

How to Perform Economic Evaluations of Digital Health Technologies.

A practical guide from:

NICE National Institute for
Health and Care Excellence

Hardian Health



ISPOR

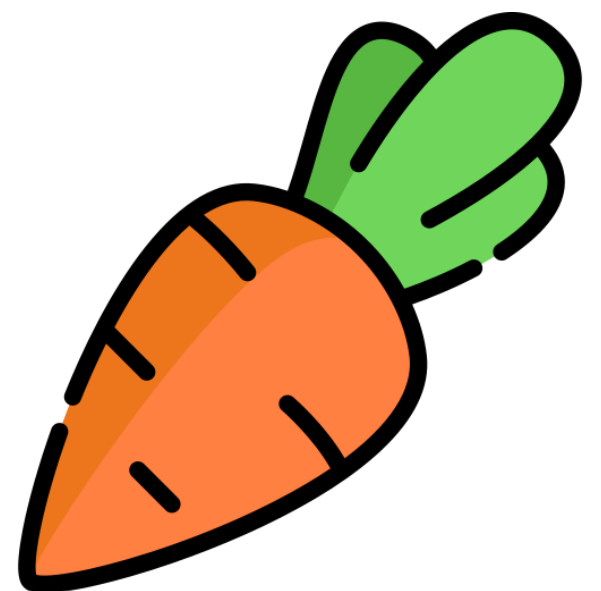
Improving healthcare decisions

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Clinicians think in **safety**
and efficacy.

Payors think in **dollars**
and cents.

Speak the right
language.



TL;DR

1. **Budget impact analysis (BIA)** is a tool that can help you assess the **expected changes in the health expenditure of the budget holder** (The healthcare system) as a result of implementing your digital product.
2. It is **increasingly required** by reimbursement authorities as part of a listing or reimbursement submission.
3. When combined with a cost-effectiveness analysis (CEA), you provide **compelling financial evidence to payors** that your product is an economically attractive one.

BUDGET IMPACT ANALYSIS (BIA)

BIAs are **increasingly required by reimbursement authorities**, along with a CEA, as part of a listing or reimbursement submission.

A BIA addresses **the expected changes in the expenditure of a health care system** after the adoption of a new intervention such as a new HealthTech product.

BIA can be freestanding or part of a comprehensive economic assessment along with a **Cost Effectiveness Analysis (CEA)**.

The **NICE evidence standards framework** requires developers to **provide commissioners with a BIA** to inform a comprehensive economic assessment of a Digital Health Technology.

The aim of a BIA is to give an estimate of the impact of the DHT on the decision-maker's budgets, **usually over the next 5 years, with a 1 to 2-year period**, being sufficient for DHTs requiring a basic level economic analysis.

In short,

The BIA is an important tool to make **a solid business case** for your product to budget holders.

PROS AND CONS.

Advantages of BIA include:

- . It helps you to understand **costs both incurred and saved** by implementing your product
- . It gives an **estimate of the impact of your product** on the decision maker's budget.

Drawbacks of BIA include:

- . It cannot tell you whether your product is **good value for money or not**.
- . It usually **excludes costs from changes in effects** that cannot be monetised, such as benefits captured by clinical measures.

5 KEY STEPS FOR A BIA.

1. Specify the target population

That is likely to be impacted by the new product.

2. Set the boundaries of the analysis

Decide the timescale for your impact analysis.

3. Determine treatment mix

Determine any changes to treatment mix as a result of making your product available.

4. Estimate product and disease-related costs

Relevant costs for BIA may differ because it often takes a more restrictive budget holder perspective.

5. Report the results

Budget impact results should be reported in a disaggregated way – that is, with main cost components reported individually.

SO, WHAT IS IN A BIA?

- **Features of the health care system**
- **Perspective**
- **Use and cost of current and new interventions**
 - Eligible population
 - Current interventions
 - Uptake of new intervention and market effects
 - Off-label uses of the new intervention
 - Cost of the current or new intervention mix
- **Impact on other costs**
 - Condition-related costs
 - Indirect costs
- **Time horizon**
- **Time dependencies and discounting**
- **Choice of computing framework**
- **Uncertainty and scenario analysis**
- **Validation**

LET US BREAK IT DOWN.

Features of the health care system

The features of the health care system that should be considered are **those that influence the budget** and may be affected by the coverage decision.

Access restrictions for health technologies are important features to consider as well.

(Whether the DHT is covered by reimbursement or not.)

Perspective

The recommended perspective of the BIA is that of the **budget holder**.

The budget holder may range from **a single payer** covering an entire health care system to **specific providers or areas within a health system**.

USE AND COST OF CURRENT AND NEW INTERVENTIONS

Eligible population

The population to be included in a BIA should be **all patients eligible for the new intervention** during the time horizon of interest, given any access restrictions.

Current interventions

The starting scenario should be the **current intervention mix for the eligible population**.

(May include no intervention as well as interventions that might be replaced by the new one.)

Uptake of a new intervention and market effects

Three types of changes should be included:

Substitution, Combination, Expansion.

Describes the cost impact of the 3 different scenarios above.

USE AND COST OF CURRENT AND NEW INTERVENTIONS

Off-label uses of the new intervention

The new intervention may be used in patients **without the treatment indication** (off-label use).

Inclusion in the BIA is not recommended unless the budget holder specifically requests its inclusion.

Cost of the current and new intervention mix

The cost of the current or new intervention mix is determined by **multiplying the budget holder's price for each intervention by proportion of the eligible population using that intervention** and by the number of people in the eligible population.

IMPACT ON OTHER COSTS.

Condition-related costs

The introduction of new interventions may result in changes in the **symptoms, disease duration, disease outcomes, or disease-progression rates** associated with the health condition and, thus, in changes in the use of condition-related health care services

Therefore, if credible data are available and these changes have an impact on health care budgets, **these should be presented in the BIA.**

Indirect costs

The impact of the new intervention on productivity, social services, and other costs outside the health care system **should not be included routinely in a BIA**, because these aspects are not generally relevant to the budget holder.

Time Horizons.

BIAs should be presented for the time horizons of relevance to the budget holder, in accordance with their budgeting process and periods (e.g., monthly, quarterly, and annual).

A time horizon of 1 to 5 years is common, with the results presented for each budget period after the new intervention is covered.

Time Dependencies and Discounting

Several aspects of a BIA may vary over time.

These include the value of the currency used (i.e., due to inflation/deflation); uptake; new interventions entering the mix; changes in prices (e.g., due to patent expiration); and changes in understanding of disease, indications, and management practices.

Choice of Computing Framework

The computing framework for a BIA can be a **simple cost calculator programmed in a spreadsheet** as well as costing templates produced by NICE.

The cost calculator approach is the preferred option because it is more easily understood by budget holders.

Uncertainty and Scenario Analyses

Uncertainty of two types is relevant to a BIA: **parameter uncertainty in the input values** used and **structural uncertainty** introduced by the assumptions made in framing the BIA.

Validation

The computing framework and input data used for a BIA must be **sufficiently valid to credibly inform** the budget holder's decisions.

DATA SOURCE

As you can now gather, the BIA requires a lot of **specific knowledge about the health system** you are selling to.

Ideally, all these data should come from the **Budget Holder themselves** as they should have the most accurate data.

However, where this is lacking, you can consider:

Table 2 – Examples of data sources to populate budget impact analyses.

- Real-life use and cost data from registries or databases reflective of the budget holder perspective.
- Data from clinical trials specific to or extrapolated to the budget holder population.
- Uptake, usage, and adherence data from international sources, from similar populations, and with similar practice patterns.
- Market research data to identify comparator product distribution and early use of intervention alternatives and trends in treatment patterns.
- Expert opinion and surveys for practice patterns.

HELPFULLY,

NICE has produced a **Budget Impact Analysis template** for innovators to use.

**NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE**

Technology appraisal

[Appraisal title and ID number]

Company budget impact analysis submission

Available here:

<https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/Company-budget-impact-analysis-submission.docx>

A GOOD EXAMPLE

Below is a great paper that you can reference to get a practical idea of what good looks like.

JOURNAL OF MEDICAL INTERNET RESEARCH

Nordyke et al

Original Paper

Estimating the Impact of Novel Digital Therapeutics in Type 2 Diabetes and Hypertension: Health Economic Analysis

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Available here:

<https://pubmed.ncbi.nlm.nih.gov/31599740/>

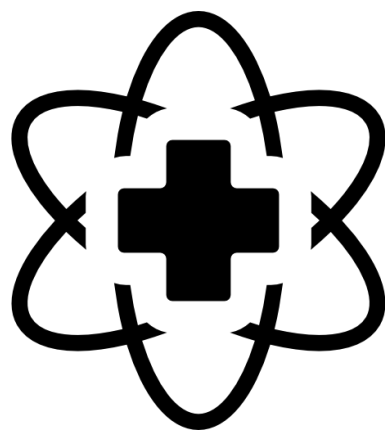
COST EFFECTIVE ANALYSIS

- A **cost-effectiveness analysis (CEA)** is a more complex economic evaluation where the financial impact and health effects of an intervention are assessed relative to the comparators.
- The common rationale for conducting these analyses is when the new intervention has a proven higher clinical benefit than an alternatives **but is likely to be more expensive**.



COST EFFECTIVE ANALYSIS

- . Typical clinical measures for a CEA are life years, **quality-adjusted life years (QALYs)** or **disability-adjusted life years (DALYs)**.
- . For example, in the UK NICE deem most interventions to be cost-effective if they generate an additional QALY for **a cost under £20,000 to £30,000**.



**Hope you found
this helpful!**



**This is a series we are making to help
HealthTech Innovators access better
resources.**

Just our small way of helping!