Guidance on Budget Impact Analysis of Health Technologies in Ireland

16 July 2015

Safer Better Care

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.

- **Supporting Improvement –** Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

- **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.

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 health technology assessment (HTA) may have implications for other stakeholders in the Irish healthcare system, including patients, the general public, clinicians, other healthcare providers, academic groups and the health technology 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. These guidelines provide an overview of the principles and methods that are used in assessing health technologies. They are intended to be 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.

This document is part of the series of guidelines that also includes the Guidelines for Economic Evaluation of Health Technologies in Ireland (2014), Guidelines for Budget Impact Analysis of Health Technologies in Ireland (2014), Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland (2014), Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland (2014) and the Guidelines for the Retrieval and Interpretation of Economic Evaluations of Health Technologies in Ireland (2014).

This document is limited to guidance on budget impact analysis and supports our published Guidelines for Budget Impact Analysis of Health Technologies in Ireland. It is designed to provide more detailed advice and examples to aid those conducting a budget impact analysis in Ireland. It has been primarily designed to support clinical guideline developers as well as other practitioners within the HSE tasked with conducting a budget impact analysis. It is also 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 HSE, to include health technology suppliers preparing applications for reimbursement.

This guidance document has been developed in consultation with the HTA 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, Prof Michael Barry from the National Centre for Pharmacoeconomics, and all who have contributed to the production of these guidelines.

Dr Máirín Ryan

Director of Health Technology Assessment and Acting Deputy Chief Executive Officer
Health Information and Quality Authority

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Process and Acknowledgements

This document is a complementary document to previously published guidelines. This guidance document is limited to budget impact analysis in health technology assessment and is intended to promote best practice in this area. It will be reviewed and revised as necessary, with updates provided online through the Authority's website, www.hiqa.ie. This document forms part of a series of national guidelines for health technology assessment (HTA) in Ireland that the Authority has developed and will continue to expand and review.

The guidance has been developed by the Authority in consultation with its HTA Scientific Advisory Group (the Group). This group includes methodological experts from the field of 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 Scientific Advisory Group meetings, as appropriate

- be prepared to occasionally provide expert advice on relevant issues outside of Scientific Advisory Group 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 membership of the Scientific Advisory Group is as follows:

Professor Michael Barry (Chairperson)	National Centre for Pharmaceoeconomics
Dr J. M. Morris	Director of Scientific Affairs, Health Products Regulatory Agency
Orlaith Brennan	Director of Commercial Affairs, Irish Pharmaceutical Healthcare Association
Eibhlin Mulroe	Chief Executive Officer, Irish Platform for Patients' Organisations, Science and Industry
Dr Eibhlín Connolly	Deputy Chief Medical Officer, Department of Health
Professor Ciarán O'Neill	Professor of Health Technology Assessment, NUI Galway
Dr Anne Dee	Consultant in Public Health Medicine, Health Service Executive (HSE)
Sarah O'Neill	Technical Director, DCC Vital, Irish Medical and Surgical Trade Association
John Dowling	Patient Representative, Irish Cancer Society
Dr Máirín Ryan	Director, Health Technology Assessment, HIQA
Professor Mike Drummond	Professor of Health Economics, University of York
Professor Mark Sculpher	Professor of Health Economics, University of York
Shaun Flanagan	Chief Pharmacist, Corporate Pharmaceutical Unit, HSE
Professor Linda Sharp	Epidemiologist, National Cancer Registry
Dr Patricia Harrington	Head of Assessment, HTA Directorate, HIQA
Dr Alan Smith	Medical Director, Screening Policy, National Cancer Screening Service
Sinead Keogh	Director, Irish Medical Devices Association
Dr Conor Teljeur	Senior Statistician, HTA Directorate, HIQA
Dr Teresa Maguire	Health of the Research Management Unit, Health Research Board
Dr Lesley Tilson	Chief Pharmacist, National Centre for

	Pharmacoeconomics
Dr Brendan McElroy	Lecturer in Economics, University College Cork
Dr Valerie Walshe	Economist, HSE
Stephen McMahon	Chief Executive Officer, Irish Patients Association
Professor Cathal Walsh	Professor of Statistics, University of Limerick

Contributors

The Authority gratefully acknowledges all those that contributed to the development of this guidance. In particular, the Authority acknowledges the support of the following individuals including clinical guideline developers and others involved in the development of National Clinical Guidelines for quality assurance by the National Clinical Effectiveness Committee.

Dr Sarah Condell, Clinical Effectiveness Unit, Department of Health

Dr Veronica Lambert, School of Nursing and Human Sciences, Dublin City University

Professor Ann Mathews, School of Nursing and Human Sciences, Dublin City University

Dr Kathleen Mac Lellan, Director of Clinical Effectiveness, Department of Health

Dr Eileen Nolan, National Cancer Control Programme

Dr Niamh O'Rourke, Clinical Effectiveness Unit, Department of Health

Record of Updates

Date	Title/Version	Summary of changes
July 2015	Guidance on Budget Impact Analysis	First budget impact analysis guidance document.

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

Other guidelines in the series include:

Guidelines for Economic Evaluation of Health Technologies in Ireland (2014)

Guidelines for Budget Impact Analysis of Health Technologies in Ireland (2014)

Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland (2014)

Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland (2014).

Guidelines for the Retrieval and Interpretation of Economic Evaluations of Health Technologies in Ireland (2014).

List of abbreviations and acronyms

BIA	budget impact analysis
CPI	consumer price index
CSO	Central Statistics Office
GP	general practitioner
HSE	Health Service Executive
HTA	health technology assessment
ICT	information communication technology
NCEC	National Clinical Effectiveness Committee
NCPE	National Centre for Pharmacoeconomics
OECD	Organisation for Economic Co-operation and Development
PCRS	Primary Care Reimbursement Service
PPP	purchasing power parities
PRSI	pay-related social insurance
RCT	randomised control trial
VAT	value-added tax

1.   Introduction

In 2010, the Authority published its Budget Impact Analysis Guidelines (updated in 2014) as part of its suite of HTA guidelines. These guidelines are limited to the methodological guidance on the conduct of budget impact analysis (BIA) and are intended to promote best practice in BIA.

This guidance document is intended as a complementary document to the BIA guidelines. It has been created primarily to support clinical guideline developers who must provide analysis of the budget impact of their recommendations as part of quality assurance by the National Clinical Effectiveness Committee (NCEC) prior to the guidelines being mandated as national clinical guidelines. It may also be used by other practitioners conducting budget impact analysis of new technologies in Ireland. It provides advice on technical aspects that need to be considered when estimating the budget impact. The document is intended to be applicable to all healthcare interventions, including pharmaceuticals, procedures, medical devices, broader public health interventions, and service delivery models. Consequently, the document is broad in scope and some aspects can be more relevant to particular interventions than others.

1.1   Document layout

This document is divided into two distinct sections: the first discusses some general issues when conducting a budget impact analysis which are likely to be of relevance to all budget impact analyses, including the perspective, timeframe, recommended methods for estimating staff costs, inflating and transferring to the most up-to-date values, and useful Irish data sources. The second section outlines the key steps involved in creating a budget impact analysis. For each step in the process, a number of questions that should be considered are listed. To illustrate how the issues can be addressed, examples from a selection of published budget impact analyses are provided as an aid.

1.2   Explanation of terms

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

'Technology' includes any intervention that can 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 this document the terms 'intervention' and 'technology' should be considered to be interchangeable.

1.2.1 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.[1] Although different specifications can be used for a BIA, within the context of this document BIA refers to an analysis of the added financial impact of a new health technology for a finite period that can be useful for resource or budget planning.

2.   Budget Impact Analysis Guidance General Points

2.1   Perspective

The perspective of a study is the viewpoint from which the study is conducted (for example public payer, individual, society) and defines whose costs and resources should be examined. The chosen perspective is a key element,[2] as the budget impact can vary depending on the perspective taken. The BIA should be conducted from the perspective of the publicly-funded health and social care system (HSE) in Ireland, as recommended in the 'Guidelines for the Budget Impact Analysis of Health Technologies in Ireland'.[3] Only those costs and resource requirements relevant to the HSE should be included in the primary analysis.

In some instances, there may be reasons for adopting a broader (for example societal) or narrower (for example within a single institution) perspective, but these alternative perspectives should be presented in addition to the reference case of the HSE.

2.2   Comparator

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.

2.3   Timeframe

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

The timeframe represents the most immediate horizon over which resource use is planned. The annual financial impact of a technology should be estimated for a minimum of five years from the time of its introduction. Timeframes longer than a few years involve considerable assumptions, however they can be useful to demonstrate the cost savings that arise in future years.[4] This may occur when peak or steady state resource use may not be achieved within five years. 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. Reasons for a delay in achieving steady state 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 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.

Some guideline recommendations may be brought in with a relatively short lead in time; others however might need more substantial system change which may take considerable time. The availability of trained staff, equipment, and premises, and the time required to plan and coordinate change all need consideration. For instance, switching patients from one drug to another where both drugs are readily available and in general use might happen relatively quickly. In comparison, service reorganisation may require capital investment undertaken of necessity on an incremental basis which may result in a prolonged lead in.

2.4   Target population

The target population is defined as those with a specified disease who may avail of the technology being considered in the defined time horizon. It is important to note that in each year of the time horizon, people might join or leave the target population, mirroring the real-life situation (for example through developing the

disease, meeting treatment restrictions, disease recovery or death). When the rates for both entering and leaving are the same, the target population size is stable over time. However, the size of the target population will change if the new technology increases time spent in treatment, slows the disease progression, or leads to a reduction in mortality without curing the disease (for example, if treatment is aimed at those with a moderate disease severity and the new treatment slows progression to severe disease, the target population will grow). In addition, an improved ability to identify target patients (for example new diagnostic tests) that increases the target population size needs to be captured.[4] For a chronic disease, it is important to consider whether there is a catch-up effect.[4]

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 should be reported. This can be identified by a top-down population approach: that is, an estimate of the annual number of target people informed by the demographic and epidemiology data.[1]

2.4.1 Unit of analysis

There are two possible units of analysis on which to base a BIA: per patient or per episode of care. The two units differ as individual patients may have repeated episodes of care. The BIA should clearly state which approach is adopted. Specified interventions may range from once-only, repeated, periodic or continuous interventions; it needs to be clear the number of times or the length of time people might experience the intervention or how many treatment events might arise.

2.4.2 Subgroups

Some disease areas might include several subgroups, and this should be considered during the BIA. For instance, a recommendation for early-stage HER-2-positive breast cancer will need an estimation of the annual incidence of breast cancer, the proportion diagnosed at an early stage, and the proportion of these who are HER-2 positive.[5]

2.5 Costing

Costs and savings are classified as actual or opportunity. It should be clear into which category they fall, otherwise there could be a misleading impression of the budget impact of implementing the technology or guideline.[5]

Actual costs or savings involve cash payments or provide cash savings from implementing the technology or guideline.[5] Identifying actual costs is important as they will need to be sourced from within current healthcare budgets.[5] Similarly, where activity is prevented, understanding what the real savings are is necessary.[5] Real savings arise where costs are reduced. For example, ceasing to prescribe an expensive drug results in a cash saving as purchasing the drug is no longer required. In contrast, reducing admissions to intensive care units for a specific condition is unlikely to result in a reduction in overall intensive care bed usage or a reduction in the associated overhead costs; rather, by freeing up resources it could allow for efficiency gains or potentially remove the need for additional investment.

Fixed costs do not change as activity levels increase and decrease, but variable costs vary proportionally with changes in activity levels.[5] For example, a hospital will have just one chief executive constituting a fixed cost that does not change, however the number of staff needed for outpatient clinics may vary according to the outpatient activity levels. A stepped cost is where changes are absorbed to a particular point, but above which they will require substantial additional resources.[5] For example, an increase in the number of MRI scans required may be provided through increased efficiency or increased operating hours, however, beyond a certain point additional MRI machines may need to be purchased and staffed and accommodation built or refurbished to house the additional equipment.

When operating within a finite budget, there may be an opportunity cost associated with introducing a new technology, as the new technology may use additional resources that must be taken from the existing services. Therefore, any benefits from the new technology need to be considered with this in mind.[6]

Opportunity costs are the costs that arise when implementing the technology or guideline that might not affect the actual costs.[5] For instance, the cost of staff training should be estimated. However, as this can typically be a limited once-off use of staff time it will be absorbed without leading to an increase in overall staff numbers. In some instances, the technology alters healthcare use (for example, hospital days or emergency department attendances) and, therefore, impacts the capacity within the system. However, these will typically be opportunity costs which will not result in actual cost savings to the publicly-funded health and social care system (HSE). It is still worthwhile to describe these consequences on use of the health service as it will have implications for planning.[4]

2.5.1 Scope of costs

BIA should include the costs and savings directly associated with the disease for which the technology is designed. Direct costs include those that result directly from

changes to current practice due to the introduction of the guidelines. Alternative care costs that directly result from the technology in question should also be included. For a pharmaceutical, this might include the cost of the drug and costs arising from its impact on admission (for example, daycase instead of inpatient) or monitoring (for example, more or less frequent blood tests) practices. The follow-on consequences – for instance, preventing adverse events, are also considered a direct cost. Costs not directly related to the technology should not be included in the BIA, for example, all additional care costs incurred due to the extension of life following the treatment, which are unrelated to the initial indication.

Discounting is 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. In a BIA, all costs are presented in the year in which they are incurred, so no discounting is required.

2.5.2 Capital costs

In a BIA, an estimation of annual costs is needed. The annual depreciation of all capital costs should be included in the analysis.

According to HSE accounting policies, the accounting treatment 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	

2.5.3 Labour costs

Labour is calculated using consolidated salary scales available from the Department of Health for public-sector employees.[7;8] An average salary cost is used for the applicable grade by taking a cash value midway between the lowest and the highest points on the scale.[9;10] Associated non-pay costs are estimated according to the methods outlined in the Regulatory Impact Analysis guidelines issued by the Department of the Taoiseach.[9;10] This method includes adjustments for non-pay costs associated with hiring extra staff and includes employers' PRSI, superannuation, as well as general overheads for example rent, light and heat, office facilities, telephone, general supplies, etc.[9;10] The pension cost as a percentage of pensionable remuneration is an estimated 4% for public sector healthcare.[9]

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: €27,211 to €43,800 (as of 1st November 2013); the 6th point or midpoint of this scale is €34,666

- direct salary cost is €34,666 + 10.75%(€34,666) = €38,393

- total salary cost is €38,393 + 4%(€34,666) = €39,779

- total staff cost is €39,779 + 25%(€34,666) = €48,446

- therefore, the total annual cost associated with employing an additional staff nurse includes the pay and non pay costs and is estimated at €48,446

Having estimated the full cost of employing a staff member, next, it needs to be decided which measurement unit to use. This might be the annual cost to employ one whole time equivalent or the cost for a specified number of hours.[5] Formulae for the estimation of daily and hourly rates are available in the Regulatory Impact Analysis guidelines and should be consulted.[10]

Due to the introduction of differential pay scales in 2011 for new entrants to the public sector, care must be taken to ensure that estimated labour costs are reflective of the mix of salary scales in use. In the absence of applicable data, in most circumstances it can be pragmatic to use an unweighted average of the midpoint of the two scales.

2.5.4 Technology costs

Technology costs should reflect their cost to the publicly-funded health and social care system (HSE). The source of cost data must be reported along with the details of what is included in the estimate. Data should be the most recently available, with the cost year specified.

Care should be taken to include the disaggregated prices, margins and fees applicable to the comparator being considered. For instance, drug cost estimates should reflect mandatory rebates from pharmaceutical manufacturers and importers. These costs might vary with changing pharmaceutical policy. A detailed guide for including drug costs in economic evaluations is available from the National Centre for Pharmacoeconomics.[11] To ensure that the evaluation is applicable to decision making, it might, in particular circumstances, be appropriate to take into account discounted prices to reflect the true cost to the HSE. The use of price reductions for

the HSE should only be used when 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 is used in the reference case analysis. Prices for drugs supplied from the community drugs schemes are listed in the reimbursement files of the HSE Primary Care Reimbursement Service (PCRS) which is updated monthly.[12] 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 can 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 and that represents a realistic choice for use in clinical practice. Drug administration costs, the cost of drug wastage (for example, from injection vials or from patient non-compliance), and the cost of therapeutic drug monitoring should be itemised and included where appropriate.

2.5.5 Value-added tax

Value-added tax (VAT) is charged on goods and services delivered in the State, and is controlled by national and European law. VAT rates vary from 0% to 23% according to the classification of the product. For instance, the VAT rate for oral medicines is 0%, but non-oral medicines attract VAT at a rate of 23%.VAT at the appropriate rate should be applied to the applicable costs where estimating budget impact.[11] Complete and up–to-date VAT rates for Ireland can be found at: http://www.revenue.ie/en/tax/vat/rates/index.jsp

2.5.6 Cost inflation

The most up-to-date costs should be used where possible; however, if inflating retrospective costs the consumer price index (CPI) for health should be used. The CPI is the official measure of inflation in Ireland. It is designed to measure the change in the average level of prices paid for consumer goods and services within Ireland. The overall CPI is broken down into 12 divisions.

The health component is made up of three sub-sections: 1) medical products, 2) appliances and equipment, 3) outpatients services and hospital services. Each of these sub-sections is 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 alternative medical products. For each of these sub-groups, a small number of items are chosen and priced as a representative sample of goods.

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

Example:

Convert €50 (2010 to 2014) using the CPI for Health[13]

Consumer Price Index by Commodity Group and Year		
	2010	**2014**
Health	96.8	101.2

Using the Formula:

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

Price increase   =   [(101.2/96.8)x100] – 100

                      =   4.55%

Therefore, €50 in 2010 is equivalent to €52.27 in 2014.

2.5.7 Cost Transfer

Where transferring historical cost data from another country to Ireland, costs should first be inflated to current costs using the CPI data from the origin country, before converting to Irish Euro using the purchasing power parity index.[14] Most countries have a similar organisation to the CSO; the following website is a good starting point when searching for the applicable one: http://www.isi-web.org/infoservice/statistical-organisations

The purchasing power parity index is published by the Organisation for Economic Co-operation and Development (OECD). It details the number of specified monetary units required in different countries to buy the same representative basket of

consumer goods and services.[15] The purchasing power parities (PPPs) are the rates of currency conversion that equalise the purchasing power of different currencies by eliminating the differences in price levels between countries. In their simplest form, PPPs are simply price relatives that show the ratio of the prices in national currencies of the same good or service in different countries. 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. More information is available on the internet site: http://www.oecd.org/std/prices-ppp/

Example:

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

Using the Purchasing Power Parities for 2013,[15]

Purchasing Power Parity		
	UK	**Ireland**
2013	0.698	0.832

Using the Formula:

[(Irish Index Number/UK Index Number)x100] - 100

Price change   =   [(0.832/0.698)x100] – 100

      =   19.2%

Therefore, in 2013, £50 in the UK was equivalent to €59.59 in Irish Euro.

2.6 Data

2.6.1 Data Quality

The data used for BIA must be valid to inform the publicly-funded health and social care system's (HSE's) decisions.[4] The usefulness of BIA depends on the data quality and applicability. For instance, data from another country might not be realistic in Ireland. To provide a realistic estimate of the budget impact, data should come from

the best sources available and be thoroughly referenced to ensure transparency and repeatability.[4] The reliability of data should be assessed.[4]

Where Irish data are not available, it could be sourced for example from clinical trials; in this case the data should be suitably adjusted to account for differences in demography, epidemiology, Irish patient pathways and clinical practice. Where data are obtained from 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. The source of all assumptions should be clearly documented either by referencing the source or referring to expert opinion. Assumptions should be tested in a sensitivity analysis.

2.6.2 Data Sources

All data sources and any assumptions or adjustments relating to them must be clearly stated. Data may come from a wide range of sources. The data should be derived from the appropriate Irish setting, if possible.

Current practice can be sourced from HSE's own data, registries or surveys. Health service databases include patient, administrative, clinical, and financial information that may assist analysts to write BIA reports.[2] The Catalogue of National Health and Social Care Data Collections in Ireland (March 2014) provides a detailed catalogue of all national health and social care data collections in Ireland.[16] The estimate could be obtained from regional incidence or prevalence data on the disease of interest applied to the HSE's population by adjusting for characteristics that may vary from the regional population, for example sex, age, ethnicity, or risk group.[4]

The proportion that are diagnosed and treated and the mix of disease severity need to be estimated. These estimates can come from a range of sources. For example, data from studies of the natural history of chronic diseases may be required when estimating the proportion of the target population with different levels of disease severity or at different disease stages.[4]

Data on clinical effectiveness should be based on the clinical literature where available; this could be from one good quality study or a meta-analysis of the results from a number of studies. Randomised controlled trials (RCTs) demonstrate the effect of the technology and use randomisation to minimise bias between cases and controls. Observational studies follow patients in the real world where treatment may be less carefully monitored, and the patients will often have comorbid conditions for which they are also being treated. Due to the numerous possible confounders, it can be difficult to infer a treatment effect in observational studies. They are also open to numerous sources of bias. Given the difficulties in assessing

bias, observational studies do not always offer the best level of evidence, but they do provide valuable evidence on the impact a treatment will have in routine care. For further details on recommended methods see 'Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland'.[17] In the context of clinical guidelines, the clinical effectiveness estimates used in the budget impact section, should be consistent with those underpinning the clinical recommendations.

Some commonly used data sources are listed below:

- Hospital In-Patient Enquiry Scheme (HIPE): a health information system designed to collect demographic, clinical and administrative information on discharges and deaths from all public acute hospitals nationally. www.hpo.ie

- National Perinatal Reporting System (NPRS): provides national statistics on perinatal events, it collects information on approximately 70,000 birth records each year from 19 maternity units and all practicing self-employed community midwives. www.hpo.ie

- Primary Care Reimbursement Service (PCRS): is responsible for making payments to healthcare professionals, including doctors, dentists and pharmacists, for the free or reduced costs services they provide to the public www.hse.ie/eng/staff/PCRS

- CSO website: provides demographic (Census) population and some activity data www.cso.ie

- National Paediatric Mortality Register: obtains accurate, up-to-date information on all sudden, unexpected/unexplained deaths in infants and young children in Ireland. www.sidsireland.ie

- National Drug-Related Deaths Index: is an epidemiological database that records cases of drug- and alcohol-related deaths, and deaths among drug users and among alcoholics in Ireland www.hrb.ie

- National Cancer Registry: includes data on type of cancer; site; staging; age and sex; treatments and selected procedures; patient demographics; date and cause of death www.ncri.ie

- BreastCheck, CervicalCheck and BowelScreen: collect information from the national breast, cervical and bowel cancer screening services www.breastcheck.ie, www.cervicalcheck.ie, www.bowelscreen.ie

- Health Protection Surveillance Centre: collates a wide range on information on diseases and infectious disease in Ireland (including HIV, *Clostridium difficile*, Influenza,) www.ndsc.ie/hpsc

- National Psychiatric Inpatient Reporting System (NPIRS): is a psychiatric database which provides detailed information on all admissions and discharges to in-patient psychiatric services in Ireland www.hrb.ie

- Staff costs by grade are available from the HSE-www.hse.ie/eng/staff/Benefits_Services/pay

- The costs for hospital in-patient and daycase procedure costs are available through the Healthcare Pricing office www.hpo.ie

- Published data: might include regional or national audits and results of published research available via Embase, MEDLINE and CINAHL

- Expert opinion

Several different sources might be required to derive robust data. When appraising data sources, it is important to consider the study location from which the data are derived and whether it is comparable to Ireland as well as how recent the study data are.[5]

2.6.3 Uncertainty

It is recognised that all budget impact analyses will be subject to uncertainty. However, the budget impact usually will contain helpful information for decision makers regarding the scale of the costs and savings, even if the actual cost is not precise.[5]

Budget impact analyses include many factors that vary, such as disease prevalence and incidence, drug and healthcare costs. 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. The level of uncertainty will vary with the available quality of the evidence. In some instances the results may be predicted with a reasonable level of certainty, if research provides a fair comparison of the current and alternative treatments.[5] 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 should be supported by evidence-based data, where possible.

Alternative plausible scenarios should be informed using HSE-specific information.[4]

Realistic minimum and maximum values should be noted when collating data. These will inform analysis that highlights the variables that have the greatest influence on the budget impact.[5]

3.   Steps in creating a Budget Impact Analysis

The main steps recognised in a budget impact analysis (BIA) are listed below:

1. Identify the recommendations with a resource impact (for guidelines only)
2. Identify the resources used that might change - develop treatment pathway before and after introduction of the technology (or publication of the guidelines), including an initial set-up period, note resource use may increase or decrease.
3. Estimate the size of these changes (estimate the population that will be affected, for example, all inpatients)
4. Determine the applicable costs for these changes.

Figure 1 outlines these four steps and the keys questions to be considered at each step.

3.   Steps in creating a Budget Impact Analysis

Figure 1 - Steps in creating a BIA

Step 1- Identify the recommendations with a resource impact (Guidelines only)

Step 2- Identify the resources that might change
- What is current practice? Is it consistent nationally or is there variation?
- What is the new treatment? Does this affect the ongoing treatment or the patient pathway?
- Does the intervention replace current systems?
- Who will receive treatment?
- Who delivers the current intervention? Who will deliver the new intervention?
- Where is the proposed setting for the intervention?
- Are new facilities required?
- Is new equipment required?
- For how long will patients receive treatment?
- Is there a change to outcomes?
- Are there extra/different harms or adverse events?
- What are the initial set-up requirements?
- Are there training requirements?

Step 3- Estimate the size of these changes
- How will predicted activity over the next number of years be estimated?
- How many patients will be affected? What is the incidence and prevalence of the disease?
- Where is the proposed setting for the intervention- How many of these are there? Who is delivering the intervention?
- How frequently is training offered to staff?

Step 4- Determine the applicable costs for these changes

- What are the technology costs?
- Is the training accredited and does this incur costs?
- Is new equipment required? Who are the suppliers?
- Are there start-up costs of training, equipment, rebuilding etc?
- Are there cost savings or cost offsets?
- What are the healthcare utilisation costs?

3.1   Step 1- Identify the recommendations with a resource impact

For each recommendation in the guideline consider whether this is a change from current practice. Where the recommendation reflects current practice then it can be assumed that there will be no additional resource or cost implication for this recommendation. Where a change to current practice is recommended, then consideration will need to be given to identifying, quantifying and costing these changes as outlined in the above steps. Identifying where there may be a resource impact assists the publicly-funded health and social care system (HSE) in planning. This is important as guidelines may vary considerably in scope and the number of recommendations included.

It may be appropriate to cost a general topic that covers a number of recommendations. For instance, where a number of recommendations specify care being delivered by appropriately trained staff, then it is more sensible to cost all additional training for staff in this area, rather than costing individual training elements across a number of recommendations.[5]

For completeness, where recommendations cannot be fully quantified, but are expected to have resource consequences they should still be discussed in the budget impact.[5]

3.2   Step 2- Identify the resources that might change

One of the key elements in a BIA is to determine the baseline and estimate how this may change.[5] In the case of clinical guidelines, the BIA should quantify the budget impact of changes that will arise from the implementation of the guidelines.[5] Identification of changes should be consistent with the perspective of the HSE.[4] There might be changes to: the eligible population (for example, expansion of the eligible population through increased detection or improved diagnosis); the total population size (for example, increases due to the cumulative impact of a new treatment for a chronic condition); the treatment offered including how, where and by whom it is delivered; patient outcomes (for example changes in length of stay, disease progression or adverse events rates).[5]

Occasionally, it will not be possible to quantify the consequences of introducing a guideline recommendation. Where this occurs, a clear statement about why some data items are not available should be included. [5] This might be for a number of reasons, including:

- Limited data regarding the current baseline – for instance, a guideline may specify the continued practice that patients infected with MRSA are isolated in a single room; however, there may be limited data regarding the availability of single rooms in existing buildings and the extent to which hospitals are in compliance with the existing recommendations.[18]

- Difficulty in determining the size of the affected population – for instance, the potential population for a programme of chronic disease self management that targets individuals with COPD, asthma, diabetes mellitus or cardiovascular disease will be overestimated if it simply sums the population in each of the four groups as this method will double count individuals who fall into two or more groups.[19]

- In some instances there is a lack of systematically collected data, for example the number of women who have been identified as carriers of a *BRCA1* or *BRCA2* gene mutation.[20]

Questions to consider:

- **What is current practice and, is it consistent nationally or is there variation?**

If the activity may be performed in a number of different ways, there should be clarity on how the activity is currently being performed.[5] If there are several types of practice in current use, but only a few are commonly used, it may be reasonable to restrict the description of current practice to those that are commonly used in Ireland.

Example: from the Health Technology Assessment of surveillance of women aged less than 50 years at elevated risk of breast cancer[20]

The existing system is of 'no organised surveillance', that is where limited surveillance is provided on an ad hoc basis. It was assumed that women with known high penetrance genetic mutations currently receive MRI surveillance in line with the 2006 NICE guidelines:[21] women with *BRCA1* and *BRCA2* mutations and other identified mutations other than *TP53* receive annual MRI from age 30, and women with a *TP53* mutation receive annual MRI from age 20. It was assumed that these women also receive digital mammography surveillance from age 30 or 35. The 2006 NICE guidelines recommend the addition of digital mammography from the age of 40.

Based on a review of a local hospital database the following definition was used to describe the existing ad hoc surveillance for women at high familial risk: from the age of 30, 85% annual surveillance, 11% biennial surveillance and 4% no

surveillance. For women at moderate risk the following surveillance was assumed: from the age of 30, 70% annual surveillance, 24% biennial surveillance and 6% no surveillance. It was assumed that only digital mammography is used for surveillance in women at high familial and moderate risk. These assumptions, based on local hospital data, were agreed with members of the expert advisory group for the HTA, and were used to estimate current budget impact.

- **What is the new treatment? Does it affect the ongoing treatment or the patient pathway?**

Consideration should be paid to the entire treatment pathway, not just the new treatment itself. This may include changes to inpatient admissions (e.g. variation in admission type [emergency or elective, inpatient or daycase]); average length of stay; average operation time or cost of consumables; nursing input (if recommendations change nursing practices); outpatient appointments (change in the number of new referrals or follow-up appointment); GP visits; emergency department attendances; number of monitoring tests; direct contacts with physiotherapists or dieticians; setting (secondary to primary care); or referrals for diagnostic tests. All changes should be considered regardless of whether they will lead to actual cash changes or if they will lead to efficiency gains or opportunity costs.

Example: from National Clinical Guideline No. 2- Prevention and Control of MRSA[18]

Recommendation of an extra throat swab – The addition of a throat swab to the testing sites was expected to have a negligible cost by the guideline development group. In a number of laboratories, specimens are pooled for processing and the implication of the extra swab was not thought to add significantly to the financial or personnel resources needed for processing.

- **Does the new intervention replace current systems?**

Introducing a new technology might lead to reductions in resource use and costs elsewhere in the system. This might include reduction in the use of another technology, savings from switching a drug from an intravenous to oral route, or reduction in the use of concomitant therapies due to a reduction in adverse events. It could be simply a direct substitution where the new technology replaces one or more existing technologies, for example, replacement of the currently used observation chart, or it could be a modification of an existing system, for example a change in the recommended drug regimen. With substitution, the expense of the new technology can be partially offset by a reduction in use of current technologies. In contrast, the new technology may be used in situations where there has been no active technology

or in patients who have stopped or would not use available technologies owing to intolerance, inconvenience, loss of effect, or an alternative reason.[4]

Example: from National Clinical Guideline No. 4 - The Irish Maternity Early Warning System (IMEWS)[22]

The IMEWS chart will replace currently used charts which vary across sites; in some instances this may lead to a reduction in printing and related costs and in others potentially an increase, depending on the use of colour and number of sheets in the currently used charts.

- **Who will receive treatment?**

Consider who the target population will be and if this differs from the existing standard of care. There could be a change to the target population through for example improved awareness leading to improved referral, improved detection or improved diagnosis.[5] Consider if it is applicable to all patients or if it will only affect some subgroups.

Example: from the Health Technology Assessment of prion filtration of red cell concentrates to reduce the risk of variant Creutzfeldt-Jakob disease transmission in Ireland [23]

In this case the intervention is applied not to the individuals transfused, but to all units of blood donated and costs of introducing the technology are calculated on that basis.

- **Who delivers the current intervention? Who will deliver the new intervention?**

Consider which staff groups will be affected by the introduction of the guidelines, or if there will be changes to the staff resources required (additional staff, more staff input, a change in who delivers a service).

It is essential to clarify the way the technology may be used by staff, and to document the typical staff grade(s). There may be differences in those offering new appointments or initiating treatment from those providing follow-up appointments and maintaining treatment.[5] Introduction of a new technology might lead to reduced staff requirements, however, it can be difficult for the publicly-funded health and social care system (HSE) to realise all potential savings (for example, through staff redeployment).

Example: from National Clinical Guideline No. 5 - Communication (Clinical Handover) in Maternity Services[24]

The guideline recommends that the healthcare organisation should ensure that there is mandatory protected time for shift clinical handover (Recommendation 15). It is acknowledged that this could have opportunity costs and therefore a budget impact for some maternity units, should it lead to the need for extra staff hours; however such costs might be minimised or eliminated with judicious rostering.

- **Where is the proposed setting for the intervention?**

Consider where the intervention will be delivered and by whom. Some recommendations could state that an intervention may be provided in a number of locations, for example, an outpatient clinic or GP surgery. In this case, the options would result in different costs to the HSE as, for example, there will be differences in overhead costs, reimbursement rates, or the extent to which costs may need to be borne by the patient. When considering current practice any assumptions should be clearly documented and the potential for variation noted.[5]

Example: from National Clinical Guideline No. 6 - Sepsis Management[25]

International guidance advocates point-of-care (POC) lactate measurement as part of a suite of triggers to identify sepsis. Traditionally lactate is measured on a blood gas machine. Blood gas machines, although accurate and necessary medical equipment, are expensive, require regular calibration and are not as robust as the smaller handheld POC machines on the market. One Irish level three hospital currently has 10 handheld POC machines in use. These machines have been positioned in areas that frequently see the acutely ill patient.

Clinical Area	Number of hand held PCO machines
Emergency Department	2
Intensive Care Unit	1
Acute Medical Assessment Unit	1
Paediatric Unit	1
Maternity Unit	1
Respiratory Ward	1
Coronary Care Unit	1
Medical Laboratory	1
Cardiac Nurse Team	1

■ **Are new facilities required?**

Consider if the new technology can be adequately supported by the facilities and resources in the healthcare facility where it will be introduced.[6] There could be a need for additional laboratories, or new IT infrastructure or an updating of current facilities. Capital investment can be needed when implementing some new technologies, for instance, investment in a new information communications technology (ICT) system or additional accommodation to ensure a screening programme. Such costs are usually only incurred on a once-off basis.

> **Example:** from National Clinical Guideline No. 3 - Surveillance, Diagnosis and Management of *Clostridium difficile* Infection in Ireland[26]
>
> Single Irish Reference laboratory: There is no single Irish *Clostridium difficile* reference laboratory; UK laboratories are used to perform this testing instead. Introducing a single Irish reference laboratory would potentially produce savings derived from the reduction of UK laboratory costs and the improved capacity to capture important intelligence around *Clostridium difficile* types prevalent in the Irish setting. However, significant costs would be incurred by the setting up and resourcing of a national centre.

■ **Is new equipment required?**

Consider what the expected lifetime of the equipment is and where it will be stored. Equipment incurring capital costs might also have associated regular maintenance costs that must be considered in the analysis. Costs associated with recalibration, sterilisation costs and costs associated with disposal of items should be included. Any protective equipment, protective clothing and disposable items for once-off or limited use also need to be included. If specialist equipment or consumables are needed, these should be included as separate, specific cost items. There could also be IT expenses (hardware purchase, software purchase/licence fees, and maintenance).

> **Example:** from the Health Technology Assessment of public access defibrillation[27]
>
> A typical AED system consists of a lightweight, portable AED device, battery, electrocardiograph electrodes and pads. In addition it needs to be stored in cabinets, and have appropriate signage so it can be quickly located. The AED, pads and batteries all had associated lifetimes and would need replacement at different time points, for example, after eight years for AEDs, two years for the pads, and after five years for the battery. These estimates were sourced from the device manufacturers.

> **Example:** from the Health Technology Assessment of robot-assisted surgery in selected surgical procedures[28]
>
> Along with the capital cost for the robot and its associated maintenance, there were also additional costs from sterilisation and incineration. It was assumed that it took an additional 55 minutes to sterilise equipment for the robot after a procedure and that a sharps bin weighs on average 6.2kg after an open operation and 8.25kg after a laparoscopic or robot-assisted operation.

- **For how long will patients receive treatment?**

Determining the dose and duration of an average treatment course is an essential part of the BIA. Treatment could take many forms, for example, drug therapy, surgery or radiation therapy. The choice of treatment may impact the duration of care and have additional consequences such as a requirement for additional monitoring during or after treatment.[5]

- **Is there a change to outcomes?**

Data regarding the consequence of a technology on patient outcomes that affect resource utilisation should be incorporated into the BIA. This could include improved survival, change in the symptoms, shortened disease duration, change to length of intensive care unit stay, change in disease progression or change in the complications or recurrence rates. Where available, data from randomised clinical trials (RCTs) are used to quantify efficacy in the reference case analysis. Meta-analysis can be used to synthesise outcome evidence provided the homogeneity and quality of the studies included justifies this approach.

- **Are there extra/different harms or adverse events?**

For instance, device failure in a pacemaker involves further surgery to remove the current device and potentially implant a new device. Here, the device failure rate is a relevant outcome as it leads to further service use with resource implications. 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 information sources examined need to be clearly documented. All adverse events that are of economic importance should be included in the analysis. Attention is paid to those instances where there are substantive differences between the technologies being compared. Consideration should also be paid to the potential

impact of adverse events on an individual's ability to comply with therapy as well as possible results for resource utilisation (for example prolongation of hospitalisation, extra medication use, etc.).

> **Example:** from the Health Technology Assessment of robot-assisted surgery in selected surgical procedures[28]
>
> Failure of the robot, if it occurs peri-operatively, typically leads to conversion to open surgery. The rates of conversion from robot-assisted and conventional laparoscopic to open were incorporated into the model. It is assumed that robot-assisted surgery converts to open rather than conventional laparoscopic. In the event of conversion to open prostatectomy, outcomes from open surgery are used.

- **What are the initial set-up requirements?**

There may be initial set-up costs that are required when preparing to introduce a recommendation.[5] These could include awareness or briefing sessions.

- **Are there training requirements?**

Training may be required to implement a guideline or new technology. All those who will be involved with the technology, including medical staff, nursing staff and allied health professionals and on occasion patients need to be taken into consideration.[6]

There are additional questions that should be considered: Does a training programme exist or does it need to be developed? Is the training part of the core training or is it specific to the guidelines or new technology? Who needs training? Is backfill for participating staff needed or is training time built into rotas? Who might provide the training – internal or external staff? How is training to be delivered (face-to-face, online, onsite/ offsite etc.)? Will there be travel and subsistence costs? How long will the training programme last? How are trainers trained? Is refresher training need? Does initial training vary from refresher training? How frequently is refresher training needed? What materials are required (manual, online resources, apps etc.)? What credentialing and competency assurance are needed to ensure safe implementation of the technology or guideline recommendations?

> **Example:** from National Clinical Guideline No. 1- National Early Warning Score[29]
>
> The amended COMPASS© Programme takes approximately 8.5 hours which consists of reading the manual (2 hours), working from an interactive education CD (15 minutes), an on-line quiz (15 minutes) and a 6 hour face-to-face session.

Example: from National Clinical Guideline No. 1 - National Early Warning Score[29]

A 'train the trainer' model was adopted for introduction of the COMPASS© Education Programme, that is, suitable staff, doctors, nurses and physiotherapists train as trainers and provide the multidisciplinary programme to staff. For this type of training model, the time of both those delivering and attending the training needs to be included in the costs.

3.3   Step 3- Estimate the size of these changes

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

- additional resource requirements, particularly where there can be capacity constraints regarding the provision of such resources (for example, number of screening colonoscopies)

- resource savings, particularly where the potential to realise such savings can be difficult.

This information is best presented in a tabular format, broken down by the resource type.

Questions to consider

- **How will predicted activity over the next number of years be estimated?**

Activities can be considered in a variety of ways including number of patients, discharges, outpatient clinic visits, bed days etc.[6] The healthcare service use over the timeframe of the BIA is estimated using Irish data sources; where these are unavailable, consultation with those who frequently treat individuals with the disease of interest can be used.[4]

Example: from the Health Technology Assessment of public access defibrillation[27]

Between 2012 and 2013, there was an average of 1,850 out-of-hospital cardiac arrests in Ireland for which resuscitation was attempted by the emergency medical services. (Source: National Out-of-Hospital Cardiac Arrest Register[30]) A BIA was carried out to estimate the total cost of implementing each of the comparator public access defibrillation strategies over the first five years of the programme, given an average of 1,850 out-of-hospital cardiac arrests per annum.

- **How many patients will be affected? What is the incidence and prevalence of the disease?**

An essential step when estimating the budget impact of introducing the new technology or guideline recommendations is to identify the population affected by them.[5] Once the size of the population with the disease of interest has been estimated, the proportion that are diagnosed and treated and the mix of disease severity need to be estimated.[4]

Incidence and prevalence, although they are related, quantify different aspects of the disease burden. The incidence of a disease is the number of new cases of the disease in a particular group of individuals over a particular time period. The prevalence of a disease is the number of individuals in a specified group or population who have the disease at a specified time. Examples of incidence and prevalence measures include:

- Annual incidence – the number of individuals who develop a disease in one year.
- Point prevalence – the burden of disease in a population at a specified time point.
- Period prevalence – the burden of disease in a population during a specific period of time.
- Lifetime prevalence –the number of individuals affected by a disease over their lifetime.

Both incidence and prevalence data may be required to allow accurate estimation of the budget impact of different recommendations. For instance, prevalence data will be required to estimate the annual cost of treatment for a long term chronic disease, while annual incidence rates will be used to inform the annual cost of the initial diagnosis. Considerations regarding which data to use include:

- Disease duration: if a condition resolves spontaneously in a short period of time or is curable (for example acute otitis media), then the prevalence rate will be much lower than the incidence rate whereas the prevalence of a chronic condition such as rheumatoid arthritis will greatly exceed its incidence. The annual incidence should be used if the condition or disease lasts less than year.

- Disease progression: an aggressive cancer with a high mortality rate may have a similar prevalence and incidence, whereas the prevalence of cancers that typically pursue a more indolent course may exceed the annual incidence.[5]

Some disease areas may comprise several subgroups. If looking at more than one subgroup, care should be taken to avoid double counting if the subgroups overlap.[5] When estimating treatment numbers, it also important to consider how many individuals would be targeted for treatment, choose treatment, and continue with the treatment.

Example: from the Health Technology Assessment of surveillance of women aged less than 50 years at elevated risk of breast cancer[20]

Estimating the number of women in each risk category in Ireland is complicated by a lack of evidence regarding prevalence. There is no national registry of women with relevant genetic mutations.[31] International data suggest that approximately 25% of breast cancer incidence is due to familial risk.[32] It is generally assumed that 5% to 10% of cancer incidence is attributable to genetic factors, half of which is in *BRCA1* and *BRCA2* mutation carriers.[33] In a Dutch study, the relative contribution to incidence of *BRCA1* and *BRCA2* was in the ratio of 4:1,[34] although this ratio is subject to substantial variability. An Irish study reported an incidence ratio of 4:5 for *BRCA1*:*BRCA2* breast cancer patients.[31] By using the estimated proportions of cancers attributable to each level of risk in combination with the reported probabilities of breast cancer and observed incidence, it is possible to estimate the approximate numbers of women in each risk category. The estimates of population in each risk group are based on the proportions outlined above which are often based on small study populations. It is assumed that those proportions will be broadly applicable to the Irish population. In Ireland, the percentage of women less than 50 years in the average, moderate and high risk groups is estimated to be 92.4%, 5.7% and 1.9%, respectively.

For the BIA it was assumed that not all women would present at screening. It was assumed that uptake was age-specific and was equivalent for all elevated risk subgroups.[35] It was assumed that the same uptake rates would apply irrespective of imaging modality or surveillance frequency. It was assumed that some proportion of women would avail of prophylactic mastectomy as a primary preventive measure, and that for these surveillance would no longer be necessary.[36] It was assumed that women who become pregnant would not avail of surveillance for two consecutive six-month cycles.

- **Where is the proposed setting for the intervention- How many of these are there? Who is delivering the intervention?**

Consider if additional clinical personnel and expertise will be required to implement the guidelines. The range of healthcare professionals required to perform the intervention, their relative proportions, and their respective pay scales must be

documented to calculate the additional staff cost.[5] If new equipment is required, consider how many units will be needed.

Example: from National Clinical Guideline No. 1 - National Early Warning Score[29]

There are approximately 17,500 WTE nurses working in acute public hospitals
Source: Personnel Census Report
http://www.hse.ie/eng/staff/Resources/Employment_Reports/

Although this underestimates the full number of nurses, not all will require education, in particular those working in administration roles or outside the areas that are using the NEWS, and those who will have received the training as part of their undergraduate education. Therefore it was chosen as a conservative estimate of the number of nurses who require training.

A specified proportion of doctors and allied health professionals will also require training. Using the current numbers trained across staff groups, and based on the latest NEWS audit evidence, it was estimated that in total an estimated 20,500 staff require training, split between nurses (17,500), doctors (2,000) and allied health professionals (1,000).

Approximately 300 staff have been trained to provide the education programme consisting of 80% nurses, 10% doctors, 10% allied health professionals. Delivering a training session is estimated to take eight hours. On average the education sessions are predicted to include 10 trainees, so approximately 2,050 training sessions will be required.

- **How frequently is training offered to staff?**

The number of staff who will require training needs to be estimated. Realistic estimates of the proportion of the total target staff population who may receive training in one year should be provided.

Example: from National Clinical Guideline No. 4 - The Irish Maternity Early Warning System (IMEWS)[22]

Ongoing education will consist of a short refresher course to be completed every two years. This refresher education programme takes approximately one hour.

3.4   Step 4- Determine the applicable costs for these changes

Ireland does not have a central medical costs database.[37] As a result, the generation of valid Irish cost data is challenging and time consuming. There is a requirement for flexibility regarding costing of resources. To maximise reproducibility and transferability, all assumptions must be clearly reported.

Both the current and anticipated future costs should be estimated, as the initially high costs may be likely to reduce over time.[6] Recurrent costs are the annual costs of implementing a technology or guideline recommendation. For acute conditions that only persist for a short duration, this is related to the annual incidence. For chronic conditions that persist for several years or that are lifelong, consideration must be given to the cost of treating both the stable population and the new cases that present during the year.[5]

In the absence of national cost data, unit costs may be sourced from publicly-funded health and social care system (HSE) organisations currently offering the service. When using local data, information should be sought from more than one organisation to confirm they reflect realistic national average costs. Another method is to consider the costs from first principles and calculate the inputs required. The costs may be based on assumptions regarding the amount of patient contact time with staff and the rate of pay using Department of Health pay scales. For pay-related costs, the full cost to the HSE of employing someone, which includes employer's contributions to PRSI and pensions, must be considered.[3;5]

Where a procedure is undertaken as a day case in some areas and as an inpatient procedure in others, the weighted average cost may be used in the BIA ideally also providing detail of the constituent costs.[5]

To estimate the total budget impact, the following should be considered. What is the extra or saved annual cost per patient? What is the total extra or saved cost in the next five years? Multiply the number of individuals by the extra/lower cost per patient, leading to the five-year total extra/lower cost.[6]

Questions to consider

▪   **What are the technology costs?**

It will be essential to establish how the new technology costs compare with the current technologies.

Example: from National Clinical Guideline No. 6 - Sepsis Management[25]

International guidance advocates point of care (POC) lactate measurement as part of a suite of triggers to identify sepsis.

Handheld POC readers cost approximately €5,000 each. It was estimated that approximately 205 POCs, calculated as one POC machine each per acute setting including AMU (MAU), SAU, ITU, CCU, ED, maternity units and one machine per a proportion of general medical and surgical wards (1 machine per 5 wards) would be required. This proportion is based on the numbers of POC machines currently in use in the general wards of the aforementioned level-3-hospital.

Total = €5,000 X 205 = €1,025,000.

An integrated interface with LAB IT costs approximately €10,000 per hospital. It was assumed that each acute hospital has one laboratory network and would require just one interface regardless of the size/extent of the hospital.

Total = €10,000 X 39 = €390,000.

POC Machine is a reader device only and does not require a maintenance contract. However, there will be costs of external quality control estimated at €600 per annum for 39 hospitals.

Total = €600 X 39 = €23,400.

Cartridges require one off batch validation @ €200 for a box of controls that lasts at least 2 years. Costs are determined by the number of validations and cartridges used.

Total = €200 X 39 = €7,800.

For lactate, a venous sample from a regular blood sample/syringe can be used. When reviewing a deteriorating patient, routine bloods are typically drawn. A lactate test can be done using this blood sample. A single use cartridge costs €10 each. The population is based on an average of 8,036 sepsis discharges recorded per annum. This is an underestimation as more sepsis cases may have occurred than were recognised or recorded, and patients will be tested that do not prove to be septic.

Total = €10 X 8,036 = €80,367.

▪ **Is the training accredited and does this incur costs?**

Example: from National Clinical Guideline No. 1 - National Early Warning Score[29]

The COMPASS© Education Programme which incorporates the NEWS for the early detection and management of the deteriorating patient was chosen as the national education programme. The COMPASS© Education Programme is replacing the previously used ALERT™ system which included an annual licence fee of approximately €600 for each organisation and which was being paid by 10 hospitals.

Changing to COMPASS© resulted in an annual saving of 10 X €600 = €6,000.

▪ **Is new equipment required? Who are the suppliers?**

Example: from the Health Technology Assessment of robot-assisted surgery in selected surgical procedures[28]

The technology being assessed is robot-assisted laparoscopic surgery using the da Vinci S 4-arm System with HD Vision®. The da Vinci robot is manufactured by Intuitive© Surgical, Inc which sells the robot, the instruments for the robot and its service contract.

Item	Cost (€)	VAT rate
Robot purchase	1.45 million	21%
Additional robot capital equipment	4,600	21%
Annual robot maintenance fee	150,000	13.5%

▪ **Are there start-up costs of training, equipment, rebuilding etc?**

The costs might cover training, rebuilding, new equipment or patient information.[6] Some training will be included as a recurrent cost in particular if refresher training is needed.[5]

Example: from National Clinical Guideline No. 1 - National Early Warning Score[29]

To cost the staff time for education an average salary (Source: Consolidated Salary Scales, HSE, 2012) for each of the three staff groups was assumed as follows: nurses were staff nurses, doctors were registrars, and allied health professionals were physiotherapists. Using these estimates the approximate cost for staff time

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spent on education is €7.3 million.

	number to be trained	Midpoint of salary	Annual cost*	Annual Leave	Hourly Rate**	8.5 hours training
Staff nurse	17,500	37,408	60,171	25	38.65	€5,749,230
Registrar	2,000	66,840	107,512	24	68.75	€1,168,797
Physiotherapists	1,000	39,457	63,467	27	41.13	€349,644
					total	€7,267,672

*Includes PRSI, pension contributions and overheads, the estimated rates used have been reduced since estimation.

**The hourly rate is estimated as

$$\frac{annual\ cost}{(249 - annual\ leave\ entitlement) \times 6.95}$$

Although the staff resources consumed during the education phase is significant, these may be opportunity costs, i.e. diverting staff members from their usual activities to attend education, rather than an actual cash cost to the HSE. This cost may be realised through efficiencies and flexibility in rostering; direct staff replacement may not be required.

Example: from National Clinical Guideline No. 1 - National Early Warning Score[29]

To support the initial phase of education and training, education materials were provided by the Office of the Nursing and Midwifery Services Directorate through the Nursing and Midwifery Planning and Development Units. These included 5,000 Manuals, 700 CDs, 10,000 sample observation charts and 3,000 ISBAR Charts, costing a total of €17,982. This cost includes VAT at the appropriate rate of 23%.

■ **Are there cost savings or cost offsets?**

The offset should consider the technologies displaced and any associated aspects, for example, laboratory testing or managing side effects.[4] The guidelines could result in costs or savings for other settings, for example hospital, primary care.[6]

Example: from National Clinical Guideline No. 3- Surveillance, Diagnosis and Management of *Clostridium difficile* Infection in Ireland[26]

Fidaxomicin is significantly more expensive than other treatment alternatives, however it has been shown to be cost-effective in Ireland at a willingness to pay

threshold of €45,000/QALY. The potential budget impact was reported in the company submission to the NCPE over a five year timeframe horizon assuming that 25% of fidaxomicin prescribing would be on the High Tech drug scheme and the remainder in the hospital setting. The gross drug budget impact was estimated to range from approximately €88,000 in year one to approximately €1.55 million by year five. The net budget impact was estimated to increase from €20,000 in year one to €0.3 million by year five. This includes the cost offsets from replacing prescriptions for vancomycin and metronidazole and reduced length of stay from recurrences avoided.

However, the NCPE noted that this analysis may have overestimated the reduction in recurrence rates, and potential savings, as many of these patients will have co-morbidities which may prolong hospital stay, thus underestimating the potential budget impact.[38]

- **What are the healthcare utilisation costs?**

Unit costs appropriate to the publicly-funded health and social care system (HSE) are applied to the anticipated changes in healthcare use to estimate the BIA of the change in health service use and health outcomes.[4] Costs of managing all complications or side effects should be included.[4] The cost of treating adverse events may be incurred due to treatment withdrawals or the requirement for the HSE to manage adverse events.[4]

3.5 Reporting

As recommended in the 'Guidelines for the Budget Impact Analysis of Health Technologies in Ireland'[3], a well structured report should be provided with information provided on each of the elements outlined in the guidelines. All results should be presented both in their disaggregated and aggregated forms for each year of the timeframe. It should be clear where assumptions have been made and the sources underpinning them. In the context of clinical guidelines, if a comprehensive budget impact analysis cannot be created for some recommendations, then as much detail as possible should be presented, and clarity must be provided on why certain aspects could not be completed.

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