Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guidelines for the Budget Impact Analysis of Health Technologies in Ireland

2014

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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Foreword

The Health Information and Quality Authority (the Authority) has a statutory remit to evaluate the clinical and cost-effectiveness of health technologies, providing advice to the Minister for Health and to the Health Service Executive (HSE). It is also recognised that the findings of a HTA may have implications for other key stakeholders in the Irish healthcare system, including patient groups, the general public, clinicians, other healthcare providers, academic groups and the manufacturing industry. To ensure consistency in the HTAs undertaken by the Authority and others, the Authority continues to develop guidelines on the conduct of HTA in Ireland.

The HTA guidelines provide an overview of the principles and methods used in assessing health technologies. They are intended as a guide for all those who are involved in the conduct or use of HTA in Ireland, promoting the production of assessments that are timely, reliable, consistent and relevant to the needs of decision makers and key stakeholders in Ireland.

These guidelines are intended to inform technology assessments conducted by, or on behalf of the Health Information and Quality Authority, the National Centre for Pharmacoeconomics, the Department of Health and the Health Service Executive (HSE), to include health technology suppliers preparing applications for reimbursement. The guidelines are intended to be applicable to all healthcare technologies, including pharmaceuticals, procedures, medical devices, broader public health interventions and service delivery models.

This document, *Guidelines for the Budget Impact Analysis of Health Technologies in Ireland,* is part of the series of guidelines that also includes the *Guidelines for Economic Evaluation of Health Technologies in Ireland* (2014) and the *Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland* (2011). This document is limited to methodological guidance on the conduct of economic assessments. The guidelines will be reviewed and revised as necessary. For ease of use, guideline statements that summarise key points are included prior to each section in italics.

The guidelines have been developed in consultation with the Scientific Advisory Group of the Authority. Providing broad representation from key stakeholders in healthcare in Ireland, this group includes methodological experts from the field of HTA. The Authority would like to thank the members of the Scientific Advisory Group and its Chairperson, Dr Michael Barry from the National Centre for Pharmacoeconomics, and all who have contributed to the production of these Guidelines.

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Process and Acknowledgements

The budget impact analysis guidelines were developed by the Authority with technical input from the National Centre for Pharmacoeconomics and in consultation with its Scientific Advisory Group (SAG). Providing broad representation from key stakeholders in Irish healthcare, this group includes methodological experts from the field of health technology assessment (HTA). The group provides ongoing advice and support to the Authority in its development of national HTA guidelines. The terms of reference for this group are to:

- contribute fully to the work, debate and decision-making processes of the Group by providing expert technical and scientific guidance at SAG meetings as appropriate
- be prepared to occasionally provide expert advice on relevant issues outside of SAG meetings, as requested
- support the Authority in the generation of Guidelines to establish quality standards for the conduct of HTA in Ireland
- support the Authority in the development of methodologies for effective HTA in Ireland
- advise the Authority on its proposed HTA Guidelines Work Plan and on priorities as required
- support the Authority in achieving its objectives outlined in the HTA Guidelines Work Plan
- review draft guidelines and other HTA documents developed by the Authority and recommend amendments as appropriate
- contribute to the Authority's development of its approach to HTA by participating in an evaluation of the process as required.

The Authority gratefully acknowledges all those who contributed to the development of these guidelines.

The membership of the Scientific Advisory Group is as follows:

Chairperson: Dr Michael Barry
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The Authority gratefully acknowledges all those that contributed to the development of these guidelines.

Record of Updates

Date	Title/Version	Summary of changes
November 2010	*Guidelines for the Budget Impact Analysis of Health Technologies in Ireland*	First national budget impact analysis guidelines
January 2014	*Guidelines for the Budget Impact Analysis of Health Technologies in Ireland 1.1*	Minor revisions and reorganisation of text. Updated VAT rate and pay-related costs calculation.
July 2014	*Guidelines for the Budget Impact Analysis of Health Technologies in Ireland 1.2*	Minor revisions to Appendix 4

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This document is one of a set that describes the methods and processes for conducting health technology assessment in Ireland.

The document is available from the HIQA website (www.hiqa.ie).

List of Abbreviations

BIA	budget impact analysis
CBA	cost-benefit analysis
CEA	cost-effectiveness analysis
CMA	cost-minimisation analysis
CPI	Consumer Price Index
CUA	cost-utility analysis
DPS	drugs payment scheme
DRG	diagnosis related groups
EU	European Union
GMS	general medical services
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
LTI	long-term illness
LYG	life years gained
PCRS	Primary Care Reimbursement Service
PPP	purchasing power parity
PRSI	pay-related social insurance
PSA	probabilistic sensitivity analysis
QALY	quality-adjusted life years
RCT	randomised controlled trials
RIA	regulatory impact analysis
SAG	Scientific Advisory Group
VAT	Value Added Tax

1. Introduction

Health technology assessment (HTA) has been described as 'a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner'.[1] The scope of the assessment depends on the technology being assessed, but may include any, or all of these issues. The purpose of HTA is to inform health policy decisions that promote safe, effective, efficient, patient-focussed healthcare.

The primary audience for HTAs is decision makers within the publicly-funded health and social care system. It is recognised that the findings of a HTA may also have implications for other key stakeholders in the Irish healthcare system. These include patient groups, the general public, clinicians, other healthcare providers, academic groups and the manufacturing industry.

The HTA guidelines provide an overview of the principles and methods used in assessing health technologies. They are intended as a guide for those involved in the conduct or use of HTAs in Ireland. The purpose of the HTA guidelines is to promote the production of assessments that are timely, reliable, consistent and relevant to the needs of decision makers and key stakeholders.

The Budget Impact Analysis Guidelines represent one component of the overall HTA guidelines. They are limited to the methodological guidance on the conduct of budget impact analysis (BIA) and are intended to promote best practice in BIA. These guidelines are intended to be viewed as a complementary document to the economic guidance section of the HTA guidelines. They are intended to inform BIA conducted by, or on behalf of the Health Information and Quality Authority, the National Centre for Pharmacoeconomics, the Department of Health and Children and the Health Service Executive (HSE), to include health technology suppliers preparing applications for reimbursement.

The guidelines are intended to be applicable to all healthcare interventions, including pharmaceuticals, procedures, medical devices, broader public health interventions, and service delivery models. Consequently, the guidelines are broad in scope and some aspects may be more relevant to particular interventions than others.

These guidelines have drawn on existing guidelines for BIA and published research[2-10] and are reviewed and revised on an ongoing basis following consultation with the various stakeholders, including those in the Scientific Advisory Group.

1.1. Budget impact analysis guidelines

The guidelines outline what are considered to be the optimal methods for conducting budget impact analysis in health technology assessment (HTA) in Ireland. The goal of the guidelines is to inform decision making within the publicly-funded health and social care system in Ireland, so that the resources available to the system can be used 'in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public'.[11]

1.2. Document layout

For ease of use, a list of the guideline statements that summarise the key points of the guidance is included at the end of this chapter. These guideline statements are also included in italics at the beginning of each section for the individual elements of the assessment in chapter 2.

1.3. Explanation of terms

A number of terms used in the guidelines may be interpreted more broadly elsewhere or have synonymous terms that may be considered interchangeable. The following outlines the specific meanings that may be inferred for these terms within the context of these guidelines and identifies the term that will be used throughout the guidelines for the purpose of consistency.

'Economic evaluation' refers to an analysis that evaluates the costs and consequences of heath technologies. It includes cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA). These are reviewed in detail in the *Guidelines for the Economic Evaluation of Health Technologies in Ireland*. The term 'economic evaluation' should be considered to be interchangeable with any of the terms CEA, CUA or CBA, with the term 'economic evaluation' used throughout these guidelines for the purpose of consistency.

'Technology' includes any intervention that may be used to promote health, to prevent, diagnose or treat disease, or that is used in rehabilitation or long-term care. This includes: pharmaceuticals, devices, medical equipment, medical and surgical procedures, and the organisational and supportive systems within which healthcare is provided. Within the context of these guidelines the terms 'intervention' and 'technology' should be considered to be interchangeable, with the term 'technology' used throughout for the purpose of consistency.

'Reimbursement' refers to the decision to fund a new technology. This includes: agreements to pay a manufacturer for a good or service supplied, decisions to implement new programmes (e.g. a public health screening

programme) and decisions regarding changes to the service setting within which care is provided.

1.3.1. Definition of budget impact analysis

Budget impact analysis (BIA) has been defined as a tool to predict the potential financial impact of the adoption and diffusion of a new technology into a healthcare system with finite resources.[12] Although different specifications may be used for a BIA, within the context of these guidelines, BIA refers to an analysis of the added financial impact of a new health technology for a finite period.

1.3.2. Distinction between economic evaluation and budget impact analysis

Whereas an economic analysis addresses the additional health benefit gained from investment in a technology – such as the cost per additional quality-adjusted life year (QALY) gained – BIA addresses the affordability of the technology, for example the net annual financial cost of adopting the technology for a finite number of years. Although BIA and an economic evaluation have many similar data and methodological requirements, there are key distinctions between the two approaches:

- BIA is not an economic analysis, but is based on the principles of accounting[7]
- economic evaluations are typically not modelled for the actual anticipated size of the patient population, whereas this is required for BIA
- economic evaluations report costs and consequences (health outcomes), while BIA report costs only (see Table 1 on the next page)
- the results of economic evaluation are presented as the discounted present value of costs and effects in one period, while BIA report the costs for each year in which they occur
- BIA is typically concerned with costs over a short time horizon, whereas the time horizons required in economic evaluations are generally much longer.

Where both an economic evaluation and a BIA are conducted as part of a HTA, they are expected to be driven by the same core assumptions and evidence and should be complementary and consistent with each other.

Table 1: Comparison of budget impact analysis and economic evaluations

Parameter	Budget impact analysis	Economic evaluation
Underlying concept	Affordability	Value for money
Purpose	Financial impact of introducing a technology	Efficiency of alternative technologies
Study timeframe	Usually short-term (1 to 5 years)	Usually long-term (e.g. lifetime)
Health outcomes	Excluded	QALYs (quality-adjusted life years)
Discounting	No	5%
Result	Total and incremental annual costs	Incremental cost per unit of health outcome achieved

1.3.3. Purpose and timing of budget impact analysis

BIA helps to predict how adoption of a new technology for a given condition will impact on the overall expenditure for that condition. BIA may then be used to:

- provide data to inform an assessment of the affordability of a technology at a given price for a specified population prior to its reimbursement
- act as a budget or service planning tool to inform decisions regarding the allocation or re-allocation of resources subsequent to a decision to reimburse a technology.

Within HTA, a BIA complements the information obtained from the medical, social, economic and ethical assessment of a technology. As a comprehensive HTA may be time and labour intensive, a BIA may be conducted in isolation to determine the financial impact of a technology. This may then be used as one of the criteria to determine if the expense of a full HTA is warranted.

1.4. Reference case

Key to any HTA is a comprehensive, transparent and reproducible budget impact analysis that includes all relevant costs. While acknowledging the need for flexibility, a consistent methodological approach is required to facilitate comparisons between technologies and disease areas and over time.

These guidelines specify the preferred methods or 'reference case' that should be used in the primary analysis for HTAs. Use of a standard reference case approach increases transparency in the process and confidence that differences in study outcomes are representative of differences between technologies as opposed to differences in methodologies.

The use of a reference case does not preclude the inclusion of other analyses in the assessment. However, the rationale supporting the inclusion of additional non-reference case analyses should be outlined and the information presented separately from that of the reference case. It is also recognised that adoption of the reference case methods may not always be possible.

The use of any alternate methods in the primary analysis should be clearly documented and justified and an attempt should be made to quantify the likely consequences of such an approach.

1.5. Summary of Guideline Statements

Perspective (Section 2.1) The BIA should be conducted from the perspective of the publicly-funded health and social care system (HSE) in Ireland.

Technology (Section 2.2) The technology should be described in sufficient detail to differentiate it from its comparators and to provide context for the study.

Choice of comparator(s) (Section 2.3) The preferred comparator for the reference case is 'routine care,' that is, the technology or technologies most widely used in clinical practice in Ireland. When both an economic assessment and BIA are conducted, the same comparator(s) should be used in both assessments.

Timeframe (Section 2.4) The core analysis should estimate the annual financial impact over a minimum timeframe of five years.

Target population (Section 2.5) The target population should be defined based on the approved indication for the technology. Stratified analysis of subgroups (that have been ideally identified a priori) is appropriate; these should be biologically plausible and justified in terms of clinical and cost-effectiveness evidence, if conducted.

Costing (Section 2.6) The costs included should be limited to direct costs associated with the technology that will accrue to the publicly-funded health and social care system. The methods used to generate these costs should be clearly described and justified, with all assumptions explicitly tested as part of the sensitivity analysis. As costs are presented in the year they are incurred, no discounting is required.

Efficacy, Effectiveness and Safety (Section 2.7) For the reference case, evidence regarding the impact of a technology on patient outcomes that affect resource utilisation must be incorporated into the BIA. Where available, evidence from randomised clinical trials (RCTs) should be used to quantify efficacy in the reference case analysis. Meta-analysis may be used to synthesise outcome data provided the homogeneity and quality of the studies included justifies this approach.

Budget impact model (Section 2.8) The budget impact model should be clearly described, with the assumptions and inputs documented and justified. Two primary scenarios should be modelled: the baseline scenario that reflects the current mix of technologies and forecasts the situation should the new technology not be adopted, and the new technology scenario, where it is. The methods for the quality assurance of the model should be detailed and documentation of the results of model validation provided. Key inputs should be varied as part of the sensitivity analysis. The model should be of the simplest design necessary to address the budget impact question using a readily available software package.

Uncertainty (Section 2.9) Scenario analyses for a range of plausible scenarios and sensitivity analysis must be employed to systematically evaluate the level of uncertainty in the budget estimates due to uncertainty associated with the model and the key parameters that inform it. The range of values provided for each parameter must be clearly stated and justified, and justification provided for the omission of any model input from the sensitivity analysis

Reporting (Section 2.10) A well structured report should be provided with information provided on each of the elements outlined in the guidelines. Input parameters and results should be presented both in their disaggregated and aggregated forms with both incremental and total budget impact reported for each year of the timeframe. A fully executable budget impact model should be submitted to enable (confidential) third-party validation of the results.

2. Budget Impact Analysis Guidelines in Detail

2.1. Perspective

The BIA should be conducted from the perspective of the publicly-funded health and social care system (HSE) in Ireland.

The perspective of a study is the viewpoint from which the study is conducted (e.g. public payer, individual, society) and defines whose costs and resources should be examined.

The costs perspective for the reference case should be that of the publicly-funded health and social care system. Only those costs and resource requirements relevant to the HSE should be included in the analysis.

There may be reasons for adopting a broader or a narrower perspective in some cases:[13]

- a broader public sector budget perspective may be justified where significant budget implications for other publicly-funded services or transfer payments are anticipated. For example, interventions enabling patients to return to employment will have resource implications for incapacity benefits, consumption and employment-related taxes. The use of this perspective must be justified and the data, assumptions and costs from this broader perspective clearly documented and presented as a scenario analysis in addition to the reference case
- a narrower perspective may be useful for BIA conducted at the local healthcare level (e.g., a decision to introduce a technology within an individual hospital or clinic setting) or when considering the distribution of budget impacts within different parts of the HSE and the possible requirement for internal budget rebalancing (e.g., the drug budget perspective).

2.2. Technology

The technology should be described in sufficient detail to differentiate it from its comparators and to provide context for the study.

Information should be provided about the technology under assessment to include sufficient information on its technical characteristics to differentiate it from comparator technologies, its regulatory status and the specific application (e.g., treatment indication / intended use, purpose, place and context) that is being explored as part of the assessment. Pertinent information on necessary investments, information requirements, tools or additional training specific to the technology should be included, as appropriate. The technology may form part of a treatment sequence, in which

case the associated technologies in the sequence also need to be clearly defined and described.

2.3. Choice of comparator(s)

The preferred comparator for the reference case is 'routine care', that is, the technology or technologies most widely used in clinical practice in Ireland. When both an economic assessment and BIA are conducted, the same comparator(s) should be used in both assessments.

The usual comparator should be 'routine care', that is, the treatment that is most widely used in clinical practice in Ireland. There may be more than one appropriate comparator technology because of variations in routine practice within the Irish healthcare system, including where routine practice may differ from what is considered best practice (as defined by evidence-based clinical practice guidelines) or the most appropriate care. When both an economic assessment and BIA are conducted, the same comparator(s) should be used in both assessments.

The comparators should be clearly identified and justified with sufficient detail provided, so that their relevance may be assessed. Any technology may be considered for the comparator if it is part of established clinical practice for that indication in Ireland. The evidence of efficacy and safety included must be relevant to the target population and indication to which the assessment relates. In practice, this could mean, for example, that a pharmaceutical without marketing authorisation for the indication and target population defined in the assessment could be included as a comparator. However, it must be evident that due regard has been given to the extent and quality of evidence for the unlicensed use.

Where the technology and its comparator(s) form part of a treatment sequence, a comparison of different sequencing options and their impact on the total cost of various options should be considered. Comparators are not limited to specific interventions, but may include alternative treatment sequences or alternative rules for starting and stopping therapy. 'Routine care' may be defined by a complex amalgam of treatments including first and second line treatments. In the absence of an active comparator, it is appropriate to have a comparator of 'no intervention.' In some situations, such as when current practice is not well defined or standardised, the use of a comparator of 'no intervention' in addition to 'routine care' can provide useful information on the relative benefits of the technologies.

2.4. Timeframe

The core analysis should estimate the annual financial impact over a minimum timeframe of five years.

The timeframe represents the most immediate planning horizon over which resource use will be planned. The annual financial impact of a technology should be estimated for a minimum of five years from the time of reimbursement. It is noted that peak or steady-state resource use may not be achieved in such a timeframe. Reasons include:

- slow diffusion of the new technology, possibly due to capacity constraints or slow adoption by practitioners
- some technologies may be used for many years, such as treatment for chronic conditions or screening programmes, consequently they may take time to achieve their steady state number of users.

The 'steady state' is used to describe the situation where the numbers of treated individuals may still be growing, but only slowly due to population growth and demographic ageing, rather than marked changes in the proportion of eligible individuals using the technology. The timeframe should also take consideration of the specific technical characteristics of individual devices, for example, battery life and the requirement for replacement of same. The same time horizon should be applied to all technologies in the assessment.

Using a short timeframe may result in inadequate estimates of the long-term resource requirements. The requirement for a longer-term analysis should be considered in each case and conducted as necessary.

2.5. Target population

The target population should be defined based on the approved indication for the technology. Stratified analysis of subgroups (that have been ideally identified a priori) is appropriate; these should be biologically plausible and justified in terms of clinical and cost-effectiveness evidence, if conducted.

The target population is defined as the individuals with a given condition or disease who might avail of the technology being assessed within the defined time horizon. It is important to note that the target population represents an open cohort. In each year of the time horizon, individuals may join or leave the target population, mirroring the real-life situation. This is in contrast to economic evaluations, where modelling exercises frequently use a closed cohort (no additions to, or removals from the population) and results are extrapolated to the general population.

2.5.1. Demography

The age and sex of the target population should be described in adequate detail. Population data should be the most up to date available to facilitate an

accurate estimate of the target population size. The absolute size of the target population must be reported.

2.5.2. Epidemiology

To determine the potential demand for the new technology being assessed, clear information on the index condition is required. Irish epidemiology data should be used where available. Use of any non-Irish data sources should be justified. The prevalence of the condition under consideration should be reported, where applicable. The expected annual incidence of the condition for the study timeframe (e.g., the first five years following introduction of the technology) and mortality rates, where applicable should be reported, so that an accurate reflection of the changes to the size and makeup of the target population is given. Depending on the technology under assessment, data on the frequency of service usage (e.g. episodes of care, frequency of device reprogramming or service monitoring) may be required, and should be reported where relevant.

2.5.3. Unit of analysis

There are two possible units of analysis on which to base a BIA: patients and episodes of care. The two units differ as individual patients may have repeated episodes of care. A patient-based analysis is likely to be compatible with the methodology used in the majority of economic evaluations, while an episode-based methodology corresponds both with the basis on which costs are incurred and with episode-based data. A BIA should clearly state which approach was adopted.

Given that interventions can range from once-only, repeated, periodic or continuous interventions, it should be made clear the number of times or the length of time individuals may experience the intervention or how many treatment events may occur.

2.5.4. Projected demand

The recipient population should be defined based on the approved indication or intended use of the technology. This likely recipient group may be identified by two means,[(14)] with the approach adopted depending on the data available:

- a top-down population approach: this starts from the eligible population, that is, an estimate of the annual number of eligible individuals informed by the demographic and epidemiology data (sum of the prevalent plus the incident cases, excluding those who recover or die) and adjusting for the likely uptake
- a bottom-up approach: this starts from the number of individuals likely to avail of the technology. It includes the number of individuals that will

switch from an existing technology as well as the number of newly treated patients. These estimates may be informed by existing claims-based data (e.g., the number of patients currently receiving care for a condition).

Consideration should be given to the likely uptake of the new technology and changes in its demand over the BIA timeframe. Market growth estimates should be evidence-based (e.g., published projections for the population and disease area or condition of interest). This may include the use of international data where the technology or a similar technology has already been introduced, although expert opinion may be used in the absence of appropriate data. Market estimates should account for prevalent and incident cases, including projected changes to the prevalent population because of the introduction of the technology.

2.5.5. Subgroups

The purpose of BIA is to inform decision making. Consideration should thus be given to the inclusion of eligible subgroups that have been clearly defined and identified based on an a priori expectation of differences, supported by a plausible biological or clinical rationale for the subgroup effect. Options for subgroup analysis include by treatment indication (e.g., first-line, second-line, salvage therapy) and by treatment setting (primary or secondary care). If both an economic evaluation and BIA are conducted, the same subgroups should be used for both analyses, with the BIA limited to those subgroups for which a difference in cost-effectiveness versus usual care has been determined. A subgroup analysis will have additional data requirements. Such analyses must be supported by relevant and reliable data.

2.6. Costing

The costs included should be limited to direct costs associated with the technology that will accrue to the publicly-funded health and social care system. The methods used to generate these costs should be clearly described and justified, with all assumptions explicitly tested as part of the sensitivity analysis. As costs are presented in the year they are incurred, no discounting is required.

Three steps are recognised in costing: identifying the resource use that may change, estimating the size of these changes and determining the relevant costs for these changes. The perspective that should be adopted is that of the publicly-funded health and social care system for both the use and cost-basis of these resources. As costs are presented in the year they are incurred, no discounting is required.

The resource-use analysis should include both the candidate technology (for which the BIA is conducted) and the concomitant and resulting care technologies.

2.6.1. Scope of costs

The BIA should include the costs directly associated with the condition for which the intervention is designed. Other care costs directly resulting from the intervention in question should also be included. For a pharmaceutical, this may include the cost of the drug and any other drug-related costs (concomitant therapies, adverse events and infusion-related costs such as consumables and staffing). Costs not directly related to the intervention should not be included in the BIA, such as any additional care costs incurred due to the extension of life following the treatment, but otherwise unrelated to the initial health condition. While the exclusion of such costs may be debated, in many cases they would not be incurred in the timeframe of a BIA, and so would be irrelevant to the core analysis.

2.6.2. Distinction between incremental and total costs

There is an important distinction between the incremental and total cost of introducing a technology. The incremental cost is a net cost, that is, the total cost of the technology less what would have been spent on the current standard of care. The total cost is the gross cost of the technology without excluding displaced costs (costs not incurred) due to replacement of the previous standard of care. The incremental cost will be most relevant to reimbursement decisions, while total cost is often more important to budget and resource use planning (see section 2.6.6).

2.6.3. Capital costs

Capital investment may be required when introducing some new technologies, for example, investment in a new information communications technology (ICT) system or additional accommodation to support a screening programme. Such costs are typically only incurred on a once-off basis. In a BIA, an estimation of annual costs is required. The annual depreciation of any capital costs should be included in the analysis. Guidelines for the appropriate rate of depreciation for specific capital costs and an example of how to depreciate capital costs are included in Appendix 1. Equipment incurring capital costs may also have associated regular maintenance costs that must be taken into account in the analysis.

2.6.4. Labour costs

Labour (pay) should be calculated using consolidated salary scales available from the Department of Health and Children for public-sector employees.[15;16] Associated non-pay costs should be estimated in accordance with the methods outlined in the Regulatory Impact Analysis guidelines issued by the Department of the Taoiseach,[17;18] taking into account the most current information on the cost of superannuation for the public sector.[19;20] If specialist equipment or consumables are also required, these should not be

included as part of the general non-pay costs, but rather included as separate, specific cost items. An example of how to calculate labour (pay) and non-pay costs is included in Appendix 2. Due to the introduction of differential pay scales in 2011 for new entrants, care must be taken to ensure that estimated labour costs are reflective of the mix of salary scales in use. In the absence of relevant evidence, in most circumstances it may be pragmatic to use an unweighted average of the midpoint of the two scales and then use scenario analyses to separately test the impact of using the existing and new entrant pay scales.

2.6.5. Technology costs

Ireland does not have a central medical costs database.[21] As a result, the generation of valid Irish cost data is challenging and time consuming. Until a valid Irish cost model is established, there is a need for flexibility regarding costing of resources. To maximise reproducibility and transferability, all assumptions must be clearly reported and subjected to sensitivity analysis. In particular, where costs are applied from other countries, the assumptions necessary to transfer this data must be explicit, with all costs converted to euro using Purchasing Power Parity indices and reported clearly.[22] An example of how to transfer costs is included in Appendix 3.

Inflation of retrospective costs should use the Consumer Price Index for health.[23] A worked example is included in Appendix 3. If transferring costs from another currency, the inflation should be calculated using the Consumer Price Index for the local currency prior to conversion to euro using Purchasing Power Parity indices (see Appendix 4 for an example).[24]

Technology costs in the assessment should reflect their cost to the HSE. The source of cost data must be reported with the details of what is included in the estimate. Data should be the most recently available, with the cost year specified. Costs based on average resource use (e.g., average dose for average duration of time) should be included annually for the timeframe of the BIA for new and existing technologies. The cost of a new technology should be the most up to date at the time of the BIA submission. It should be consistent with that used in the economic analysis (if conducted) and should reflect the maximum intended reimbursement price sought.

Care should be taken to include the disaggregated prices, margins and fees relevant to the scenario being evaluated. For example, drug cost estimates should reflect mandatory rebates from pharmaceutical manufacturers and importers. These costs may vary with changing pharmaceutical policy. A detailed guide for including drug costs in economic evaluations is available from the National Centre for Pharmacoeconomics.[25] In order to ensure that the evaluation is relevant to decision making, it may in certain circumstances be appropriate to take into account discounted prices in order to reflect the true cost to the HSE. The use of price reductions for the HSE should only be

used if these are consistently available throughout the HSE and are known to be guaranteed for the time specified.

In general, the public list price paid for a drug or device should be used in the reference case analysis. Prices for drugs supplied through the community drugs schemes are listed in the reimbursement files of the HSE Primary Care Reimbursement Service (PCRS) which is updated monthly.[26] For new drugs, a system of external reference pricing is used by the Government based on a currency-adjusted average price to the wholesaler in nine EU Member States. In the absence of a published list price, the price submitted by a manufacturer for a technology may be used, provided this price would apply throughout the HSE. The drug cost used in the reference case should reflect that of the product, formulation and pack size that gives the lowest cost, provided that this represents a realistic choice for use in clinical practice. Drug administration costs, the cost of drug wastage (e.g., from injection vials or from patient non-compliance), and the cost of therapeutic drug monitoring should be itemised and included where appropriate.

In contrast to the economic evaluation where VAT is excluded, VAT at the appropriate rate should be applied to the relevant costs when estimating budget impact.[25] Value-added tax (VAT) is charged on goods and services provided within the state, and is controlled by national and European law. VAT rates vary from 0% to 23% (correct as of September 2013) depending on the classification of the product. For example, the VAT rate for oral medicines is 0% whereas non-oral medicines (including topical preparations and injectables) attract VAT at a rate of 23% (correct as of September 2013).

2.6.6. Cost offsets

The introduction of a new technology may lead to reductions in resource use and costs elsewhere in the system. This may include reduction in use of another technology, savings from switching a drug from intravenous to oral, or a reduction in the use of concomitant therapies due to a reduction in adverse events. The ability of the budget holder to realise savings should be explored through scenario analysis. Although introduction of a new technology may lead to a reduction in staff requirements, it may be difficult for the budget holder to realise any potential savings (e.g., redeployment of staff). The data to support cost-offsets should be evidence-based and use final rather than surrogate outcomes, with all assumptions clearly stated and uncertainty explored as part of a sensitivity analysis.

2.7. Efficacy, Effectiveness and Safety

For the reference case, evidence regarding the impact of a technology on patient outcomes that affect resource utilisation must be incorporated into the BIA. Where available, evidence from randomised clinical trials (RCTs) should

be used to quantify efficacy in the reference case analysis. Meta-analysis may be used to synthesise outcome data provided the homogeneity and quality of the studies included justifies this approach.

Any characteristics of a technology that impact on cost must be incorporated into a BIA. This includes efficacy, effectiveness, safety, and related parameters such as disease prevalence and uptake. These parameters may influence the use of a technology and the need for further treatment.

For the purposes of BIA, relevant patient outcomes are those that influence the use of a technology and the need for further treatment. For example, device failure in a pacemaker will require further surgery to remove the existing device and potentially implant a new device. In that case, the device failure rate is a relevant outcome as it leads to further service use with resource implications. In the reference case, evidence on outcomes should be obtained by means of a systematic review with all data sources clearly described.[27] Where available, evidence from randomised clinical trials (RCTs) should be used to quantify efficacy in the reference case analysis. Evidence generated from this phase is necessary to populate the BIA model. Meta-analysis may be used to synthesise outcome data provided the homogeneity and quality of the studies included justifies this approach.

Experimental, quasi-experimental and non-experimental or observational data may be used to supplement the available RCTs and to enhance the generalisability and transferability of the results. This data can be particularly valuable when estimating baseline event risks (with existing treatments) and for extrapolation of data. The validity of these studies should be assessed as part of the critical appraisal. Potential bias arising from the design of these studies should be assessed and documented.

A structured and systematic approach should also be adopted in assessing the safety of the product. Rare or infrequent adverse events as well as late-onset events are unlikely to be detected as part of RCTs, so the analyst must usually rely on case reports, cohort studies, patient registries and pharmacovigilance or post-marketing spontaneous reports. The sources of information examined should be clearly stated.

All adverse events that are of economic importance should be included in the analysis. Particular attention should be paid to those instances where there are substantive differences between the technologies being compared. Consideration should also be given to their impact on patients' ability to comply with therapy (adherence and persistence) as well as possible consequences for resource utilisation (e.g. prolongation of hospitalisation, use of additional medications, etc.).

2.8. Budget Impact Model

The budget impact model should be clearly described, with the assumptions and inputs documented and justified. Two primary scenarios should be modelled: the baseline scenario that reflects the current mix of technologies and forecasts the situation should the new technology not be adopted, and the new technology scenario, where it is. The methods for the quality assurance of the model should be detailed and documentation of the results of model validation provided. Key inputs should be varied as part of the sensitivity analysis. The model should be of the simplest design necessary to address the budget impact question using a readily available software package.

The BIA model should be transparent with all assumptions explicitly stated and all conclusions drawn from the model conditional on these assumptions. Good modelling practice should be adhered to, so that the quality of the model and the analysis can be ensured.

Data to populate the BIA should be consistent with that used in the corresponding economic evaluation, if conducted. All data sources and any assumptions or adjustments relating to them must be clearly stated. Data can come from a wide range of sources and need not be restricted to a trial setting. The data should be derived from the appropriate Irish setting, if possible. Where Irish data are not available, the data should be suitably adjusted to account for differences in demography, epidemiology and clinical practice. Where data are obtained through unpublished sources, such as expert panels, it is important to state possible sources of bias or conflict of interest in the derivation of those data. All assumptions should be explicitly stated and the impact of changes in the parameter comprehensively tested as part of the sensitivity analysis.

2.8.1. Scenarios to be evaluated

A BIA usually involves the evaluation of a series of scenarios that include a range of technologies rather than a comparison of specific technologies. Two primary scenarios should be modelled:

- the baseline scenario – a forecasted version of the current mix of technologies for the chosen population and subgroups. This forecasts the situation should the new technology not be recommended for reimbursement
- the new technology scenario – a forecasted version of events should the new technology be recommended for reimbursement.

In determining the baseline scenario, the current mix of technologies may include no technology, technologies that may be replaced by the new technology or to which it would be added, or a mix of technologies.

As noted in section 2.5.3, both the baseline forecast and the new technology forecast should anticipate, where possible, changes that are likely to occur in the market during the study timeframe, such as the introduction of other new technologies, new indications for existing technologies (e.g. if the technology is being investigated for other indications) or changes to the reimbursement of a technology (e.g. availability of generic pharmaceuticals following patent expiry of a branded drug). Either population or claims-based data may be used to estimate the size of the current market. All assumptions should be explicitly stated and the validity verified by the use of historical data. Assumptions should be comprehensively tested as part of the sensitivity analyses and include the use of scenarios for high and low uptake respectively.

To facilitate a critical appraisal of the outputs of a model, full documentation of the structure, data elements (identification, modelling and incorporation) and validation (internal, between-model and external) of the model should be addressed in a clear and transparent manner in the model, with explicit justification provided for the options chosen.

2.9. Uncertainty

Scenario analyses for a range of plausible scenarios and sensitivity analysis must be employed to systematically evaluate the level of uncertainty in the budget estimates due to uncertainty associated with the model and the key parameters that inform it. The range of values provided for each parameter must be clearly stated and justified, and justification provided for the omission of any model input from the sensitivity analysis.

There is considerable uncertainty in a BIA. As the purpose of BIA is to inform financial planning and resource allocation, it is critical that the decision maker has an appreciation of the level of uncertainty inherent in the estimates. Uncertainty should be explored through the use of scenario analysis, and deterministic and probabilistic sensitivity analysis, so that the decision maker is informed regarding the sensitivity of the model to specific assumptions. The final analysis should summarise a range of realistic scenarios, rather than be restricted to a single 'best estimate' of the results. The range of values used in the sensitivity analysis should be supported by evidence-based data, where possible.

2.9.1. Parameters

As a minimum, uncertainty around the following key parameters should be explored:

- eligible patient population

- uptake rate of the new technology including the potential for the treatment indication to widen in the timeframe of the analysis (e.g. where a technology is currently being investigated for other indications)
- cost of a new technology and any comparator for which uncertainty exists (e.g. comparators not currently reimbursed or for which published prices are not available)
- cost offsets.

To illustrate the impact of costs on the results, costs should be varied. Where no evidence of cost variation is available, it is pragmatic to vary costs by +/- 20%. The impact of using alternative comparator technologies and variations in the reimbursement scheme for a technology should also be explored, as appropriate.

2.9.2. Deterministic sensitivity analysis

Deterministic sensitivity analysis examines how parameter variables (included as point estimates) impact on model output. These include univariate and multivariate sensitivity analysis.

The simplest form of deterministic sensitivity analysis is the univariate or one-way sensitivity analysis. Here the impact of each variable in the study is examined by varying it across a plausible range of values while holding all other variables constant at their 'best estimate' or baseline value. The resulting difference provides some indication of how sensitive the results might be to a substantial, but not implausible change in that parameter.

In a multivariate analysis, two or more parameters are varied simultaneously in order to study the combined effect of these parameters on the results of the analysis. An example would be to change the projected population and the uptake rate to simultaneously capture the combined impact on resource consumption and the budget. The greater the number of the parameters in the model, the harder it becomes to represent the results. To overcome this difficulty, the multivariate analyses may be presented in the form of scenario analyses, where a series of scenarios are constructed that represent a subset of the possible multivariate analyses. Examples include the use of extreme scenarios, corresponding to the best-case and worst-case situations, or the use of a range of probable scenarios.

2.9.3. Probabilistic sensitivity analysis

Probabilistic sensitivity analysis (PSA) is the preferred approach for exploring uncertainty arising from parameter imprecision (e.g. uncertainty around the true mean values of cost and efficacy inputs) in decision-analytic modelling. With this approach, probability distributions are applied using specified plausible ranges for the key parameters rather than the use of varied point estimates for each parameter. Samples are then drawn at random from these distributions through a large number of simulations, as in the Monte Carlo

simulation method. This enables the uncertainty associated with all parameters to be simultaneously reflected in the results of the model. In addition to reporting the number of Monte Carlo iterations, the range of values for each parameter as well as the distribution range used should be reported and justified. The amount that each parameter contributes to decision uncertainty should be quantified. Although computationally challenging, PSA produces a more realistic assessment of parameter uncertainty that the more simplistic deterministic analyses methods.[28]

2.10. Reporting

A well structured report should be provided with information provided on each of the elements outlined in the guidelines. Input parameters and results should be presented both in their disaggregated and aggregated forms with both incremental and total budget impact reported for each year of the timeframe. A fully executable budget impact model should be submitted to enable (confidential) third party validation of the results.

2.10.1. General remarks

The purpose of HTA is to inform decision making about new and existing technologies. Implicit then is the requirement that a HTA should address the needs of those charged with making decisions. Within this context, BIA should be transparent, accessible and explicitly state and justify any assumptions that have been made. Input parameters and results should be presented annually in their disaggregated and aggregated forms. All input parameters should be consistent with those used in the economic analysis, if conducted. Estimated annual resource use should be reported in terms of natural units as well as the financial costs. The limitations of the report should be explicitly noted.

2.10.2. Resource use

Annual estimates of resources used should be reported for each year of the timeframe. Results should be reported in terms of their natural units as well as their financial cost. Reporting in natural units is important to indicate the potential for:

- additional resource requirements, particularly where there may be capacity constraints regarding the provision of such resources (e.g., number of screening colonoscopies)
- resource savings, particularly where the potential to realise such savings may be difficult (such as reallocation of staff or capital equipment).

This information should be presented in a tabular format, broken out by the resource type (such as for an intravenous drug, costs should be broken out by drug cost and infusion-related costs [consumables, nursing time]).

2.10.3. Costs

Costs should be reported on an annual basis for each year of the timeframe. As costs are presented in the year they are incurred, no discounting is required. The financial costs of the different types of resource use should be reported in a disaggregated form (such as component cost, mark-up, professional fees, VAT).

2.10.4. Budget impact

The estimated annual total and incremental budget impacts should be reported separately for each year of the timeframe. The total budget should reflect the annual cost of providing the technology. The incremental budget impact should reflect the annual net budget implications and should specify relevant replacement costs for existing technologies and any potential cost offsets.

2.10.5. Reporting by subgroup

There may be justification for presenting results on a disaggregated basis for particular subgroups. This is particularly relevant where cost-effectiveness differs by subgroup. Evidence of varying cost-effectiveness could provide grounds for a selective approval of a technology for particular subgroups. The BIA should provide the necessary information to support the decision-makers in their deliberations.

2.10.6. Scenario and sensitivity analysis

The results of the scenarios analysed should be described in summary form. The range for each parameter estimate used in the sensitivity analysis should be tabulated with sources for those distributions listed. The results of the sensitivity analysis should be described and a graphical representation of the results (such as a tornado chart) included for clarity.

2.10.7. Budget impact model

Technology manufacturers making submissions for the purpose of reimbursement of their product should include a fully executable budget impact model as part of the submission to enable confidential third-party validation of the results and to enable the decision maker test alternate plausible parameter values, as required.

Appendices

Appendix 1 - Depreciation of assets [*]

In accordance with Health Service Executive accounting policies, the accounting treatment to be used depends on the asset type.

Asset Type	Accounting treatment
Land	Land is not depreciated
Buildings	Depreciated at 2.5% per annum, straight line basis
Modular buildings (i.e. prefabricated)	Depreciated at 10% per annum, straight line basis
Work in progress	No depreciation
Equipment – computers and ICT systems	Depreciated at 33.33% per annum, straight line basis
Equipment – other	Depreciated at 10% per annum, straight line basis
Motor vehicles	Depreciated at 20% per annum, straight line basis

Example: Depreciate a new office block valued at €5,000,000 completed 1 January 2014	
Year	**Depreciation Charge**
2014	€125,000
2015	€125,000
2016	€125,000
2017	€125,000
2018	€125,000
2019	€125,000
2020	€125,000
2021	€125,000
Continue charging for each year until the asset is disposed of or fully depreciated	

[*] Personal Communication, J Leech, General Manager, Vote, Treasury and Capital Finance Directorate, HSE

Of note, within the HSE, depreciation is not charged to the Income and Expenditure account, but is instead is charged to the Capitalisation Account in the Balance Sheet.

Appendix 2 - Adjusting for pay-related costs in Ireland

Labour (pay) should be calculated using consolidated salary scales available from the Department of Health for public-sector employees.[15;29] An average salary cost should be used for the relevant grade by taking a cash value mid-way between the lowest and the highest points on the scale.[17;18]

Associated non-pay costs should be estimated in accordance with the methods outlined in the Regulatory Impact Analysis (RIA) guidelines issued by the Department of the Taoiseach. This method includes adjustments for non-pay costs associated with hiring additional staff including employers' PRSI, superannuation, as well as general overheads such as rent, light and heat, office facilities, telephone, general supplies, etc.[17;18] The net pension cost as a percentage of pensionable remuneration is an estimated 4% for healthcare workers in the public sector.[17]

The total staff cost is calculated as follows:

A	Pay	Mid-point of pay range
B	Direct Salary Cost	A + Employers PRSI
C	Total Salary Cost	B + (Imputed Pension Cost = 4% of A)
D	Total Staff Cost	C + Overheads (25% of A)

Example:

- a staff nurse has 11 points on a pay scale ranging from:€30,234 to €43,800 (as of 1st January 2010); the 6th point or mid point of this scale is €37,408.
- direct salary cost is €37,408 + 10.75%(€37,408) = €41,429
- total salary cost is €41,429 + 4%(€37,408) = €42,925
- total staff cost is €42,925 + 25%(€37,408) = €52,277
- therefore, the total cost associated with employing an additional staff nurse includes the pay and non pay costs and is estimated at €52,277.

Notes:

- If specialist equipment or consumables are also required these should not be included under the general, non-pay costs, but rather as separate cost items.
- These are average costs and are applicable only on a general basis.
- Formulae for the calculation of daily and hourly rates are available in the RIA guidelines and should be consulted, where appropriate.

Appendix 3 - Inflating retrospective health costs using the Consumer Price Index

The most up-to-date costs should be used where possible, however if inflating retrospective costs the CPI for health should be used.

The CPI is the official measure of inflation in Ireland. It is designed to measure, in index form, the change in the average level of prices paid for consumer goods and services within Ireland. The overall CPI is broken down into the 12 divisions (of which health is one), and each of these divisions is constructed based on a weighted aggregation of subsections.

The health component is made up of three sections: medical products, appliances and equipment, outpatients services and hospital services. Each of these sub-sections are in turn broken down further. So for 'medical products, appliances and equipment' there are three further sub-groups: pharmaceutical products, therapeutic appliances and equipment, and other medical products. For each of these sub-groups, a small number of items are chosen and priced as a representative sample of goods.

If one of sub indices is used in place of the overall CPI for health the reasons why it is the more relevant index must be clearly justified, and the underlying items included in calculating the index should be checked.

Data on all 12 divisions, sub-sections, and the groups within them are produced monthly and available on the CSO website.
http://www.cso.ie/px/pxeirestat/Database/eirestat/Consumer%20Prices%20Monthly%20Series/Consumer%20Prices%20Monthly%20Series_statbank.asp?SP=Consumer%20Prices%20Monthly%20Series&Planguage=0

Example:

Convert €50 (2010 to 2013) using the CPI for Health[23]

Consumer Price Index by Commodity Group, Month and Statistic		
Month	**2010**	**2013**
January	98.2	101.2
February	96.2	101.4
March	96.1	101.5
April	96.1	101.7
May	96.2	101.5
June	96.2	101.6
July	96.7	101.7
August	96.7	-
September	96.7	-
October	97.6	-
November	97.5	-
December	97.5	-
Average	96.8	101.5

Using the Formula:

[(Latest Index Number/Earlier Index Number)x100] - 100

Price increase = [(101.6/96.2)x100] – 100

= 5.61%

Therefore, €50 in 2010 is equivalent to €52.81 in 2013.

When converting historical cost data from one country to another, costs should first be inflated to current costs using the CPI data from the origin country, before converting to local currency using the purchasing power parity index (see Appendix 4).

Appendix 4 - Transferring costs to Ireland using the Purchasing Power Parity Index

The Organisation for Economic Co-operation and Development (OECD) details the number of specified monetary units needed in 30 different countries to buy the same representative basket of consumer goods and services. In each case the representative basket costs a hundred units in the country whose currency is specified.[30]

The purchasing power parities (PPPs) used to derive the table are obtained by extrapolating the 2011 PPPs for private final consumption expenditure using the relative rates of inflation between the countries as measured by their consumer price indices. Unless a country is a high inflation country, its PPP will tend to change slowly over time. Month-to-month changes in comparative price levels are more likely to be the result of exchange rate fluctuations. Of note:

- for European countries:
  - PPPs for **2006-2007, 2009-2010, 2012** are benchmark results calculated by Eurostat[31]
  - PPPs for 2009 are OECD estimates
- for non-European countries, all PPP are OECD estimates based on the triennial benchmark results for 2011.

More information is available on the internet site:
http://www.oecd.org/std/prices-ppp/

Example:

Convert £50 (year 2013) to (Irish costs in €) using the PPP

Using the Purchasing Power Parities for 2013,[22] the UK has a PPP of 0.694, and the value is 0.806 for Ireland.

Representative basket costs (U.K.)	0.694
Comparative price level for Irish basket	0.806
2013 value (£)	£50
Converted to Irish costs in €	€58.07

Appendix 5 - HTA Glossary

Some of the terms in this glossary will not be found within the body of these guidelines. They have been included here to make the glossary a more complete resource for users.

Accuracy: the extent to which a measurement, or an estimate based on measurements, represents the true value of the variable being measured. (See also **Validity**).

Adverse event: an undesirable effect of a health technology.

Affordability: considered in a budget impact analysis – can the healthcare system absorb the cost of introducing the new technology? This cost is measured as the net financial cost of adopting the technology for a specified number of years.

Baseline: a term used to describe the initial set of measurements taken at the beginning of a study (after a run-in period, when applicable).

Baseline scenario or Baseline forecast: a forecasted version of the current mix of technologies for the chosen population and subgroups, which forecasts the situation should the new technology not be recommended for reimbursement.

Bias: systematic (as opposed to random) deviation of the results of a study from the 'true' results.

Budget impact analysis (BIA) or Financial analysis: a procedure for comparing only the financial costs and cost offsets of competing options, rather than comparing their clinical and economic costs and benefits.

Capital costs: the costs of buying land, buildings or equipment (e.g. medical equipment) to provide a service (e.g. healthcare).

Comorbidity: the coexistence of a disease, or more than one disease, in a person in addition to the disease being studied or treated.

Comparator: the alternative against which the intervention is compared.

Confidence interval: the computed interval with a specified probability (by convention, 95%) that the true value of a variable such as mean, proportion, or rate is contained within the interval.

Consumer Price Index: this index measures the change in the average price levels (including all indirect taxes) paid for consumer goods and services by all private households in the country and by foreign tourists holidaying in the country.

Cost: the value of opportunity forgone, as a result of engaging resources in an activity (see opportunity cost); there can be a cost without the exchange of money; range of costs (and benefits) included in a particular economic evaluation depends on perspective taken; average costs are average cost per unit of output (i.e. total costs divided by total number of units produced);

incremental costs are extra costs associated with intervention compared to alternative; marginal cost is cost of producing one extra unit of output.

Cost, financial: the monetary value of providing a resource accounted for in the budget of the provider.

Cost analysis: a partial economic evaluation that only compares the costs in monetary units of the proposed technology with its main comparator(s).

Cost-benefit analysis (CBA): an economic evaluation that compares the proposed technology with its main comparator(s) in which both costs and benefits are measured in monetary terms to compute a net monetary gain/loss or benefit gain/loss.

Cost-effective (value for money): a proposed technology is considered cost-effective for a specified main indication if the incremental benefits of the proposed technology versus its main comparator(s) justify its incremental costs and harms.

Cost-effectiveness analysis (CEA): an economic evaluation that compares, for example, a proposed technology with its main comparator(s) having common clinical outcome(s) in which costs are measured in monetary terms and outcomes are measured in natural units, e.g. reduced mortality or morbidity.

Cost-minimisation analysis (CMA): an economic evaluation that finds the least costly alternative technology, for example, after the proposed technology has been demonstrated to be no worse than its main comparator(s) in terms of effectiveness and adverse events.

Cost-utility analysis (CUA): an economic evaluation that compares the proposed technology with its main comparator(s) in which costs are measured in monetary terms and outcomes are measured in terms of extension of life and the utility value of that extension, e.g. using quality-adjusted life years (QALYs).

Critical appraisal: a strict process to assess the validity, results and relevance of evidence.

Deterministic sensitivity analysis (DSA): a method of decision analysis that uses both one-way (variation of one variable at a time) and multi-way (two or more parameters varied at the same time) sensitivity analysis to capture the level of uncertainty in the results that may arise due to missing data, imprecise estimates or methodological issues. (Compare with **Probabilistic sensitivity analysis**.)

Direct costs: the fixed and variable costs of all resources (goods, services, etc.) consumed in the provision of a technology as well as any consequences of the intervention such as adverse effects or goods or services induced by the intervention. These include direct medical costs and direct non-medical costs such as transportation or child care.

Direct medical costs: medical costs that vary with the healthcare provided (e.g. doctors' salaries).

Direct non-medical costs: the non-medical costs of treating a patient, e.g. transportation provided to and from a medical appointment.

Disability-adjusted life years (DALYs): a unit of healthcare status that adjusts age-specific life expectancy by the loss of health and years of life due to disability from disease or injury. DALYs are often used to measure the global burden of disease.

Discounting: the process used in economic analyses to convert future costs or benefits to present values using a discount rate. Discounting costs reflects societal preference for costs to be experienced in the future rather than the present. Discounting benefits reflects a preference for benefits to be realised in the present rather than at a later date.

Discount rate: the interest rate used to discount or adjust future costs and benefits so as to arrive at their present values, e.g. 5%. This is also known as the opportunity cost of capital investment.

Economic evaluation: application of analytical methods to identify, measure, value, and compare costs and consequences of alternatives being considered; addresses issue of efficiency to aid decision making for resource allocation. It is an umbrella term covering CBA, CEA, CMA and CUA.

Economic model: economic models provide a means of bringing together different types of data from a range of sources and provide a framework for decision making under conditions of uncertainty. Modelling may be used to combine different data sets changing the information collected from a clinical trial into a form that can be used, to extrapolate short-term clinical data to longer term, to link intermediate with final endpoints, to generalise from clinical trial settings to routine practice and to estimate the relative effectiveness of technologies where these have not been directly compared in clinical trials.

Effectiveness: the extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) in routine clinical practice (contrast with **Efficacy**).

Efficacy: the extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) when studied under controlled research conditions (contrast with **Effectiveness**).

Epidemiology: the study of the distribution and determinants of health-related conditions or events in defined populations.

Extrapolation: prediction of value of model parameter outside measured range or inference of value of parameter of related outcome (e.g. extrapolation of reduction in rate of progression to AIDS from improvement in HIV viral load).

Final outcome: a health outcome that is directly related to the length of life, e.g. life-years gained or quality-adjusted life years.

Generalisability: the problem of whether one can apply or extrapolate results obtained in one setting or population to another. Term may also be

referred to as 'transferability', 'transportability', 'external validity', 'relevance', or 'applicability'.

Gross or Macro costing: costing approach that uses large components as basis for costing, such as cost per hospital day (compare with **Micro-costing**).

Health outcome: a change (or lack of change) in health status caused by a therapy or factor when compared with a previously documented health status using disease-specific measures, general quality of life measures or utility measures.

Health technology: the application of scientific or other organised knowledge – including any tool, technique, product, process, method, organisation or system – in healthcare and prevention. In healthcare, technology includes drugs, diagnostics, indicators and reagents, devices, equipment, and supplies, medical and surgical procedures, support systems and organisational and managerial systems used in prevention, screening diagnosis, treatment and rehabilitation.

Health technology assessment (HTA): this is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.

Healthy-years equivalent (HYE): this is a health outcome measure that combines preferences for quality of life and quantity of life in a single metric. It represents that hypothetical number of years spent in good health that is considered equivalent to the actual number of years spent in a defined imperfect state of health or a series of defined imperfect states of health.

Heterogeneity: in the context of meta-analysis, clinical heterogeneity means dissimilarity between studies. It can be because of the use of different statistical methods (statistical heterogeneity), or evaluation of people with different characteristics, treatments or outcomes (clinical heterogeneity). Heterogeneity may render pooling of data in meta-analysis unreliable or inappropriate. Finding no significant evidence of heterogeneity is not the same as finding evidence of no heterogeneity. If there are a small number of studies, heterogeneity may affect results but not be statistically significant.

Incidence: the number of new cases of a disease or condition that develop within a specific timeframe in a defined population at risk. It is usually expressed as a ratio of the number of affected people to the total population.

Incremental costs: the absolute difference between the costs of alternative management strategies of the same medical condition, disease or disorder.

Indication: a clinical symptom or circumstance indicating that the use of a particular intervention would be appropriate.

Indirect costs: the cost of time lost from work and decreased productivity due to disease, disability, or death. (In cost accounting, it refers to the overhead or fixed costs of producing goods or services.)

Intangible costs: the cost of pain and suffering resulting from a disease, condition, or intervention.

Marginal benefit: the additional benefit (e.g. in units of health outcome) produced by an additional resource use (e.g. another healthcare intervention).

Marginal cost: the additional cost required to produce one additional unit of benefit (e.g. unit of health outcome).

Meta-analysis: systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. (Also known as data synthesis or quantitative overview).

Micro-costing: costing approach based on detailed resources used by patient on item-by-item basis (compare with **Gross costing**).

Net benefit: refers to a method of reporting results of economic evaluations in terms of monetary units (called net monetary benefit) or units of outcome (called net health benefit); in cost-benefit analysis, (incremental) net benefit is the difference in total benefit and total cost of the technology less the difference in total benefit and total cost of the comparator.

New technology scenario or New technology forecast: a forecasted version of events should the new technology be recommended for reimbursement.

Opportunity cost: costs of resources consumed expressed as value of next best alternative for using resources.

Outcome: consequence of condition or intervention; in Economic Guidelines, outcomes most often refer to health outcomes, such as surrogate outcomes or patient outcomes.

Perspective: this is the viewpoint from which an economic evaluation is conducted. Viewpoints that may be adopted include that of the patient, the public healthcare payer or society.

Purchasing power parity: this theory states that in an efficient market, the exchange rate of two currencies results in equal purchasing power. The purchasing power indices are currency conversion rates that both convert to a common currency and equalise the purchasing power of different currencies. In other words, they eliminate the differences in price levels between countries in the process of conversion.

Prevalence: the number of people in a population with a specific disease or condition at a given time and is usually expressed as a ratio of the number of affected people to the total population.

Probability: expression of degree of certainty that an event will occur, on scale from zero (certainty that event will not occur) to one (certainty that event will occur).

Probability distribution: portrays the relative likelihood that a range of values is the true value of a treatment effect. This distribution often appears in the form of a bell-shaped curve. An estimate of the most likely true value of the treatment effect is the value at the highest point of the distribution. The area under the curve between any two points along the range gives the probability that the true value of the treatment effect lies between those two points. Thus, a probability distribution can be used to determine an interval that has a designated probability (e.g. 95%) of including the true value of the treatment effect.

Probabilistic sensitivity analysis (PSA): a type of sensitivity analysis where probability distributions are applied to a plausible range of values for key parameters to capture uncertainty in the results. A Monte Carlo simulation is performed and a probability distribution of expected outcomes and costs is generated (contrast with **Deterministic sensitivity analysis**).

Productivity costs: the costs associated with lost or impaired ability to work because of morbidity or death.

Quality-adjusted life year (QALY): a unit of healthcare outcomes that adjusts gains (or losses) in years of life subsequent to a healthcare intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost-utility across different technologies and health problems. Analogous units include Disability-Adjusted Life Years (DALYs) and Healthy-Years Equivalents (HYEs).

Sensitivity analysis: a means to determine the robustness of a mathematical model or analysis by examining the extent to which results are affected by changes in methods, parameters or assumptions.

Scenario analysis: a method of decision analysis that considers future events by considering possible alternative scenarios. It can use both one-way (variation of one variable at a time) and multi-way (two or more parameters varied at the same time) to capture the level of uncertainty in the results.

Statistical significance: a conclusion that a technology has a true effect, based upon observed differences in outcomes between the treatment and control groups that are sufficiently large so that these differences are unlikely to have occurred due to chance, as determined by a statistical test. Statistical significance indicates the probability that the observed difference was due to chance if the null hypothesis is true. It does not provide information about the magnitude of a treatment effect. (Statistical significance is necessary but not sufficient for clinical significance.)

Steady-state resource use: the situation where the numbers of treated individuals still be stable or growing slowly, due to population growth and demographic ageing, rather than marked changes in the proportion of eligible individuals using the technology.

Stratified analysis: a process of analysing smaller, more homogeneous subgroups according to specified criteria such as age groups, socioeconomic status, where there is variability (heterogeneity) in a population.

Subgroup: a defined set of individuals in a population group or of participants in a study such as subgroups defined by sex or age categories.

Subgroup analysis: an analysis in which the intervention effect is evaluated in a subgroup of a trial, including the analysis of its complementary subgroup. Subgroup analyses can be pre-specified, in which case they are easier to interpret. If not pre-specified, they are difficult to interpret because they tend to uncover false positive results.

Surrogate endpoint: a measure that is used in place of a primary endpoint (outcome). Examples are decrease in blood pressure as a predictor of decrease in strokes and heart attacks in hypertensive patients, and increase in T-cell (a type of white blood cell) counts as an indicator of improved survival of patients with AIDS. Use of a surrogate endpoint assumes that it is a reliable predictor of the primary endpoint(s) of interest.

Target population: in the context of a budget impact analysis the individuals with a given condition or disease who might avail of the technology being assessed within the defined time horizon.

Technology: the application of scientific or other organised knowledge – including any tool, technique, product, process, method, organisation or system – to practical tasks. In healthcare, technology includes drugs, diagnostics, indicators and reagents, devices, equipment and supplies, medical and surgical procedures, support systems, and organisational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation.

Technology costs: the average costs associated with implementing the technology.

Time horizon or Timeframe: the time span used in the assessment that captures the period over which meaningful differences between costs and outcomes between competing technologies would be expected to accrue.

Tornado diagram: diagrammatic display of the results of one-way sensitivity analysis. Each bar represents the range of change in model results when the parameter is varied from its minimum to maximum values.

Transferability: a trial, study or model has transportability if it can produce unbiased inferences to another specified healthcare system (e.g. from overseas to Ireland).

Transfer (or income transfer) payment: payment made to individual (usually by a government body) that does not perform any service in return; examples are social security payments and employment insurance benefits.

Uncertainty: where the true value of a parameter or the structure of a process is unknown.

Usual care: this is the most common or most widely used alternative in clinical practice for a specific condition. This is also referred to as 'routine care' or 'current practice' or 'typical care'.

Validity: the extent to which technique measures what it is intended to measure.

Valuation: the process of quantifying desirability of outcome in utility or monetary terms or of quantifying cost of resource or individual's productivity in monetary terms.

Value Add Tax: this is a tax on consumer spending. It is collected by VAT-registered traders on their supplies of goods and services to customers. Each such trader in the chain of supply from manufacturer through to retailer charges VAT on his or her sales and is entitled to deduct from this amount the VAT paid on his or her purchases, that is, the tax is on the added value. For the final consumer, not being VAT-registered, VAT is simply part of the purchase price.

Variability: this reflects known differences in parameter values arising out of inherent differences in circumstances or conditions. It may arise due to differences in patient population (e.g. patient heterogeneity – baseline risk, age, gender), differences in clinical practice by treatment setting or geographical location.

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