EEPRU

Policy Research Unit in Economic Evaluation of Health and Social Care Interventions

Research Report

# Title: Getting cost-effectiveness technologies into practice: the value of implementation.

Authors: Walker S, Dixon S, Palmer S, Sculpher M.

Correspondence to: Simon Walker, Centre for Health Economics, University of York, Alcuin A Block, Heslington, York, YO10 5DD

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## 1. Framework for the value of implementation initiatives

### 1.1 Introduction

Getting cost-effective health technologies into practice is one of the priorities for the NHS identified in Innovation, Health and Wealth [1]. This involves not only identifying cost-effective technologies, which is the responsibility of the National Institute of Health and Care Excellence (NICE), but also understanding the potential barriers to the uptake of these technologies and evaluating possible solutions to these barriers (implementation initiatives). The research presented here sets out a framework for examining the latter (i.e. the solutions to the barriers), in a manner consistent with the estimation of value of the technologies by NICE.

The aim of this research is not to create an additional barrier (or "fifth hurdle") for health care technologies to get into regular use in the NHS but instead to set out a formal analytic framework to allow for the evaluation of different implementation initiatives in a manner consistent with those methods currently employed for health technology assessment by NICE in England and Wales. The use of this framework recognises that the different types of barriers identified and the range of possible implementation approaches that maybe considered appropriate will invariably be associated with different resource implications and potential outcomes. Consequently, it will be important to ensure that the type and intensity of the implementation approach adopted is commensurate with the anticipated value to the NHS.

### 1.2 NICE and cost-effectiveness

- *The value of the new health care technology to the NHS is established by the Appraisal Committee after reviewing evidence.*
- *The value of the new technology, in terms of an incremental cost per QALY, is then compared to the cost-effectiveness threshold (k) to see if it represents a cost-effective use of resources.*
- *Alternatively, but equivalently, the net value to the NHS of treating a patient with the technology can be calculated in terms of monetary or health benefits.*

In 1999 the National Institute of Health and Clinical Excellence (NICE) was created with the aim of ensuring that everyone have equal access to medical treatments and high quality care from the UK National Health Service (NHS) [2]. Further, it aimed to maximise the health produced by the NHS (i.e. to use resources efficiently). These objectives are, however, constrained by the budget allocated to the NHS by the government. One of the ways NICE accomplishes these objectives is through their Medical Technology Evaluation Programme [3], which provides recommendations on the use of new and existing medicines and treatments within the NHS. Recommendation decisions are based on the value of treatments and the uncertainty around that value. Importantly, these decisions require an assessment of both the costs and health effects of a new intervention, as well as the health effects of activities that will have to be displaced elsewhere in the NHS in order to fund any new (and more costly) health care technology.

The methods recommended by NICE provide standardised and systematic ways to evaluate the overall cost and health effects of new health care technologies [3]. Health effects contain both changes in the quality and length of life. NICE recommends measuring health effects in quality-adjusted life-years (QALY) using the EQ-5D instrument [4]. The use of a generic measure of quality of life is important both in ensuring consistency in decision making across different treatments and diseases, as well as ensuring that decisions are consistent with the objective of maximising health gain within a fixed NHS budget. The current perspective used by NICE considers the impact of a new intervention on the resource use and costs on the NHS and Personal Social Services [3].

A new health care technology is considered valuable if it provides more overall health than it displaces as a result of any additional cost displacing other health care interventions elsewhere in the NHS. In other words, there are two types of outcomes to be considered when deciding whether to fund a new health care technology. The first is the effect on the patient receiving the health care technology. The second is the effect on others who must then be treated from a reduced budget. Currently NICE assumes the value of displaced treatments is between £20,000 and £30,000 per QALY. This suggests that the marginal treatment in the NHS (i.e. the treatment that would no longer be funded to release resources to fund a new treatment) provides 1 additional QALY for an additional £20,000-£30,000 spent. To ensure that the funding of a new intervention is consistent with the objective of maximising health gain subject to a budget constraint, new health care technologies must, therefore, provide an incremental cost per QALY compared to current care of less than £20,000-£30,000 per QALY. The incremental cost per QALY of a health care technology is referred to as its incremental cost-effectiveness ratio, or ICER. The calculation of the ICER is show in Equation 1 below.

1. $$ICER = \frac{C_A - C_B}{H_A - H_B} = \frac{\Delta C_{AB}}{\Delta H_{AB}}$$

Where $C_A$ represents the cost of treatment with the new health care technology, $C_B$ the cost of treatment with current care, $H_A$ the QALYs resulting from treatment with the new health care technology, $H_B$ the QALYs resulting from treatment with current care, $\Delta C_{AB}$ the incremental cost of the new technology compared to current care and $\Delta H_{AB}$ the incremental effect of the new technology compared to current care.

The value of the new health care technology to the NHS is established by the Appraisal Committee after reviewing evidence submitted by the manufacturer, its' evaluation by the independent evidence review group and the comments by the public and consultees. The value of the new technology, in terms of an ICER, is then compared to the cost-effectiveness threshold (k). NICE generally accepts those technologies with a cost-effectiveness of less than £20,000 per QALY but requires increasingly strong reasons to accept interventions with a cost-effectiveness ratio of over £30,000 per QALY [3]. A new health care technology is therefore cost-effective when:

2. $ICER = \frac{\Delta C_{AB}}{\Delta H_{AB}} \leq k$

Alternative but equivalent decision rules to using an ICER, where the cost per QALY is compared to the cost-effectiveness threshold, are net monetary benefit (NMB) or net health benefit (NHB). These involve transforming the ICER statistic into a measure of the monetary value of the intervention to the NHS in the case of NMB, or the QALY, or health, value of the intervention to the NHS in the case of NHB. This requires knowledge of the cost-effectiveness threshold (k). The net monetary benefit statistic is shown in Equation 3 below.

3. $NMB = k \cdot (H_A - H_B) - (C_A - C_B) = k \cdot \Delta H_{AB} - \Delta C_{AB}$

The net health benefit statistic is shown in Equation 4.

4. $NHB = (H_A - H_B) - \frac{(C_A - C_B)}{k} = \Delta H_{AB} - \frac{\Delta C_{AB}}{k}$

These equations represent the net gain to the NHS in terms of money or health respectively from the introduction of a new health care technology. They capture the gains directly from the technology and compare it to the loss from any technologies displaced elsewhere within the NHS to fund the new technology.

A new health care technology is cost-effective if its ICER is less than the cost-effectiveness threshold, its NMB is positive or its NHB is positive. It should be noted that these are all equivalent. All things equal, the further the ICER is below the cost-effectiveness threshold or the greater the NMB or the NHB then the greater the value of the technology to the NHS for each patient treated. In other words, the magnitude of cost effectiveness will vary across technologies and interventions even if they are recommended by NICE.

### 1.3 Literature review

A scoping literature review was undertaken to identify existing analytic frameworks that have been developed to evaluate the value of implementation initiatives. The objective of the review was to examine the underlying principles and approaches applied within these existing frameworks in order to inform the subsequent development and specification of our own analytical framework. This framework would assess the maximum expenditure on activities to promote the implementation of

health technologies which is consistent with value as determined by the process for health technology assessment conducted by NICE [3]. Full details of the review can be found in Essat et al (2013) [5].

Whilst subtle differences exist between the frameworks identified in the review, the general principle that the value of an implementation strategy is dependent not only on the effects and costs of the implementation strategy but also the effects and costs of the health care intervention being implemented (the magnitude of its value or cost effectiveness) is consistent across frameworks. These general principles will provide the basis for the development of our analytical framework.

The review of frameworks also outlined a number of important factors which determine the value of implementation initiatives, for example the rate of utilisation without an implementation strategy and the size of the patient population. Many of the existing studies appear to have incorporated these factors using simplifying assumptions or stylised examples. While the basis for informing these assumptions are not critical to the development of the conceptual framework itself, further consideration will be needed on how these aspects should be more appropriately informed in the subsequent case studies.

### 1.4 Analytical framework

Below we set out an analytical framework for evaluating the value of implementation initiatives in a manner consistent with the identification of cost-effective technologies by NICE. This framework has been developed based on our review of analytical frameworks for valuing implementation initiatives for health care technologies. We first set out a simple framework for evaluating the value of implementation initiatives which considers a homogenous patient population with common costs and outcomes and does not account for changes over time (i.e. it is static). This simple framework is then extended to consider multiple patient populations (in terms of subgroups of patients receiving the same treatment, or alternatively groups of patients receiving different therapies) and the impact of implementation across time (a multi-period analysis).

#### 1.4.1 Simple static framework

The simple framework considers only a homogenous patient population with common costs and outcomes and only one time period (i.e. it does not account for varying utilisation rates over time). The framework is set out below as follows: firstly, we consider the value to the NHS of each patient treated with the health care technology for which we are considering an implementation initiative; secondly, we consider the value to the NHS of all patients currently treated with the health care technology without the use of an implementation initiative; thirdly, we consider the maximum potential gains to the NHS of any implementation initiative (those by achieving full utilisation of a technology); fourthly, we consider the value to the NHS of achieving a particular change in utilisation

rate; fifthly we incorporate the costs of any implementation initiative with its impact on utilisation rate, to demonstrate the overall value of the implementation initiative to the NHS; and finally, we consider how mutually exclusive implementation initiatives for the health care technology should be compared.

#### *1.4.1.1 Net benefit of the technology (monetary and health)*

- *The net monetary benefit (NMB) and net health benefit (NHB) represent the additional value of treating a patient with a health care technology in terms of money or health respectively.*
- *Evidence requirements: Estimates of incremental health and costs of the technology compared to its comparator and knowledge of the cost-effectiveness threshold.*

As previously described, the net monetary benefit (NMB) and net health benefit (NHB) represent the added value to the NHS of treating a patient with a health care technology instead of its' comparator in monetary or health terms respectively. Equation 5 and Equation 6 represent the NMB and NHB respectively:

5. $NMB = k \cdot \Delta H - \Delta C$

6. $NHB = \Delta H - \frac{\Delta C}{k}$

Where k is the cost-effectiveness threshold, $\Delta H$ is the health gain of the technology over its' comparator and $\Delta C$ is the incremental cost over its' comparator. For a technology to add value to the NHS these must be positive. It should be noted that this framework aims to value implementation initiatives for those health care technologies which have already been approved by NICE, therefore this criteria has already been fulfilled. However, the greater the value of NMB or NHB the greater the value to the NHS of treating a patient with the health care technology (it should be noted that, other things equal, this is akin to the ICER being further below the cost-effectiveness threshold).

A further issue when considering the value of the health care technology relates to the choice of comparator. When considering increasing the utilisation of the health care technology, it seems appropriate that the technology is compared to routine care for those not currently receiving the new technology, as it will be from routine care that the patients will switch to the new technology. However, routine care may be variable, and this may not be reflected in the original NICE appraisal, with, for example, the technology being considered against a specific comparator. We return to this issue in Section 1.6.

#### *1.4.1.2 Current value to the NHS of the health care technology*

- *The current value to the NHS of the health care technology is the value from all the patients who currently receive the technology without an implementation initiative, and is determined by the NMB or NHB of treating each patient.*
- *Evidence requirements (in addition to previous evidence): Size of the eligible patient population and current utilisation rate of the technology in the patient population.*

Without the use of an implementation initiative to encourage utilisation of the new health care technology, some patients may receive the technology. If there is a total patient population eligible for treatment (n) and a proportion of these patients ($\rho$) are already receiving the technology, then the current value to the to the NHS of patients already receiving therapy (referred to as the *current value to the NHS of health care technology*) is defined in terms of monetary value in Equation 7 and health value in Equation 8:

7. $n \cdot \rho \cdot NMB$

8. $n \cdot \rho \cdot NHB$

Where n is the total patient population eligible for treatment and $\rho$ is the current utilisation rate of technology where $0 \leq \rho \leq 1$. These represent the value to the NHS of patients currently treated with the health care technology.

#### *1.4.1.3 Expected value of perfect implementation*

- *Any gains to the NHS from an implementation initiative can only result from gains from those patients receiving the technology who would not have done so without an implementation initiative. There is no additional benefit from treating those who would have received it without an initiative.*
- *The expected value of perfect implementation represents the maximum possible gain from implementation of the health care technology to the NHS and is calculated as the difference in value to the NHS of all eligible patients receiving the technology and those who would receive it without additional implementation (current value to the NHS of the health care technology).*

To consider what is the maximum that can be gained from an implementation initiative it is important to note that some patients will receive the health care technology without the use of an implementation initiative (as represented by the *current value to the NHS of the health care technology*). The implementation initiative can only, at best, result in gains from those patients

receiving the new technology who would not have done so without the implementation initiative. Therefore, the maximum that could possibly be gained from an implementation initiative can be calculated as the difference between the total value to the NHS of treating all eligible patients with the health care technology and the value to the NHS of those patients who would be treated without the implementation initiative (the *current value to the NHS of health care technology*). This maximum is referred to as the *expected value of perfect implementation.* Equation 9 sets out the monetary value of perfect implementation to the NHS and Equation 10 the health value:

9. $n \cdot NMB - n \cdot \rho \cdot NMB = n \cdot (1 - \rho)(NMB)$

10. $n \cdot NHB - n \cdot \rho \cdot NHB = n \cdot (1 - \rho) \cdot NHB$

As this is the maximum that could be gained from an implementation initiative, it would never be worth the NHS spending more than this on such an initiative. Therefore, it can be said that this represents a *necessary* condition for the cost-effectiveness of an implementation initiative (i.e. that the cost must be less than the expected value of perfect implementation for it to be possible for it to be a cost-effective use of resources).

It should be noted that the expected value of perfect implementation has been categorised based on full implementation (of 100%) in a specific patient group (of size n). In the case of NICE recommendations, the optimal level of implementation might not be 100% in all patients eligible for a treatment, for example, in the case of Single Technology Appraisals where NICE has recommended several technologies as cost-effective. We return to this issue in section 1.6.

#### *1.4.1.4 Expected value of actual implementation*

- *The actual gains to the NHS from an implementation initiative are from those patients receiving the technology who would not have done so without the initiative.*
- *The expected value of actual implementation represents the gains to the NHS as a result of the increase in utilisation of the health care technology by the implementation initiative, without considering the costs of the initiative itself.*
- *It is calculated as the difference between the total value of patients receiving the technology following an initiative and the total value of patients receiving the technology without an initiative (current value to the NHS of the health care technology).*
- *Evidence requirements: Evidence on the increase in utilisation as a result of the implementation initiative (the absolute effectiveness of the intervention).*

An initiative will not necessarily achieve perfect implementation, instead it is important to value the actual increase in implementation resulting from an initiative. The *expected value of actual*

*implementation* (previously referred to as the expected value of specific implementation by Fenwick et al [6]) is the gains to the NHS from those extra patients treated as a result of the implementation initiative. This can be calculated as the difference in the value to the NHS of all patients treated with the technology following an implementation initiative (where $\sigma$ is the proportion treated with the initiative) and the value to the NHS from those patients who would be treated without the implementation initiative (the *current value to the NHS of health care technology,* determined by $\rho$), such that the difference in utilisation rates represents the absolute effectiveness of the implementation initiative ($\sigma - \rho$). The expected value of actual implementation in terms of monetary value to the NHS is shown in Equation 11 and in health value to the NHS in Equation 12.

11. $n \cdot \sigma(NMB) - n \cdot \rho(NMB) = n \cdot (\sigma - \rho) \cdot NMB$

12. $n \cdot \sigma \cdot NHB - n \cdot \rho \cdot NHB = n \cdot (\sigma - \rho) \cdot NHB$

These represent the value to the NHS of the increase in utilisation of the health care technology resulting from the implementation initiative. As with the *expected value of perfect implementation* it should be noted that this does not take account of the cost of the implementation initiative. The *expected value of actual implementation* represents the maximum the NHS would be willing to pay for the implementation initiative, if it exceeds this level, the value to the NHS is less than the cost and as such the implementation initiative is not worthwhile. This is, therefore, a *sufficient* condition for the cost-effectiveness of an implementation initiative. If the cost of the initiative in terms of money or health is less than the *value of actual implementation*, then the implementation initiative is of value to the NHS.

#### *1.4.1.5 Costs of implementation activity*

- *Previous analyses have not considered the costs of the implementation initiatives, only the gains as a result of patients receiving the health care technology. To see if an implementation initiative is of value, its' gains need to be compared to its costs.*
- *The costs of implementation are costs separate from those considered to be the costs of the health care technology, which are considered in the NMB or NHB. It is important to distinguish between these costs to avoid double counting or inappropriate omission of costs.*
- *Evidence requirements: Evidence on the costs of the implementation initiative and the costs of the health care technology considered as part of NMB or NHB.*

When considering whether an implementation initiative is worthwhile, it is essential to compare its benefit to its cost. We have previously shown that the benefit of an implementation initiative is the *expected value of actual implementation* and stated that this must be at least as great as its cost for the implementation initiative to be worthwhile. The *expected value of actual implementation*

already takes into account the costs of the health care technology being implemented (i.e. $\Delta C$), but does not account for the implementation initiative cost, which we will refer to as $I$.

For the implementation initiative cost it is important to distinguish between any cost involved in the initiative which would have been captured in the original appraisal valuation of the health care technology cost by NICE (i.e. $\Delta C$) and any cost that is above and beyond this. It is only the latter component which should be considered for $I$, with the former cost already captured in $\Delta C$. Failure to make this distinction will result in double counting. Alternatively, failure to include costs which were not included in the cost to NICE will lead to underestimation of the costs of implementation.

It should be noted that when there is no implementation initiative we are assuming there are no implementation costs above and beyond those considered in the original technology appraisal. However, this is unlikely to be the case and it is possible that there will be initiatives already ongoing to improve utilisation of the health care technology in question, for example local or *ad hoc* initiatives. Such activities could be crowded out/substituted for by a formal implementation initiative, and as such there may be cost savings involved with a formal implementation initiative which are not accounted for.

#### *1.4.1.6 Incremental net benefit of the implementation initiative*

- *An implementation initiative is worthwhile if its benefit to the NHS in terms of increased utilisation of the health care technology (the expected value of actual implementation) is greater than its cost.*

We have previously demonstrated the actual value of an implementation initiative to the NHS and the cost of the implementation initiative. To see whether the implementation initiative is worthwhile the value and the cost must be compared. The net benefit of an implementation initiative is the difference between the *expected value of actual implementation* and the cost of the initiative. This is referred to as the *incremental net benefit of the implementation initiative* and, as with previous measures of benefit, can be measured in either monetary or health terms. The *incremental net monetary benefit of an implementation initiative* is shown in Equation 13 and the *incremental net health benefit of an implementation initiative* is shown in Equation 14. For the implementation initiative to be worthwhile these values must be positive.

13. $n \cdot \sigma \cdot NMB - n \cdot \rho \cdot NMB - I = n \cdot (\sigma - \rho) \cdot NMB - I$

14. $n \cdot \sigma \cdot NHB - n \cdot \rho \cdot NHB - \frac{I}{k} = n \cdot (\sigma - \rho) \cdot NHB - \frac{I}{k}$

These equations can be rearranged to show the value of the implementation initiative in terms of an incremental cost-effectiveness ratio (ICER). This is shown in Equation 15, where the ICER must be less than for the cost effectiveness threshold ($k$) for the implementation initiative to be worthwhile.

15. $\frac{n(\sigma-\rho)\Delta C+I}{n(\sigma-\rho)\Delta H} \leq k$

#### *1.4.1.7 Multiple mutually exclusive implementation initiatives*

- *When there are alternative implementation initiatives available for a health care technology, the benefit of each to the NHS, in terms of increasing utilisation, need to be compared to their cost to see which initiative has the most value to the NHS.*
- *Evidence requirements: Evidence on the effects on utilisation and costs of each implementation initiative.*

The previous discussion considered the possibility of one implementation initiative. However, there are potentially many different implementation initiatives which could be used to encourage the uptake of health care technologies, which will have different effects and costs associated with them. If we consider that there are X possible implementation initiatives which could be used, then for each initiative $x$, $\sigma_x$ is the proportion treated with the initiative and the initiative cost is $I_x$. Here we define no implementation initiative, as initiative x=0 such that $\sigma_0$=$\rho$ and $I_0 = 0$. The optimal initiative, that which has the most value to the NHS, is then the initiative which maximises the following equations representing the overall benefits to the NHS in terms of monetary benefit (Equation 16) and health benefit (Equation 17).

16. $\max_X \; n \cdot \sigma_x \cdot NMB - I_x$

17. $\max_X \; n \cdot \sigma_x \cdot NHB - \frac{I_x}{k}$

It should be noted that these are equivalent to comparing any two strategies using the *incremental net monetary benefit of an implementation initiative* shown in section 1.4.1.6.

## 1.5 Extensions to the framework

### 1.5.1 Expanding the framework to consider different subgroups or multiple treatments

- *A health care technology may have different effects or costs in different subgroups of the eligible patient population (i.e. different NMB or NHB and therefore different value to the*

*NHS of a patient treated with the technology), or alternatively, we may be interested in examining increasing the utilisation of different health care technologies across different eligible populations.*

- *To appropriately value implementation initiatives aimed at increasing the utilisation of a health care technology across different subgroups, or alternatively of different health care technologies across different patient populations, knowledge of the benefits and costs to each group of receiving the technology and the utilisation in each group with and without the implementation initiative are required.*
- *The value of an initiative to the NHS is then the aggregation of the value across each of the different patient populations.*
- *Evidence requirements: Estimates of NMB or NHB of the technology (or technologies) in each patient group and the utilisation with and without the implementation initiative.*

The previous analysis has considered the value of different implementation initiatives assuming a homogenous patient population where the expected benefits and costs of the technology are common for all patients. However, there may be identifiable subgroups of patients such that the expected costs and benefits of the health care technology differ between subgroups. Similarly, we might want to examine implementation initiatives which involve increasing the uptake of multiple health care technologies across different patient groups. The previous analyses can be easily extended to account for different costs and effects of a treatment, or multiple treatments, as well as different levels of implementation in the different patient populations.

If we now consider heterogeneous costs and outcomes in N different patient populations, be they subgroups receiving the same health care technology or different patient populations receiving different health care technologies. The net monetary benefit or the net health benefit of the health care technology can then be defined for each patient population j as shown in Equations 18 and 19 respectively.

18. $NMB_j = k \cdot \Delta H_j - \Delta C_j$

19. $NHB_j = \Delta H_j - \frac{\Delta C_j}{k}$

As with the NMB and NHB for each patient population, the level of implementation without an implementation initiative and with an implementation initiative can also be defined ($\rho_j$ and $\sigma_j$ respectively). This clearly increases the informational requirements for the analysis. The incremental net benefit of the implementation initiative is then the summation across all patient populations (N) of the incremental net benefit of the implementation initiative in each patient population (j). The incremental net monetary of the implementation initiative is shown in Equation 20 and the incremental net health benefit of the implementation initiative is shown in Equation 21.

20. $(\sum_{j=1}^{N} n_j \cdot (\sigma_j - \rho_j) \cdot NMB_j) - I$

21. $(\sum_{\mathrm{j}=1}^{\mathrm{N}} \mathrm{n_j} \cdot (\sigma_\mathrm{j} - \rho_\mathrm{j}) \cdot \mathrm{NHB_j}) - \frac{\mathrm{I}}{k}$

An implementation initiative is worthwhile if these are positive. The analysis can be expanded to look at different costs of the implementation activity for each subgroup if necessary, this is shown in Appendix 1 in Equations 31 and 32.

### 1.5.2 Moving to a multi-period analysis with varying implementation rates under no implementation strategy and with an implementation strategy

- *Previous analyses have considered only a one off patient population with a fixed utilisation rate without an implementation initiative.*
- *They do not consider the impact of time and how future patients and changes in utilisation of the technology over time will affect the value of implementation initiatives.*
- *Focusing only on the current (or prevalent) patient population will not accurately reflect the value of implementation initiatives which impact on utilisation rates in more than the current period.*

In the previous analyses, we have not considered the impact of time and how new patients and changes in utilisation rates of the health care technology over time will affect the value of implementation initiatives. Focusing only on the current (or prevalent) patient population will not accurately reflect the value of implementation initiatives which could be reasonably expected to impact on utilisation rates in more than the current period.

The framework can be easily expanded to incorporate how new patients and changing utilisation rates over time impact on the value of implementation initiatives. As with the previous simple static case, we set out the framework using the same steps but expanded to a multi period analyses. We take the example of a homogenous patient population with common costs and outcomes suffering from an acute illness (this allows us to ignore the impact of patients switching treatments over time and having differential costs and effects as well as to ignore issues of prevalent and incident populations). In the next section we will discuss the valuation of implementation activities for health care technologies for the treatment of chronic diseases.

In this section, firstly, we set out the value to the NHS of all patients treated with the health care technology without an implementation initiative. Secondly we determine the maximum possible gains to the NHS of an implementation initiative. Thirdly, we consider the value to the NHS of

achieving a particular gain in implementation. Finally, we incorporate the costs of any implementation initiative with its impact on utilisation rate to demonstrate the overall value of the implementation initiative to the NHS.

#### *1.5.2.1 Current value to the NHS of the health care technology*

- *The current value to the NHS of the health care technology is not just the value from all the current patients who receive the technology without an implementation initiative but also all future patients who would receive the technology without an initiative.*
- *The proportion of patients who would receive the technology (the utilisation rate) may change over time and this must be accounted for when assessing the current value to the NHS of the health care technology.*
- *The current value to the NHS of the technology is the aggregation across all time periods of interest of the benefit from the patients who will receive the technology in each period without an implementation initiative.*
- *Evidence requirements: Size of the patient population in each time period of interest, the utilisation rate in each time period of interest without an implementation initiative and the NMB or NHB per patient treated with the technology.*

As with the previous analysis we assume a homogenous patient population with common costs and outcomes from treatment, and therefore common net monetary benefit (NMB) and net health benefit (NHB). However, we now examine the impact of considering the patient population over time and changing utilisation rates over time.

In any time period t there is a number of patients ($n_t$) with the disease who are eligible for treatment with the health care technology. As with the static analysis, without any implementation initiative there will be a proportion of these patients who would receive the health care technology (the utilisation rate), although this may vary over time ($\rho_t$). The path of the proportion of patients who would receive the health care technology over time without an implementation initiative is the diffusion curve of the technology (see Essat et al (2013)[5] section 7 and brief discussion in section 1.6). It should be noted that this increases the informational requirements for the analysis as rather than just the current utilisation rate, we need to know future utilisation rates as well.

The net present current value to the NHS of this technology is then an aggregation of the benefits across the patient populations receiving the health care technology over time and is defined in terms of monetary value in Equation 22 and in health value in Equation 23 (as previously these are referred to as the *current value to the NHS of the health care technology*). These are represented as net present values as benefits to patients in future years are valued less (discounted) than current patients as a result of positive time preference [3, 7].

22. $\sum_{t=1}^{T} \frac{n_t \cdot \rho_t \cdot NMB}{(1+r)^{t-1}}$

23. $\sum_{t=1}^{T} \frac{n_t \cdot \rho_t \cdot NHB}{(1+r)^{t-1}}$

Where $n_t$ is the total patient population eligible for the treatment at time t, $\rho_t$ is the proportion of the eligible population at time t (the utilisation rate) who would receive the treatment without an implementation initiative and r is the discount rate. T represents the total time period of interest, the appropriate length of which is discussed in section 1.6. It is again worth noting the additional information that is required here compared to the static analysis. Now detailed information on the patient population and the utilisation rate without an implementation initiative into the future are required. This will require evidence to predict future incidence of the disease and diffusion of the health care technology (see discussion of diffusion curves in Essat et al (2013) section 7 [5])

#### *1.5.2.2 Expected value to the NHS of perfect implementation of the health care technology*

- *Any gains to the NHS from an implementation initiative can only result from the gains from those patients receiving the technology who would not have done so without the initiative. There is no additional benefit from treating those who would have received it without an initiative.*
- *The potential benefits of increasing utilisation to the NHS are not just from the current eligible patients who would not receive the technology without an initiative, but also all future patients who would not receive the technology without an initiative.*
- *The expected value of perfect implementation represents the maximum gain from implementation of the health care technology to the NHS and is calculated as the aggregation across all time periods of interest of the difference between the value to the NHS of all eligible patients in each period receiving the technology and the value to the NHS of those patients who would receive it without an implementation initiative.*

Any implementation initiative can only, at best, result in gains from those patients who would not have been treated without the initiative. Therefore, the maximum that could possibly be gained from any implementation initiative can be calculated as the difference between the total value to the NHS of treating all eligible patients with the health care technology and the value to the NHS of those patients who would be treated without an implementation initiative (the *current value to the NHS of the health care technology*). As with the static analysis, this value is referred to as the *expected value of perfect implementation* and represents a *necessary* condition for the cost-effectiveness of an implementation initiative (i.e. the cost of the implementation initiative must be less than this for it to be possible for the implementation initiative to be worthwhile). Equation 24 sets out the monetary value of perfect implementation to the NHS and Equation 25 sets out the health value.

24. $\sum_{t=1}^{T} \frac{n_t(1-\rho_t)\cdot NMB}{(1+r)^{t-1}}$

25. $\sum_{t=1}^{T} \frac{n_t(1-\rho_t)\cdot NHB}{(1+r)^{t-1}}$

As with the static analysis, issues persist about the optimal level of utilisation of the health care technology. This will be discussed further in section 1.6.

#### *1.5.2.3 Expected value of actual implementation*

- *The actual gains to the NHS from an implementation initiative are from those patients who would receive the technology with an initiative but would not receive it without one.*
- *The expected value of actual implementation represents the actual gains to the NHS as the result of an implementation initiatives increase in utilisation of the health care technology, excluding any costs of the initiative.*
- *This is calculated as the aggregation across all periods of interest of the difference between the total value to the NHS of patients receiving the technology in each period with an implementation initiative and the total value to the NHS of patients receiving the technology in each period without an implementation initiative.*
- *Evidence requirements: Evidence on the increase in utilisation as a result of the implementation initiative in each time period of interest (the absolute effectiveness of the intervention in each time period).*

As previously, an implementation initiative will not necessarily achieve perfect implementation. The value of the actual increase in implementation must instead be valued. The *expected value of actual implementation* is the gains to the NHS from those extra patients treated as a result of the implementation initiative. This is calculated as the aggregation across all periods of interest (defined by T) of the difference in the value to the NHS of all patients treated with the health care technology with an implementation initiative (where $\sigma_t$ is the proportion treated with an initiative in each time period t) and the value to the NHS from those patients who would be treated without an implementation initiative (the *current value to the NHS of health care technology*). The expected value of actual implementation to the NHS is shown in monetary terms in Equation 26 and in health terms in Equation 27.

26. $\sum_{t=1}^{T} \frac{n_t(\sigma_t-\rho_t)\cdot NMB}{(1+r)^{t-1}}$

27. $\sum_{t=1}^{T} \frac{n_t(\sigma_t-\rho_t)\cdot NHB}{(1+r)^{t-1}}$

These represent the value to the NHS of the actual increase in utilisation of the health care technology resulting from the implementation initiative, although they do not take account of cost of the implementation initiative. As with the current value to the NHS of a technology, detailed information on the patient population and the utilisation rate without an implementation initiative into the future are required. Further to this, evidence on the effectiveness of the implementation initiative over time would also be required (i.e. $\sigma_t - \rho_t$).

#### *1.5.2.4 Implementation cost over time*

- *Previous analyses have not considered any costs of the implementation initiatives, only the gains to the NHS as a result of extra patients receiving the health care technology. To see if the initiative itself is of value, its gains need to be compared to its costs.*
- *The implementation costs may not be a one off investment but could involve continued costs and effort over time to increase the utilisation of the health care technology.*
- *As with the simpler static case, it is important to distinguish between costs of the implementation initiative and costs of the health care technology, which are included in the NMB or NHB, so as to avoid double counting or inappropriate omission of costs.*
- *Evidence requirements: Evidence on the costs of the implementation initiative and the costs of the health care technology considered as part of NMB or NHB over time.*

As with the static case, the expected value of actual implementation takes into account the costs of the health care technology being implemented ($\Delta C$) but not the costs of the implementation initiative. The implementation costs may not be a one off investment but could involve continued costs and effort over time to increase the utilisation of the health care technology. In the case of implementation costs over time, we can consider the cost of implementation in each period t, which we notate as $i_t$, or alternatively the net present value of all implementation costs across time ($I$). The costs of the implementation initiative over time are represented in Equation 28 below.

28. $I = \sum_{t=1}^{T} \frac{i_t}{(1+r)^{t-1}}$

#### *1.5.2.5 Incremental net benefit of increasing utilisation*

- *An implementation initiative is only worthwhile its benefits to the NHS in terms of increasing the utilisation of the health care technology (expected value of actual implementation) exceed its costs.*

To see whether an implementation initiative is worthwhile, the value and the cost must be compared. As with the static case, the net benefit of an implementation initiative is the difference between the *expected value of actual implementation* and the cost of the implementation initiative. The *incremental net monetary benefit of an implementation initiative* is shown in Equation 29 and

the *incremental net health benefit of an implementation initiative* is shown in Equation 30. The first representation of each equation uses a time period specific implementation cost and the second representation the net present value of implementation costs across all periods. These are, however, equivalent. For the implementation activity to be worthwhile, these values must be positive.

29. $\sum_{t=1}^{T} \frac{n_t(\sigma_t - \rho_t)\cdot NMB - i_t}{(1+r)^{t-1}} \; or \; \sum_{t=1}^{T} \frac{n_t(\sigma_t - \rho_t)\cdot NMB}{(1+r)^{t-1}} - I$

30. $\sum_{t=1}^{T} \frac{n_t(\sigma_t - \rho_t)\cdot NHB - \frac{i_t}{k}}{(1+r)^{t-1}} \; or \; \sum_{t=1}^{T} \frac{n_t(\sigma_t - \rho_t)\cdot NHB}{(1+r)^{t-1}} - \frac{I}{k}$

#### *1.5.2.6 Extensions to the multi-period framework*

As with the static framework, the multi-period framework can be extended to consider multiple implementation activities and to consider the implementation across different subgroups or different treatments. Equations representing the value of implementation initiatives for these two extensions are presented in Appendix 1.

### 1.5.3 Moving to a multi-period analysis –the case of chronic diseases

- *All the previous analyses have focused on the treatment of an acute disease such that patients will be treated with the technology or not immediately upon point of presentation. However, many diseases are chronic, and involve patients receiving treatment for long periods.*
- *This increases the complexity of the analysis around implementation initiatives, as increasing utilisation of the health care technology may result in patients switching treatments years into their disease. Therefore evidence on the costs and effects of delaying treatment are required (e.g. NMB or NHB if we delay treatment for one year, two years etc). Similarly, evidence around utilisation in any period will require an ability to distinguish between patients who are now receiving the technology who have switched treatments and incident patients who immediately receive the new technology.*
- *Evidence requirements: Evidence on the costs and effects of delaying treatment (NHB and NMB) and disaggregated evidence on utilisation of the technology in each period by disease duration.*

All previous analyses have focused on the treatment of an acute disease, such that only the incident patient population need be considered and a patient will be immediately treated at point of presentation with a new health technology or with the comparator. This allows for the use of common benefits of treatment with the health care technology (i.e. $NMB$ or $NHB$). However, many diseases are chronic, and involve patients receiving treatment for long periods. This raises added

complexity for the valuation of implementation initiatives. For example, in such cases, patients who develop the disease at the same time may switch from the comparator to the new health care technology at different time points, therefore receiving different benefits from the new health care technology.

We do not present the formulae for the value of implementation initiatives for health care technologies for chronic diseases here as the analytical framework presented previously becomes increasingly intractable in algebraic form as issues around mortality of patients are considered (a value which is captured within the net monetary benefit or net health benefit of treating one patient with a health care technology in the previous analyses).

The informational requirements for the valuation of implementation initiatives for treatments of chronic diseases will be very large and will involve access to the decision models used to inform NICE decisions (as benefits of treatment with a new health care technology, in terms of net monetary or net health benefit, based on delaying treatment will not typically be available) as well as evidence on utilisation rates of the health care technology over time for patients who developed the disease at different time points.

### 1.6 Practical challenges of implementing the framework

Previously we have set out an analytic framework for valuing implementation initiatives to increase the utilisation of health care technologies by the NHS which have been found to be cost-effectiveness by NICE. The use of this framework will involve a number of challenges, both conceptual and evidentiary. Below we discuss some of these challenges in more detail.

#### 1.6.1 The value of the technology and the comparator

To appropriately value any implementation initiative for a health care technology the value of the health care technology to individual patients must be established. The value to the NHS of treating an individual patient was set out in terms on monetary or health benefits in Equations 5 and 6 respectively in section 1.4.1.1. As noted previously, the aim of this work is to evaluate implementation initiatives for those health care technologies which have been approved by NICE. It should be noted that the value of a technology is subject to uncertainties and judgements and members of NICE committees will come to an agreement on what the value of a technology is to the NHS and then accept or reject it accordingly (i.e. decide whether the technology's NMB or NHB is positive or not). It seems appropriate to take the value of the technology to the NHS as agreed by NICE as the basis for assessing the value of increasing its utilisation via implementation initiatives. This raises a number of issues. It is not always clear what value a NICE committee has agreed that the technology represents to the NHS. This is further complicated that any agreements on value available from documentation are generally presented in the form of incremental cost effectiveness

ratios (ICERs) (see Equation 1 in section 1.2) (for example, for rixaroxaban, a novel oral anticoagulant, NICE's Committee agreed that the ICER compared to warfarin would lie somewhere between £2,870 per QALY and £29,500 per QALY [8]). The analytical framework presented in this report requires values in terms of NMB or NHB, which whilst equivalent decision rules to ICERs, can only be calculated from ICERs with additional information on incremental costs or effects of the treatment. Therefore we need not only know the agreed ICER but also one of the agreed incremental costs or effects.

The difficultly of establishing the value of a technology that NICE has agreed upon is further complicated by issues of comparators. Specifically, the comparator compared to which NICE has agreed a technology is cost-effective may not be the same comparator which a patient would receive in usual practice. Ideally, when examining the value of increasing utilisation of a health care technology, the value of the health care technology should be that resulting from a comparison with routine practice for those patients not currently receiving the health care technology. Whilst NICE has in the past considered the cost-effectiveness of technologies compared to routine practice (or a blended comparator), for example in the case of lapatinib for the treatment of advanced and metastatic breast cancer [9], this is not routinely done. This clearly raises further issues around interpreting NICE's agreed value of the health care technology.

As discussed previously in this report, there are further issues around the value of a technology, for example the value in different subgroups or for chronic diseases the value around delaying treatment. Further issues include different values of treatment to prevalent and incident populations [10]. It seems unlikely that evidence on these values will be available in public documents and may require access to the decision analytic models used to produce the estimates of costs and effects of the health care technologies.

### 1.6.2 Costs

As previously stated it is important to distinguish any costs of the implementation initiative ($I$) from any costs of the health care technology considered by NICE ($\Delta C$). This is essential to avoid double counting or omission of costs which would result in biased estimates of the value of implementation initiatives. To do so accurately will required detailed information about the costs included in the value NICE has agreed on for the health care technology and also detailed information on the costs of any implementation initiatives. The costs considered by NICE may also not be available in documents in the public domain as a result of being considered commercial in confidence.

### 1.6.3 The rate of perfect implementation

As part of the analytical framework, it was demonstrated what the maximum gain to the NHS could be from achieving perfect implementation of a health care technology which has been found to be

of value by NICE. However, the concept of perfect implementation (e.g. 100% utilisation in the target patient population) is complicated by the fact that rarely is only one treatment recommended for a patient population. Guidance will be required on what is the desired level of utilisation of a technology in a particular patient population so as to estimate the maximum gains achievable from an implementation initiative.

### 1.6.4 Appropriate time horizon of analysis

When calculating the value of an implementation initiative, we need to know the total time period of interest (T). Typically in economic evaluation, the time period of interest is any period over which value could be expected to differ between the alternative options [7]. Alternative views can be taken on this, for example, it could be the lifetime of the technology or the length until implementation strategies achieve the same utilisation. Phillips et al (2008) have discussed the benefits of alternative approaches to time horizons for valuing research decisions and the benefits of modelling future changes [11].

### 1.6.5 Diffusion curves

In the multi period framework presented previously, the diffusion curves of the health care technology (i.e. the utilisation rates over time) in the absence of an implementation initiative are important in determining the value of any initiative. Essat et al (2013 forthcoming) found that the heterogeneity of data on diffusion curves makes estimation difficult and suggest that generating plausible diffusion scenarios from the most relevant evidence for each case study or formal elicitation of expert opinion on likely diffusion paths are possible solutions [5].

### 1.6.6 Uncertainty

No discussion of uncertainty has yet been presented in this document. The importance of the consideration of uncertainty when valuing health care technologies has been discussed extensively elsewhere [12-14]. It may be of particular importance when considering implementation, as levels of uncertainty might impact upon utilisation rates for health care technologies [15-17].

## 1.7 References


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**Appendix 1**

***Consideration of different implementation costs in different patient populations***

Equations 31 and 32 show the incremental net monetary benefit and incremental net health benefit of an implementation initiative respectively whilst allowing for the consideration of different implementation costs for different patient populations, where $i_j$ is the cost of the implementation initiative in patient population j.

31. $\sum_{j=1}^{N} n_j \cdot (\sigma_j - \rho_j) \cdot NMB_j - i_j$

32. $\sum_{j=1}^{N} n_j \cdot (\sigma_j - \rho_j) \cdot NHB_j - \frac{i_j}{k}$

**Consideration of multiple mutually exclusive implementation initiatives over time**

When there are multiple mutually exclusive implementation initiatives that could be used to increase uptake, the optimal initiative is the one which maximises Equations 33 and 34 which represent the value to the NHS in terms of monetary or health benefit. Where x represents each strategy, $\sigma_{tx}$ the utilisation rate at time t for strategy x and $i_{tx}$ the implementation cost at time t for strategy x. Strategy 1 (x=1) represents no implementation such that: $\sigma_{tj1}$=$\rho_{tj}$ & $i_{tj1} = 0$

33. $\max_x \sum_{t=1}^{T} \frac{n_t \sigma_{tx} \cdot NMB - i_{tx}}{(1+r)^{t-1}}$

34. $\max_x \sum_{t=1}^{T} \frac{n_t \sigma_{tx} \cdot NHB - \frac{i_{tjx}}{k}}{(1+r)^{t-1}}$

**Consideration of different subgroups or multiple treatments over time**

Equations 35 and 36 show the incremental net monetary benefit and incremental net health benefit respectively of an implementation initiative aimed at increasing utilisation across different subgroups, or across multiple treatments, over time. In the equation $i_{tj}$ represents e cost of the implementation initiative allocated to subgroup j in period t.

35. $\sum_{j=1}^{N} \sum_{t=1}^{T} \frac{n_{tj}(\sigma_{tj} - \rho_{tj}) \cdot NMB_j - i_{tj}}{(1+r)^{t-1}}$

36. $\sum_{j=1}^{N}\sum_{t=1}^{T}\frac{n_{tj}(\sigma_{tj}-\rho_{tj})\cdot NHB_j-\frac{i_{tj}}{k}}{(1+r)^{t-1}}$