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

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Aim. In a budget-constrained health care 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 article 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

Over recent years, there has been widespread acknowledgment of the lack of resources available to satisfy the growing demand for health and health care. This awareness has led to a global perfect information and perfect implementation are identified. These factors include the maximum acceptable costeffectiveness 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 not distinguished the value of efficacy research and the value of strategies to change the level 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 health care services, further research, and adopting implementation strategies that are likely to differ between technologies.

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 costeffective. In reality, implementation is rarely perfect, with some practitioners maintaining nonoptimal preguidance practice. The reasons for nonimplementation 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 health care system in terms of the health that can be generated subject to a given budget constraint. As a result,

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there has been growing interest in strategies to improve implementation of technologies.

In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) has been issuing guidance regarding the use of health technologies since its 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.<sup>1</sup> In response to variation in and uncertainty about the implementation of guidance, NICE charged recently appointed an implementation systems director task with the of creating a work plan to "enable the NHS [National Health Service] to implement NICE guidance."<sup>2</sup>

There are 3 main tasks for decision makers such as NICE: first, to identify and issue guidance about cost-effective health technologies; second, to issue guidance regarding the need for further research concerning health technologies; and third, to promote implementation of guidance and uptake of cost-effective technologies. In a budget-constrained health care 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.<sup>3-6</sup> Policy decisions regarding investment in future research and the collection of further information can be supported by value-of-information (VOI) analysis.<sup>7-14</sup> These techniques provide a monetary value for the potential benefits of research that can be compared with the costs to determine if further research is worthwhile. However, it is less clear how to evaluate and support decisions regarding investment in strategies to change implementation. The studies that have examined interventions to change implementation have tended to concentrate on the cost-effectiveness of specific policies rather than identifying the potential value of investing in implementation policies.<sup>15-17</sup>

This article proposes a single, unified framework to address the problem of allocating funds between these separate but linked activities. The article builds on an established framework that unifies decisions concerning investment in research and service provision to ensure that investment in research is subject to the same evaluation of efficiency as investment in health care provision.<sup>11, 18, 19</sup> The proposed framework separately but simultaneously establishes costeffective service provision and the maximum returns to investment in further research (through the expected value of perfect information) and implementation activities (through the expected value of perfect implementation). These upper bounds provide necessary conditions for conducting further research and/ or implementation strategies and should be compared to the costs of these policies to determine whether they are *potentially* worthwhile. Identifying whether specific investments in research and/or implementation strategies are worthwhile, per se, will require a sufficient condition that identifies the benefits and costs associated with the specific policy.

The framework is distinct from "payback" methodologies that attempt to measure the costeffectiveness, or value, of further research through an assessment of the likely impact of the research on clinical practice.<sup>20-26</sup> In these approaches, trials are seen as "an investment in information which will contribute to the ... extent of product adoption through the strength and relevance of the information they produce." $^{20(p617)}$  As such, these approaches do not distinguish the value of research to reduce uncertainty from the value of changing clinical practice. Valuable though the impact of research on behavior 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 2 separate, but related, activities.

This article 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 that 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.

# FRAMEWORK

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.

# Table 12 × 2 Matrix for Determining the<br/>Expected Value of PerfectInformation, Expected Value of Perfect<br/>Implementation, and Expected<br/>Value of Perfection

Implementation	Information	
	Current	Perfect
Current	А	В
Perfect	С	D

The issues of interest are a) the level of information available about a particular health technology and b) 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 that can be illustrated through a  $2 \times 2$  matrix (see Table 1). The implications of this simplification are examined in the Discussion section along with suggestions for expanding the framework beyond this simple 4-state world.

The 2 columns represent the state of the world with regard to the level of information available about the technology (perfect or current). The 2 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 ( $\rho$ ). 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 maximizes net benefit) and  $\rho = 0$  otherwise. The current level of implementation can, however, take any value between 0 and 1 depending on the uptake of the technology.

Each entry within the matrix represents the expected value of a decision made in that state of the world, measured in terms of net monetary benefits. Thus, cell A represents the expected value of a decision made on the basis of current information with the current level of implementation, cell B represents the expected value of a decision made on the basis of perfect information with the current level of implementation, cell C represents the expected value of a decision made on the basis of current information with perfect implementation, and cell 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 great as the expected value of the decision made on the basis of a current state. Therefore,  $B \ge A, C \ge A, D \ge C, D \ge B$ , and  $D \ge A$ .

Initially, a simplifying assumption is made—that information alone has no effect on the current level of implementation, which is instead only influenced as a result of direct implementation strategies (i.e., that there is no relationship between information and implementation). Under this assumption, cell B = cell A. The effect of relaxing this assumption is 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), as well as the value of implementation strategies that 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 on investment within the area (implementation or information) and provide a necessary condition for determining whether such investments are potentially worthwhile.

# **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.<sup>7</sup> Value of information analysis implicitly assumes 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  $2 \times 2$  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.

# "Realizable" EVPI

Given that implementation is rarely perfect, the "realizable" EVPI identifies the expected value of research that is realizable without actively undertaking strategies to change implementation. In the  $2 \times 2$  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 values for realizable EVPI of 0. This assumption is relaxed within the sensitivity analysis.

### **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 ( $\rho$  is either 0 or 1 as dictated by the cost-effectiveness of the technology) 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 on which the decision is based and can be based on either information position. In terms of the  $2 \times 2$  matrix, the EVPIM based on the current level of information is simply the difference between cell C and cell A. The EVPIM based on perfect information is simply the difference between cell D and cell B in the matrix.

# **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  $2 \times 2$  matrix, the EVP is simply the difference between cell D and cell A.

# CASE STUDIES

The simple 4-state framework is illustrated through the use of 3 case studies that were selected from those recently considered by NICE.<sup>27-29</sup> The case studies examine the use of orlistat for the treatment of obesity (NICE publication no. 22),<sup>29</sup> the use of zanamivir for the treatment of influenza (NICE publication no. 15),<sup>28</sup> and the prophylactic extraction of wisdom teeth (NICE publication no. 1).<sup>27</sup> For each of the case studies, a simple, stylized decision model was constructed to represent the decision problem. The parameter estimates used within the stylized 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 randomized controlled trial (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 judgment). The population size and the estimate of the current level of implementation were also taken from public sources (where possible, these were the assessment reports and guidance documents).

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 3 case studies.

### RESULTS

Each of the case studies included uncertain parameters ( $\theta$ ). Probabilistic sensitivity analysis was conducted using Monte Carlo simulation and provided the joint distributions of costs, quality-adjusted life years (QALYs), and net benefits (NB) associated with each of the alternative technologies (j = 1, ..., J). The expected value of the decisions in each of the 4 states of the world (cells A, B, C, and D in Table 1) was calculated directly from the simulated output:

Technology	Orlistat: Obesity	Zanamivir: Influenza	Wisdom Teeth: Prophylactic Extraction of Wisdom Teeth	
Publication	No. 22	No. 15	No. 1	
Guidance	Adopt for body mass index > 30 Must lose 5% at 3 months and 10% at 6 months	Adopt for high risk when influenza is circulating	Reject	
Evidence	RCTs, $n > 1500$ 2 CEA	RCTs, $n > 1250 4 \text{ CEA}$	1 RCT, <i>n</i> < 300 4 CEA	
Estimate of ICER	£10,400–£46,000 per QALY	£5000–£28,000 per QALY	Dominated	
Population	Inc 11,000	End 97,000 Epi 497,000	Inc 11,000	
Review	02/04	06/02	03/03	

**Table 2**Summary of the Case Studies

RCT, randomized controlled trial; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; CEA, cost-effectiveness analysis.

Cell A = 
$$\sum_{j=1}^{J} \rho_j^c . E_{\theta} \text{NB}(j, \theta)$$
,  
Cell B =  $E_{\theta} \sum_{j=1}^{J} \rho_j^p . \text{NB}(j, \theta)$ ,  
Cell C = max<sub>j</sub>  $E_{\theta} \text{NB}(j, \theta)$ ,  
Cell D =  $E_{\theta} \max_j \text{NB}(j, \theta)$ ,

where

 $\rho_j^c =$  probability of implementing technology *j* with current information,

 $\rho_j^p$  = probability of implementing technology *j* with perfect information,

$$\sum_{j=1}^{J} \rho_{j}^{c} = 1,$$
$$\sum_{j=1}^{J} \rho_{j}^{p} = 1.$$

Each iteration of the simulation represents a possible resolution of the uncertain parameters ( $\theta$ ). Given current information, the cost-effective technology is alterative *j*, which provides the maximum expected net benefit (e.g.,  $\max_j E_{\theta} \text{NB}(j, \theta)$  in cell C). With perfect information, the alterative that provides the maximum NB for each resolution of the uncertain parameters can be chosen ( $\max_j \text{NB}(j, \theta)$ ). The expected net benefit with perfect information is then the expectation of these maximum net benefits over all the resolutions of  $\theta$  (e.g.,  $E_{\theta} \max_j \text{NB}(j, \theta)$  in cell D). However, if implementation is not perfect (i.e., the *j* that maximized net benefit is not always chosen), then the expected net benefits are a weighted average of the net benefits of each alternative, where the weights are the probability of implementing each technology ( $\rho_j^c$  with current information in cell A and  $\rho_i^p$  with perfect information in cell B).

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  $2 \times 2$  matrix, are detailed below. All values are based on a maximum acceptable cost-effectiveness ratio ( $\lambda$ ) of £30,000 per QALY.

### 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 body weight at 3 months and 10% at 6 months for continued treatment.<sup>29</sup> 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 stylized model calculated the incremental cost-effectiveness ratio associated with orlistat to be £21,267 per QALY (Table 3). Given a cost-effectiveness threshold of £30,000 per QALY, orlistat was cost-effective given the information available.

implementation (EVPIN), and Expected value of Perfection (EVP)						
	ICER	ρ	Pop <sup>n</sup>	EVPI (in £ Millions)	EVPIM (in £ Millions)	EVP (in £ Millions)
Orlistat	£21,267	0.504	83,406	2.0	6.8	8.7
Zanamivir	£22,739	0.0034	895,204	5.6	6.6	12.1
Wisdom teeth	Dominates	0.20	72,406	0.0	5.7	5.7

**Table 3** Expected Value of Perfect Information (EVPI), Expected Value of PerfectImplementation (EVPIM), and Expected Value of "Perfection" (EVP)

Table 4 Framework Matrix for Orlistat

$\rho = 0.504$	Information		
Implementation	Current (in £)	Perfect (in £	
Current	82	82	
Perfect	163	187	

Table 4 presents the  $2 \times 2$  matrix for orlistat. The expected value of the decision made purely on the basis of this current information was estimated to be  $\pounds 163$  (cell C), whereas 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 (cell D – cell C), giving an EVPI of  $\pounds 2$  million for the eligible population. With the current implementation level ( $\rho^c$ ) of 0.504, the realizable 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 (cell C – cell A), giving an EVPIM of £6.8 million for the eligible population. The expected value of "perfection" was calculated to be  $\pounds 105$  per decision (cell D – cell A), £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 ( $\rho^c = \rho^p$ ), the expected value of the decision made on the basis of perfect information (cell B) was equivalent to the expected value of the decision made on the basis of current information (cell A) at £82. Thus, the realizable EVPI (cell B – cell A) was 0.

# Zanamivir

The NICE guidance recommended that zanamivir be adopted for high-risk patients when influenza was circulating.<sup>28</sup> 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 2000–2001, 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 stylized model calculated the incremental cost-effectiveness ratio associated with zanamivir to be £22,739 per QALY (Table 3). Given a cost-effectiveness threshold of £30,000 per QALY, zanamivir was cost-effective given the information available.

Table 5 presents the  $2 \times 2$  matrix for zanamivir. The expected value of the decision made purely on the basis of this current information was estimated to be  $\pounds 7$  (cell C), whereas 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 ( $\rho^c$ ) of 0.0034, the realizable expected value of the decision made on the basis of current information was £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.

# Wisdom Teeth

The NICE guidance recommended that prophylactic extraction of wisdom teeth should not be undertaken.<sup>27</sup> The annual incident population with disease-free molars was estimated to be 11,000, for whom 80% received (inappropriate) extraction of wisdom teeth ( $\rho^c = 0.2$ ). The total eligible population (discounted over 8 years) was approximately 72,000. The analysis of the stylized model showed that a policy of the 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).

Table 6 presents the  $2 \times 2$  matrix for the prophylactic extraction of wisdom teeth. The expected

$\rho = 0.0034$	Information		
Implementation	Current (in £)	Perfect (in £)	
Current	0.02	0.02	
Perfect	7	14	

 Table 5
 Framework Matrix for Zanamivir

**Table 6**Framework Matrix for Wisdom Teeth

$\rho = 0.20$	Information		
Implementation	Current (in £)	Perfect (in £)	
Current	20	20	
Perfect	99	99	

value of the decision made purely on the basis of this current information was estimated to be £99 (cell C), whereas 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 0. With the current implementation level ( $\rho^c$ ) of 0.2, the realizable 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.

### **Sensitivity Analysis**

Level of the cost-effectiveness threshold ( $\lambda$ ). Figures 1 and 2 illustrate the relationship between the value of the cost-effectiveness threshold ( $\lambda$ ) and the population values for EVPI, EVPIM, and EVP for orlistat and zanamivir, respectively.

As the cost-effectiveness threshold approaches the incremental cost-effectiveness ratio (ICER), the uncertainty surrounding the decision to implement the technology reaches a maximum, the incremental net benefit approaches 0 (the decision maker is indifferent between the 2 technologies), and the level of perfect implementation is in transition (from 0 to 1). As a result, the EVPI is large (although not necessarily at a maximum), the EVPIM is close to 0, and the EVP is close to the EVPI.

For values of  $\lambda$  up to the ICER, the error probability (reflected by the cost-effectiveness acceptability curve<sup>30</sup>—not shown) and the value of the consequences of an error are both increasing with  $\lambda$ .



Figure 1 Expected value of information, implementation, and perfection for orlistat. EVPI, expected value of perfect information; EVPIM, expected value of perfect implementation; EVP, expected value of "perfection"; ICER, incremental cost-effectiveness ratio.



Figure 2 Expected value of information, implementation, and perfection for zanamivir. EVPI, expected value of perfect information; EVPIM, expected value of perfect implementation; EVP, expected value of "perfection"; ICER, incremental cost-effectiveness ratio.

Hence, the EVPI must also increase (as illustrated in Figures 1 and 2). Beyond this point, the error probability falls, whereas the value of the consequences continues to rise along with the cost-effectiveness threshold. Here, for both orlistat and zanamivir, the fall in the error probability outweighs the rise in the value of the consequences, and EVPI falls for values of  $\lambda$  beyond the ICER, but this need not be the case. The EVPIM has the inverse relationship with the

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cost-effectiveness threshold, reaching a minimum at the point where the cost-effectiveness threshold is equal to the ICER (incremental net benefit [INB] is 0). At this point, the decision maker is indifferent about whether to adopt the technology, and strategies to change implementation between the old and new technology will have no value. The behavior of the EVPIM curve for values of  $\lambda$  above and below the ICER will depend on the interaction between the perfect and current levels of implementation. For values of the cost-effectiveness threshold below the ICER, the optimal decision is not to provide the technology (perfect level of implementation is 0). However, for orlistat (Figure 1), the current level of implementation exceeds 0. As such, strategies to change implementation away from orlistat have value (positive EVPIM). The value of such strategies will fall as the cost-effectiveness threshold increases toward the ICER and the negative impact of the current implementation falls (INB rises toward 0). For zanamivir (Figure 2), the current level of implementation ( $\rho^c = 0.0034$ ) is very close to the perfect level of implementation ( $\rho = 0$ ). Thus, strategies to change implementation away from zanamivir have negligible value.

When the cost-effectiveness threshold is above the ICER, the optimal decision is to provide the technology (perfect level of implementation is 1). Given that the current level of implementation is less than 1 (for both orlistat and zanamivir), strategies to change implementation *toward* the technology will have value (positive EVPIM). The value of such strategies will rise as the cost-effectiveness threshold increases beyond the ICER and the negative impact of the current implementation increases (INB rises).

Level of current implementation. Figure 3 examines the impact that the current level of implementation has on the expected values of perfect information, perfect implementation, and perfection associated with orlistat. The figure is drawn for a costeffectiveness threshold of £30,000 per QALY, a level at which orlistat is the most cost-effective decision, and the optimal level of implementation  $(\rho)$  is 1. When the current level of implementation is 1, the expected value of perfect implementation will be 0 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



Figure 3 Sensitivity analysis on current implementation proportion—orlistat. EVPI, expected value of perfect information; EVPIM, expected value of perfect implementation; EVP, expected value of "perfection."

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 cost-effectiveness threshold were taken to be  $\pounds 20,000$  (not shown), orlistat would not be cost-effective, the optimal level of implementation would be 0, and the graph would be reversed, with the expected value of implementation and the EVP rising as the level of current implementation rises.

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 affect 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 (realizable EVPI) is 0. 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 realizable EVPI is affected by relaxing the simplifying assumption and allowing the level of implementation to change on the basis of information alone  $(\rho^p \neq \rho^c)$ . The figure is drawn for orlistat and a costeffectiveness threshold of £30,000 per QALY, a level



Figure 4 Sensitivity analysis on postinformation implementation proportion for orlistat. EVPI, expected value of perfect information; EVPIM, expected value of perfect implementation; EVP, expected value of "perfection."

at which orlistat is the most cost-effective decision and the optimal level of implementation  $(\rho)$  is 1. When the level of implementation following the information is 1 (perfect implementation), the realizable 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 realizable EVPI is 0. 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 realizable EVPI is positive. When the level of implementation following the information is below the current level, the realizable EVPI is negative. In this situation, 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 postinformation implementation level  $(\rho^p)$  because they are calculated with respect to the proportion of current implementation and/or the value of perfect implementation.

If the cost-effectiveness threshold were taken to be £20,000 (not shown), orlistat would not be costeffective, and the optimal level of implementation would be 0. In this case, the realizable EVPI would have the inverse relationship, with the postinformation level falling as the level of postinformation implementation increased from 0 to 1. In this circumstance, the realizable EVPI would reach a maximum (equal to EVPI) when the level of postinformation implementation is 0 and would be negative when the level of implementation postinformation exceeded the current level of implementation.

# DISCUSSION

#### 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 (EVPIM =  $\pounds 6.8$  million) than was associated with further research (EVPI =  $\pounds 2$  million), although both were potentially worthwhile assuming the cost of investment in either activity was less than the value indicated. With zanamivir, the value associated with further research (EVPI =  $\pounds 5.6$  million) was equivalent to the value associated with strategies to change implementation (EVPIM =  $\pounds 6.6$  million). Again, assuming that the costs associated with the investments were below these values, both were potentially worthwhile. In the case of prophylactic extraction of wisdom teeth, the value of further research was negligible, whereas the value associated with strategies to change implementation was substantial (EVPIM =  $\pounds 5.7$  million). In this case, the cost of investing in further research would exceed the potential value of such investment, and no funding should be allocated for further research. Instead, assuming that the cost of strategies to improve implementation is lower than the potential value associated with changing practice (£5.7 million), funding effort should be focused on strategies to reduce the number of prophylactic wisdom teeth extractions that are performed.

# **Key Factors**

Several key factors affect the expected values of perfect information, perfect implementation, and perfection, which in turn influence the allocation of funds between service provision, further research, and implementation strategies. These include the following:

- i) The level of the cost-effectiveness threshold ( $\lambda$ ). As discussed above, the calculations of the expected values of perfect information, perfect implementation, and perfection all depend on the value of the cost-effectiveness threshold ( $\lambda$ ). This is due to the interaction between the cost-effectiveness threshold 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.
- 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 ( $\pounds$ 0.02, not shown).

- iii) The extent of the expected INB. The calculation of the expected values of perfect information, perfect implementation, and perfection is 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 compared to £81); this affected the value of information and implementation strategies (at the decision level), which were lower for zanamivir (£6 and £7 compared with £24 and £81, respectively).
- iv) The current level of implementation. As illustrated in Figure 3, 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 EVPIM is negligible. For example, given a cost-effectiveness threshold 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 large. For example, the population values of the EVPI were larger for zanamivir than for orlistat (£5.6 million compared with £2 million) despite lower values at the decision level (£6 compared with £24) due to the size of the estimated eligible population (895k compared to 83k).

The allocation of funds between health care, research, and implementation strategies will depend crucially on 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.

### **Future Developments of the Framework**

This article has introduced a simple unified framework that sets out the necessary conditions for assessing the value of implementation and the value of information to address decisions concerning health care funding allocations. A number of simplifying assumptions have been made. 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 examines 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 on the current level of implementation, which is only influenced as a result of direct implementation strategies (i.e., 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 realizable EVPI is 0.

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 on the level of implementation. An estimate of the relationship could be achieved via investigation of historic implementation levels and publication of research results or formal elicitation of priors.

An initial sensitivity analysis illustrated the impact of relaxing the assumption (Figure 4). Where information led to a positive change in implementation (a move toward the perfect level), the realizable EVPI was positive, but where information led to a change in implementation away from the perfect level (a negative change), the realizable 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, or where clinical practitioners do not base their decisions on costeffectiveness. For example, research that strengthens the evidence about a technology's positive effectiveness may lead to increased implementation despite evidence that shows it not to be cost-effective. When formalizing 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. It has been assumed 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 establish 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 article 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  $2 \times 2$  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), as well as 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.

To determine whether specific implementation strategies are worthwhile, it is necessary to value improvements in implementation that 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.

# The Next Steps with the Framework

In addition to developing the theoretical foundations of the framework and relaxing the simplifying assumptions, a series of steps must 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 prospective application of the framework within an ongoing technology appraisal, before the framework is piloted prospectively as part of the NICE process.

# **CONCLUSIONS**

In a budget-constrained health care system, decisions regarding investment in implementation strategies must be made alongside those regarding investment in health care services and further research. We present a simple, unified framework that examines the value of information and the value of implementation simultaneously. Policy makers can compare these maximum returns to investment with the costs of investment in each area to inform policy decisions about the allocation of funds between these activities.

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