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The Value of Implementation and the Value of Information: Combined and Uneven Development

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The Value of Implementation and the Value of Information: Combined and Uneven Development

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Abstract

Aim: In a budget constrained healthcare system the decision to invest in strategies to improve the implementation of cost-effective technologies must be made alongside decisions regarding investment in the technologies themselves and investment in further research. This paper presents a single, unified framework that simultaneously addresses the problem of allocating funds between these separate but linked activities.

Methods: The framework presents a simple 4 state world where both information and implementation can be either at the current level or 'perfect'. Through this framework it is possible to determine the maximum return to further research and an upper bound on the value of adopting implementation strategies. The framework is illustrated through case studies of health care technologies selected from those previously considered by the UK National Institute for Health and Clinical Excellence (NICE).

Results: Through the case studies, several key factors that influence the expected values of perfect information and perfect implementation are identified. These factors include the maximum acceptable cost-effectiveness ratio, the level of uncertainty surrounding the adoption decision, the expected net benefits associated with the technologies, the current level of implementation and the size of the eligible population.

Conclusions: Previous methods for valuing implementation strategies have confused the value of research and the value of implementation. This framework demonstrates that the value of information and the value of implementation can be examined separately but simultaneously in a single framework. This can usefully inform policy decisions about investment in healthcare services, further research and adopting implementation strategies which are likely to differ between technologies.

Key words: Value of information analysis; value of implementation; healthcare decision-making, Bayesian analysis

1. Introduction

Over recent years there has been widespread acknowledgement of the lack of resources available to satisfy the growing demand for health and healthcare. This has led to a global increase in the use of cost-effectiveness analysis to support decisions regarding service provision. However, identifying and issuing guidance regarding the use of cost-effective health technologies does not, in itself, lead to cost-effective service provision. This requires that practitioners implement the guidance. The implicit assumption within analyses is that practitioners immediately alter their practice to implement a technology once it is identified as cost-effective. In reality implementation is rarely perfect, with some practitioners maintaining non-optimal pre-guidance practice. The reasons for non-implementation are various and include practitioners facing different incentives or possessing different perspectives on cost-effectiveness, the existence of imperfect clinical governance and an asymmetry of information between policy-makers and local decision-makers. Irrespective of the cause, less than perfect implementation reduces the efficiency of the healthcare system in terms of the health that can be generated subject to a given budget constraint. As a result, there has been growing interest in strategies to improve implementation.

In the UK, the National Institute for Health and Clinical Excellence (NICE) has been issuing guidance regarding the use of health technologies since its original inception in 1999. However, NICE has no power to enforce adherence to guidance, and a recent study has shown varying degrees of success regarding implementation.¹ In response to variation in and uncertainty about implementation of guidance, NICE has recently appointed an Implementation Systems Director with the remit to work to 'enable the NHS to implement NICE guidance'.²

There are threemain tasks for decision-makers such as NICE. Firstly, to identify and issue guidance about cost-effective health technologies; secondly, to issue guidance regarding the need for further research concerning health technologies; and, thirdly, to promote implementation of guidance and uptake of cost-effective technologies. In a budget constrained healthcare system, such as the UK National Health Service (NHS), there is a single 'pot' of resources from which funds must be found to support these activities. There is an established literature concerning the use of cost-effectiveness analysis to support decisions regarding service provision. ³⁻⁶ Policy decisions regarding investment in future research and the collection of further information can be supported by Value of Information (VOI) analysis. ⁷⁻¹² However, it is less clear how to evaluate and support decisions regarding investment in strategies to change implementation. The papers that have examined interventions to change implementation have tended to concentrate on the cost-effectiveness of these policies. ¹³⁻¹⁵

This paper proposes a single, unified framework to address the problem of allocating funds between these separate but linked activities. The paper builds on an established framework which unifies decisions concerning investment in research and service provision in order to ensure that investment in research is subject to the same evaluation of efficiency as investment in healthcare provision. ^{16, 17} The proposed framework separately but simultaneously establishes cost-effective service provision, the potential worth of further research (through the expected value of perfect information) and the potential worth of investment in implementation activities (through the expected value of perfect implementation). In this way, it is possible for the decision-maker to identify an efficient allocation of the budget across their three main activities.

The framework is distinct from 'payback' methodologies which attempt to measure the cost-effectiveness or value of further research through an assessment of the likely impact of the research on clinical practice. ¹⁸⁻²⁵ These approaches conflate the value of research to reduce uncertainty and the value of implementation strategies to change clinical practice. Valuable though the impact of research on behaviour is, it is not the primary reason for conducting clinical research and it is certainly not the only - or necessarily a cost-effective way - to change clinical practice. The failure of payback methods to distinguish the value of reducing uncertainty through research from the value of altering clinical practice means that they provide no information with respect to the allocation of funds between these two separate, but related, activities.

The paper starts with an outline of the proposed framework. The framework is then illustrated through a series of case studies, each of which involves a technology previously considered by NICE. The article concludes with a discussion of the key factors which could affect the valuations and influence

the allocation of resources, as identified through the case studies, and some suggestions for the future direction of this research.

2. Framework

As stated above, the proposed framework builds on Bayesian VOI analysis to simultaneously address decisions concerning investment in research and service provision. This established framework is expanded to incorporate decisions regarding investment in implementation activities through an assessment of the expected value of implementation strategies in a way analogous to the use of VOI analysis to determine the expected value of information.

Within this framework the issues of interest are: (1) the level of information available about a particular health technology, and (2) the level of implementation of the health technology. For the moment, the framework is restricted to consider 2 circumstances with respect to the level of information and implementation: (1) the current level and (2) the perfect level. Thus, the framework represents a simple 4 state world which can be illustrated through a 2 x 2 matrix (see Table 1). The implications of this simplification will be examined within the discussion along with suggestions for expanding the framework beyond this simple 4 state world.

Table 1: 2 x 2 matrix for determining the expected value of perfect information, expected value of perfect implementation and expected value of perfection

	Information	
Implementation	Current	Perfect
Current	A	В
Perfect	С	D

The two columns represent the state of the world with regard to the level of information available about the technology (perfect or current). The two rows represent the state of the world with regard to the implementation of the technology (perfect or current). The level of implementation is denoted by the proportion of the eligible patient base that receives the technology (ρ). Perfect implementation requires that $\rho=1$ when the technology is determined as the most cost-effective (i.e. generates a positive incremental net benefit or maximises net benefit) and $\rho=0$ otherwise. The current level of implementation can, however, take any value between 0 and 1 depending upon the uptake of the technology.

Each entry within the matrix represents the expected value of a decision, measured in terms net monetary benefits, made in that state of the world. Thus, A represents the expected value of a decision made on the basis of current information with the current level of implementation, B represents the expected value of a decision made on the basis of perfect information with the current level of implementation, C represents the expected value of a decision made on the basis of current information with perfect implementation, and D represents the expected value of a decision made on the basis of perfect information with perfect implementation. The expected value of the decision made on the basis of a perfect state (with regard to information and/or implementation) must be at least as good as the expected value of the decision made on the basis of a current state. Thus, it is possible to establish some important axioms regarding the 4 states:

$$\label{eq:bound} B \geq A \qquad \qquad C \geq A \qquad \qquad D \geq C \qquad \qquad D \geq B$$
 Therefore $D \geq A$

Initially, a simplifying assumption is made - that information alone has no effect upon the current level of implementation which is only influenced as a result of direct implementation strategies (i.e. that there is no relationship between information and implementation). Under this assumption the B=A. The effect of relaxing this assumption will be investigated within a sensitivity analysis.

Through comparison and subtraction of the respective expected values, the simple framework can be used to determine the value of further research that shifts the state of information from the current

level to the perfect level (perfect information), and the value of implementation strategies which shift the level of implementation from current to perfect (perfect implementation). It is through this process that the expected value of perfect information and the expected value of perfect implementation are identified. These values establish a maximum return to investment within the area (implementation or information) and provide a necessary condition for determining whether the investment is potentially worthwhile.

2.1 Expected value of perfect information (EVPI)

Value of information analysis involves establishing the difference between the expected value of a decision made on the basis of existing evidence and, following the collection of further information, the expected value of a decision made on the basis of the new evidence.²⁶ Value of information analysis involves the implicit assumption that there is perfect implementation in both the current and the perfect information state.

The expected value of perfect information (EVPI) is calculated as the difference between a position of perfect information about the technology (no uncertainty) and the current information position. In terms of the 2 x 2 matrix, the EVPI is simply the difference between cell D and cell C.

The information provided by research is a public good. As such, the societal value of research should be calculated across the population of future patients for whom this decision is relevant. It is this population EVPI that provides a measure of the maximum return to further research, providing a necessary condition for determining whether further research is potentially worthwhile, under the assumption that provision is perfectly dictated by the expected value of the decision.

2.2 'Realisable' EVPI

Given that implementation is rarely perfect, the 'realisable' EVPI identifies the expected value of research that is realisable without actively undertaking strategies to change implementation. In the 2×2 matrix, this is simply the difference between cell B and cell A. The simplifying assumption that there is no relationship between information and implementation results in 'realisable' EVPI of zero. This assumption will be relaxed within a sensitivity analysis.

2.3 Expected value of perfect implementation (EVPIM)

Value of implementation analysis involves establishing the difference between the expected value of a decision with the current level of implementation and the expected value of the decision with a revised level of implementation.

The expected value of perfect implementation (EVPIM) is calculated as the difference between the expected value of a decision that is implemented perfectly (ρ is either zero or 1) and the expected value of the decision with implementation at its current level. Where the current level of implementation is 'perfect' there will be no value in strategies to change implementation. The population EVPIM gives a measure of the maximum return to strategies to change implementation and provides a necessary condition for determining whether such strategies are potentially worthwhile.

The calculation of the EVPIM requires no assumption about the level of information upon which the decision is based and can be based on either information position. In terms of the 2 x 2 matrix, the EVPIM based upon the current level of information is simply the difference between cell C and cell A. The EVPIM based upon perfect information is simply the difference between cell D and cell B in the matrix.

2.4 Expected value of 'perfection' - EVP

Finally, a comparison of the difference in the expected value of the decision made in the perfect state, with respect to information and implementation, and that made in the current state provides the decision-maker with the expected value of 'perfection' (EVP) in terms of information and implementation. The population EVP provides a measure of the maximum return to resources

expended on research and implementation strategies. In terms of the 2 x 2 matrix, the EVP is simply the difference between cell D and cell A.

3. Case studies

The simple 4 state framework is illustrated through the use of three case studies which were selected from those recently considered by NICE. 27-29 The case studies examine the use of Orlistat for the treatment of Obesity (NICE publication no. 22), the use of Zanamivir for treatment of influenza (NICE publication no. 15) and the prophylactic extraction of wisdom teeth (NICE publication no. 1). For each of the case studies, a simple, stylised decision model was constructed to represent the decision problem. The parameter estimates used within the stylised models were publicly available in either the assessment reports or guidance documents. In each case, the estimates of effectiveness were based on the reported meta analysis of the RCT evidence but other key inputs, such as cost, baseline risks, health state utilities and/or other relevant epidemiological variables were based on other sources (observational studies and in some cases informed judgement). The population size and the estimate of the current level of implementation were also taken from public sources (where possible this was the assessment reports and guidance documents).

These case studies were originally created as part of a pilot project to assess the applicability of Bayesian value of information analysis to the NICE assessment process.³⁰ It should be stressed that the case studies are used here purely as a vehicle to demonstrate the proposed framework. Table 2 contains further details of the three case studies.

Table 2: Summary of the case studies

Technology	Orlistat	Zanamivir	Wisdom teeth
	Obesity	Influenza	Prophylatic extraction of
			wisdom teeth
Publication	No 22	No 15	No 1
Guidance	Adopt for BMI>30 Must lose	Adopt for high risk when	Reject
	5% at 3 months and 10% at 6	influenza is circulating	
	months		
Evidence	RCTs, n>1500 2 CEA	RCTs, n>1250 4 CEA	1 RCT, n<300 4 CEA
Estimate of ICER	£10,400 - £46,000 per QALY	£5,000 - £28,000 per	Dominated
		QALY	
Population	Inc 11,000	End 97,000 Epi 497,000	Inc 11,000
Review	02/04	06/02	03/03

4. Results

Table 3 presents the results for the 3 case studies detailing the incremental cost-effectiveness ratio associated with the technology, the estimate of the current level of implementation and the expected value of perfect information, perfect implementation and 'perfection' in £ millions for the estimated eligible population. The results for each case study, including the individual elements of the 2 x 2 matrix, are detailed below. All values are based on a maximum acceptable cost-effectiveness ratio (λ) of £30,000 per QALY.

Table 3: Expected value of perfect information, expected value of perfect implementation and expected value of 'perfection'

	ICER	ρ	Pop ⁿ	EVPI	EVP Imp	'Perfection'
Orlistat	£21,267	0.504	83,406	£2.0 m	£6.8 m	£8.7 m
Zanamivir	£22,739	0.0034	895,204	£5.6 m	£6.6 m	£12.1 m
Wisdom teeth	Dominates	0.20	72,406	£0.0	£5.7 m	£5.7 m

4.1 Orlistat

The NICE guidance recommended that Orlistat be adopted for patients with a body mass index in excess of 30, with the requirement that patients lose 5% of their bodyweight at 3 months and 10% at 6 months for continued treatment.²⁹ The estimated population eligible for treatment was 22,000, with an annual incident population of 11,000 and an estimated 11,000 patients receiving treatment. The current level of implementation was 0.504 and the total eligible population (discounted over 8 years) was approximately 83,000.

The analysis of the stylised model calculated the incremental cost-effectiveness ratio associated with Orlistat to be £21,267 per QALY (Table 3). Given a maximum acceptable ratio of £30,000 per QALY, Orlistat was cost-effective given the information available. The expected value of the decision made purely on the basis of this current information was estimated to be £163 (cell C) while the expected value of the decision made on the basis of perfect information was estimated to be £187 (cell D). The expected value of perfect information was £24 per decision, £2 million for the eligible population. With the current implementation level (ρ) of 0.504 the 'realisable' expected value of the decision made on the basis of current information was reduced to £82 (cell A). The expected value of perfect implementation, based on the current level of information, was £81 per decision, £6.8 million for the eligible population. The expected value of 'perfection' was calculated to be £105 per decision, £8.7 million for the eligible population. Given the simplifying assumption that the level of implementation does not change on the basis of information alone, the expected value of the decision made on the basis of perfect information was reduced to £82 (cell B). This reduced the 'realisable' EVPI to zero. All values are shown in Table 4.

Table 4: Framework matrix for Orlistat

ρ= 0.504	Information	
Implementation	Current	Perfect
Current	£82	£82
Perfect	£163	£187

Figure 1 illustrates the relationship between the value of the maximum acceptable ratio (λ) and the population values for EVPI, EVPIM and EVP. The EVPI increases with the maximum acceptable ratio up to the value of the ICER (£21,267), and then falls as the ratio increases beyond this point. For values of λ up to the ICER, the error probability (reflected by the cost-effectiveness acceptability curve³¹ – not shown) and the value of the consequences of an error are both increasing with λ . Hence the EVPI must increase. Beyond this point, the error probability falls whilst the value of the consequences continues to rise as the maximum acceptable ratio increases. In this particular case, the fall in the error probability outweighs the rise in the value of the consequences and EVPI falls.

The EVPIM has the inverse relationship with the maximum acceptable ratio - falling as the ratio increases up to the value of the ICER and increasing as the ratio increases beyond the ICER. As the maximum acceptable ratio increases the incremental net benefit (INB) associated with Orlistat increases from negative to positive. At the point where the maximum acceptable ratio is equal to the ICER, the INB associated with Orlistat is zero and the decision-maker is indifferent about whether or not to adopt the technology. Strategies to change implementation will have no value at this point. When the maximum acceptable ratio is below the ICER, the optimal decision is not to provide Orlistat (perfect level of implementation is zero). Given that the current level of implementation exceeds zero, strategies to change implementation away from Orlistat have value (positive EVPIM). The value of such strategies will fall as the maximum acceptable ratio increases towards the ICER and the negative impact of the current implementation falls (INB rises towards zero). When the maximum acceptable ratio is above the ICER, the optimal decision is to provide Orlistat (perfect level of implementation is 1). Given that the current level of implementation is less than 1, strategies to change implementation toward Orlistat will have value (positive EVPIM). The value of such strategies will rise as the maximum acceptable ratio increases beyond the ICER and the negative impact of the current implementation increases (INB rises).

In this case the EVP has a similar relationship with the value of the maximum acceptable ratio as the EVPIM, albeit smoother, reflecting the dominating effect of the EVPIM.

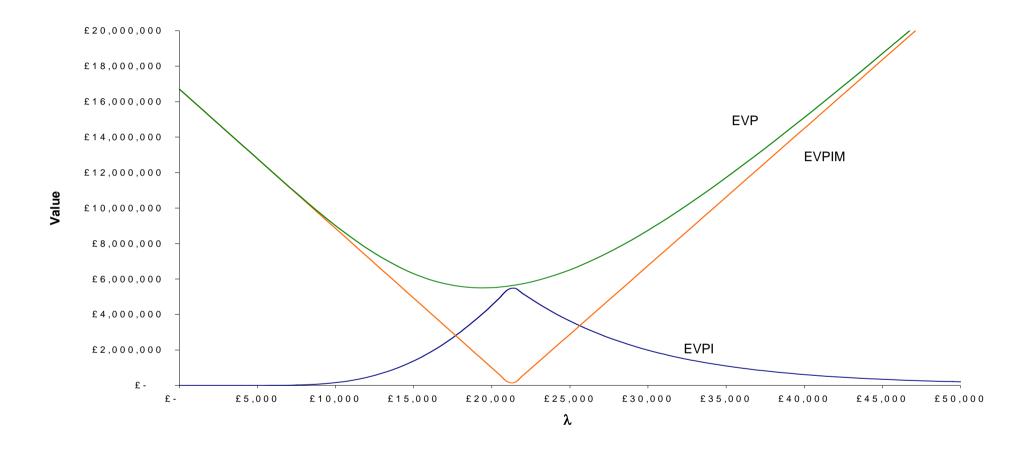


Figure 1: Expected value of information, implementation and 'perfection' for Orlistat

4.2 Zanamivir

The NICE guidance recommended that Zanamivir be adopted for high risk patients when influenza was circulating.²⁷ The estimated annual population eligible for treatment was 136,000 (based on an endemic population of 97,000 with an epidemic population of 487,000 occurring every 10 years). With an estimated 458 patients receiving treatment in 2000-01, the current level of implementation was 0.0034 and the total eligible population (discounted over 8 years) was approximately 895,000.

The analysis of the stylised model calculated the incremental cost-effectiveness ratio associated with Zanamivir to be £22,739 per QALY (Table 3). Given a maximum acceptable ratio of £30,000 per QALY, Zanamivir was cost-effective given the information available. The expected value of the decision made purely on the basis of this current information was estimated to be £7 (cell C) while the expected value of the decision made on the basis of perfect information was estimated to be £14 (cell D). The expected value of perfect information was £6 per decision, £5.6 million for the eligible population. With the current implementation level (ρ) of 0.0034 the 'realisable' expected value of the decision made on the basis of current information was reduced to £0.02 (cell A). The expected value of perfect implementation, based on the current level of information, was £7 per decision, £6.6 million for the eligible population. The expected value of 'perfection' was calculated to be £14 per decision, £12.1 million for the eligible population. All values are shown in Table 5.

Table 5: Framework matrix for Zanamivir

ρ= 0.0034	Information	
Implementation	Current	Perfect
Current	£0.02	£0.02
Perfect	£7	£14

Figure 2 illustrates the relationship between the value of the maximum acceptable ratio (λ) and the population values for EVPI, EVPIM and EVP. These relationships are similar to those illustrated for Orlistat (Figure 1) with EVPI and EVPIM moving in different directions as the maximum acceptable ratio increases beyond the ICER. For values of the maximum acceptable ratio (λ) below the ICER, the EVPIM is negligible. This is due to the proximity of the current level of implementation (ρ = 0.0034) to the perfect level (ρ = 0) for this range of the maximum acceptable ratio.

4.3 Wisdom teeth

The NICE guidance recommended that prophylactic extraction of wisdom teeth should not be undertaken. The annual incident population with disease free molars was estimated to be 11,000 for whom 80% received (inappropriate) extraction of wisdom teeth (ρ = 0.2). The total eligible population (discounted over 8 years) was approximately 72,000.

The analysis of the stylised model showed that a policy of prophylactic extraction of wisdom teeth was dominated by a policy of no prophylactic extraction (Table 3) with very little uncertainty surrounding the decision (not shown). The expected value of the decision made purely on the basis of this current information was estimated to be £99 (cell C) while the expected value of the decision made on the basis of perfect information was estimated to be £99 (cell D). Thus, the expected value of perfect information was zero. With the current implementation level (ρ) of 0.2 the 'realisable' expected value of the decision made on the basis of current information was reduced to £20 (cell A). The expected value of implementation and the expected value of 'perfection', based on the current level of information, were £79 per decision, £5.7 million for the eligible population. All values are shown in Table 6.

Table 6: Framework matrix for Wisdom teeth

ρ= 0.20	Information	
Implementation	Current	Perfect
Current	£20	£20
Perfect	£99	£99

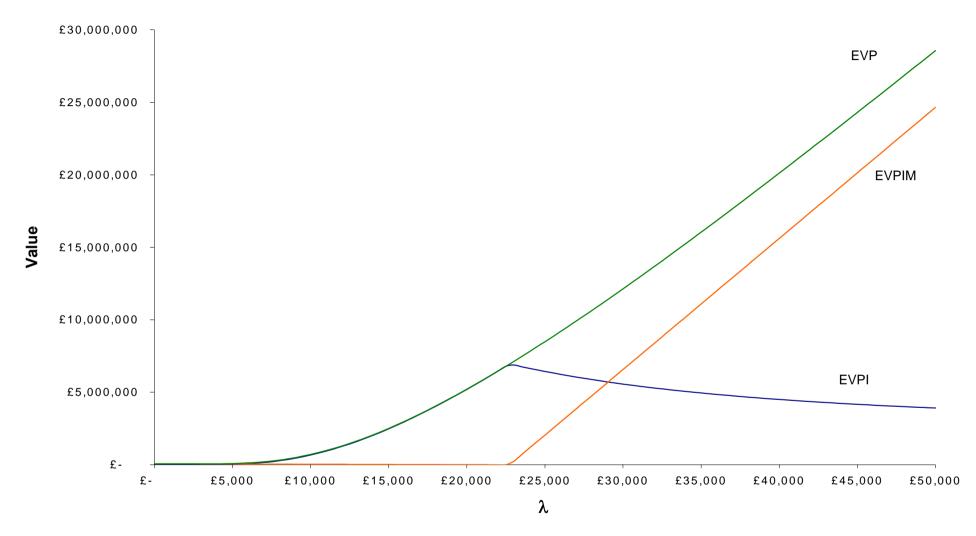


Figure 2: Expected value of information, implementation and 'perfection' for Zanamivir

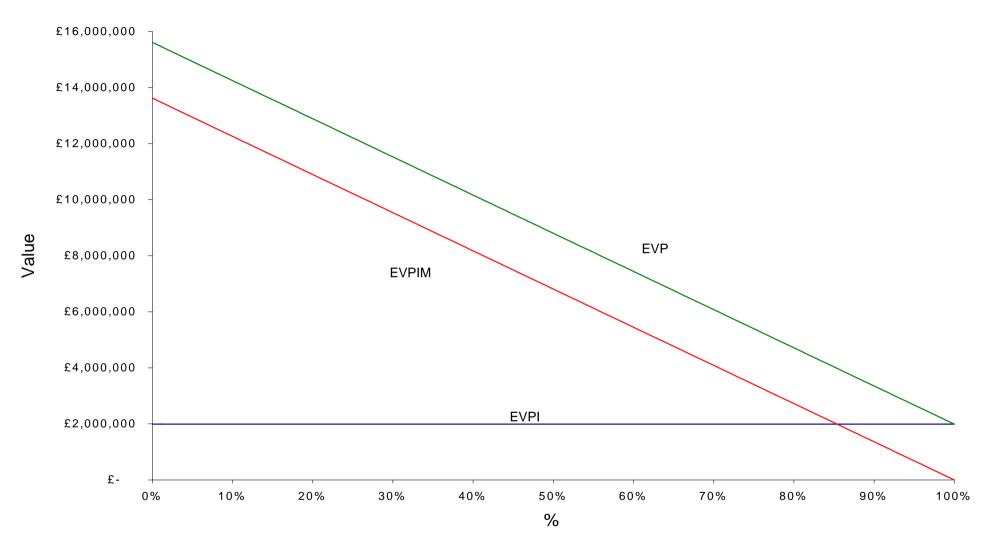


Figure 3: Sensitivity analysis on current implementation proportion - Orlistat

The relationship (not shown) between the value of the maximum acceptable ratio and the population values for EVPIM and EVP are similar to those illustrated for Orlistat and Zanamivir (Figures 1 and 2). Both the EVPIM and EVP increase as the maximum acceptable ratio increases. The EVPI remains negligible over the entire range of the maximum acceptable ratio (λ).

4.4 Sensitivity analysis

The level of current implementation

Figure 3 examines the impact that the current level of implementation has on the expected values of perfect information, implementation and perfection associated with Orlistat. The figure is drawn for a maximum acceptable ratio of £30,000 per QALY, a level at which Orlistat is the most cost-effective decision and the optimal level of implementation (ρ) is 1. When the current level of implementation is 1, the expected value of perfect implementation will be zero as all patients are already receiving Orlistat. When the current level of implementation is 0, the expected value of perfect implementation is £13.6 million. As the current level of implementation increases from 0 to 1 the expected value of perfect implementation falls as a larger proportion of patients receive Orlistat and strategies to change implementation have less value. The EVPI is constant irrespective of the level of current implementation as the calculation is made on the assumption of perfect implementation. The EVP falls as the proportion of current implementation rises over the range from 0 to 1.

If the maximum acceptable ratio were taken to be £20,000 (not shown), Orlistat would not be cost-effective and the optimal level of implementation would be 0. In this case, the expected value of implementation and the EVP would rise along with the level of current implementation.

Revising the level of current implementation in response to information

The initial analyses were undertaken on the basis of a simplifying assumption that information alone did not impact on the level of implementation, which could only be influenced by implementation strategies (i.e. there was no relationship between the level of information and the level of implementation). Under this assumption, the expected value of perfect information achievable without implementation policies ('realisable' EVPI) is zero. However, it is likely that the provision of information would alter the level of implementation to some extent independent of implementation effort.

Figure 4 illustrates how the value of the 'realisable' EVPI is impacted by relaxing the simplifying assumption and allowing the level of implementation to change on the basis of information alone (post-information). The figure is drawn for Orlistat and a maximum acceptable ratio of £30,000 per QALY, a level at which Orlistat is the most cost-effective decision and the optimal level of implementation (ρ) is 1. When the level of implementation following the information is 1 (perfect implementation) the 'realisable' EVPI equals the EVPI. When the level of implementation following the information is equal to the current level (the information has no effect on implementation) the 'realisable' EVPI is zero. When the level of implementation following the information is above the current level, the information has increased implementation in the desired direction (positive impact) and the 'realisable' EVPI is positive. When the level of implementation following the information has had a negative impact on implementation, reducing implementation away from the desired level. The EVPI, EVPIM and EVP are all constant irrespective of the post information implementation level because they are calculated with respect to the proportion of current implementation and/or the value of perfect implementation.

If the maximum acceptable ratio were taken to be £20,000 (not shown), Orlistat would not be cost-effective and the optimal level of implementation would be 0. In this case, the 'realisable' EVPI would have the inverse relationship with the post-information level falling as the level of post-information implementation increased from 0 to 1. In this circumstance, the 'realisable' EVPI would reach a maximum (equal to EVPI) when the level of post-information implementation is 0 and would be negative when the level of implementation post-information exceeded the current level of implementation.

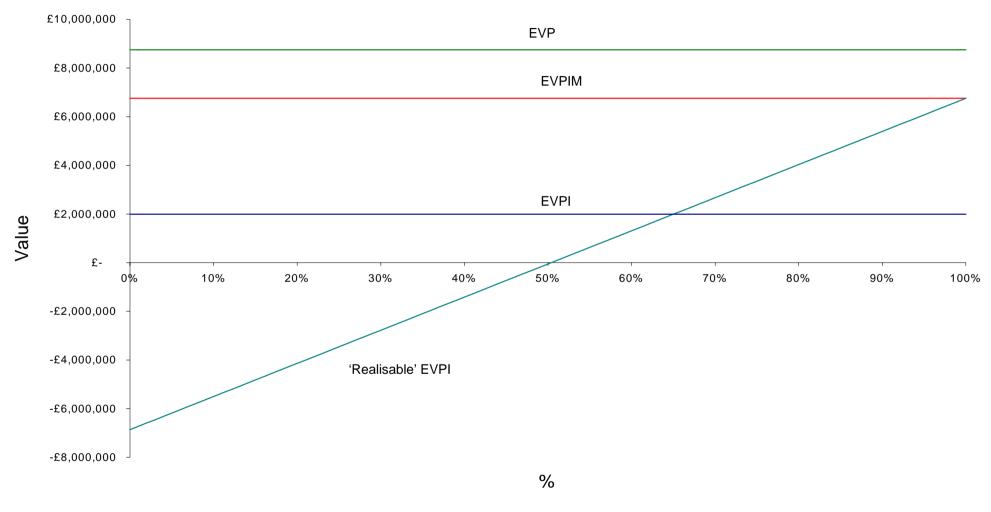


Figure 4: Sensitivity analysis on post information implementation proportion - Orlistat

5. Discussion

5.1 The results of the case studies

The results of the case studies have shown that the value associated with funding further research and/or strategies for changing implementation will differ markedly between technologies. In the case of Orlistat, more value was associated with strategies to change implementation (EVPImp = £6.8m) than was associated with further research (EVPI = £2m) although both were potentially worthwhile. With Zanamivir the value associated with further research (EVPI = £5.6m) was equivalent to the value associated with strategies to change implementation (EVPImp = £6.6m). Again both were potentially worthwhile. In the case of prophylactic extraction of wisdom teeth, the value of further research was negligible while the value associated with strategies to change implementation was substantial (EVPImp = £5.7m). In this case, funding effort should be focused upon strategies to improve implementation i.e. to reduce the amount of prophylatic wisdom teeth extractions that are performed.

5.2 The key factors

Through the analyses of the case studies several key factors have been identified that affect the expected values of perfect information, perfect implementation and perfection. These factors in turn influence the allocation of funds between service provision, further research and implementation strategies. The key factors include:

- (i) The level of the maximum acceptable ratio (λ)
- As shown in figures 1 and 2 the calculations of the expected values of perfect information, perfect implementation and perfection all depend on the value of the maximum acceptable ratio (λ) . This is due to the interaction between the maximum acceptable ratio and (i) the uncertainty surrounding the decision (see below), (ii) the extent of the net benefits (see below) and (iii) the level of perfect implementation. Where the maximum acceptable ratio is close to the ICER, the uncertainty surrounding the decision is maximised, the incremental net benefits are minimised and the level of perfect implementation is in transition. As a result, the EVPi is large (although not necessarily at a maximum), the EVPIM is close to zero and the EVP is close to the EVPI.
- (ii) The uncertainty surrounding the adoption decision

 The uncertainty surrounding the adoption decision is a crucial element in the calculation of the

expected value of perfect information, with the EVPI increasing with increased uncertainty. Where the uncertainty surrounding the decision is low (e.g. prophylactic extraction of wisdom teeth) the EVPI is negligible (£0.02, not shown).

(iii) The extent of the expected incremental net benefits

The calculation of the expected values of perfect information, perfect implementation and perfection are affected by the extent of the expected INB. Where the INB are small, the returns available from research and strategies aimed at improving implementation are small. As such, the EVPI and EVPIM are small. For example, the INB associated with Zanamivir were less than those associated with Orlistat (£7.33 compared to £80.99) this impacted the value of information and implementation strategies (at the decision level) which were lower for Zanamivir (£6.22 and £7.33 compared with £23.85 and £80.99 respectively).

(iv) The current level of implementation

The calculations of the expected values of perfect implementation and perfection are both affected by the current level of implementation. Where the current level is close to the perfect level the EVPImp is negligible. For example, given a maximum acceptable ratio of £20,000 per QALY the current level of implementation of Zanamivir (0.0034) was close to the perfect level (0) and the EVPIM was negligible (£0.01).

(v) The size of the eligible population

The size of the population eligible for treatment has a direct impact on the population level estimates of the expected values of perfect information, perfect implementation and perfection. Where the population is large the scaled up population values will be larger. For example, the population values of the EVPI was larger for Zanamivir than for Orlistat (£5.6 million compared with £2 million) despite

lower values at the decision level (£6.22 compared with £23.85) due to the size of the estimated eligible population (895k compared to 83k).

The allocation of funds between healthcare, research and implementation strategies will depend crucially upon these factors. As a result, policies regarding the collection of further information and the funding of strategies to improve implementation are likely to differ between technologies.

5.3 Future developments of the framework

This paper has introduced a simple unified framework for assessing the value of implementation and the value of information in order to address decisions concerning healthcare funding allocations. In setting up the framework there are a number of areas where simplifying assumptions have been made. In order for the framework to have merit within decision-making, these simplifying assumptions must be relaxed and the framework developed to incorporate these issues. The proposed further development of the framework will examine the following issues:

(i) The relationship between information and the current level of implementation. The framework presented and applied to the case studies involved a simplifying assumption that information alone had no effect upon the current level of implementation which is only influenced as a result of direct implementation strategies (i.e. that there is no relationship between information and implementation). Under this assumption the expected value of a decision made with and without perfect information is equivalent unless implementation strategies are employed to change implementation (B = A). The 'realisable' EVPI is zero.

However, it is likely that the level of implementation is a function of the level of information and that provision of information would alter the level of implementation, for example through publication of the results of the research. It is important for the framework to capture and incorporate this relationship in order to appropriately value research efforts. This will require formal assessment of the impact that research has upon the level of implementation. An estimate of the relationship could be achieved via investigation of historic implementation levels and publication of research results within a few key areas (e.g. cardiac, neurology, surgery).

 $\rho = f$ (information)

An initial sensitivity analysis illustrated the impact of relaxing the assumption (Figure 4). Where information led to a positive change in implementation (a move towards the perfect level) the 'realisable' EVPI was positive, but where information led to a change in implementation away from the perfect level (a negative change) the 'realisable' EVPI was negative. In this case, information reduced the expected value of the decision. Negative changes of this type may occur where the message from research gets confused or interpreted inappropriately. For example, research that strengthens the evidence about a technologies positive effectiveness may lead to increased implementation despite evidence that shows it not to be cost-effective. When formalising and incorporating the relationship between information and implementation within the framework it will be important to consider both the positive and negative impacts of research.

(ii) Uncertainty about the current level of implementation.

Another simplifying assumption made within the framework and case studies was that the current level of implementation was fixed and known. The level of implementation, like all parameters in the model, is subject to uncertainty which should be captured within the model. It is only by incorporating the uncertainty around the current level of implementation within the model that it is possible to get an appropriate estimate of the expected value of a decision that is implemented at the current level and the expected value of implementation strategies. In addition, incorporating this uncertainty within the model would enable the calculation of the expected value of information about the level of implementation i.e. whether research to get a better estimate of the current level of implementation is worthwhile.

(iii) Valuation of specific implementation strategies

The framework presented within this paper was restricted to consider only 2 circumstances with respect to the level of information and implementation (1) the current level and (2) the perfect level. The framework described a very simple 4 state world (illustrated through a 2 x 2 matrix) that enabled

calculation of the value of further research that shifts the state of information from the current level to the perfect level (EVPI), and the value of implementation strategies that shift the level of implementation from current to perfect (EVPIM). These values establish a maximum return to investment within the area (implementation or information) and provide a necessary condition for determining whether the investment is potentially worthwhile.

In order to determine whether specific implementation strategies are worthwhile it is necessary to value improvements in implementation which are achievable rather than perfect implementation. Calculation of the expected value of specific implementation (EVSIM) will involve determining the change in implementation levels resulting from specific implementation strategies, and computing the expected value of those changes. It is only through comparison of the EVSIM with the cost of the specific implementation strategies that it is possible to determine whether it is worthwhile employing the strategies. The concept is similar to that of the expected value of sample information (EVSI) used to determine the value and worth of information available from specific research.

Incorporating the EVSIM within the framework will require a movement away from the simple 4 state world, to include a situation of 'improved' implementation. Current and recent studies examining the cost-effectiveness of implementation strategies could provide information about the effectiveness of different strategies in achieving 'improved' implementation.

5.4 The next steps with the framework

In addition to developing the theoretical foundations of the framework and relaxing the simplifying assumptions, there are a series of steps that need to be taken to demonstrate and establish the practical significance and merit of the framework for decision-makers. The initial stage in this process would involve the retrospective application of the framework to a series of recent technology appraisals undertaken by NICE. This would be followed by a prospective application of the framework within an on-going technology appraisal. Finally, the framework could be piloted prospectively as part of the NICE process.

6. Conclusions

In a budget constrained healthcare system, decisions regarding investment in implementation strategies must be made alongside those regarding investment in healthcare services and further research. We present a simple, unified framework that examines the value of information and the value of implementation simultaneously in order to inform policy decisions about allocation of funds.

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