Pricing Committee and Pharmacoeconomics Evaluation Unit, National Department of Health

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HEALTH TECHNOLOGY ASSESSMENT FOR MEDICINES IN SOUTH AFRICA

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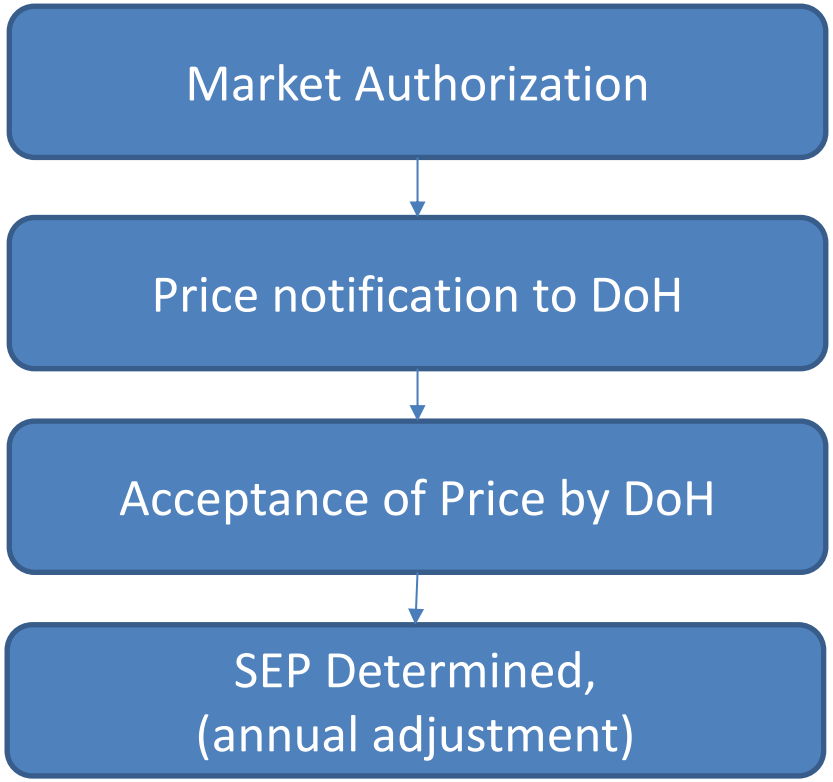
Disclaimer: Views expressed are solely of TW and not reflective of either University of Cape Town or the Pricing Committee

Current Practice for Single Exit Price determination:



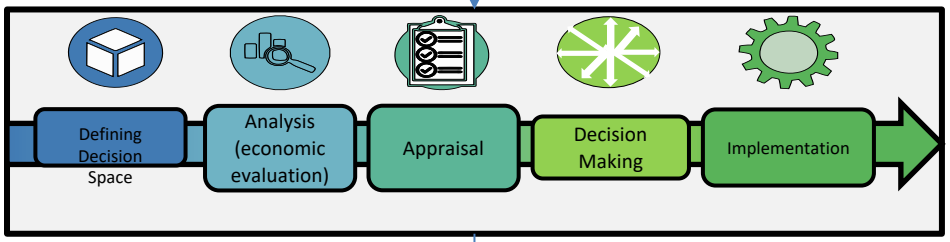
- Passive process or “price taking”
- Pharmacoeconomic guidelines exist (published in 2012)
- Voluntary pharmacoeconomic submissions
- No instances of price determination using the PE Guidelines

Potential practice for Single Exit Price determination:

Market Authorization

Price notification to DoH

Using established criteria, applied consistently



Acceptance of Price by DoH

SEP Determined
(annual adjustment)

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Key challenges:

1. The “payer” of the Single Exit Price is individuals (either directly through out of pocket or indirectly through medical schemes): the methods used for public sector pharmacoeconomics may need to be modified

2. Staffing and resources to manage a HTA process

3. Availability of South African-context evidence to support price determination using pharmcoeconomics

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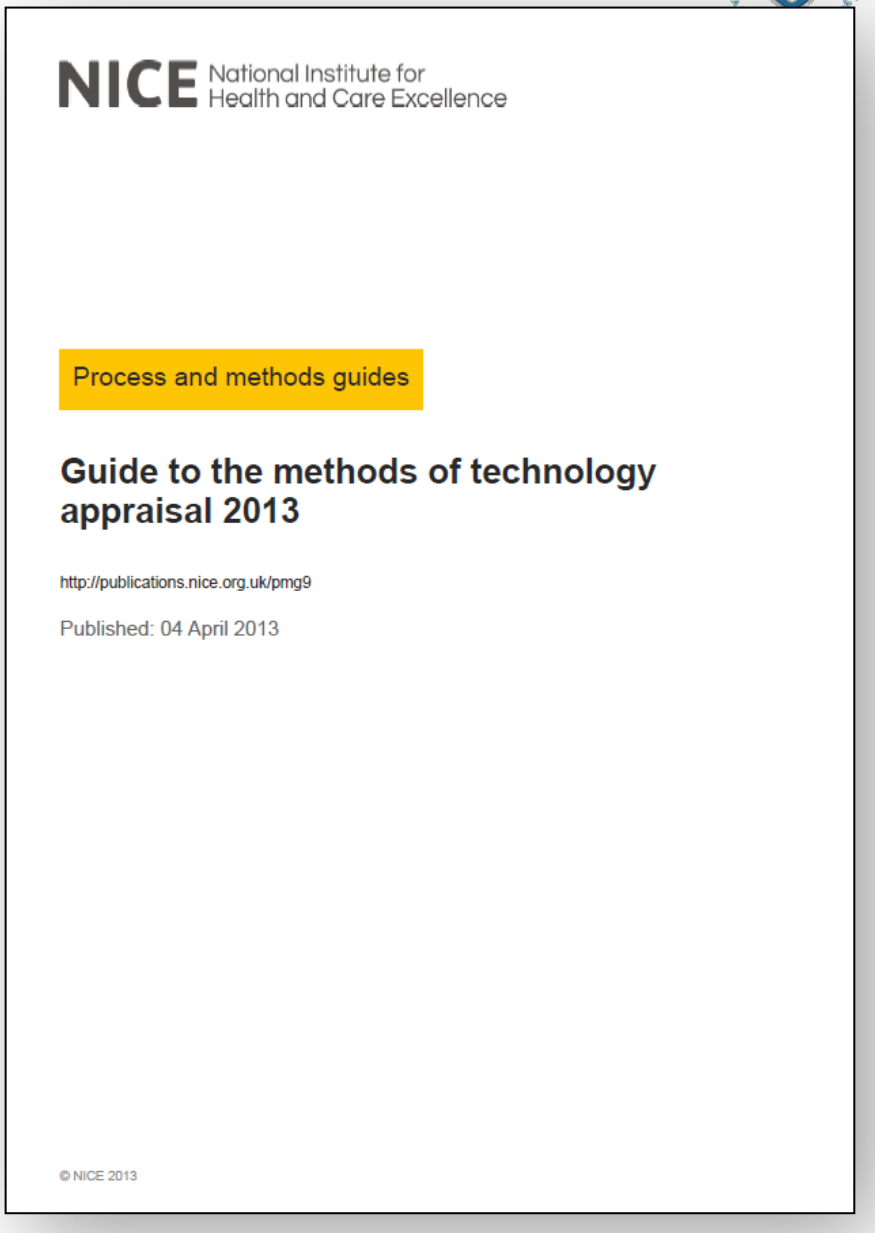
Example: NICE reference case for economic evaluation in UK

- First edition published in 2004
- Second edition in 2008
- Supplementary advice/clarifications in 2009, 2011)
- Third edition published in April 2013


NICE National Institute for Health and Care Excellence

Process and methods guides

Guide to the methods of technology appraisal 2013

http://publications.nice.org.uk/pmg9

Published: 04 April 2013

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Methods: the NICE reference case

Element of health technology assessment	Reference case
Defining the decision problem	The scope developed by NICE
Comparator(s)	As listed in the scope developed by NICE
Perspective on outcomes	All direct health effects, whether for patients or, when relevant, carers
Perspective on costs	NHS and PSS
Type of economic evaluation	Cost–utility analysis with fully incremental analysis
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared
Synthesis of evidence on health effects	Based on systematic review
Measuring and valuing health effects	Health effects should be expressed in QALYs. The EQ-5D is the preferred measure of health-related quality of life in adults.
Source of data for measurement of health-related quality of life	Reported directly by patients and/or carers
Source of preference data for valuation of changes in health-related quality of life	Representative sample of the UK population
Equity considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit
Evidence on resource use and costs	Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS
Discounting	The same annual rate for both costs and health effects (currently 3.5%)

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The IDSI Reference Case for Economic Evaluation

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VALUE IN HEALTH ▮ (2016) ▮▮▮–▮▮▮

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The International Decision Support Initiative Reference Case for Economic Evaluation: An Aid to Thought

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ABSTRACT

Background: Policymakers in high-, low-, and middle-income countries alike face challenging choices about resource allocation in health. Economic evaluation can be useful in providing decision makers with the best evidence of the anticipated benefits of new investments, as well as their expected opportunity costs—the benefits forgone of the options not chosen. To guide the decisions of health systems effectively, it is important that the methods of economic evaluation are founded on clear principles, are applied systematically, and are appropriate to the decision problems they seek to inform. **Methods:** The Bill and Melinda Gates Foundation, a major funder of economic evaluations of health technologies in low- and middle-income countries (LMICs), commissioned a "reference case" through the International Decision Support Initiative (iDSI) to guide future evaluations, and improve both the consistency and usefulness to decision makers. **Results:** The iDSI Reference Case draws on previous insights from the World Health Organization, the US Panel on Cost-Effectiveness in Health Care, and the UK National Institute for Health and Care Excellence. Comprising 11 key principles, each accompanied by methodological specifications and reporting standards, the iDSI Reference Case also serves as a means of identifying priorities for methods research, and can be used as a framework for capacity building and technical assistance in LMICs. **Conclusions:** The iDSI Reference Case is an aid to thought, not a substitute for it, and should not be followed slavishly without regard to context, culture, or history. This article presents the iDSI Reference Case and discusses the rationale, approach, components, and application in LMICs.

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Transparency

Comparator

Evidence

Measure of health outcome

Costs

Equity

Reference case principles

Time horizon and discount rate

Impact on constraints

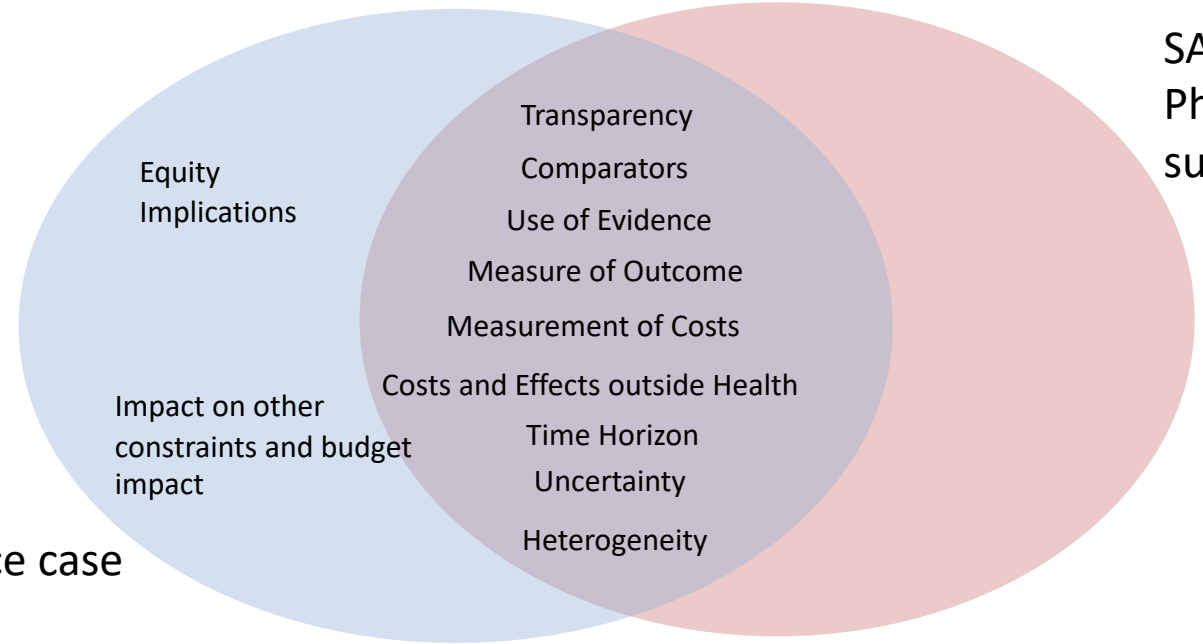
Uncertainty

Heterogeneity

Perspective

Pharmacoeconomic Guidelines vs. IDSI Reference Case

How many of these principles are covered by both the guidelines for Pharmaco-economic submission in SA and what are the gaps?



Acknowledgement for slide production: Alex Winch, Imperial College London

Transparency

IDSI Reference Case:
An economic evaluation should be **communicated clearly and transparently** to allow the decision maker(s) to **interpret** the methods and results

South African PE Guidelines:

- "Only models that are transparent, as determined by the Pricing Committee, will be considered"
- "Transparency includes the structure of the model as well as all the information required by the Pricing Committee to test the assumptions and inputs"
- "The Economic Evaluation Model and its workings used in submissions must be clearly transparent, and designed so that sub-committees and reviewers are able to change inputs and variables to determine the impact on the outcome"

Comparators

IDSI Reference Case:

The **comparators** against which costs and effects are measured should accurately **reflect the decision problem**.

South African PE Guidelines:

- "In some cases, comparisons with more than one comparator will be necessary."
- "All possible comparators should be listed, then describe and justify the comparators that are chosen for the evaluation and give an explanation for those that are not chosen."
- "The comparators should also include the lowest cost alternative based on the Single Exit Price (SEP)"

Use of Evidence

IDSI Reference Case:
An economic evaluation should consider **all available evidence** relevant to the decision problem.

South African PE Guidelines:

- "The selection of trials for analysis must start with a consideration of all relevant trials that enable a comparison between the medicine and the main comparator for the main indication."
- " A comprehensive search strategy must be used to identify these trials. This should involve at least three approaches:

(a) A search of the published literature;
(b) A search of the Cochrane Controlled Trials Register; and
(c) A check with the manufacturer for additional and unpublished information"

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Measure of outcome

IDSI Reference Case:
The measure of health outcome should be **appropriate to the decision problem,** should **capture measurements of both length of life and quality of life, and should be generalizable** across disease states.

South African PE Guidelines:

- "It is preferred that, wherever possible, the outcomes presented include final outcomes such as deaths prevented, life-years gained, or quality-adjusted life-years gained."
- "The evaluation should be based on the outcome measure(s) that most closely and validly estimates the final outcome"
- "All quality of life instruments should be validated using South African data. Where South African validation is not available, compelling justification should be made as to the relevance to the South African population."

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Measurement of costs

IDSI Reference Case:
All **differences** between the intervention and the comparator in **the expected resource use and costs of delivery** to the target population(s) should be incorporated into the evaluation.

South African PE Guidelines:

- "Where necessary ensure that:
  (a) Past costs are adjusted to reflect the costs in the year stated for the study with an explanation of the methodology used to adjust these costs and
  (b) Future costs valued at current prices."

- As a minimum, provide a table clearly identifying:
  (a) Each type of resource included in the evaluation(s);
  (b) Its natural unit of measurement;
  (c) The unit cost used to value that resource in the evaluation(s); and
  (d) The source/reference of the unit cost.

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Time Horizon for costs and effects

IDSI Reference Case:
The **time horizon** used in an economic evaluation should be of sufficient length to capture all costs and effects **relevant to the decision problem**; an appropriate **discount rate** should be used to **discount cost and effects to present values**

South African PE Guidelines:

- "State and justify the time horizon applied in the pharmacoeconomic submission. It is important that the time horizon is sufficient to capture all relevant clinical outcomes and future costs."
- "Discounting should be at the discretion of the applicant. However, if discounting is performed then the impact of discounting must still be included in a sensitivity analysis. Undiscounted outcomes should always be reported."
- "If discounting Is performed, a baseline annual discount rate of 5% for costs and benefits is proposed with a sensitivity analysis measuring the impact of a discount rate from 0% to 10%"

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Costs and Effects outside Health

IDSI Reference Case:

Non-health effects and **costs that do not fall on the health budget** that are associated with gaining or providing access to health interventions should be identified where relevant to the decision problem. All **costs and effects should be disaggregated**, either by sector of the economy or by who incurs them.

South African PE Guidelines:

- "In general, indirect costs should not be included in the submission"
- "Present the estimated costs in disaggregated form, i.e. separately for each type of resource provided. All steps taken to calculate costs should be clear during the evaluation"

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Uncertainty

IDSI Reference Case:

The uncertainty associated with an economic evaluation should be appropriately characterised.

South African PE Guidelines:

- "One-way sensitivity analyses must be conducted on all variables using an appropriate range (confidence intervals, best-case/worst-case, etc.) that needs to be justified and supported by evidence."
- "A two-way sensitivity analyses could be conducted on all variables shown to be sensitive in the one-way analyses."
- "Where complex models have been approved, serious consideration should be given to a probabilistic sensitivity analysis."

Methods Gaps in the PE Guidelines:

Impact on other constraints and budget impact

IDSI Reference Case:

The impact of implementing the intervention on health budget and on other constraints should be clearly and separately identified.

Equity implications

IDSI Reference Case:

An economic evaluation should explore the equity implications of implementing the intervention.