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Introduction

Health technology assessment is a widely used methodology for informing payers about the value of health care interventions. Its prominence within decision making has grown by its adoption by reimbursement bodies around the world.[1] Despite this prominence, its impact on clinical practice remains highly variable, especially within publically funded health systems. For instance, several studies within the United Kingdom have identified low uptake of recommendations by the National Institute for Health and Care Excellence (NICE).[2-5]

The notion of slow diffusion is not new.[6] Neither is knowledge about the effectiveness of interventions to improve implementation.[7] Information about the cost-effectiveness of these interventions has been less well developed, with early attempts being very simplistic.[7]

In this paper, I outline a new economic framework that seeks to estimate the value realised to payers when health technologies are implemented appropriately; this value could be in the form of lives saved or quality of life gains. The value of these realised gains is termed the value of implementation (VOImp). Two case studies are then presented that highlight how the VOImp framework can be used. Further work which has incorporated more realistic features relating to the dynamics of diffusion and reimbursement processes is also introduced. Lessons that this literature provides for payers and manufacturers is then outlined. The paper ends with a short discussion and a conclusion as to the relevance of this work to payers and manufacturers.

The work presented in this paper is based on standard methods and decision rules associated with economic evaluation in healthcare.[8] Specifically, cost-effectiveness is measured by an incremental cost-effectiveness ratio (ICER), with the measure of effectiveness being the quality adjusted life year (QALY). Decisions about whether a technology is cost-effective are made by comparing the ICER to a threshold value for a QALY gained. This threshold value represents the maximum price a payer can spend on a QALY in order that the gains from adopting the new technology are greater than the potential gains from alternative uses of the same investment. If an ICER is greater than the threshold value, this suggests that investing in alternative uses would generate more QALYs, i.e. the new technology is not cost-effective and should not be funded. Of note is that this threshold varies between countries, principally due to different funding levels.

The paper is not written for, not its conclusions restricted to, any specific health system. However, the use of economic evaluation in the form summarised above is more closely aligned to the notion of payers seeking health maximisation within a fixed budget. As such, the paper is most relevant to publicly funded health systems.

Valuing implementation

A major step forward in our assessment of the value of implementation initiatives was developed by Fenwick and colleagues in 2008.[9] Their work was the first to link the value of implementation to the value of information (VOI), which had already been demonstrated as being important to decision makers.[10] In the VOI approach, an estimate is made of the losses associated with the current estimate of cost-effectiveness potentially being wrong due to the imprecision of its constituent parameters. For example, the analysis may conclude that technology is cost-effectiveness, but with perfect information, the analysis could show that it is not cost-effective. Knowing the value of this

perfect information is a useful starting point for decisions about whether to collect more information (which leads to improvements in the precision of our estimates).

A major weakness of the VOI approach is that it assumes that all the estimated benefits of the health technology are fully realised; in other words, it assumes perfect implementation. Adding implementation into this framework allows us to estimate an expected value of implementation, which can be interpreted as the amount of money we can invest in an implementation initiative before it is no longer cost-effective to do so. In its most basic form, the value of implementation is the net monetary benefit of the technology (which is another way of expressing the ICER), multiplied by the uptake of the technology. Linking VOI and VOImp allows the joint consideration of evidence generation, implementation and their associated uncertainties.

Extensions to the VOImp framework

The incorporation of patient sub-groups

Faria and colleagues introduced one important extension to the framework developed by Fenwick; comparing the value of implementation across patient subgroups.[11] The work used evidence from the NICE Technology Appraisal of dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation.[12] Their study evaluated a 5% improvement in absolute uptake, costing £3.66 million nationally.

Based on the NICE cost-effectiveness threshold of £20,000, the assessed implementation activity generates £1.42 million (or 71 QALYs) of benefit to England and Wales per annum.[11] However, these results mask a huge disparity in the cost-effectiveness of using dabigatran in different patient populations. Importantly, investing in implementation was not cost-effective for severe patient subgroups, even though dabigatran is more cost-effective in these groups. The reason for this result was that the cost of the intervention were fixed, regardless of the population size, so whilst dabigatran was more cost-effective in the severe patient population, the cost of increasing uptake were greater than the health benefits it produced . When this same cost was spread across a bigger patient population the value to the payer was higher.

The incorporation of diffusion dynamics

Whyte and colleagues developed the VOImp framework by undertaking a multi-period analysis that included dynamic diffusion for both the intervention and the baseline.[13] The dynamics used s-shaped diffusion curves which were fitted to available data.[6] The analysis used the NICE analysis of natriuretic peptide testing for suspected heart failure, with a 5% improvement in absolute uptake for a national cost of £28,186.[14]

Based on a cost-effectiveness threshold of £20,00 the modelled activity had a value of £15,915,094 over a 10 year period.[13] Importantly, the vast majority of this value was within the first five years of the modelled period as the utilisation rates with and without the implementation activity were close to 100% at this point (due to natural diffusion in the absence of the initiative).

The impact of evidence on the value of implementation

Grimm and colleagues examined the potential effect that improved evidence relating to clinical effectiveness may have on implementation.[15] This work examined a screening technology for preterm birth. Two potential research studies were then considered; a diagnostic accuracy study which assesses the accuracy of the screening technology and a randomised controlled trial which jointly assesses the effectiveness of the screen and subsequent treatment.

Diffusion curves associated with the two research studies were generated through elicitation of expert beliefs.[16] The experts considered the trial to produce more convincing evidence which would generate faster and higher levels of diffusion. This, in turn, increased the expected value of the trial as its associated recommendations were realised by a greater proportion of the eligible patient population.

The impact of price changes on the value of implementation

In a further extension, Grimm and colleagues examined the ways in which implementation can alter the cost-effectiveness of the underlying health technology.[17] Their work examined the possibility that the wider use of a technology can produce lower prices due to increased competition between manufacturers and/or economics of scale.

Evidence of this effect has been widely examined in non-medical markets and this general relationship can be parameterised in the form of experience curves which describe price as a function of sales volume.[18] Incorporation of this experience curve effect into the same preterm birth evaluation described earlier demonstrated an increased value of any intervention that increased implementation (due to the associated price reductions making the technology more cost-effective).

Lessons for payers and manufacturers

The developments in assessing the value of implementation seen in the last 10 years have improved our understanding of how to assess value. From this growing body of work, we are able to distil some important lessons for payers and manufacturers. These lessons can be quantified by the application of the framework. Such analyses can be complex, however, the same lessons can be considered qualitatively in decisions relating to research design, reimbursement and investment in implementation initiatives.

Lesson 1: pricing up to the threshold provides no incentive for payers to invest in implementation

If a manufacturer prices a new technology such that the ICER is equal to the funding threshold, there is no incentive for the payer to invest in implementation. This is because, by definition, when a technology's ICER is equal to the threshold, its benefits are equal to its opportunity costs, consequently, so any further expenditure relating to the technology is not worthwhile.

Lesson 2: the value of implementation is generally greater for larger populations and more cost-effective technologies

As the value of implementation is estimated as the net monetary benefit of the new technology multiplied by the patient population, this lesson is obvious. However, when identifying opportunities to invest in implementation initiatives, these need to be considered simultaneously.

The study by Faria and colleagues on dabigatran showed that surprising results can be produced; a population which was most cost-effective to treat was not the best investment opportunity because the costs required to increase implementation were in relation to a small number of patients.[11]

Lesson 3: naturally fast-diffusing technologies provide a reduced incentive to invest in implementation

For technologies that are expected to rapidly diffuse without additional investment, the scope for further improvement is reduced as the upper limit on diffusion is quickly hit. Identifying these technologies can be difficult because whilst there is evidence that highlights general factors associated with rapid diffusion, such as lack of safety concerns or lack of alternative treatments, context-specific factors are clearly important.[19] The flip side of this argument is that for technologies with expected slow diffusion, investment is required to generate more extensive health gains, which in turn requires the technology to be priced sufficiently below the threshold to incentivise investment.

Lesson 4: diffusion generates further evidence

The more a technology is used, the more is learnt about it. Such evidence can be anecdotal and piecemeal (e.g., case series), or it can be more formal (e.g., disease registries). This evidence is of value to payers if it allows the uncertainty relating to the funding decision to be reduced. Managed access schemes, whereby reimbursement is granted in exchange for further data collection,can be useful for gathering this evidence.

Lesson 5: better evidence can generate higher implementation

The study by Grimm and colleagues showed that better quality evidence was thought by experts to produce quicker and higher levels of implementation. As such, better research design not only improves the reimbursement decision by reducing uncertainty, it can increase the value of implementation. Once again, carefully designed managed access schemes can be useful in generating this evidence. This raises the possibility that a managed access scheme which collected data that resolved an important issue, could end up producing higher levels of implementation in the long run than if unfettered access had been granted. This is because without the collection of data, the unresolved uncertainty could limit clinicians' desire to use the new technology.

Lesson 6: get the funding threshold right

It is of fundamental importance to note that the analyses described here are reliant on having a robust cost-effectiveness threshold. From an economic perspective, that threshold should represent the opportunity costs of investing in a new technology. However, evidence suggests that the thresholds used across the world are underestimating opportunity costs.[20,21] This means that the value of new health technologies is being overestimated, which in turn, means that the value of implementing those technologies will be overestimated.

While this finding does not affect the lessons above, any quantitative assessment of the cost-effectiveness of implementation strategies could be seriously flawed. Consequently, if faced with value of implementation analyses, decision makers should ensure that the results are subjected to sensitivity analyses in relation to the value of the threshold.

Discussion

This paper sets out a framework for assessing the value of implementation and recent developments that have generated a more realistic representation of implementation dynamics. With the help of case studies that have used this framework, useful qualitative lessons have been identified for payers and manufacturers.

The main strength of this framework and paper is its alignment with the standard methods of economic evaluation that are widely used in reimbursement agencies across the world.[1] This strength also suggests its main weakness; not all reimbursement agencies adopt cost-utility analysis or apply an explicit funding threshold.[22,23]

The use of other methods of economic evaluation doesn't necessarily invalidate the analysis above. The lessons were deliberately constructed to avoid specific methodological detail, such as QALYs. However, it does require opportunity cost to be considered in a way that the objective function of the decision maker is maximised. In the language of cost-effectiveness analysis, this relates to the use of a funding threshold at the correct level. As such, the relevance of the framework is diluted for processes that pay little attention to cost constraints, have ill-defined decision making criteria or are primarily driven by extraneous personal, social or political goals.[24]

Conclusion

Too much attention is currently being paid to 'getting a positive reimbursement decision' and as a consequence, implementation of guidance is well below what is possible. This results in a huge loss of value to society. Issues relating to implementation need to be central to the considerations of payers and manufacturers. Payers need to consider identifying and investing in implementation activities for each set of guidance they issue. Manufacturers need to consider implementation in the design of their clinical studies and set their prices to give payers a margin to invest in implementation. The sooner the two camps recognise their symbiotic relationship in realising value, the quicker they can act in a way that is mutually beneficial.

References

1. WHO. *2015 Global Survey on Health Technology Assessment by National Authorities. Main findings.* Geneva: World Health Organisation; 2015.
2. Chidgey J, Leng G, Lacey T. Implementing NICE guidance. *Journal of the Royal Society of Medicine.* 2007;100(10):448-452.
3. Lowson K, Jenks M, Filby A, Carr L, Campbell B, Powell J. Examining the implementation of NICE guidance: cross-sectional survey of the use of NICE interventional procedures guidance by NHS Trusts. *Implementation science : IS.* 2015;10:93-93.
4. Sheldon TA, Cullum N, Dawson D, et al. What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ (Clinical research ed).* 2004;329(7473):999.
5. Vyawahare B, Hallas N, Brookes M, Taylor RS, Eldabe S. Impact of the National Institute for Health and Care Excellence (NICE) guidance on medical technology uptake: analysis of the uptake of spinal cord stimulation in England 2008–2012. *BMJ Open.* 2014;4(1).
6. Rogers EM. *Diffusion of innovations.* 1st ed. New York: Free Press of Glencoe; 1962.
7. Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health technology assessment (Winchester, England).* 2004;8(6):iii-iv, 1-72.
8. Drummond M, Sculpher M, Claxton K, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes.* 4th ed. Oxford: OUP; 2015.
9. Fenwick E, Claxton K, Sculpher M. The value of implementation and the value of information: combined and uneven development. *Medical decision making : an international journal of the Society for Medical Decision Making.* 2008;28(1):21-32.
10. Claxton K, Sculpher M, Drummond M. A rational framework for decision making by the National Institute For Clinical Excellence (NICE). *Lancet (London, England).* 2002;360(9334):711-715.
11. Faria R, Walker S, Whyte S, Dixon S, Palmer S, Sculpher M. How to Invest in Getting Cost-effective Technologies into Practice? A Framework for Value of Implementation Analysis Applied to Novel Oral Anticoagulants. *Medical decision making : an international journal of the Society for Medical Decision Making.* 2017;37(2):148-161.
12. NICE. *Dabigitran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation. NICE technology appraisal guidance 249.* London: National Institute for Health and Care Excellence; 2012.
13. Whyte S, Dixon S, Faria R, et al. Estimating the Cost-Effectiveness of Implementation: Is Sufficient Evidence Available? *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research.* 2016;19(2):138-144.
14. Mant J, Doust J, Roalfe A, et al. Systematic review and individual patient data meta-analysis of diagnosis of heart failure, with modelling of implications of different diagnostic strategies in primary care. *Health technology assessment (Winchester, England).* 2009;13(32):1-207, iii.
15. Grimm SE, Dixon S, Stevens JW. Assessing the Expected Value of Research Studies in Reducing Uncertainty and Improving Implementation Dynamics. *Medical Decision Making.* 2017;37(5):523-533.
16. Grimm SE, Stevens JW, Dixon S. Estimating Future Health Technology Diffusion Using Expert Beliefs Calibrated to an Established Diffusion Model. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research.* 2018;21(8):944-950.
17. Grimm SE, Dixon S, Stevens JW. When Future Change Matters: Modeling Future Price and Diffusion in Health Technology Assessments of Medical Devices. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research.* 2016;19(6):720-726.

18. Brown A, Meenan BJ, Young TP. Marketing Innovation: Medical Device Prices Follow the Experience Curve. *Journal of Medical Marketing.* 2007;7(3):203-212.
19. Chauhan D, Mason A. Factors affecting the uptake of new medicines in secondary care - a literature review. *J Clin Pharm Ther.* 2008;33(4):339-348.
20. Claxton K, Martin S, Soares M, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. *Health technology assessment (Winchester, England).* 2015;19(14):1-503, v-vi.
21. Woods B, Revill P, Sculpher M, Claxton K. Country-Level Cost-Effectiveness Thresholds: Initial Estimates and the Need for Further Research. *Value in Health.* 2016;19(8):929-935.
22. Griffiths UK, Legood R, Pitt C. Comparison of Economic Evaluation Methods Across Low-income, Middle-income and High-income Countries: What are the Differences and Why? *Health economics.* 2016;25 Suppl 1:29-41.
23. Hjelmgren J, Berggren F, Andersson F. Health economic guidelines--similarities, differences and some implications. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research.* 2001;4(3):225-250.
24. Wirtz V, Cribb A, Barber N. Reimbursement decisions in health policy--extending our understanding of the elements of decision-making. *Health policy (Amsterdam, Netherlands).* 2005;73(3):330-338.

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