




Methods of Health Technology Assessment :
Understanding Budget Impact and Cost-Effectiveness
Analysis – What are they and how do we interpret the
results?

Alex Winch - Imperial College London

Rebecca Addo - University of Technology Sydney

Setting Health Priorities 2018

Presentation overview

1. Recap on Health Technology and HTA
 2. Why the need for a reference case?
 3. Types of Analysis in the 5 steps of HTA
 4. Cost-Effectiveness Analysis
 5. Budget Impact Analysis
 6. The Bookshelf Analogy
- 

What is a health technology?

*A health technology is **any intervention** that may be used to **promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation and palliative care.***

(Definition adopted at IDSI HTA meeting March 2015, Johannesburg, SA)

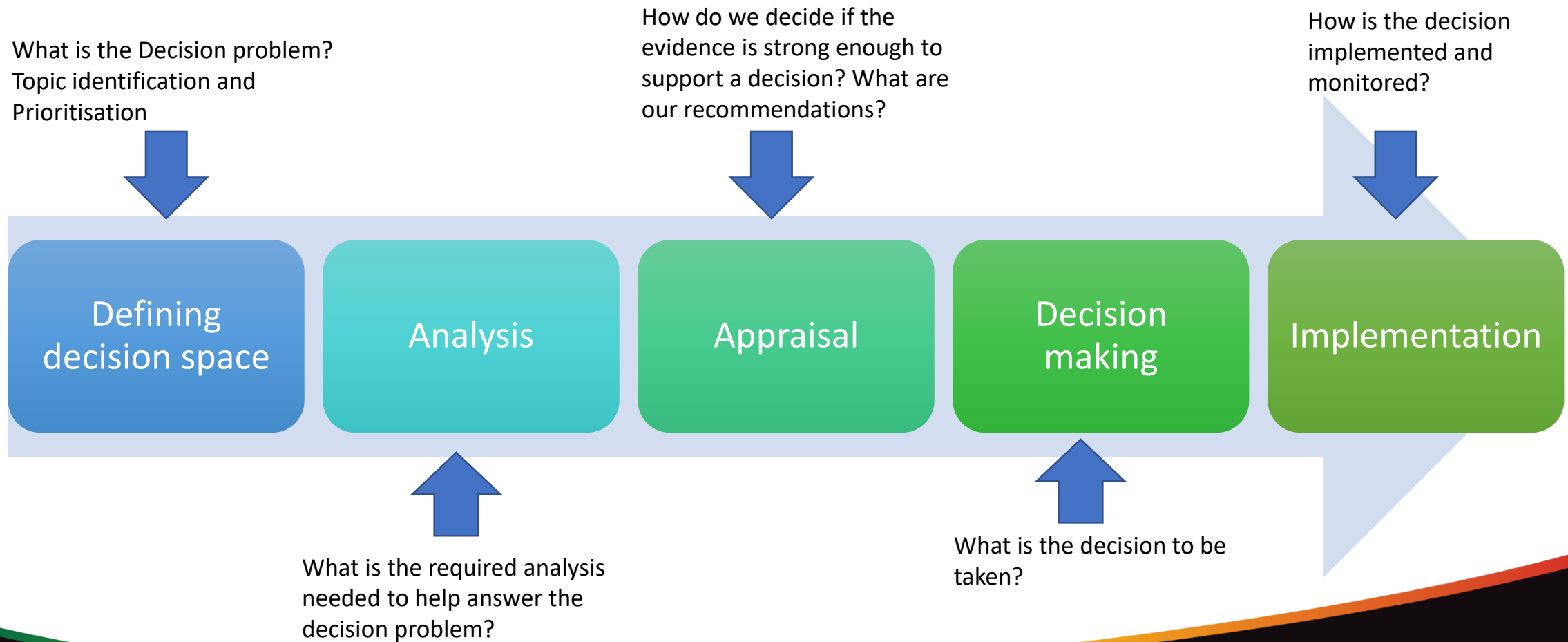
What is Health Technology Assessment?

*HTA is the **systematic evaluation** of properties, effects and/or impacts of **health technologies and interventions.** It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences*

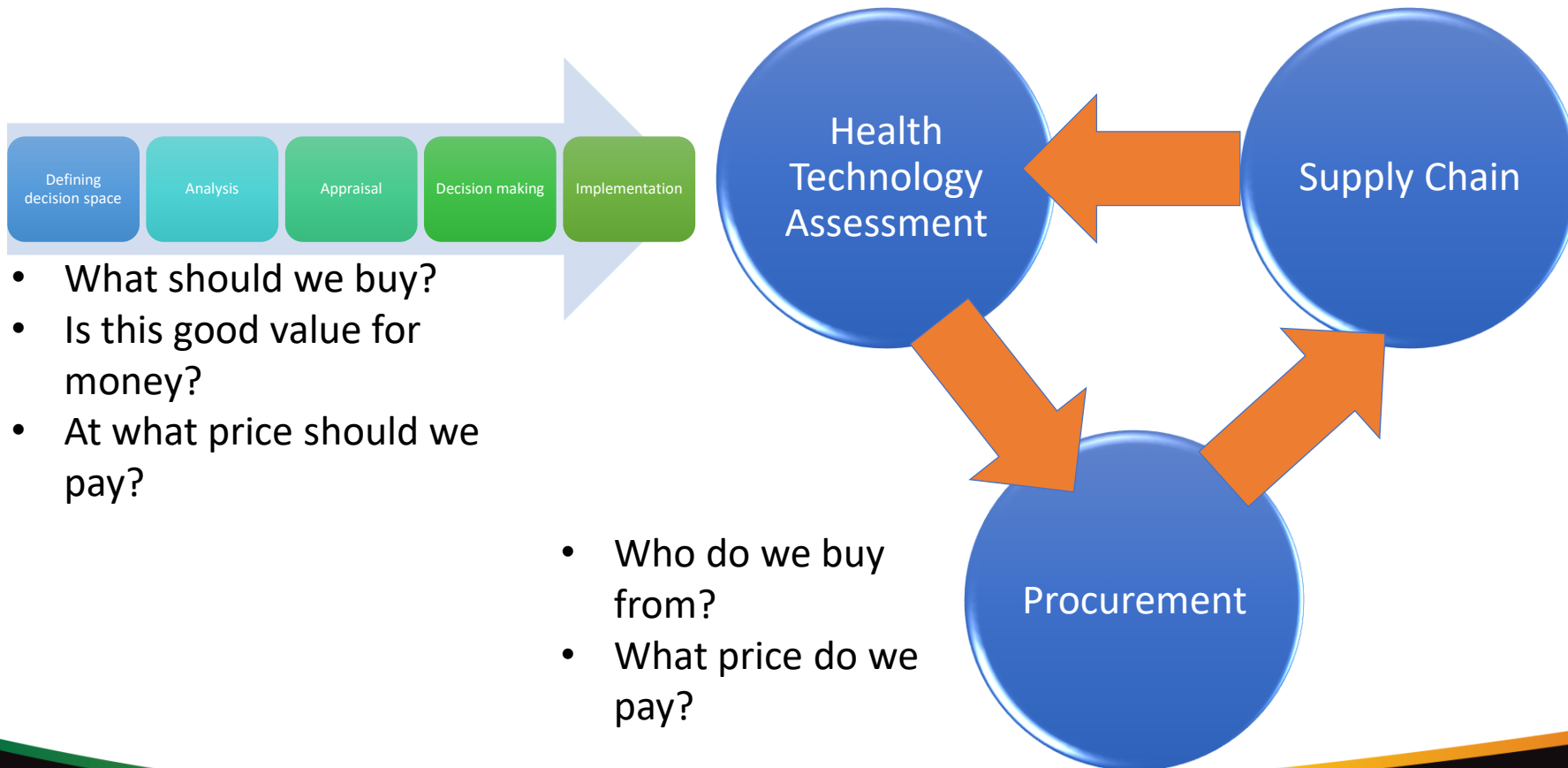
(WHO)



5 Step-HTA process



HTA process should be integrated into broader health system

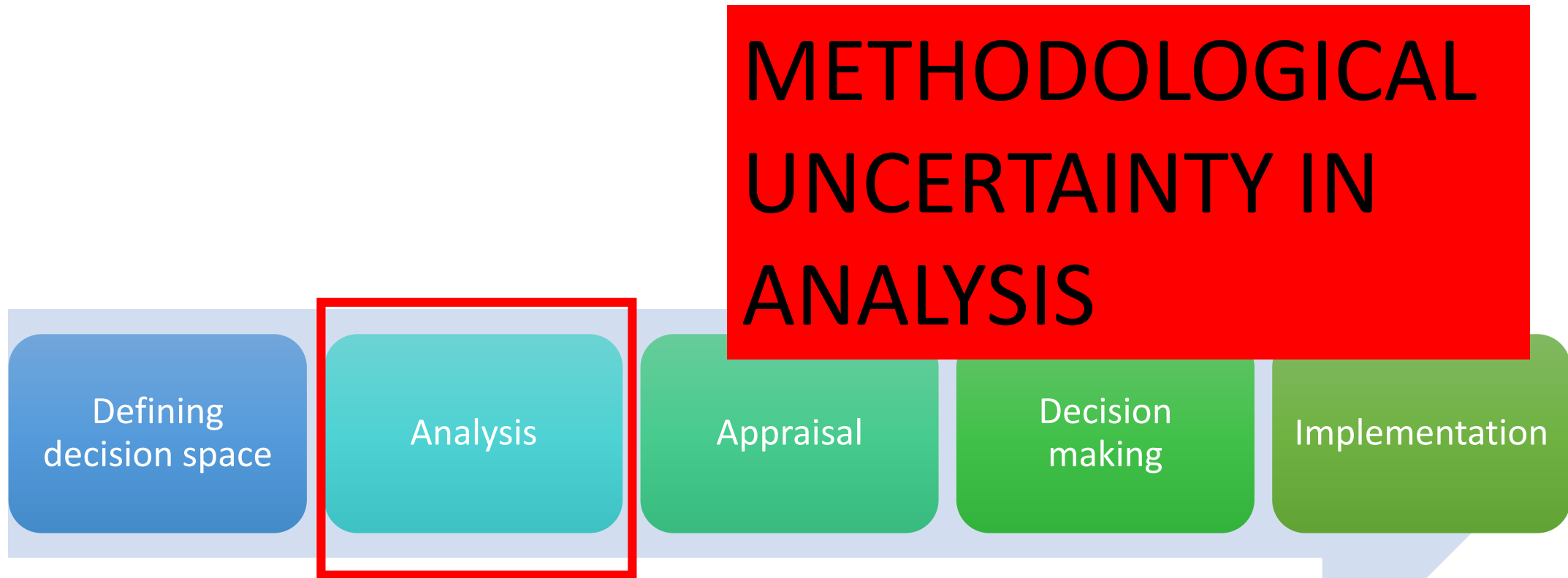


- What should we buy?
- Is this good value for money?
- At what price should we pay?

- Who do we buy from?
- What price do we pay?

- How do we ensure on time in full delivery
- How do we ensure procured commodities get to the patients who need them?

Why The Need for the Reference Case



DYNAMIC TRANSMISSION ECONOMIC EVALUATION OF INFECTIOUS DISEASE INTERVENTIONS IN LOW- AND MIDDLE- INCOME COUNTRIES: A SYSTEMATIC LITERATURE REVIEW

TOM L. DRAKE^{a,b,*}, ANGELA DEVINE^{a,b}, SHUNMAY YEUNG^c, NICHOLAS P. J. DAY^{a,b}, LISA J. WHITE^{a,b} and
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Fifty-seven studies were eligible for inclusion in the all-disease review. The most common subject disease was HIV/AIDS, followed by malaria. ***A diverse range of modelling methods, outcome metrics and sensitivity analyses were used, indicating little standardisation.*** Seventeen studies were included in the mosquito-borne disease review.

With notable exceptions, most studies did not employ economic evaluation methods beyond calculating a cost-effectiveness ratio or net benefit. Many did not adhere to health care economic evaluations reporting guidelines, particularly with respect to full model reporting and uncertainty analysis.

Standardised approaches to Economic Evaluation

- Need to reduce methodological uncertainty in health
- A way of 'standardising' so that the analytical approaches and presentation of results are more consistent

Reference Cases:

- Improve quality of the evidence available
- Enable the results of multiple assessments to be more easily understood and compared
- Describe expectations based on best practice on purely technical issues (such as the preferred approach to assessing uncertainty)....
- but can also incorporate issues that are essentially value judgements (such as equity positions), and that are likely to be **more context specific**
- Facilitate a consistent approach but should not exclude 'non-RC' analyses, especially if 'strict adherence' is not possible



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



Thomas Wilkinson, MSc^{1,2}, Mark J. Sculpher, PhD², Karl Claxton, PhD³, Paul Revill, MSc², Andrew Briggs, DPhil⁴, John A. Cairns, MPhil⁵, Yot Teerawattananon, PhD⁶, Elias Asfaw, MSc⁷, Ruth Lopert, MD, MMedSc^{8,9}, Anthony J. Culyer, BA, Hon DEcon¹⁰, Damian G. Walker, PhD¹¹

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Statement of principle

1	An economic evaluation should be communicated clearly and transparently to allow the decision maker(s) to interpret the methods and results
2	The comparators against which costs and effects are measured should accurately reflect the decision problem .
3	An economic evaluation should consider all available evidence relevant to the decision problem.
4	The measure of health outcome should be appropriate to the decision problem , should capture positive and negative effects on length of life and quality of life , and should be generalizable across disease states.
5	All differences between the intervention and the comparator in expected resource use and costs of delivery to the target population(s) should be incorporated into the evaluation.
6	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

Statement of principle

7	Non-health effects and costs associated with gaining or providing access to health interventions that don't accrue to the health budget should be identified where relevant to the decision problem . All costs and effects should be disaggregated , either by sector of the economy or to whom they accrue..
8	The cost and effects of the intervention on sub-populations within the decision problem should be explored and the implications appropriately characterized .
9	The uncertainty associated with an economic evaluation should be appropriately characterised .
10	The impact of implementing the intervention on the health budget and on other constraints should be identified clearly and separately .
11	An economic evaluation should explore the equity implications of implementing the intervention.

Transparency

Comparator

Equity

Impact on
constraints

Measure of health
outcome

An aid to
decision making

Uncertainty

Evidence

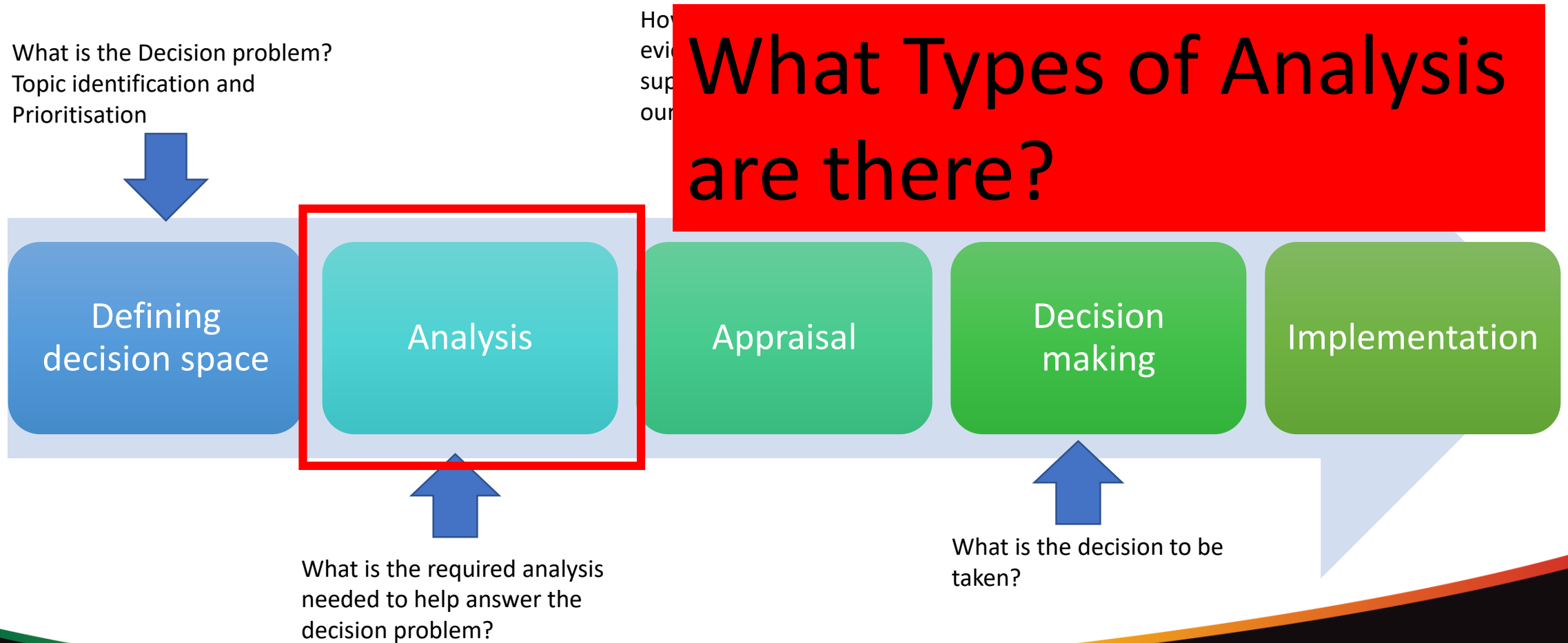
Heterogeneity

Costs

Time horizon and
discount rate

Perspective

5 Step-HTA process: Types of Economic Analysis



What type of analyses can inform a HTA?

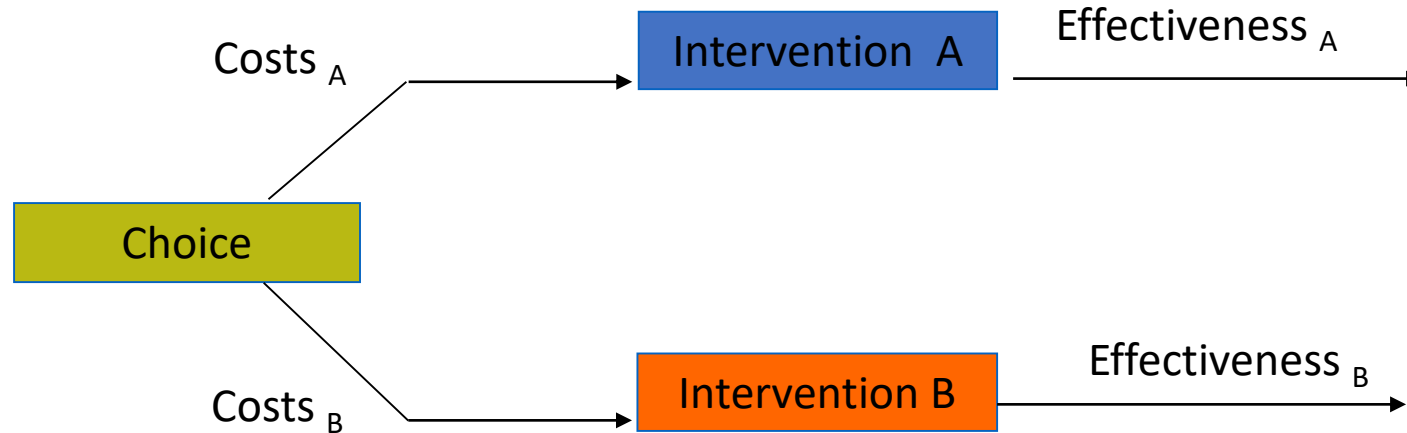
Type of analysis	Where it is used
Cost-of-illness analysis	A determination of the economic impact of an illness or condition (typically on a given population, region, or country) e.g., of smoking, arthritis, or diabetes, including associated treatment costs
Cost-Effectiveness Analysis	A comparison of costs in monetary units with outcomes in quantitative non-monetary units such as Quality Adjusted Life Years (QALYs) or averted Disability Adjusted Life Years (DALYs) , reduced mortality or morbidity. This is often termed “cost-utility analysis” (CUA) and you should give thought to whether your preferred outcome measure should be some indicator of health gain or loss or some indicator of the utility of such gains or losses. An advantage of the health gain/loss approach is that it is more readily understandable by clinicians and the public and easier to validate.
Budget Impact Analysis	Can be conducted in addition to a CEA to determine the impact of implementing or adopting a particular technology or technology-related policy on a designated budget , e.g., for a drug formulary or health plan.
Cost-Consequence analysis	A form of cost-effectiveness analysis that presents costs and outcomes in discrete categories , without aggregating or weighting them
Cost-Minimisation analysis	A form of analysis that assumes that the effects of two interventions are the same, but the costs differ . The analysis compares costs to identify the least costly
Cost-Benefit analysis	compares costs and benefits, both of which are quantified in common monetary units

What type of analyses can inform a HTA?


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Cost Effectiveness Analysis (CEA)


A comparative analysis of the costs and effects of two or more interventions to choose the one that maximises health outcomes




CEA: Steps in conducting CEA

- Define alternatives under evaluation
 - Define perspective of analysis
 - Define time frame (horizon) for the evaluation
 - Identify, measure and value costs
 - Identify, measure and value of effectiveness
 - Combine costs and effectiveness
 - Assess robustness of results (sensitivity analysis)
 - Interpret
- 

CEA steps: Defining the intervention

- Components of the program
 - Frequency of the intervention
 - Specific technologies used
 - Method of delivery
 - “Bundling” of services
 - “Starting point” for intervention
 - Target population
- 


CEA steps: Choice of comparator

- Identifying incremental costs and incremental effects
 - Comparator will depend on the policy context
 - May need a range of comparators
 - “Do nothing” / No treatment
 - Status quo (may involve a range of programs): choose one of these or what happens now?
 - Current best practice
 - 2+ alternatives against same base case
 - What do we know about current practice?
 - Comparing programs of varying intensity/duration
- 

CEA steps: Perspective of analysis

- Perspective adopted for the analysis influences the costs we include
 - Societal – all costs and benefits, irrespective of to whom they are accrued, are included
 - Includes patients, carers, Government etc
 - Government
 - Can include impact on other departments. e.g. impact of ADHD drug on department of justice and education
 - Health care system – National, Regional, District or all three.
 - Can also be the health care institution or provider
- Implications for how costs and consequences defined and measured.
- May need to present results from different perspectives

CEA steps: Time Horizon

- Most health care interventions have future costs and consequences
 - Impacts in future less certain but still relevant
 - Relates to perspective/decision context and to choice of outcome measure
 - Trying to capture all **relevant** future costs and consequences
 - Discounting of future costs and consequences
- 

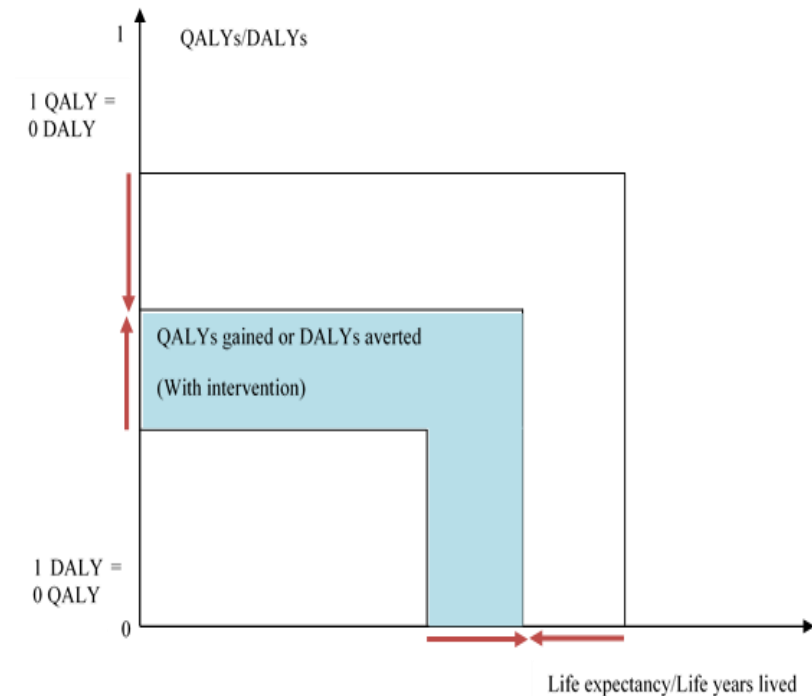
CEA steps: Measurement of costs

- Identification and estimation of resource use
 - Ghana standard treatment guidelines
 - Expert opinion
- Apportion costs to resource use
- Costs may include
 - Cost of implementing program/intervention
 - Cost to the patient and family
 - Costs to the society (Other sectors other than health)
- Sources of cost data
 - Secondary source
 - NHIS medicines list, NHIS hospital tariffs,
 - Review of folders
 - Primary data collection
 - Clinical trials, programs

CEA steps: Measurement of effectiveness

- Natural units
 - Malaria cases averted, life years gained, hospital days averted, deaths averted
 - A limitation of this measure is comparing interventions with different outcome measures
- A single measure of health outcome (an extended version of CEA: a Cost utility analysis)
 - Disability adjusted life years (DALYs)
 - Quality adjusted life years (QALYs)
 - A common health outcome measure enables decision maker to compare an array of health technologies/interventions

- Differences between DALYs and QALYs



CEA steps: Combine costs and effectiveness

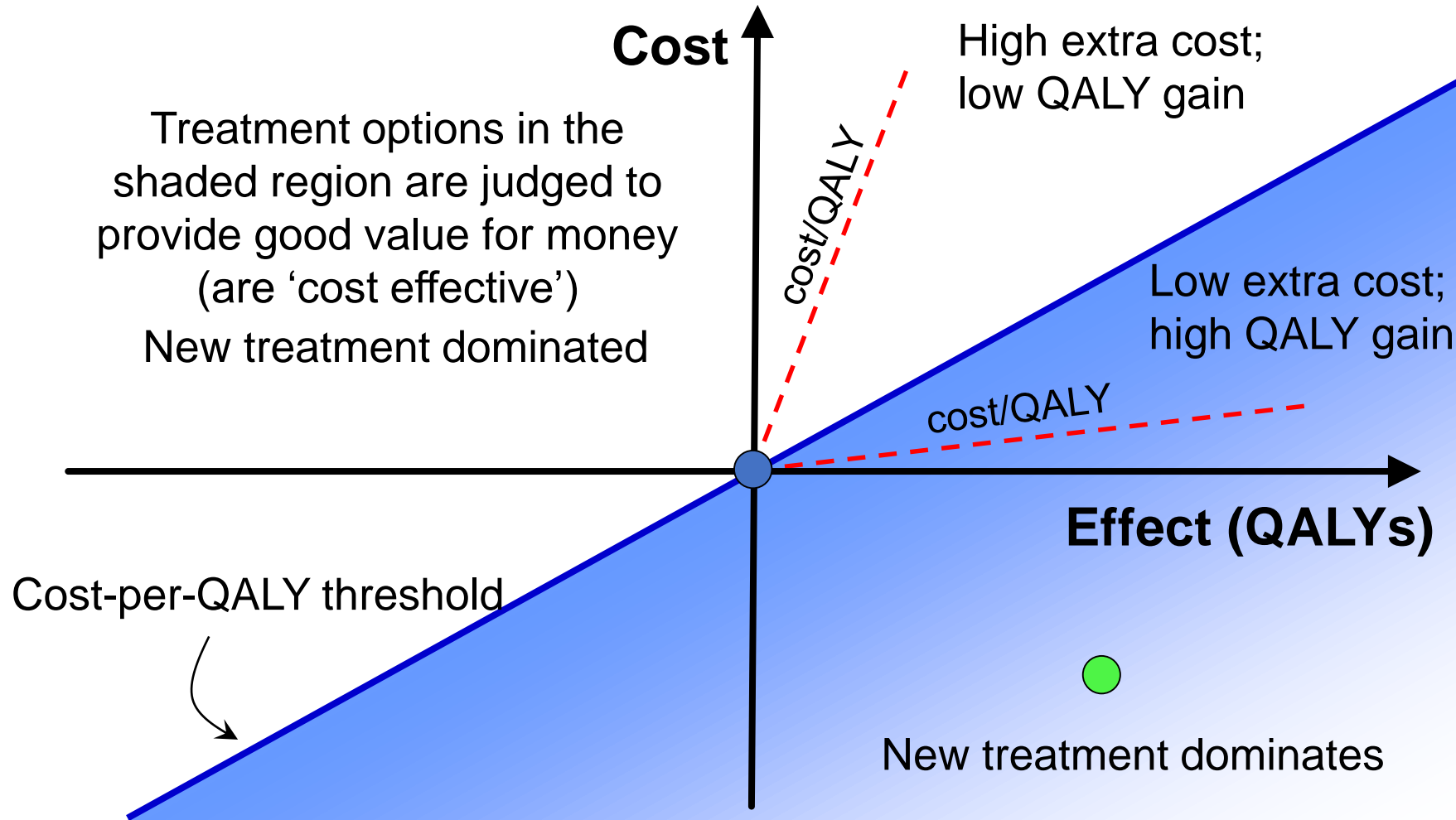
Incremental Cost-Effectiveness Ratio (ICER)

- This is defined as **“The extra cost of the additional service divided by the extra outcome of effectiveness”**

$$ICER = \frac{Cost_{New} - Cost_{Comparator}}{Effectiveness_{New} - Effectiveness_{Comparator}}$$

- How much are we, as a society, paying for each unit of outcome (death averted, sight regained etc)?
- The fundamental question is this: **“Does the difference in outcome between the approaches justify the difference in costs?”**

How do we use the ICER to assess value for money?



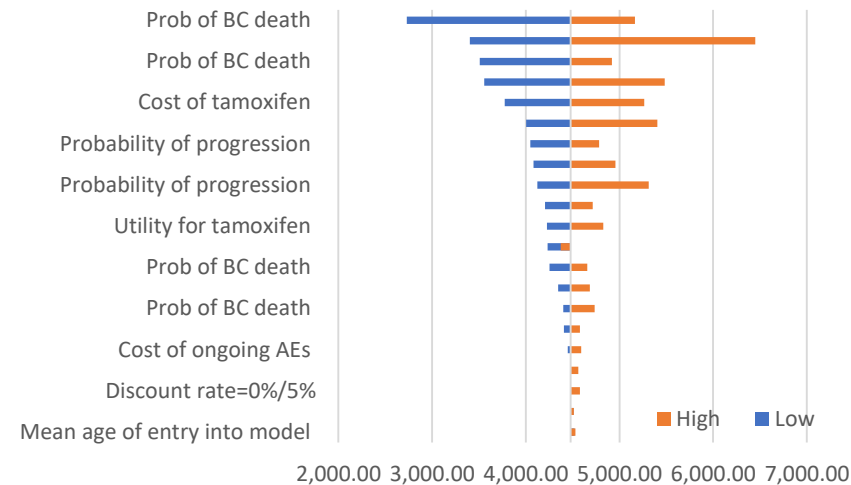
CEA steps: Sensitivity analysis

- An analysis used to explore the nature of uncertainties of inputs used for the CEA to establish their impact on the base ICER
- Source of uncertainties: costs, effectiveness, structure of model

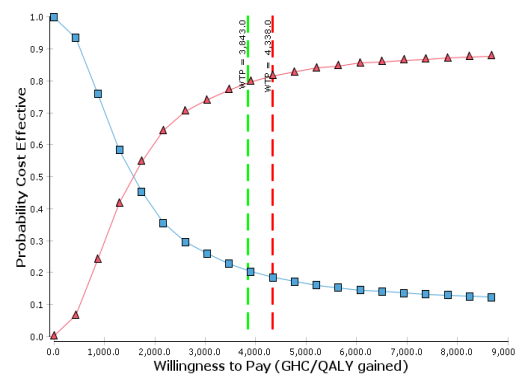
Types of sensitivity analysis

Types	Characteristics
Univariate sensitivity analysis	One input parameter is varied at a time
Multivariate sensitivity analysis	More than one input parameter is varied at a time
Probabilistic sensitivity analysis	Simultaneously vary all uncertain parameters for a specified range; distribution
Threshold analysis	Considers the value a parameter must take to achieve a target results
Scenario analysis	Assess the impact of a particular scenario on the ICER

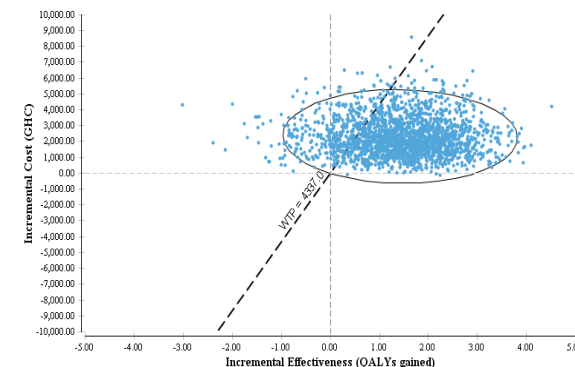
Presentation of sensitivity analysis



Tornado diagram for univariate sensitivity analysis



Cost effectiveness acceptability curve (PSA)



Scatter plot (PSA)

A number of CEA studies from Ghana

Tropical Medicine and International Health

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VALUE IN HEALTH

Is home management of fevers a cost-effective way of reducing under-five mortality in Africa? The case of a rural Ghanaian District

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Am. J. Trop. Med. Hyg., 89(4), 2013, pp. 724-736

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Cost-Effectiveness Analysis of Introducing RDTs for Malaria Diagnosis as Compared to Microscopy and Presumptive Diagnosis in Central and Peripheral Public Health Facilities in Ghana

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Cost Effectiveness of Seasonal Intermittent Preventive Treatment Using Amodiaquine & Artesunate or Sulphadoxine-Pyrimethamine in Ghanaian Children

Lesong Conteh^{1,2*}, Edith Patouillard¹, Margaret Kweku^{1,3}, Rosa Legood¹, Brian Greenwood¹, Daniel Chandramohan¹

¹ London School of Hygiene and Tropical Medicine, London, United Kingdom, ² Imperial College London, London, United Kingdom, ³ Ghana Health Service, University of Ghana, Legon, Accra, Ghana

Cost-Effectiveness of HIV Screening of Blood Donations in Accra (Ghana)

Marinus van Hulst, MSc, PharmD,^{1,2} Kwamena W. C. Sagoe, MSc,³ Jacobien E. Vermande, MSc,¹ Ido P. van der Schaaf, MSc,^{1,4} Willem P.A. van der Tuuk Adriani, MSc, PharmD,⁵ Kwasi Torpey, MD, MPH,⁶ Justina Ansah, MD,⁷ Julius A. A. Mingle, DipBactPhD,³ Cees Th. Smit Sibinga, MD, PhD, FRCP Edin, FRCPath,⁵ Maarten J. Postma, PhD¹

VanDeusen et al. *BMC Infectious Diseases* (2015) 15:130
DOI 10.1186/s12879-015-0859-2



RESEARCH ARTICLE

Open Access

Cost effectiveness of option B plus for prevention of mother-to-child transmission of HIV in resource-limited countries: evidence from Kumasi, Ghana

Adam VanDeusen¹, Elijah Paintsil^{2*}, Thomas Agyarko-Poku³ and Elisa F Long⁴

Nonvignon et al. *Malar J* (2016) 15:367
DOI 10.1186/s12936-016-1418-z

Malaria Journal

RESEARCH

Open Access



Cost-effectiveness of seasonal malaria chemoprevention in upper west region of Ghana

Justice Nonvignon¹, Genevieve Cecilia Aryeetey¹, Shamwill Issah², Patrick Ansah³, Keziah L. Malm⁴, Winfred Ofofu⁵, Titus Tagoe⁵, Samuel Agyei Agyemang¹ and Moses Aikins^{1*}

A case of CEA studies from Ghana

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Cost-Effectiveness Analysis of Introducing RDTs for Malaria Diagnosis as Compared to Microscopy and Presumptive Diagnosis in Central and Peripheral Public Health Facilities in Ghana

Evelyn K. Ansah, Michael Epokor, Christopher J. M. Whitty, Shunmay Yeung, and Kristian Schultz Hansen*

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Abstract. Cost-effectiveness information on where malaria rapid diagnostic tests (RDTs) should be introduced is limited. We developed incremental cost-effectiveness analyses with data from rural health facilities in Ghana with and without microscopy. In the latter, where diagnosis had been presumptive, the introduction of RDTs increased the proportion of patients who were correctly treated in relation to treatment with antimalarials, from 42% to 65% at an incremental societal cost of Ghana cedis (GHS)12.2 (US\$8.3) per additional correctly treated patients. In the “microscopy setting” there was no advantage to replacing microscopy by RDT as the cost and proportion of correctly treated patients were similar. Results were sensitive to a decrease in the cost of RDTs, which cost GHS1.72 (US\$1.17) per test at the time of the study and to improvements in adherence to negative tests that was just above 50% for both RDTs and microscopy.

Characteristics	Inputs used for analysis
Intervention	Rapid diagnostic test (RDT)
Comparators	Microscopy diagnosis Presumptive diagnosis
Type of evaluation	Cost effectiveness analysis
Perspective of analysis	Health system and societal
Time horizon	1 year
Method of analysis	Decision tree model
Outcome (effectiveness measure)	Correctly treated fever
Costs	Direct and indirect costs
Discount rate	5%
Sensitivity analysis	Univariate and multivariate

A case of CEA studies from Ghana

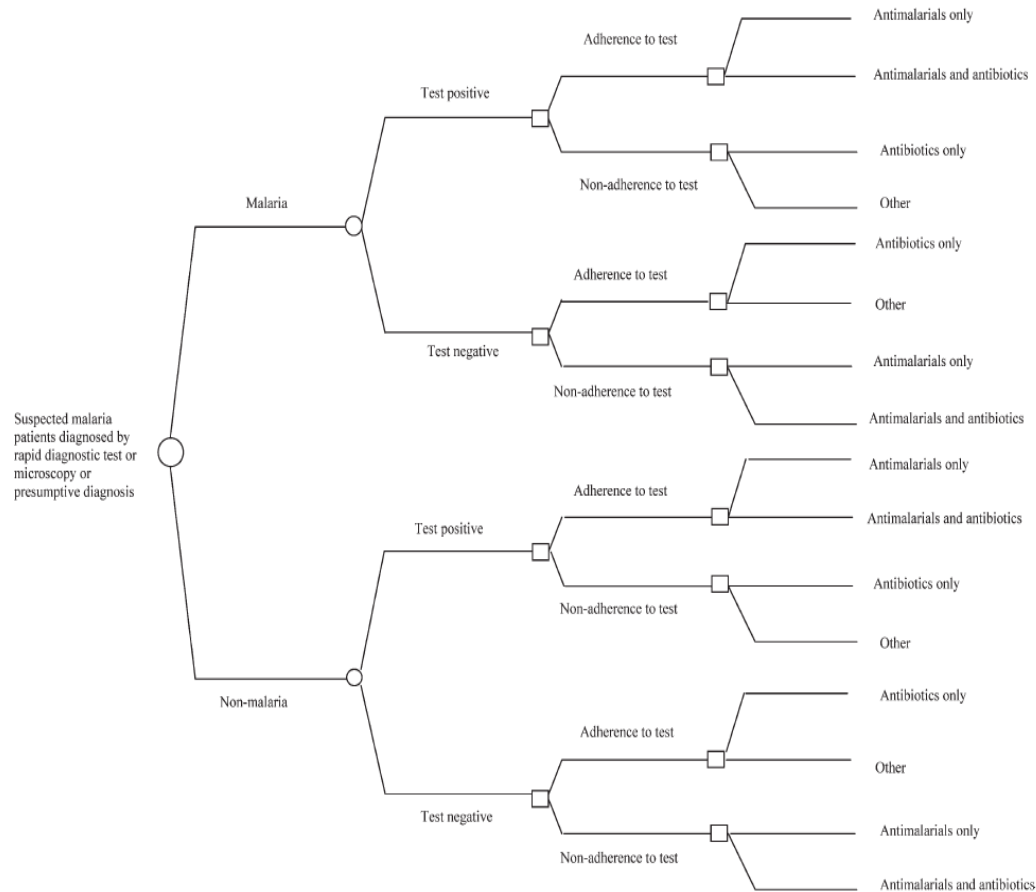



FIGURE 1. Decision tree.

Analytical approach

Outcomes and costs	Microscopy setting		Presumptive diagnosis setting	
	RDT arm	Microscopic arm	RDT arm	Presumptive diagnosis arm
Treatment for Suspected malaria patients (N=1,000 per treatment arm)				
Antimalarials, no antibiotics	508	527	550	696
Antimalarials and antibiotics	116	116	150	231
Antibiotics, no antimalarials	168	159	158	38
Other	207	198	141	35
Outcome				
Correctly treated patients (CTP)	601 (60%)	569 (57%)	651 (65%)	420 (42%)
Costs				
Costs to the health sector (TCHS)				
Diagnostics	2,824	2,028	3,919	0
Drugs	2,743	3,433	2,891	3,131
Salaries, supplies, buildings	9,849	9,743	10,451	10,564
Total cost to the health sector (TCHS)	15,416 (69%)	15,204 (69%)	17,260 (71%)	13,695 (64%)
Cost to the patient				
Out-of-pocket (travel, drugs)	973	986	901	896
Opportunity cost (travel, waiting)	1,619	1,603	1,556	1,572
Opportunity cost (work time lost)	4,257	4,303	4,466	5,209
Total cost to the patient	6,849 (31%)	6,892 (31%)	6,924 (29%)	7,677 (36%)
Societal cost				
Total societal cost (TCHS + TPC)	22,265	22,096	24,184	21,373
Incremental analysis				
Incremental outcome (CTP)		32		231
Incremental cost, health sector		212		3,565
Incremental cost, societal		170		2,812
ICER, health sector		6.7		15.4
ICER, societal		5.3		12.2

Budget Impact Analysis (BIA)

What is it?

- Understand the fiscal impact and diffusion of introducing a new health intervention, or expanding access to an existing, health intervention
 - BUT – It will not give you an idea about value for money
- 

Budget Impact Analysis (BIA)

- Variety of users of budget impact analyses in health, primarily those who manage and plan health care budgets
 - Administrators of national or regional health care programs
 - Private health insurance plans
 - Health care delivery organisations
 - Employers who pay directly for health care

Budget Impact Analysis: How is it different to Cost-Effectiveness Analysis?

	BUDGET IMPACT ANALYSIS	COST EFFECTIVENESS ANALYSIS
Objective	Impact on resources consumed	Determine an interventions net health return on investment
Outcomes	Net resource consumption	Net Health Benefit/ Net resource consumption
Perspective	Payer	Health System or Societal, or payer
Time Horizon	Over a Budget Cycle(Normally 1-5 Years)	Longer Term(For all relevant benefits and costs to be realised)
Unit of Measurement	Absolute Costs and Savings	Incremental Cost Effectiveness Ratio (ICER)
Interpretation	Lower costs = Greater Affordability	A smaller ICER indicates a lower incremental cost per health gain (greater cost-effectiveness)
Threshold	No Standard Approach to determine affordability	New Intervention is cost-effective if it falls below a CE Threshold determined by Willingness to Pay
Measures What?	Financial Costs	Financial and Opportunity Costs

Is it important to do both?: 'Cost Effective' and Unaffordable

A pill too hard to swallow: how the NHS is limiting access to high priced drugs

BMJ 2016 ; 354 doi: <https://doi.org/10.1136/bmj.i4117> (Published 27 July 2016)

Cite this as: *BMJ* 2016;354:i4117

Article Related content Metrics Responses


Jonathan Gornall, freelance journalist¹, Amanda Hoey, consultant, Piotr Ozieranski, lecturer³

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A joint investigation by The BMJ and Cambridge and Bath universities uncovers how NHS England tried to limit access to expensive new drugs for hepatitis C. **Jonathan Gornall**, **Amanda Hoey**, and **Piotr Ozieranski** report

When cost-effective interventions are unaffordable: Integrating cost-effectiveness and budget impact in priority setting for global health programs

Alyssa Bilinski , Peter Neumann, Joshua Cohen, Teja Thorat, Katherine McDaniel, Joshua A. Salomon

Published: October 2, 2017 • <https://doi.org/10.1371/journal.pmed.1002397>

Editorials

Cost effective but unaffordable: an emerging challenge for health systems

BMJ 2017 ; 356 doi: <https://doi.org/10.1136/bmj.j1402> (Published 22 March 2017)

Cite this as: *BMJ* 2017;356:j1402

Article Related content Metrics Responses

Victoria Charlton, PhD student in bioethics and society¹, Peter Littlejohns, professor of public health², Katharina Kieslich, research fellow in health policy², Polly Mitchell, PhD student in philosophy⁴, Benedict Rumbold, research fellow in philosophy⁴, Albert Weale, emeritus professor of political theory and public policy³, James Wilson, senior lecturer in philosophy⁴, Annette Rid, senior lecturer in bioethics and society¹

Patients suffer when NHS buys expensive new drugs, says report

The NHS price threshold for drugs that give a year of good-quality life should be lowered to stop local budgets missing out, argue experts at the University of York



▲ Karl Claxton says the patients who lose out are invisible and have no say in the argument over how limited NHS resources are spent. Photograph: eye35/Alamy

The NHS is doing more harm than good by approving expensive drugs for a limited number of conditions such as advanced cancer, which use up funds that would benefit other parts of the health service, according to an analysis by a leading group of health economists.

Is it important to do both?: ‘Cost Effective’ and Unaffordable



“In low and middle income countries, the World Health Organization (WHO) has recommended thresholds of **1 to 3 times gross domestic product (GDP) per capita** – seemingly on the basis of recommendations from the “Commission on Macroeconomics and Health” report from 2001.”(1)

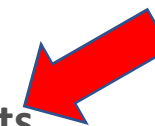


“For instance, values of **GB£20-30,000** and **US\$50,000** per QALY have commonly been applied in the United Kingdom and United States, respectively; without clear rational but with some sense they reflect the consumption value of health.”(1)

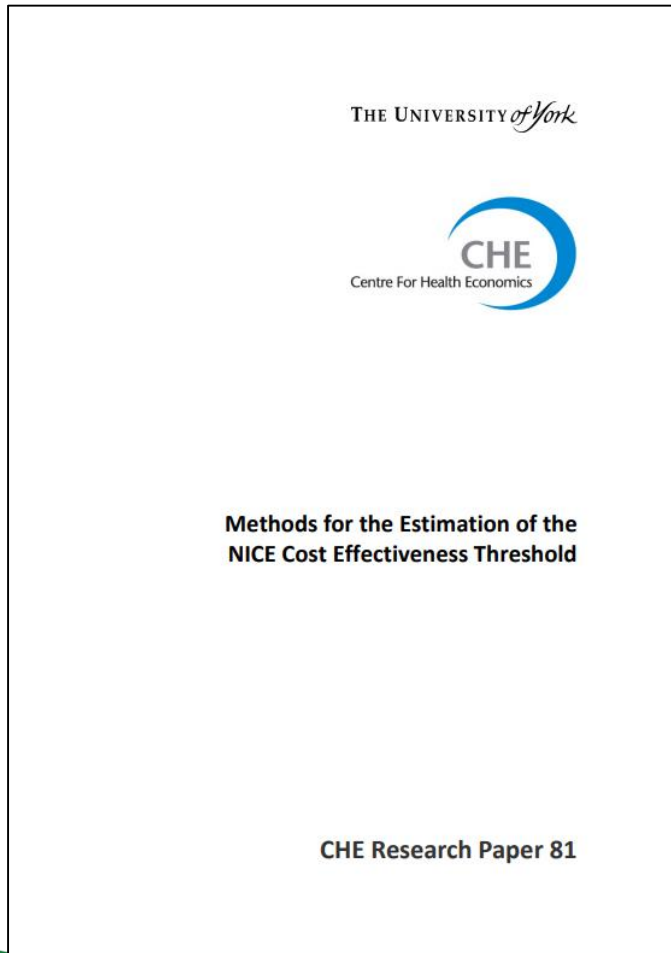


“To say that an alternative is cost-effective but not affordable must mean that the (implicit or explicit) “threshold” used to judge cost-effectiveness **does not reflect the opportunity costs** incurred given the scale of the impact on health expenditure” (Lomas et al 2018)

New Intervention is cost-effective if it falls below a CE Threshold determined by Willingness to Pay



Is it important to do both?: 'Cost Effective' and Unaffordable



Currently NICE uses a threshold range of **£20,000 to £30,000** QALY gained, and this has remained the case in NICE's methods guidance since 2004.

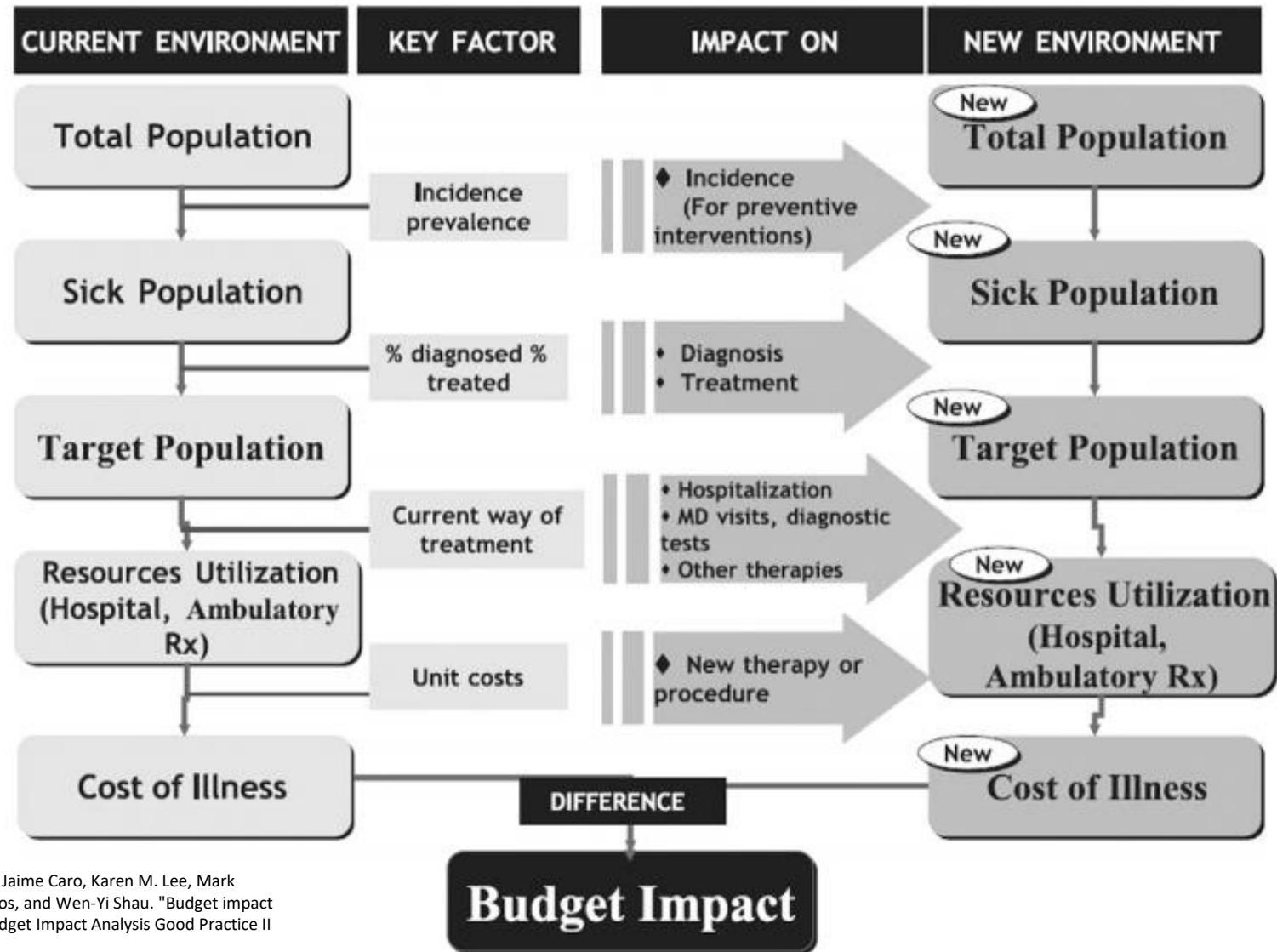
The most relevant threshold is estimated using the latest available data (2008 expenditure, 2008-10 mortality). The central or 'best' threshold is estimated to be **£12,936 per QALY**.

Is it important to do?:

YES

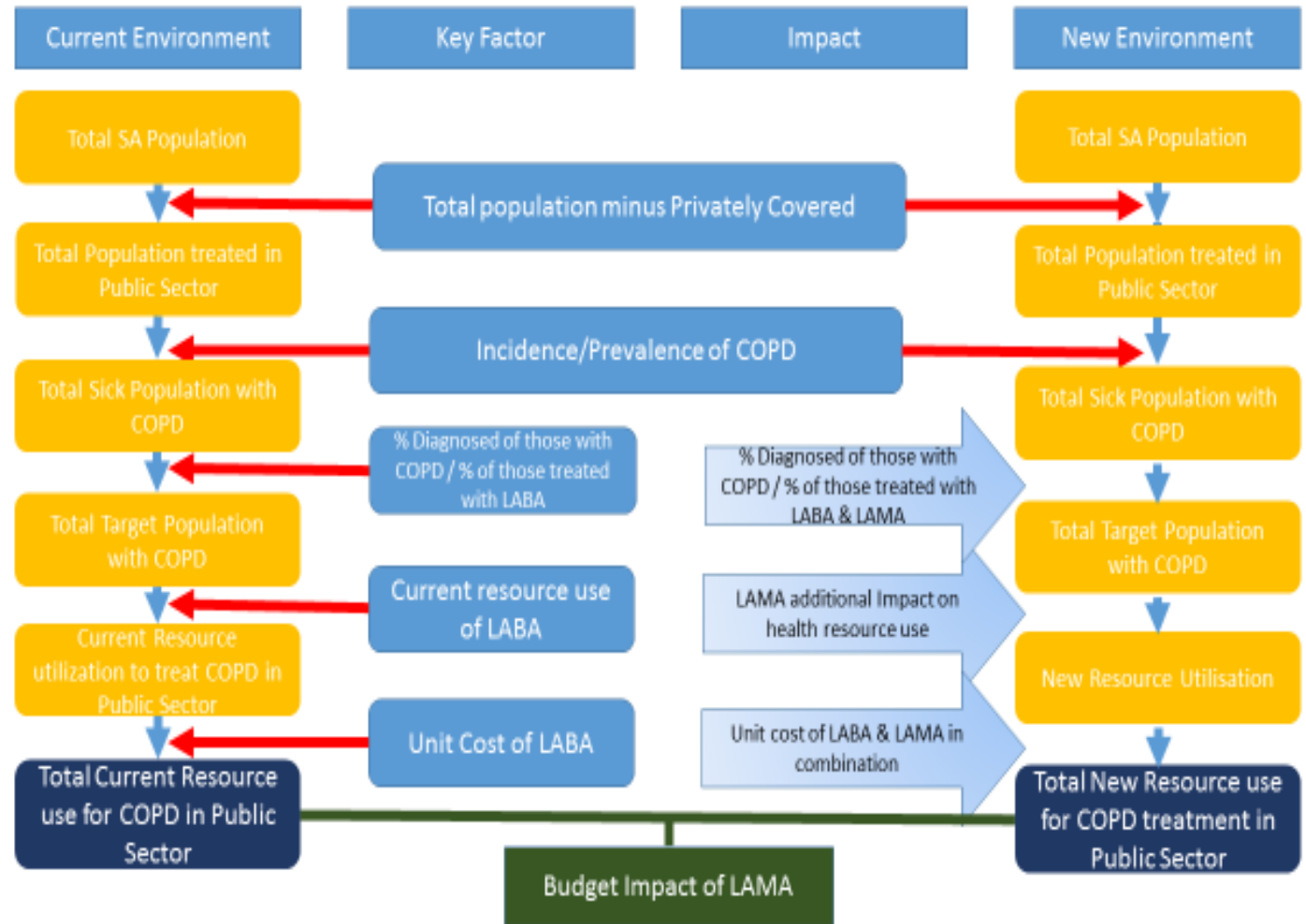
Until a meaningful discussion can be had on a properly calibrated cost-effectiveness threshold which accurately reflects Willingness to Pay

Conducting a BIA: Key Considerations



Conducting a BIA: An Example from South Africa

- Chronic Obstructive Pulmonary Disorder (COPD) affects a large number of people in the South African public sector.
- LAMAs such as tiotropium and glycopyrronium are the most widely recommended and used treatments for COPD worldwide (GOLD 2016) in addition to inhaled corticosteroids and long-acting beta agonists (LABAs).
- The Disease is managed through the use of Long acting muscarinic antagonists (LAMAs).
- Worldwide LAMAs have been shown to improve lung function, quality of life, reduce exacerbations as well as hospitalisation and duration of hospital stay.
- In 2017, the South African Govt. wanted to know the budget impact of introducing LAMAs for patients alongside the existing Long-acting Beta-agonists (LABA) in the public sector and as a replacement for LABAs
- Methodology follows ISPOR guidelines for conducting a BIA



Cost Effectiveness Analysis

- Quantify the health trade off with other health system objectives
- Consider allocative efficiency, which underpins sustainable UHC
- Reveals technical inefficiency
- All patients, conditions, are equal
- Quantify the opportunity cost per \$ spent
- Answers the question: should we do it

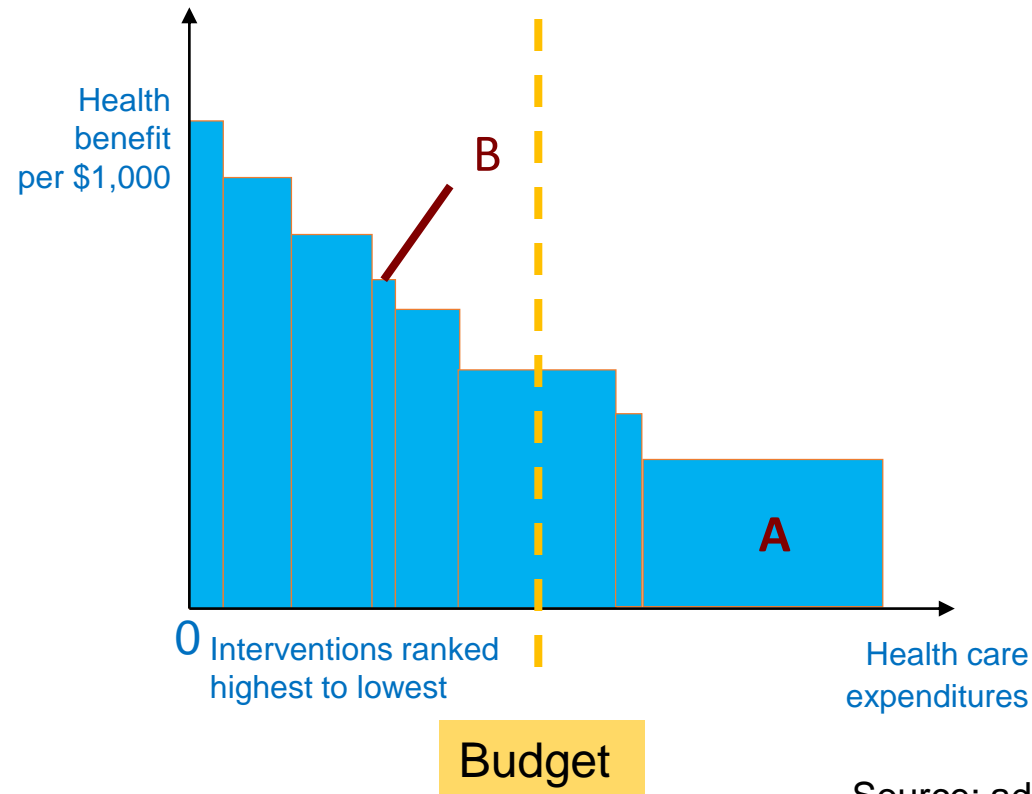
Budget Impact Analysis

- Quantify the financial trade off with other health system and wider policy objectives
- Does not consider efficiency
- Does not consider effectiveness
- Discriminates on size of the population
- Facilitates program budgeting, strategic purchasing
- Pragmatic, easily understandable
- Answers the question: can we do it

Combining CEA with BIA allows us to quantify the opportunity cost in of the decision terms of total health

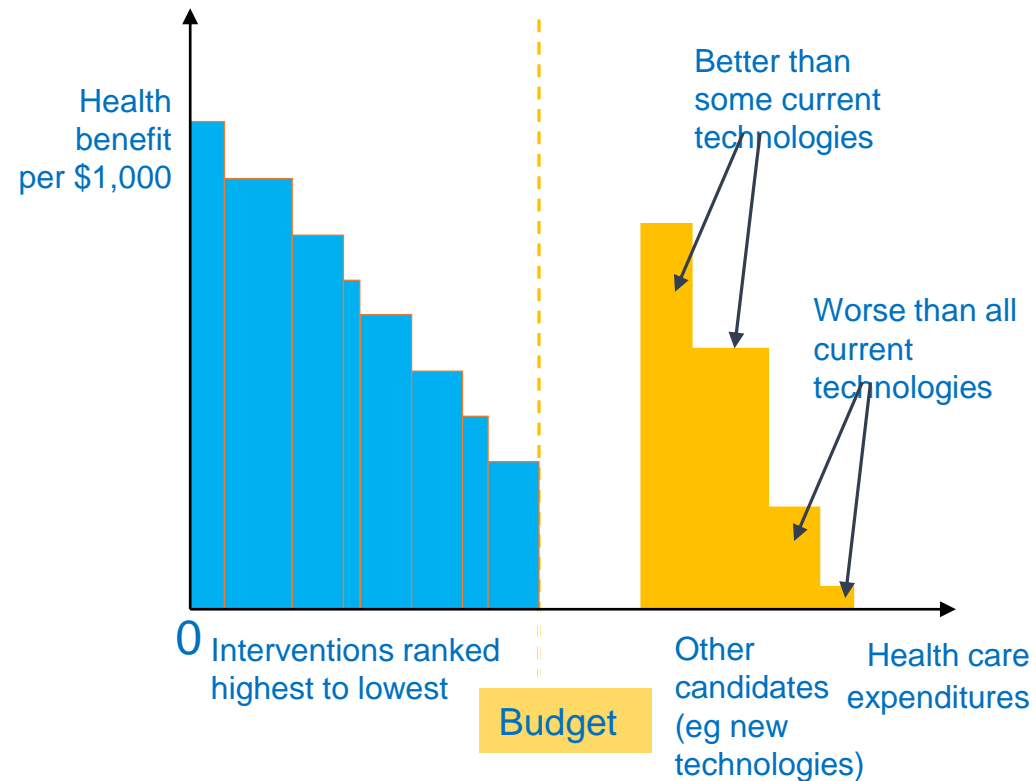
Introducing the bookshelf metaphor

Height of bars is “cost effectiveness”, width of bars is budget impact



Source: adapted from Culyer (2016)

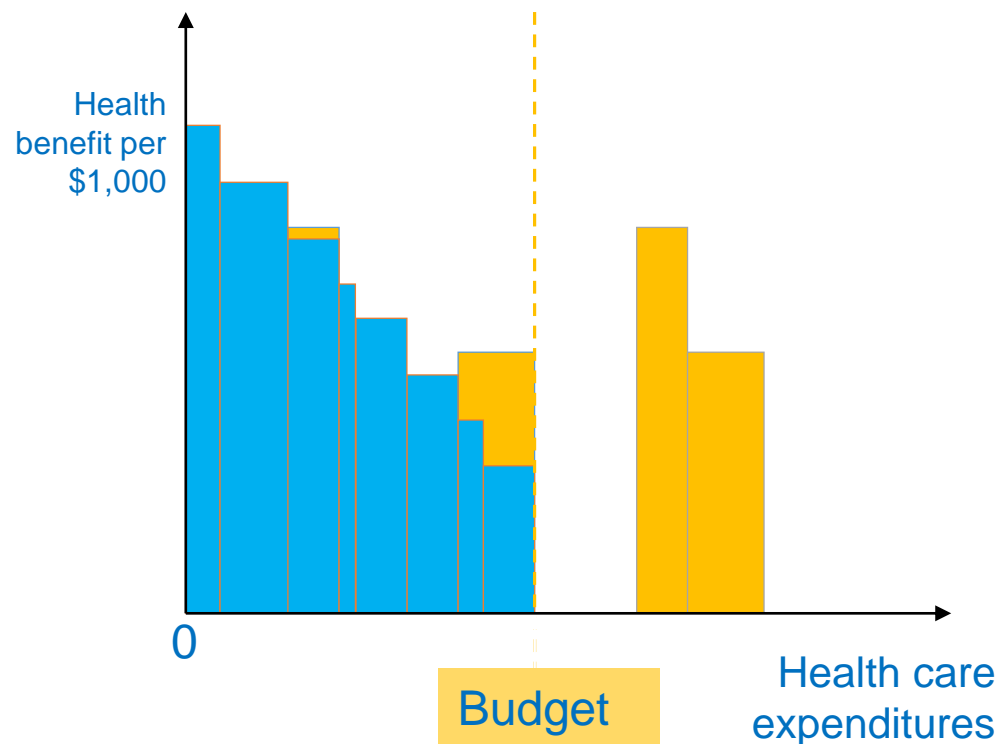
Budget impact and cost effectiveness: determining interventions that are in... and out



Reproduced from Culyer, AJ (thanks to Chris McCabe and Richard Edlin for some animation of Culyer et al. (2007))

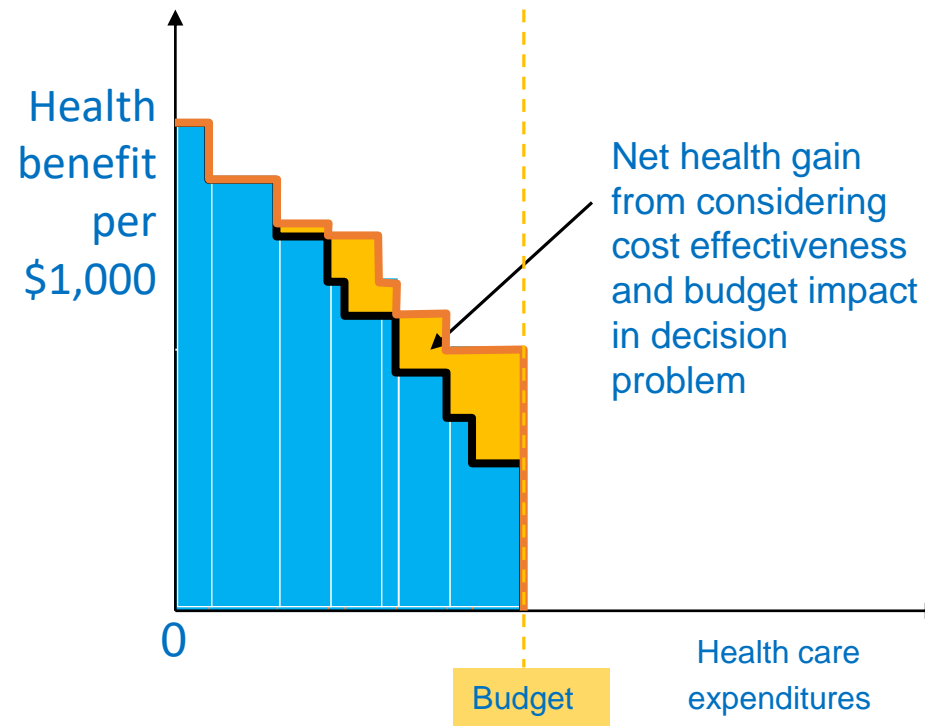
Source: adapted from Culyer (2016)

Budget impact and cost effectiveness: determining interventions that are in... and out



Source: adapted from Culyer (2016)

Budget impact and cost effectiveness: determining interventions that are in... and out



If an intervention is “cost effective but not affordable”, then the threshold used to determine “cost effectiveness” is too high or the ICER has been calculated incorrectly

Source: adapted from Culyer (2016)



THANKS

Any Questions?

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Setting Health Priorities 2018