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Review

Value of information analysis in healthcare: a review of principles and applications

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Abstract

Background:

Economic evaluations are increasingly utilized to inform decisions in healthcare; however, decisions remain uncertain when they are not based on adequate evidence. Value of information (VOI) analysis has been proposed as a systematic approach to measure decision uncertainty and assess whether there is sufficient evidence to support new technologies.

Scope:

The objective of this paper is to review the principles and applications of VOI analysis in healthcare. Relevant databases were systematically searched to identify VOI articles. The findings from the selected articles were summarized and narratively presented.

Findings:

Various VOI methods have been developed and applied to inform decision-making, optimally designing research studies and setting research priorities. However, the application of this approach in healthcare remains limited due to technical and policy challenges.

Conclusion:

There is a need to create more awareness about VOI analysis, simplify its current methods, and align them with the needs of decision-making organizations.

Introduction

Comparative effectiveness research has been proposed as a potential avenue to identify, evaluate, and provide effective, safe, and cost-effective healthcare on the basis of informed and evidence-based decisions¹. When comparing alternative healthcare options, it is essential to identify and combine the best available evidence on treatment effects, health-related preferences (utilities), resource use, and costs². Nevertheless, the evidence could be absent or uncertain due to the limitations and weaknesses of the available studies. A cost-effectiveness analysis that is based on such evidence is uncertain and, thus, any decision based on this analysis will also be uncertain³. Decision uncertainty is associated with risk, because making the wrong decision could lead to costly consequences for the healthcare system (e.g. adopting sub-optimal treatment). Acquiring additional information could reduce uncertainty and better inform decisions; however, there is a cost for obtaining further evidence in terms of the direct costs of conducting research and the opportunity cost of delaying the decision awaiting research results^{3,4}. In addition, under limited budgets, the money spent on a specific research study could be spent on healthcare or on other competing

research proposals. Therefore, it is recommended to assess the need and value of additional research before making decisions^{5,6}.

Value of information analysis has been proposed to aid decision-makers decide simultaneously on the adoption of new technologies and the need for further research. Various value of information methods have been developed and successfully applied to inform whether there is sufficient evidence to support new technologies, optimally designing research studies and setting research priorities^{7,8}.

The majority of the published papers on value of information analysis are methodological⁷. Even in the applied papers, the topic is often presented with complexity, rendering this approach difficult to grasp by non-specialists. Thus, there is a need to present the principles and advantages of value of information analysis to decision-makers, researchers, and practitioners in a succinct but comprehensive manner. The objective of this paper is to review value of information principles and applications in healthcare.

Scope

The first section of this paper describes the principles of value of information analysis, and the second section reviews the applications of value of information in healthcare. The general approach is to identify the relevant literature to inform this review, searching various databases including PubMed, Medline, CINAHL, and the National Health Service Economic Evaluation Database for value of information articles published from January 2003 to January 2013. Search terms included: 'value of information', 'value of perfect information', 'value of sampling information', and 'value of perfect parameter information'. These terms were searched in combination with the terms 'decision-making', 'trial design', and 'research prioritization'. A narrative approach is used to summarize and present the principles and applications of value of information from the reviewed articles.

Principles of value of information analysis

Value of information analysis provides an analytic framework to quantitatively estimate the value of acquiring

additional evidence to inform a decision problem. It is based on the notion that information is valuable because it reduces the expected cost of making the wrong decisions under uncertainty^{5,6}. By measuring the expected benefits of additional evidence and comparing this with the expected costs of further research, the value of information approach helps decision-makers answer the following five related questions^{8,9}:

- (1) Is additional research required? And, if yes,
- (2) What type of research?
- (3) Do the benefits of research exceed the costs?
- (4) What is the optimal research study design?
- (5) What priority should this research study take?

Is additional research required?

To know whether additional research is required, it is essential to consider the expected cost of the consequences of making a wrong decision (i.e. the cost of uncertainty)³. High expected cost of uncertainty indicates a need for acquiring further information before making a decision. The expected cost of uncertainty is determined by two factors: (1) the probability that a decision is wrong, and (2) the consequences of this potentially wrong decision⁹.

To explain how the cost of uncertainty is estimated, a simplified hypothetical example is presented for two treatment interventions (A and B) modeled in a cost-effectiveness analysis. The uncertainty in the results of the cost-effectiveness analysis is characterized by presenting the expected net benefit estimates (i.e. effects measured in monetary terms minus costs) for each intervention. In this example, the model is calculated five times to reflect various possible values of the model parameters (Table 1). Because the expected average net benefit for intervention B (\$1200) is higher than for A (\$1000), selecting intervention B would be the best decision. However, this decision is imperfect as there is a 40% probability that a wrong decision is made; in two out of five scenarios treatment A is cost effective. The consequence of this wrong decision is the opportunity loss (i.e. benefit forgone) from choosing treatment B when treatment A was the preferred intervention. This opportunity loss is calculated by taking the difference between the net benefits of the two interventions in each scenario when A was preferred. The average opportunity loss across all scenarios

Table 1. Illustrative example of the expected value of perfect information.

Sampling scenario	Intervention A net benefit	Intervention B net benefit	Optimal choice	Opportunity loss	Maximum net benefit
1	\$1000	\$1400	B	\$0	\$1400
2	\$1200	\$1100	A	\$100	\$1200
3	\$900	\$1300	B	\$0	\$1300
4	\$800	\$1200	B	\$0	\$1200
5	\$1100	\$1000	A	\$100	\$1100
Average	\$1000	\$1200		\$40	\$1240

is the expected cost of uncertainty of the decision for adopting treatment B, which is \$40 per patient in this example. Equivalently, if we knew all parameters with absolute certainty (i.e. we have perfect information), we would choose the intervention with the maximum net benefit in each scenario. Averaging the maximum values across all scenarios gives the expected benefit of a decision made with perfect information, which is \$1240. The difference between the expected benefit of a decision made with perfect information and a decision made without perfect information ($\$1240 - \$1200 = \$40$ per patient) is the expected value of perfect information (EVPI) which is also the expected cost of uncertainty¹⁰.

The EVPI calculated above is an average estimate (i.e. per patient EVPI). Multiplying per-patient EVPI by the population of patients expected to benefit from the evaluated intervention over a period of time gives the population EVPI which represents the maximum potential value (i.e. upper bound) of additional research^{8,9}. If the population EVPI appears to exceed the cost of additional research study, then this study is potentially worthwhile and further assessment is required to inform its optimal design^{9,11}. Nevertheless, it has been argued that population EVPI is neither necessary nor sufficient to inform whether additional research is worthwhile, because it is impossible to estimate the expected cost of research without knowing the specific research study design (e.g. sample size, follow-up time)⁸. However, calculating population EVPI is relatively simple and considered a continuation step to uncertainty assessment in cost-effectiveness analyses. When the population EVPI approaches zero it is unlikely that the value of additional research will exceed its cost and there will be no need to undertake further value of information analyses¹².

What type of research?

If further research appears potentially worthwhile based on the population EVPI, it would be useful to identify the particular aspects of a decision problem that are worth studying to resolve the uncertainty surrounding them¹¹. This could be achieved by estimating the expected value of information for certain input parameters in a given economic evaluation, often referred to as the partial EVPI or the expected value of perfect parameter information (EVPPI)³. EVPPI is defined as the difference between the expected value of a decision made with perfect information on the selected parameters and the decision made based on current information¹¹. EVPPI serves as a measure of the sensitivity of the economic evaluation to the uncertainty in its different input parameters^{3,11}. A parameter with a higher EVPPI is more uncertain and further research can be designed and focused to get more precise estimate of its value. Importantly, the nature of the

uncertain parameter(s) would inform the type and possibly the cost of the additional research study needed (e.g. randomized controlled or observational)^{3,11}.

Do the benefits of research exceed the costs?

When the benefits of additional research study in reducing decision uncertainty exceeds its total cost, then this study is worthwhile. EVPI and EVPPI measure the expected value of additional research providing perfect information to resolve uncertainty of all parameters or specific parameters¹⁰. However, acquiring perfect information requires a very large research sample (i.e. infinite sample size) which is not practical. In reality, it is only possible to reduce uncertainty with additional information from a research study of a finite sample size⁵. The expected value of sample information (EVS) estimates the expected value of reducing the uncertainty by a given research study with a specific sample size within a particular study design⁸. This can be calculated for all effect and cost parameters (i.e. total EVS) or for the parameter(s) of interest (i.e. partial EVS)¹³. Population EVS is calculated by multiplying the per-patient EVS by the size of the population to whom information from the trial is valuable⁸.

The expected total cost of a research study includes three components: (1) fixed cost (e.g. set-up cost, salaries), (2) variable cost per patient, and (3) an opportunity cost for those patients who receive the inferior intervention while the study is underway⁶. The total cost commonly takes a societal perspective; however, this cost may also be from the perspective of the sponsor of the study. The difference between the population EVS for a specific study design and its expected total cost is the expected net benefit of sampling (ENBS)⁸. A positive ENBS indicates that the research study is worthwhile. Conversely, when the ENBS is negative, it would be irrational to conduct further research because the expected costs of the study exceed its expected benefits, and, in this case, the current available evidence is sufficient for decision-making¹⁴. The EVS and the ENBS are the preferred measures of value of information because they are sufficient to inform whether a specific research study is potentially worthwhile⁸.

What is the optimal research study design?

The sample sizes of clinical trials are usually calculated based on type I and II error, and the minimum clinically important difference¹⁵. The value of information framework provides an alternative to the standard hypothesis testing approach which relies on arbitrary chosen error probabilities where type I and type II errors receive the same weight (e.g. 5% and 20%, respectively) regardless of the consequences of making an error^{10,16}. Figure 1 shows the population EVS across a number of sample

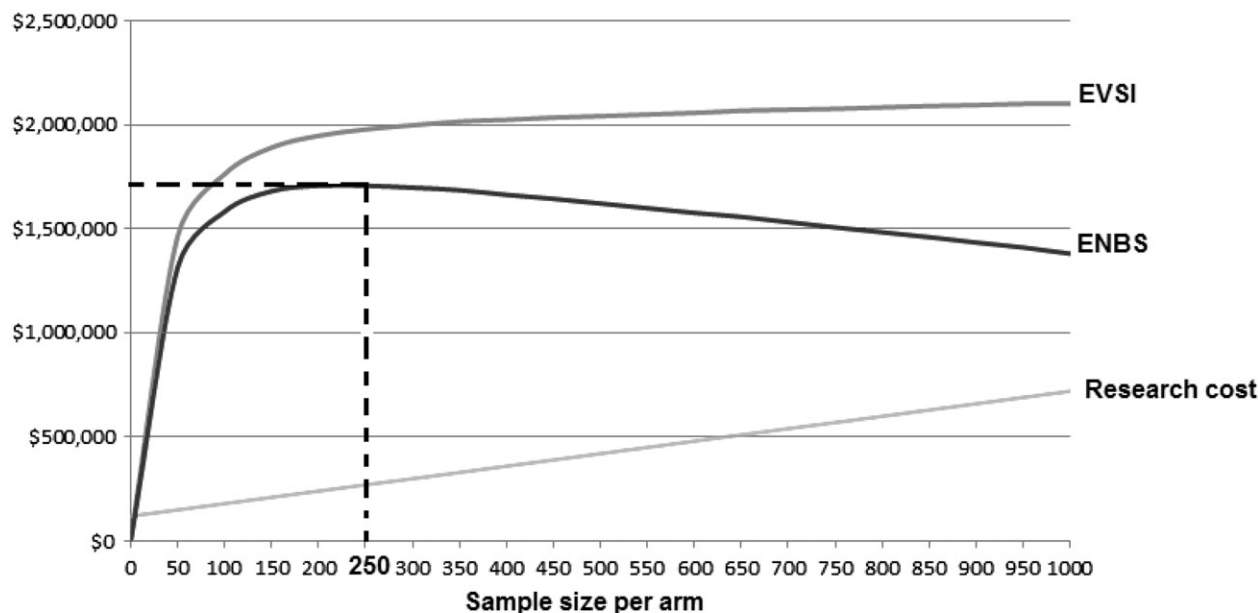


Figure 1. Optimal sample size determination using value of information methods. EVSI, expected value of sample information; ENBS, expected net benefit of sampling.

sizes for a future research study. As the sample size increases and more uncertainty resolved the calculated population EVSI converges to the population EVPI (i.e. upper bound). Deducting the expected total cost from the EVSI results in the ENBS curve which, in this example, is positive for a wide range of sample sizes; however, the ENBS is at maximum when the sample size is 250 patients in each arm, which represents the optimal sample size.

Beyond sample size determination, value of information analysis can optimize additional aspects of research design such as possible comparator arms and alternative follow-up periods^{8,17}. More uncertainty is expected to resolve with longer follow-up and more comparator arms, albeit with additional research costs. The preferred trial design would be the one that maximizes the ENBS⁸.

What priority should this research study take?

Typically, decisions to fund and prioritize research proposals have been subjectively made based on the opinions, judgments, and consensus among experts on a research panel evaluating the scientific merit and relevance of the proposals¹⁸. However, different objective approaches have been proposed and implemented to prioritize research projects such as the burden of disease and the 'payback' approach^{18,19}. In the burden of the disease, the higher the cost of a disease the greater the need for research; however, this does not take into consideration the expected incremental costs and returns from the additional research^{8,18}. Moreover, the burden of the disease approach might

undermine investment in rare diseases as it focuses the decision-maker's attention on common diseases where there is usually a high illness cost. In the 'payback' approach, however, the costs and benefits from conducting and implementing research are evaluated and compared^{8,18}. Under this approach, a research project is worthwhile if its benefits outweigh the expected costs¹⁸. Nevertheless, the 'payback' requires the comparison of the costs and benefits of undertaking a pre-designed research project, implicitly assuming that the proposed research has been optimally designed²⁰. The value of information analysis has been proposed as an alternative quantitative approach to prioritize research studies^{8,21}. Under the value of information approach, competing research proposals are ranked according to their expected values, whereby priority is given to the studies with the highest ENBS⁸. This is illustrated in a hypothetical example in Table 2 where five research proposals are being compared. Nevertheless, it has been argued that the proposal with the highest ENBS may not necessarily provide the highest return on investment (i.e. ENBS divided by the expected total cost of research)⁸.

Value of information applications in healthcare

Value of information analysis is increasingly applied in healthcare to inform decisions, optimize trial design, and prioritize research⁸. In a systematic review on the

Table 2. Prioritizing alternative research proposals using the value of information approach.

Study	EVSI	Total cost	ENBS	ROI
Study 1	\$5,000,000	\$1,500,000	\$3,500,000	233%
Study 2	\$4,500,000	\$1,250,000	\$3,250,000	260%
Study 3	\$3,000,000	\$1,250,000	\$1,750,000	140%
Study 4	\$3,000,000	\$1,500,000	\$1,500,000	100%
Study 5	\$2,000,000	\$1,250,000	\$750,000	60%

EVSI, expected value of sample information; ENBS, expected net benefit of sampling; ROI, return on investment which is the ENBS divided by the total cost.

application of value of information in health technology assessment a total of 118 papers were identified, of which 59 were applied⁷. The authors of this review observed a rapidly accumulating literature base on value of information from 1999 onwards for methodological papers and from 2005 onwards for applied papers⁷. Most of the identified applied articles estimated the EVPI and the EVPPI, indicating that the majority of the studies used the value of information approach to estimate the maximum value of additional information to assess whether further research is warranted⁷. However, a limited number of applied papers reported the preferred value of information measures of EVSI (six articles) and ENBS (four articles)⁷. Similar results were reported in a recent systematic review on value of information application in oncology, where less than 10% of the identified articles reported the use of this approach to inform optimal trial design and research prioritization²².

Informing decisions

The most explicit use of value of information methods to inform decisions is by the National Institute for Health and Clinical Excellence (NICE) in England. Claxton *et al.*⁹ have developed a value of information based framework for NICE to inform the following decision options:

- (1) Approve based on existing information.
- (2) Approval with research (i.e. Approve and ask for additional research).
- (3) Only in research (i.e. Delay approval and ask for additional research).
- (4) Reject based on existing information.

Generally, when the technology is cost-effective, 'approval with research' would be appropriate if additional research is possible and worthwhile⁹. Conversely, if the technology is not cost-effective but additional research is worthwhile, 'only in research' would be the preferred option. Nevertheless, exceptions from this general rule would be appropriate depending on the presence of irrecoverable cost associated with the adoption of the new intervention (e.g. cost of training)⁹. Thus, 'only in

research' or even 'reject based on existing information' rather than 'approval with research' or 'approve based on existing information' may be appropriate even if research is possible when there are significant irrecoverable adoption costs⁹.

A recent study reviewed NICE technology appraisals with 'only in research' or 'approval with research' recommendations and examined the key considerations that led to those decisions²³. In total, 29 final and 31 draft guidance documents included 'only in research' or 'approval with research' recommendations up to 2010. Overall, 86% of final guidance included 'only in research' recommendations. Of these, the majority was for technologies considered to be cost ineffective (83%), while 66% of the final guidance specified the need for further evidence on relative effectiveness²³.

From the industry perspective, any change in the price of the intervention, such as through patient access schemes or price negotiations, will affect the key assessments, possibly leading to a different decision^{9,24}. Subsequently, once the need for additional information and the size of irrecoverable costs are recognized, the threshold price that would lead to 'adopt based on existing evidence' rather than 'only in research' will always be lower than a single value-based price based on expected cost effectiveness alone⁹. Willan and Eckermann²⁵ have proposed a framework to bring together the societal and industry perspectives, allowing for trade-offs between the value and cost of research and the price of the new intervention. Under this framework, if the decision-maker's threshold price exceeds the sponsor's (industry), then current evidence is sufficient since any price between the thresholds is acceptable to both. However, if the decision-maker's threshold price is lower than the company's, then no price is acceptable to both and the company's optimal strategy is to conduct additional research²⁵.

Optimizing trial design

The use of the value of information methods in optimizing trial design remains limited and most applications have been restricted to the estimation of optimal sample size, and mainly in two-arm randomized trials^{14,26,27}. For example, Koerkamp *et al.*^{26,28} applied value of information analysis to patient-level data from two randomized trials on intermittent claudication and magnetic resonance imaging (MRI) in acute knee trauma. The optimal study design for the treatment of intermittent claudication would involve a randomized controlled trial collecting data on the quality-adjusted life expectancy and additional admission costs for 525 patients per treatment arm²⁶. For the MRI in acute knee trauma, three parameters were found responsible for most of the decision uncertainty: number of quality-adjusted life-years, cost of an overnight

hospital stay, and friction costs²⁸. A study in which data on these three parameters are gathered would have an optimal sample size of 3500 patients per arm²⁸. Soares *et al.*²⁹ showed how value of information analysis informed the optimal future trial design on negative-pressure wound therapy for severe pressure ulcers. In their study, a three-arm trial with 1-year follow-up and a sample size of 497 patients (in each arm) was estimated to be the most efficient²⁹.

Prioritizing research

In a survey prepared for the Agency for Healthcare Research and Quality (AHRQ), research prioritization approaches for 48 research-sponsoring organizations from the US, UK, Australia, Germany, and Canada were identified and compared³⁰. The results showed that only 31 (65%) organizations utilized specific priority-setting methods. The most explicit use of value of information and other quantitative methods was by NICE, where the assessment is usually performed by a network of academic centers under the umbrella of the National Institute for Health Research (NIHR) Health Technology Assessment program³⁰. This is expected, because in the UK, where research is often commissioned on a tender basis, the application of value of information methods in identifying areas of value for funding bodies may be useful. On the other side, in settings where grant applicants have a more active role in defining research questions (e.g. US and Australia), it is suggested that more emphasis be placed on application of value of information methods by applicants in showing the connection of proposed trial designs to value of research and decision-making⁸.

Recently, Carlson *et al.*³¹ have evaluated the feasibility and outcomes of incorporating value of information analysis into a stakeholder-driven research prioritization process within a program to prioritize comparative effectiveness research in cancer genomics. The authors described how they convened an external group of stakeholders to identify three high-priority cancer genomics tests for further research and to rank these in order of priority for conducting further research³¹. These tests included expression testing for platinum-based adjuvant therapy (ERCC) in resectable non-small cell lung cancer (NSCLC), epidermal growth factor receptor (EGFR) mutation testing for erlotinib maintenance therapy in advanced NSCLC and breast cancer tumor markers (BC markers) for detection of recurrence after primary breast cancer therapy³¹. The study demonstrated how providing the stakeholders with value of information estimates about the three tests resulted in participants changing their ranking of the tests from (1) ERCC1, (2) EGFR, and (3) BC markers to (1) ERCC1, (2) BC markers, and (3) EGFR³¹.

Challenges for value of information application

The wide adoption of value of information methods in healthcare faces technical and policy challenges. From a technical perspective, conducting value of information analyses, especially calculating the EVSI and the EVPPI in non-linear models, requires sophisticated computations together with advanced expertise in economic evaluation and simulation techniques⁷; nevertheless, recent years have witnessed a progressive evolution and simplification of methods as well as advanced computing tools to reduce computational challenges^{8,32–35}. Another technical challenge is that certain assumptions are necessary when estimating value of information measures. These include the population expected to benefit from the technology, the lifetime of the technology, and the level of its implementation since the value of research is reduced if the results were not fully implemented^{4,36–38}. Several papers have addressed these assumptions and provided guidance to handle the uncertainty surrounding their estimates^{4,36–38}.

For the policy aspect, the main issue is that the decisions to adopt technologies and to conduct research are usually separate¹¹. Claxton and Sculpher¹¹ noted this point in their first pilot study on value of information: 'The key problem seems to be the policy environment where accountability and transparency for research prioritization and commissioning lags behind adoption and reimbursement decisions, and where there appears to be a separate remit for reimbursement and research decisions' (p. 1067). Furthermore, the approach is relatively new and it will be some time before its value is realized by decision-makers. Therefore, for the value of information analysis to be more incorporated into decision-making frameworks, there is a need to create more awareness about the value of this approach and to align its methods with the needs of the decision-making organizations⁷.

Conclusion

Value of information analysis is a systematic framework to measure decision uncertainty and assess whether there is sufficient evidence to support new technologies. Various value of information methods have been developed to inform decision-making, optimally designing research studies and setting research priorities. The application of value of information analysis in healthcare is increasing but remains limited due to conceptual, technical and policy challenges. Therefore, there is a need to create more awareness about this approach, simplify its current methods, and align them with the needs of the different jurisdictions in order for this approach to be incorporated into decision frameworks.

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