduce towards 0.

**The option value of delay where decisions are reversible**

In adopting a new intervention in HTA, costs of reversal include those of reversing information to health care providers, as well as sunk costs of training and capital which have not been amortized at the expected time evidence is updated (reversal is considered). Fixed costs of capital specific to the new intervention are sunk, as Pindyck [1:1112] notes, to the extent that where evidence turns out to be bad, this capital commands commensurately lower resale value, and can even become negative where costs of disposal are faced. If a decision to adopt a new intervention has costs of reversal high enough that it is irreversible in the sense suggested by Tirole [11], then there is no value in sample information once the new intervention is adopted, and hence the EVSI should be 0. However, if costs or reversal are less than potential losses in incremental net benefit avoided by reversal, then information has some expected value in allowing reversal of decisions after the intervention has been adopted.

In general, with optimal decision making there is only value in reversing a decision to adopt if INB is less than the negative cost of reversal per remaining patient (i.e. those who could potentially benefit from the information). For INB below this level, it is optimal to reverse but the value of information is reduced, by the cost of reversal per remaining patient. Hence, where the decision is taken to adopt the new intervention, costs
of reversal effectively shift the threshold value of INB where information has value to below 0 (it is not be optimal to reverse until negative INB falls below the cost of reversal per patient), and reduce the expected value of losses avoided by the cost of reversal per patient, as illustrated in Figure 2. Therefore, for the same information from a trial the EVSI for the strategy to adopt will be lower than that for the delay due to costs of reversal. The implications of this for optimal trial design and decision making are explored in Eckermann and Willan [12].

Discussion

Inferential approaches to decision making and determining optimal trial size and design have been shown by Claxton [4] to be both inefficient and inappropriate. They fail to take into account the size of the populations who might benefit or the cost of information and employ arbitrary values of Type I and II errors and meaningful clinical difference. Maximising the expected net gain as of the expected value less cost of information in populations to be treated have been illustrated to allow more efficient trial design. However, these methods have been applied assuming that the new intervention is adopted and have not considered the option value of delay, optimal trial design with delay, or the effects of costs of reversal on EVSI or trial design with the strategy to trail and adopt.

This letter has shown that value of information methods can be used to estimate the option value of delaying decisions in HTA as the expected value of sample information (EVSI). When a decision to adopt is irreversible, this option value of delaying the decision and waiting for more evidence can be compared with the expected opportunity
cost of waiting for new evidence to identify the optimal strategy. More generally, the letter has established that while with reversible decisions an additional option to adopt and trial becomes potentially viable, the EVSI of trials when adopting are reduced by costs of reversal. The implications of this for optimal choice of strategy and trial design when decision makers are faced with reversible decisions and evidence of positive but uncertain INB are considered in Eckermann and Willan [12].

**Conclusion**

In previous research, attempts have been made to directly apply option value methods used in the stock-market to model the option value of delaying decisions in HTA [3]. However, decision making under uncertainty in HTA is different to that of investing in the stock market. Uncertainty in HTA is related to evidence over time, given information from trials, rather than variation in stochastic variable such as price, and outcomes are measured in terms of expected net benefit over a time horizon conditional on cumulative evidence, rather than expected profit cumulating with variation in stochastic variables over time. This letter has illustrated the option value of delaying irreversible decisions in HTA can be estimated with the expected value of sample information (EVSI) in comparing the expected value of trial information from delaying decision, relative to adopting the new intervention now.

The value of information of trials undertaken with a decision to adopt has also been clarified. Where decisions are irreversible trials undertaken with adoption have no value, and only delay and trial and adopt now should be considered. For reversible decisions,
adopt and trial becomes an additional viable strategy, but the expected value of sample information from these trials with adoption has been shown to be reduced by costs of reversal.

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References


Figure 1: Expected value of sample information when delaying decisions from a trial of size $n$ given prior the distribution of prior incremental net benefit

$L(b)$ is the opportunity loss of adopting $b$

$f_0(b)$ is the probability density of INB at time of decision

$E(f_1(b) | n)$ is the expected (at time of decision) probability density of INB at time of new evidence from a trial of size $n$. 

Figure 2: Expected value of sample information when adopting a new therapy from a trial of size $n$ given the distribution of prior incremental net benefit and costs of reversal ($C_r$) and patient population, $N_t$.

$$L(b | \text{adopt}) = -(b + C_r/N_t):$$

$$b < -C_r/N_t$$

$$L(b | \text{adopt}) = 0: b \geq -C_r/N_t$$