Budget impact and thresholds
as barriers for funding innovation

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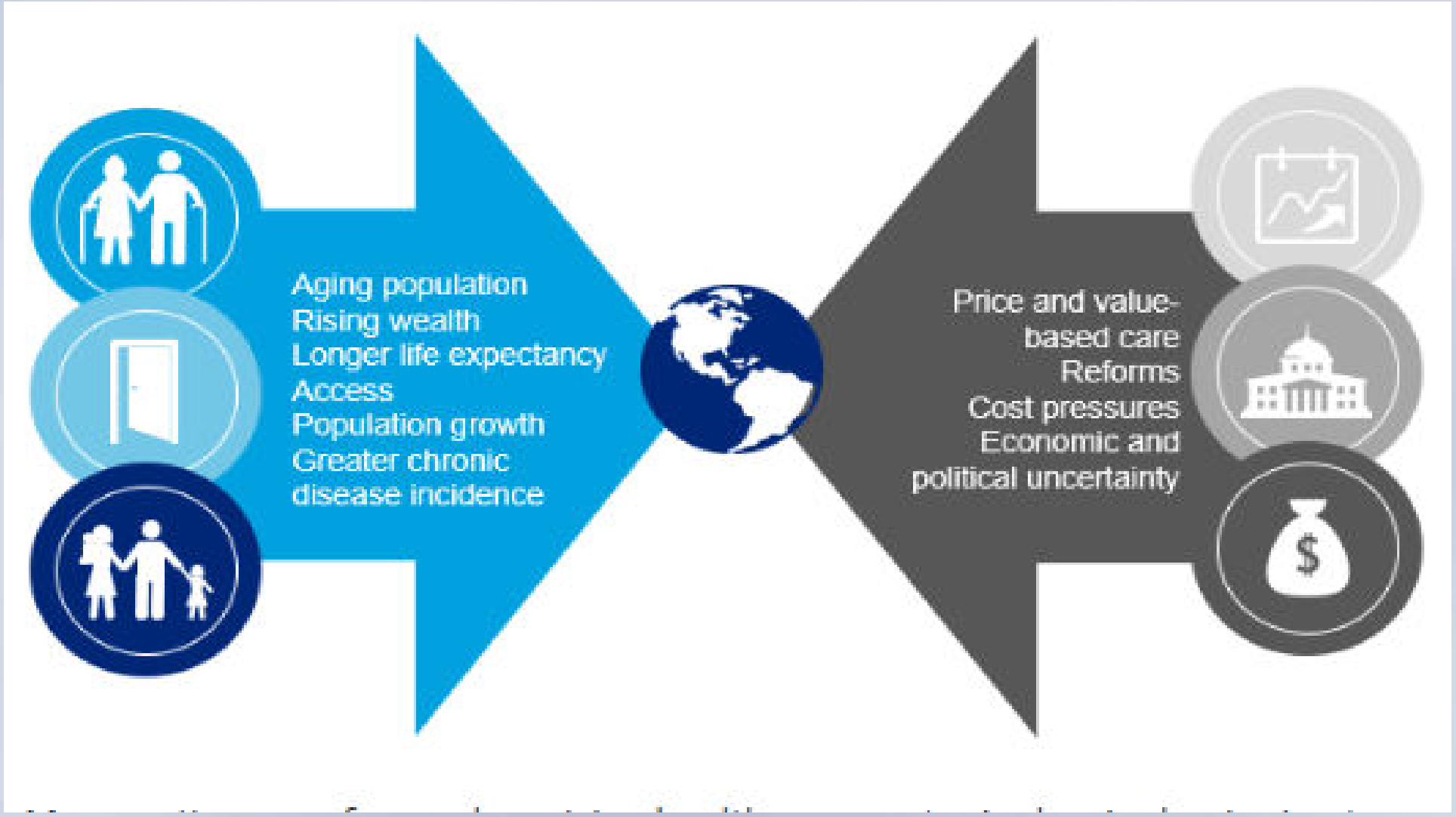
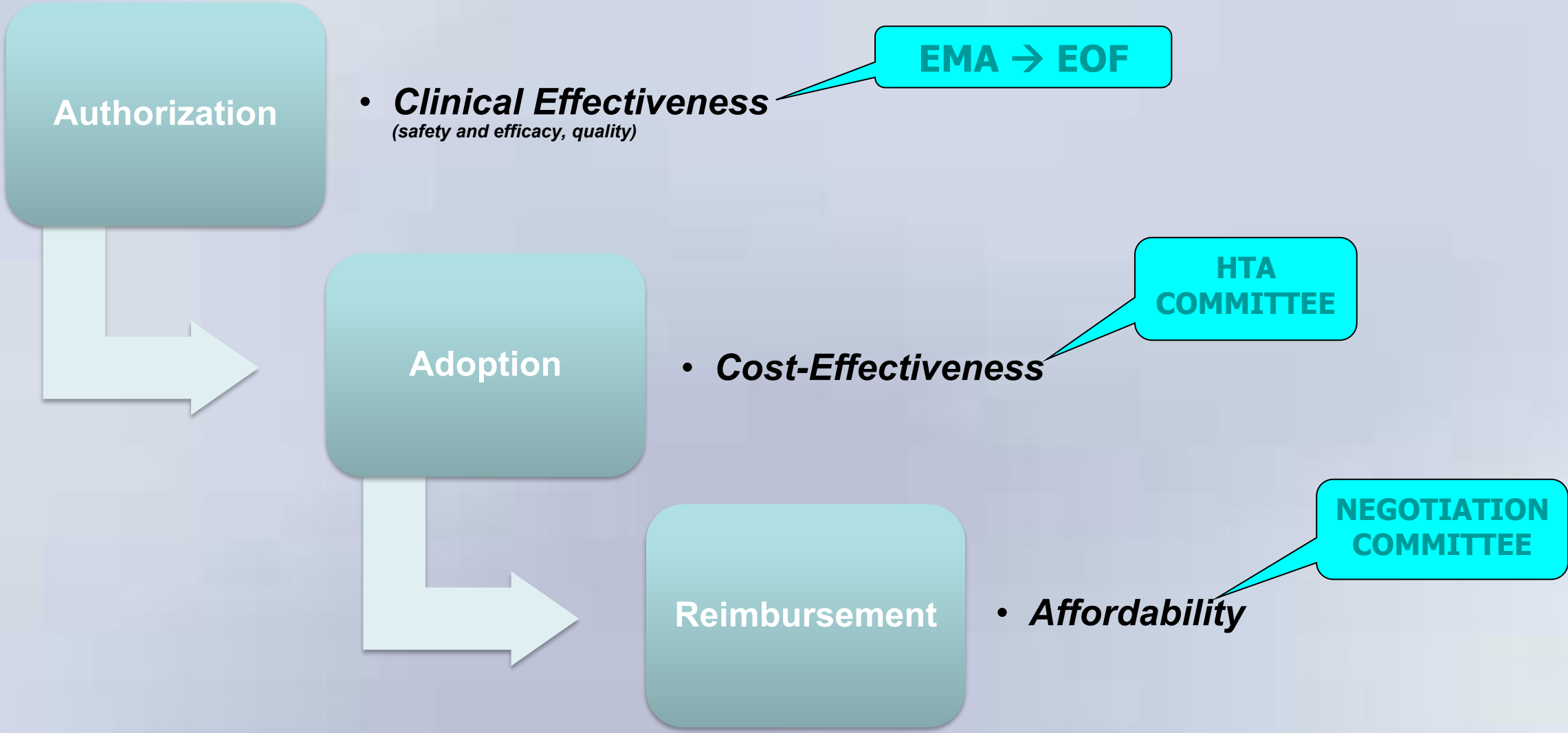
Presentation Content

1. From Authorization to Reimbursement
2. ICER Thresholds
3. Types of Budgets and Shadow prices
4. Negotiations, Scenarios and Outcomes' Assessment

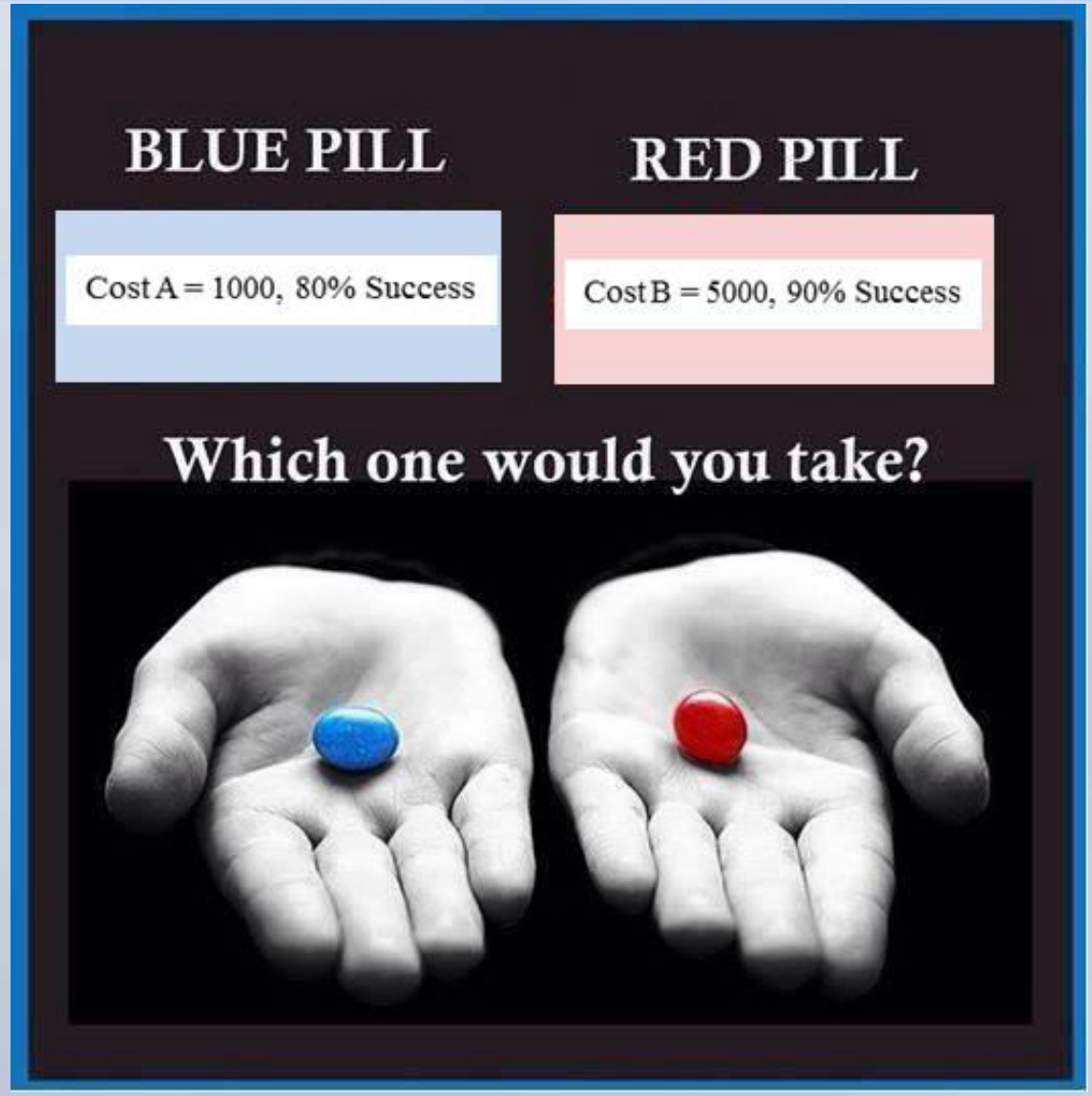
Global Downward Trends in per capita Healthcare Spending



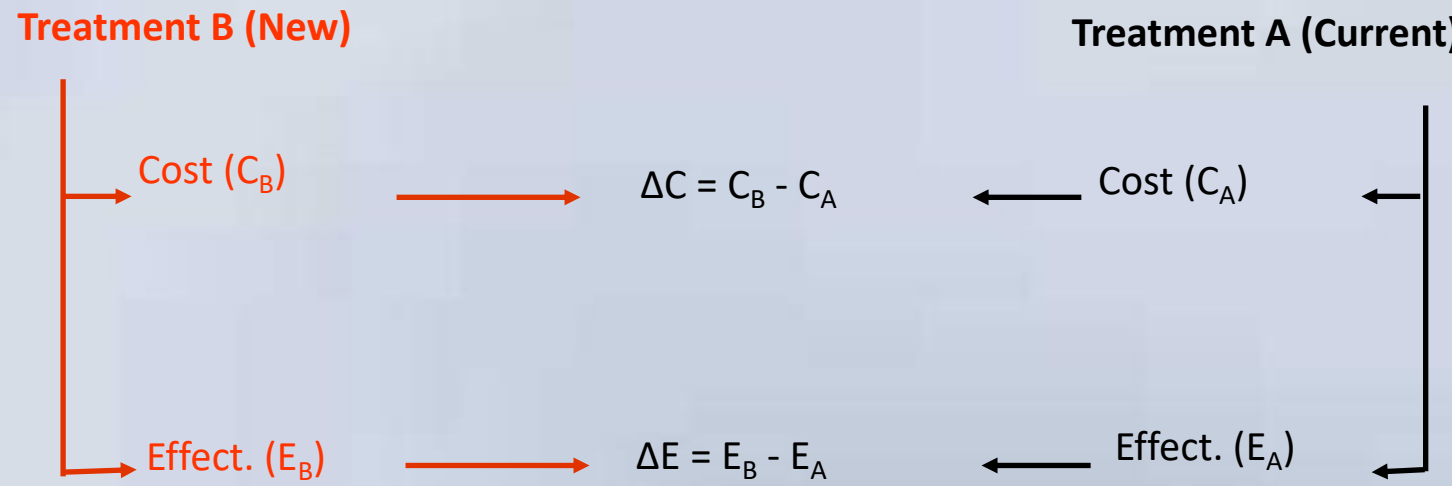
From Authorization to Reimbursement



Choices, Opportunity costs & Trade-offs



Incremental Cost–Effectiveness Ratio (ICER)



Incremental Cost-Effectiveness Ratio (ICER)

$$ICER = \frac{\Delta C}{\Delta E}$$

$$ICER = \frac{\text{Cost}}{\text{LYG}}$$

Threshold value

$$ICER = \frac{\Delta C}{\Delta E}$$

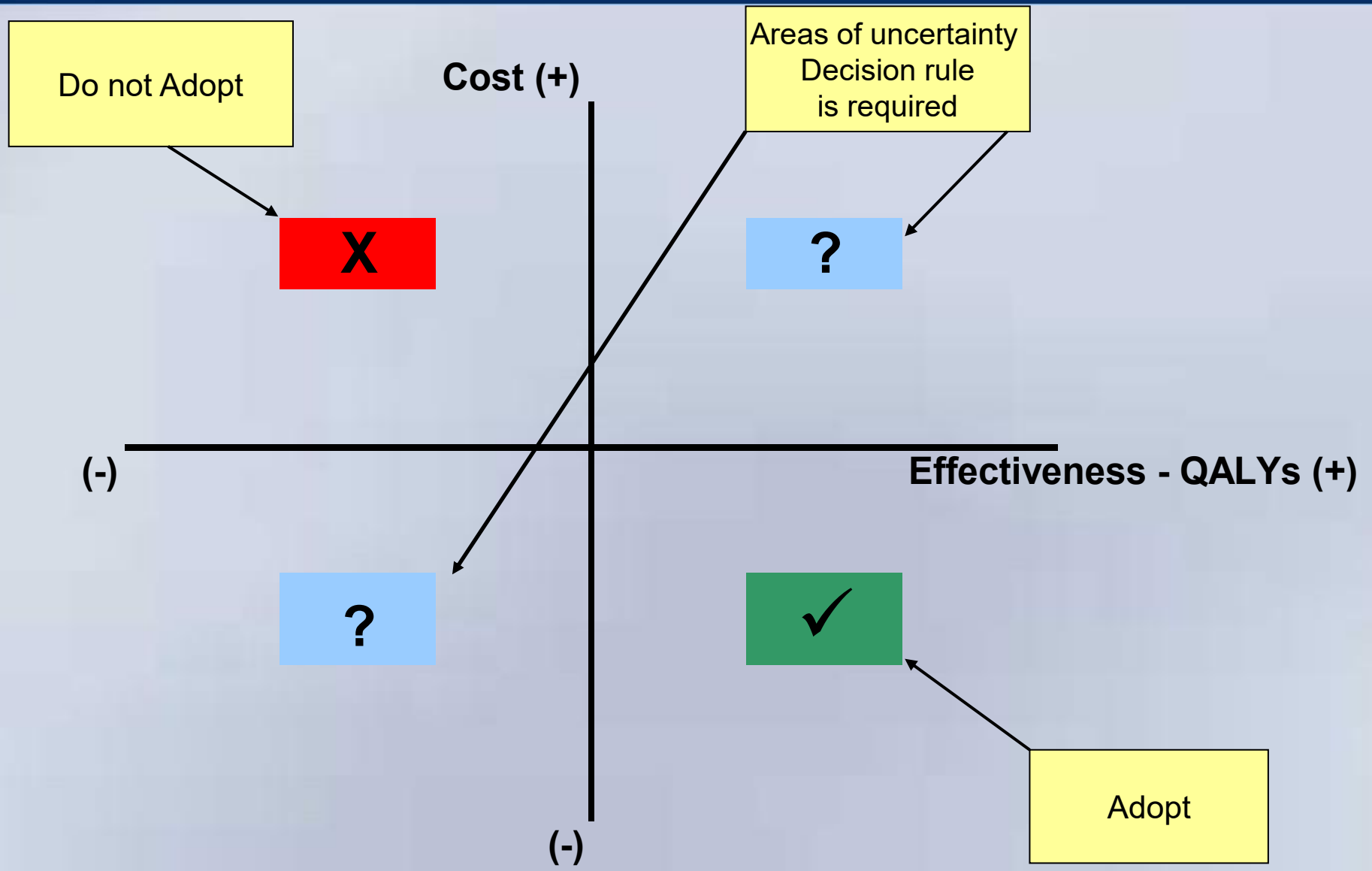
$$ICER = \frac{\Delta C}{QALY}$$

$$\frac{\text{Cost}}{\text{QALY gained}}$$

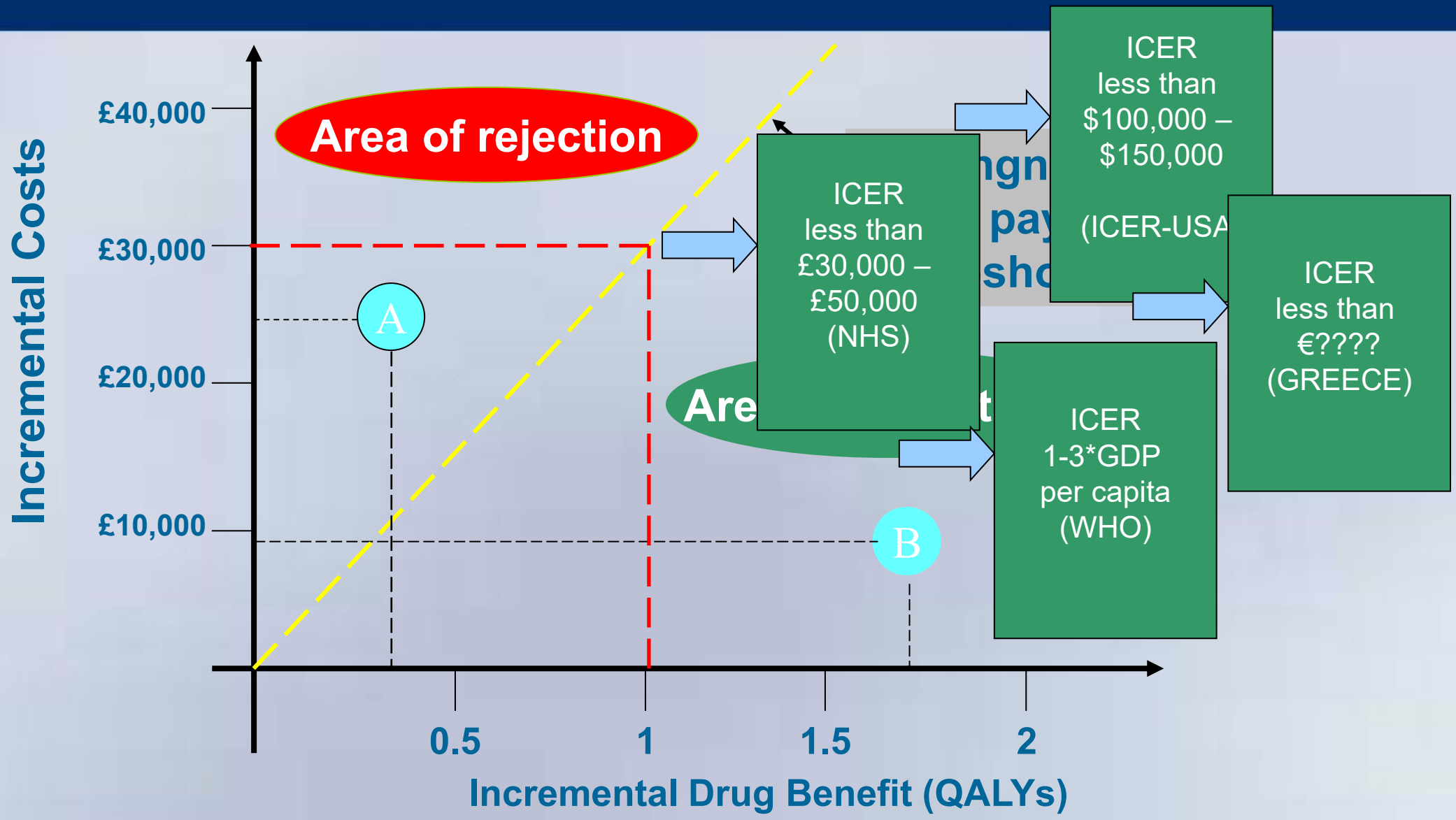
Threshold value

Should we adopt a new intervention?

The cost-effectiveness plane



Cost per QALY Thresholds



Established ICER Thresholds by Country

Country	HTA Body	Country	Currency	Threshold local currency	Threshold in Euro (Aug 2007)
Australia	Pharmaceuti Committee (	**USA**	USD	100,000-150,000	**≈73,000-110,000**
Canada	Canadian Ag Technologie	**UK**	GBP	30,000	**44,500**
Ireland	The Health I Authority (HI	**Sweden**	SEK	50,0000	**54,000**
The Netherlands	Pharmaceuti (CFH)	**The Netherlands**	EURO	20,000	**20,000**
New Zealand	Pharmaceuti (PHARMAC)	**New Zealand**	NDZ	20,000	**11,200**
Spain	The Spanish Technology collaboratio regional gov				
United Kingdom	National Inst Care Excelle Medicines C				
United States	NA	$50,000 per QALY[4,10,36,37,43,59,64,65]		1982[4,10,16,59]	No

Abbreviations: AUD, Australian dollar; CAD, Canadian dollar; HTA, health technology assessment; NA, not applicable; NR, not reported; NZD, New Zealand dollar; QALY, quality-adjusted life-year.

Ref: Jolain B. 2006

The Use of Incremental Cost-Effectiveness Ratio Thresholds in Health Technology Assessment Decisions

Merena Nanavaty, MS, BPharm;[2] Satyin Kaura, MSc, MBA;[2] Mkaya Mwamburi, MD, PhD, MA (Econ);[1,2] Anagha Gogate, BA;[1] John Proach, MBA;[1] Abner Nyandege, PhD;[1] Zeba M. Khan, RPh, PhD[2]

Cost-effectiveness threshold (CET): Behind the scene

Stakeholders (indicative)

1. Ministry of Health
2. Payers (EOPYY)
3. Social health insurance organizations
4. Health technology assessment (HTA) agencies
5. Patient Advocates
6. Disease programmes (e.g. a HIV programme)
7. Pharma Industry
8. Hospitals
9. Medical Personnel
10. Pharmacists
11. Academic & Research Organizations
12. International funders (donors) or non-governmental organizations

Methodological approaches for the definition of a Cost-effectiveness Threshold (CET)

1. The Willingness-to-Pay method
2. The Precedent method
3. The Opportunity Costs method

The important distinction between ‘demand-side’ and ‘supply-side’ CETs

Demand-side estimates of CETs

1. $100k and £30k per QALY CETs
2. CETs 1-3 times GDP per capita in a country
3. Stated prefer
4. Revealed pre

Supply-side estimates of CETs

The challenge for policy-makers, budget-holders and analysts alike is to determine and use CETs that reflect supply-side constraints. Unfortunately, however, there are few empirically estimated supply-side CETs. One exception is a study by Claxton et al (2015) that estimated the marginal productivity of the United Kingdom (UK) National Health Service (NHS) and produced a best estimate of the supply-side CET of £12,936, about half of UK GDP pc.

A summary of the evidence on supply-side cost-effectiveness thresholds (1/3)

Country	GDP per capita, 2013	Woods et al (2015) threshold range, 2013 US$	Threshold as a % of GDP	GDP per capita, 2000	Ochalek et al (forthcoming) threshold range, 2000 US$	Threshold as a % of GDP
Brazil	$11208	$2393 - $7544	21% - 67%	$3064	$575 - $1809	19% - 59%
Ethiopia	$505	$10 - $255	2% - 50%	$179	$6 - $93	3% - 52%
India	$1499	$115 - $770	8% - 51%	$548	$27 - $214	5% - 39%
Indonesia	$3475	$472 - $1786	14% - 51%	$519	$42 - $244	8% - 47%
Kazakhstan	$13610	$4485 - $8018	33% - 59%	$733	$196 - $310	27% - 42%
Malawi	$226	$3 - $116	1% - 51%	$184	$20 - $207	11% - 112%
Nepal	$694	$22 - $357	3% - 51%	$252	$32 - $141	13% - 56%
Thailand	$5779	$1181 - $3943	20% - 68%	$1770	$486 - $805	27% - 45%
Vietnam	$1911	$144 - $982	8% - 51%	$417	$110 - $369	26% - 89%

Claxton K, Martin S, Soares M, et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health technology assessment (Winchester, England). 2015 Feb;19(14):1-503, v-vi. doi: 10.3310/hta19140. PubMed PMID: 25692211; PubMed Central PMCID: PMC4781395. eng.

A summary of the evidence on supply-side cost-effectiveness thresholds (2/3)

Table 1 – Example results for a range of countries and the World Bank income classification cutoffs (2013 GDP per capita).

Country/income classification	PPP-adjusted (2013 US $)		Actual values (2013 US $)		Threshold as % GDP per capita
	GDP per capita	Threshold range*	GDP per capita	Threshold range*	
Country					
Malawi	780	9–401	226	3–116	1–51
Indonesia	9,559	1,298–4,914	3,475	472–1,786	14–51
Chile	21,911	6,819–13,141	15,732	4,896–9,436	31–60
Kazakhstan	23,206	7,648–13,675	13,610	4,485–8,018	33–59
United Kingdom	36,197	18,609–18,609	41,787	20,223–20,223	48–48†
Canada	43,247	21,051–26,564	51,958	25,292–31,915	49–61
United States	53,143	24,283–40,112	53,042	24,283–40,112	46–75
Norway	65,461	28,057–60,862	100,819	43,211–93,736	43–93
Income classification					
Low/middle income‡	1,045	16–537	NA	NA	1–51
Middle/high income‡	12,746	2,307–9,028	NA	NA	18–71

GDP, gross domestic product; NA, not available/applicable; PPP, purchasing power parity.

* Reflects range of values obtained when using elasticity estimates of 1.0, 1.5, 2.0, and 2.5 for GDP less than $10,725 (2005 PPP US $) and 0.7 for GDP greater than $10,725 (2005 PPP US $).

† For the United Kingdom, the World Bank ratio of PPP conversion factor to market exchange rate did not correspond to the ratio of reported actual GDP to reported PPP-adjusted GDP. The threshold as a % GDP value for the United Kingdom, therefore, depends on whether PPP-adjusted or actual data are used (51% and 48%, respectively).

‡ We have assumed gross national income per capita to be the same as PPP-adjusted GDP. These values relate to the income cutoffs for low- to middle-income and middle- to high-income countries as defined by the World Bank.

Value Health. 2016 Dec; 19(8): 929–935. doi: 10.1016/j.jval.2016.02.017

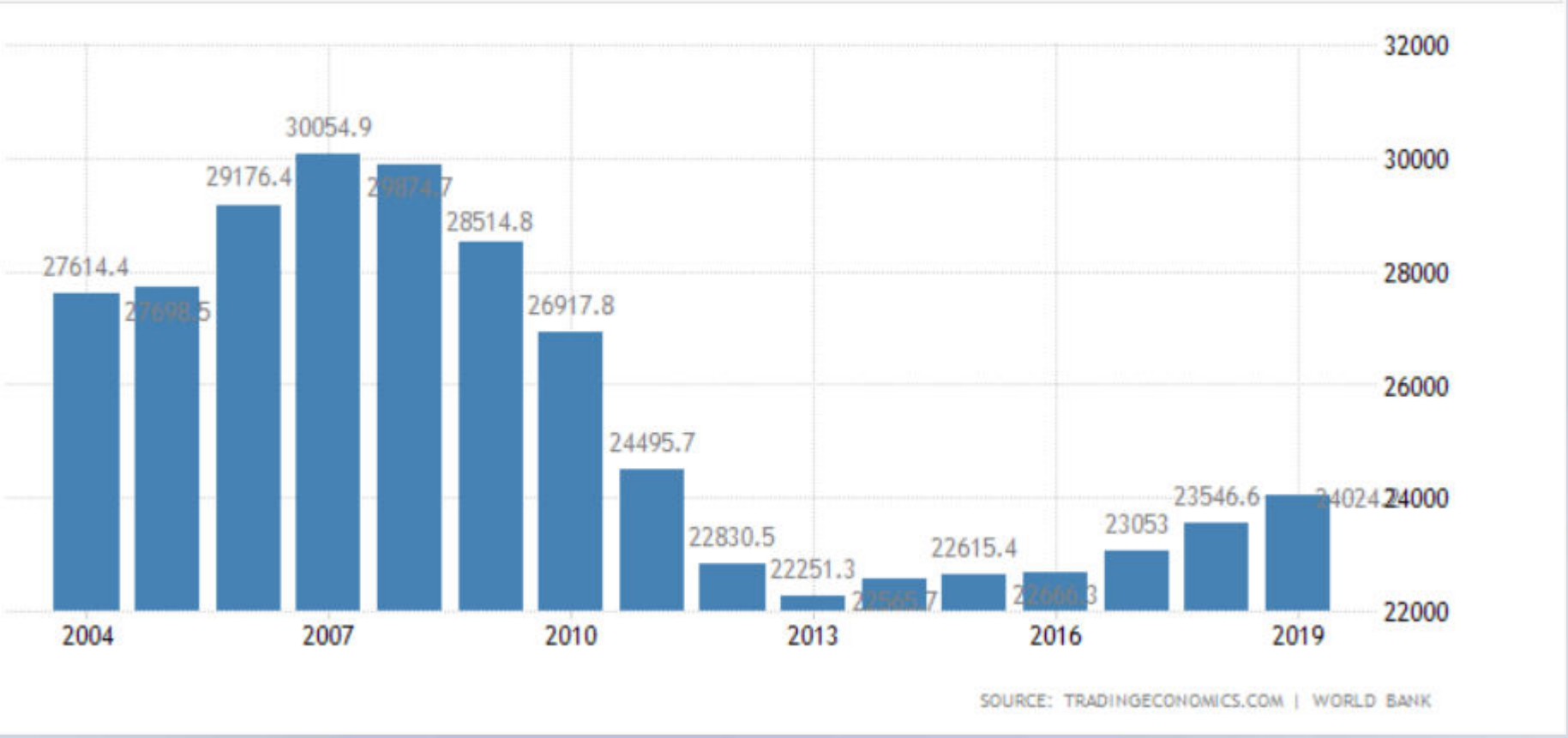
A summary of the evidence on supply-side cost-effectiveness thresholds (3/3)

Country	Unit	WTP_{sel} 95%CI		WTP_{5sel} 95%CI		WTP_{fam} 95%CI		WTP_{soc} 95%CI	
Japan	US$ 1000	41		28		52		44	
		38	44	26	32	49	55	41	47
ROK	US$ 1000	74		61		86		75	
		70	79	57	65	82	90	71	79
Taiwan	US$ 1000	77		70		70		66	
		70	84	62	77	62	77	59	70
UK	US$ 1000	36		31		41		60	
		35	39	30	35	38	44	57	61
AU	US$ 1000	47		43		57		66	
		44	50	40	46	54	60	63	68
US	US$ 1000	62		52		69		96	
		57	66	48	56	57	66	48	56

Shiroiwa, T., Sung, Y.-K., Fukuda, T., Lang, H.-C., Bae, S.-C., & Tsutani, K. (2010). International survey on willingness-to-pay (WTP) for one additional QALY gained: what is the threshold of cost effectiveness? Health Economics, 19(4), 422–437. doi:10.1002/hec.1481

The threshold value in Greece?

Greece GDP per capita 2004-2019 Data



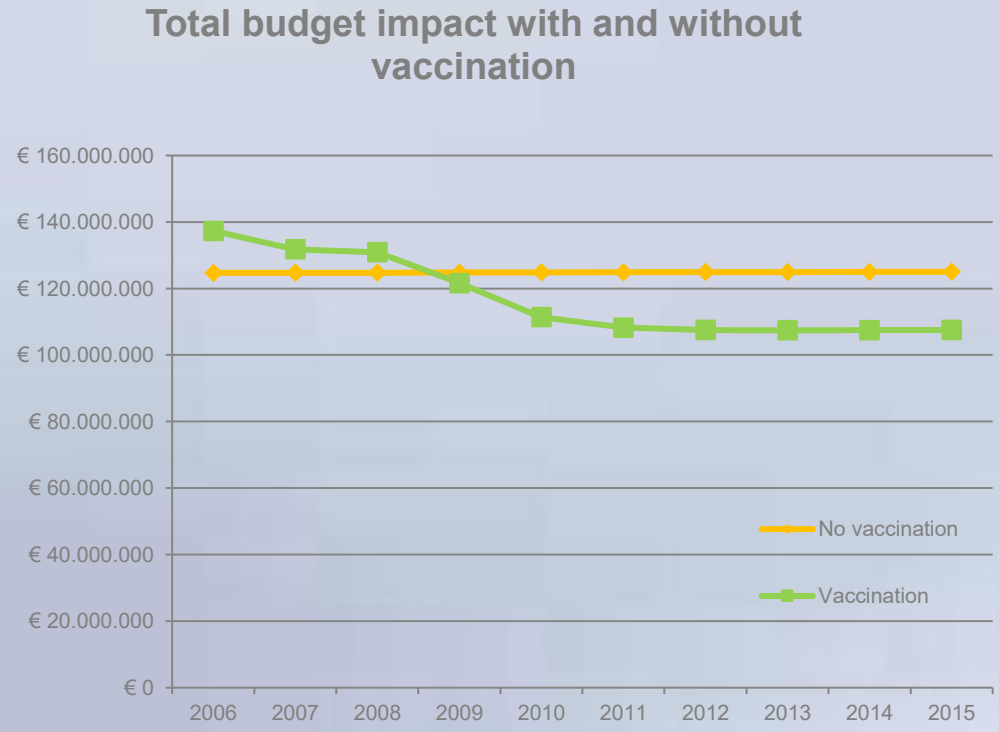
Constant 2010 USD

Affordability and/or Budget Impact Analysis

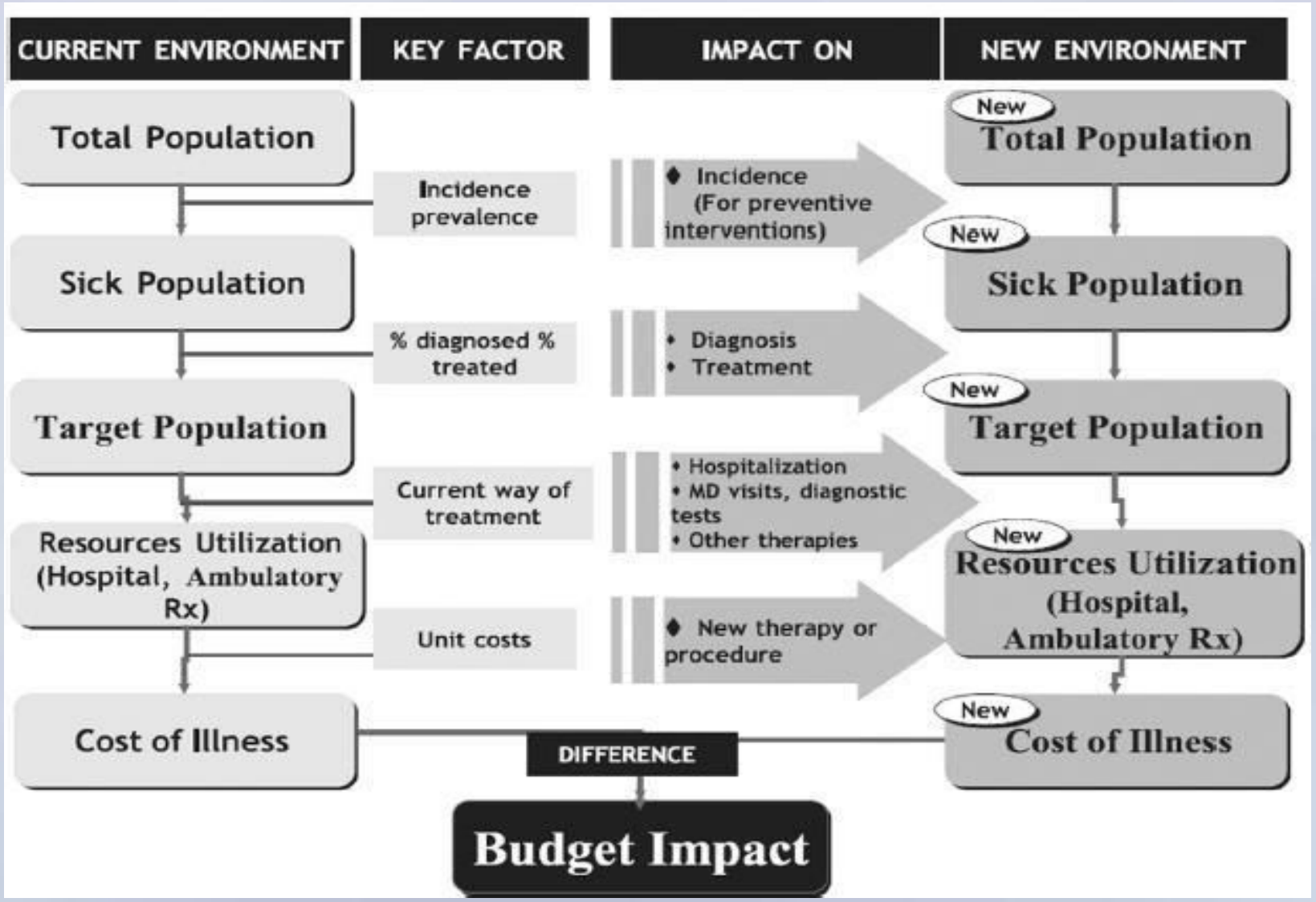
Even if a new healthcare intervention is cost-effective, **can it be afforded?**

Who will pay what, when, how from which budget?

Incremental cost (= numerator of ICER) for eligible population at different time points provides estimate of budget impact over time



Budget Impact Analysis Methodology



Four Types of Budgets

No budget

(means that there is no constraint on health expenditure. The price of a new drug is not relevant to the new drug adoption decision in this context)

An unconstrained budget

(is one that is expanded to accommodate any purchase that has an ICER at or below the maxWTP, where this maxWTP is defined by the social decision maker as in the endogenous budget)

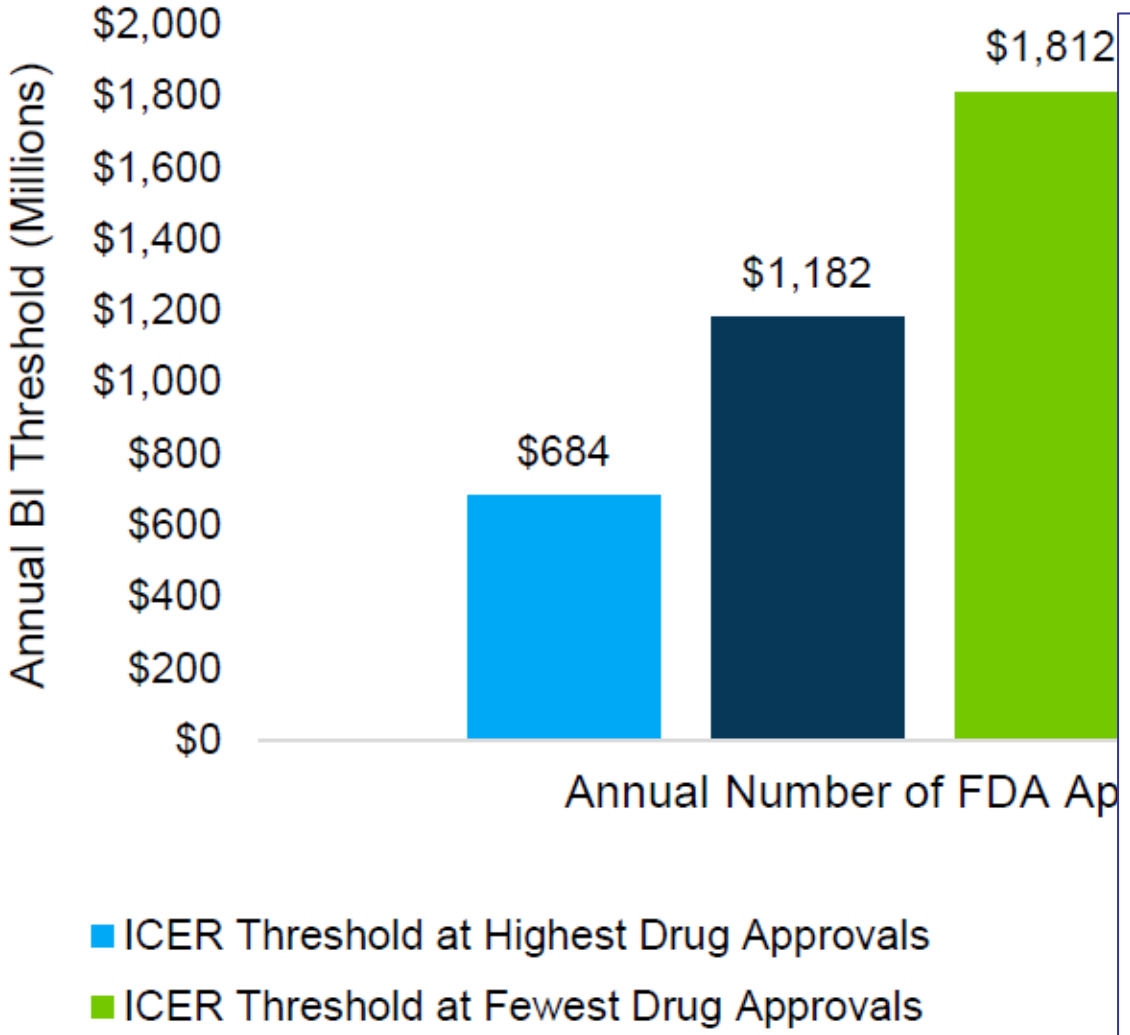
A constrained budget

(can be expanded by a trigger such as the decision to finance a new drug, but there is a foregone benefit to the expansion to finance a drug; other health and non-health programmes or investments could instead have been expanded or implemented)

A fixed budget

(cannot be expanded and any additional purchases can be funded only if an existing activity is displaced)

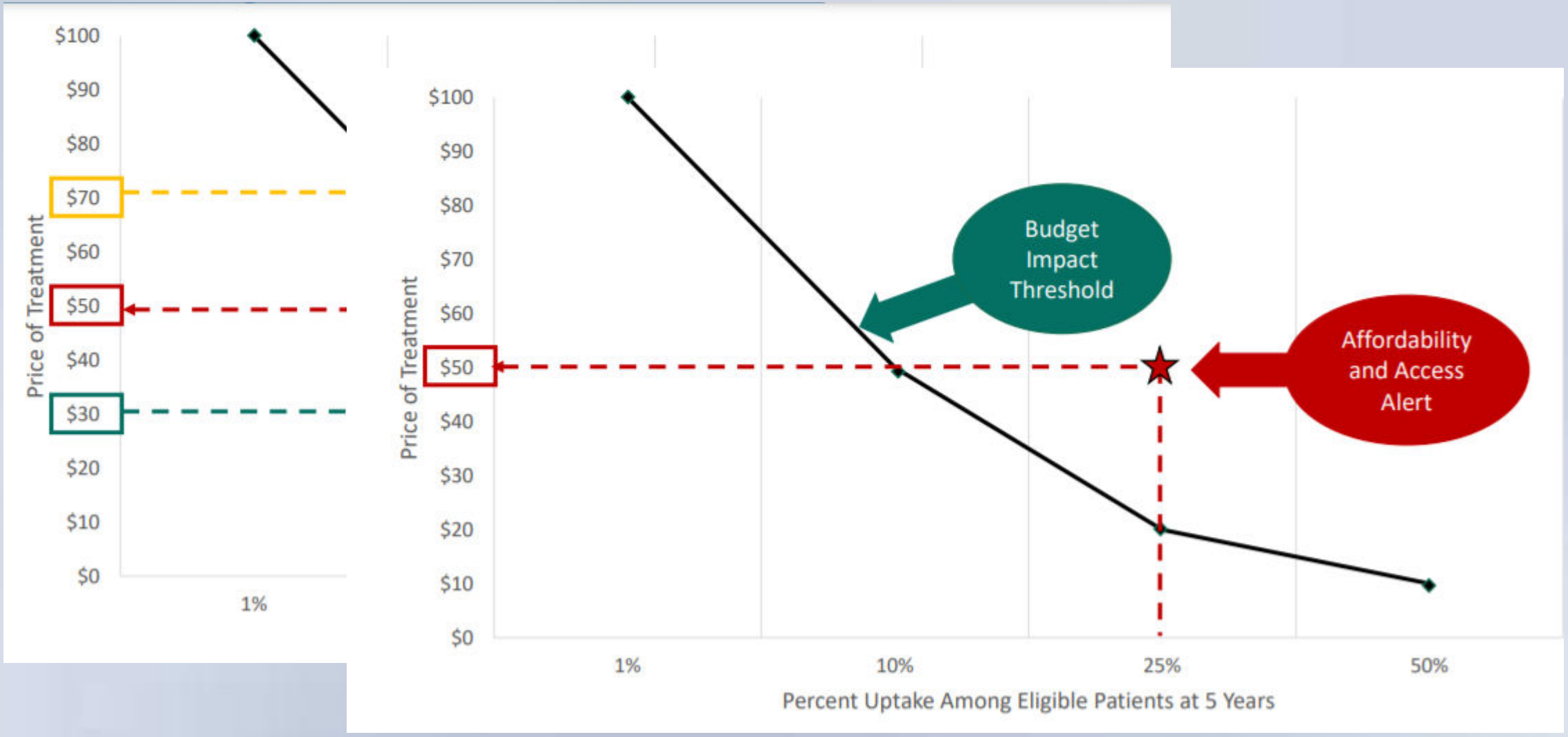
Budget Impact Thresholds by Annual Number of FDA Approvals & NICE



NICE OKs £20m budget impact limit for new drugs

16th March 2017

Potential Budget Impact Scenarios



Scenarios of Economic Context

Characteristic	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Adopting a new drug	Yes	Yes	Yes	Yes
Budget	Expandable	Fixed	Fixed	Fixed
How is additional cost of the drug financed?	Expanding budget	Displacing programmes	Displacing programmes	Displacing programmes
Price distortions?	Only new drug	new drug (+ old drugs)	new drug (+ old drugs)	new drug (+ old drugs)
Is current budget efficient?	Economically efficient	**Economically efficient**	**Allocatively inefficient**	**Technically inefficient**
Is displacement optimal? (least cost-effective drugs displaced)	Not applicable	Optimal or suboptimal	Optimal or suboptimal	Optimal or suboptimal

What price???
Let' talk about *Shadow Prices*

Reference Price	Wholesale price	Producer Price	Hospital Price	Hospital Price -5%	Hospital Price -5% - Rebate	Retail Price	List Price	Reimbursement Price

In the strictest sense

"the price given to a good or service which has no market price"

In Health Economics

"refers to the shadow price of the budget constraint or to the valuation of an input for which there is a supply but no market price"

In this case Reimburses must use PEA ≠ CEA (IPER instead of ICER)

The strategy of reimbursement comprises the actions of adoption and financing.

The health shadow price, is the IPER of the health effects gained by the target patients as a consequence of the strategy of reimbursing the new drug with clinical innovation and additional financial cost such that the funder is indifferent between the strategy of reimbursement and the best alternative strategy available to the funder using the same financial resources.

Reimbursement in a fixed budget involves

adoption + displacement + financing

Health Shadow Price and IPER

Health Shadow Price is the lowest ICER at which the health budget holder could use the funds required to finance the incremental cost of the new drug to purchase QALYs from some other source.

If a new drug's incremental price-effectiveness ratio (IPER) is above the health shadow price, the best alternative strategy to new drug reimbursement will result in more health benefits to the population, for the same financial cost

Cost-containment measures in the pharmaceutical market in Greece

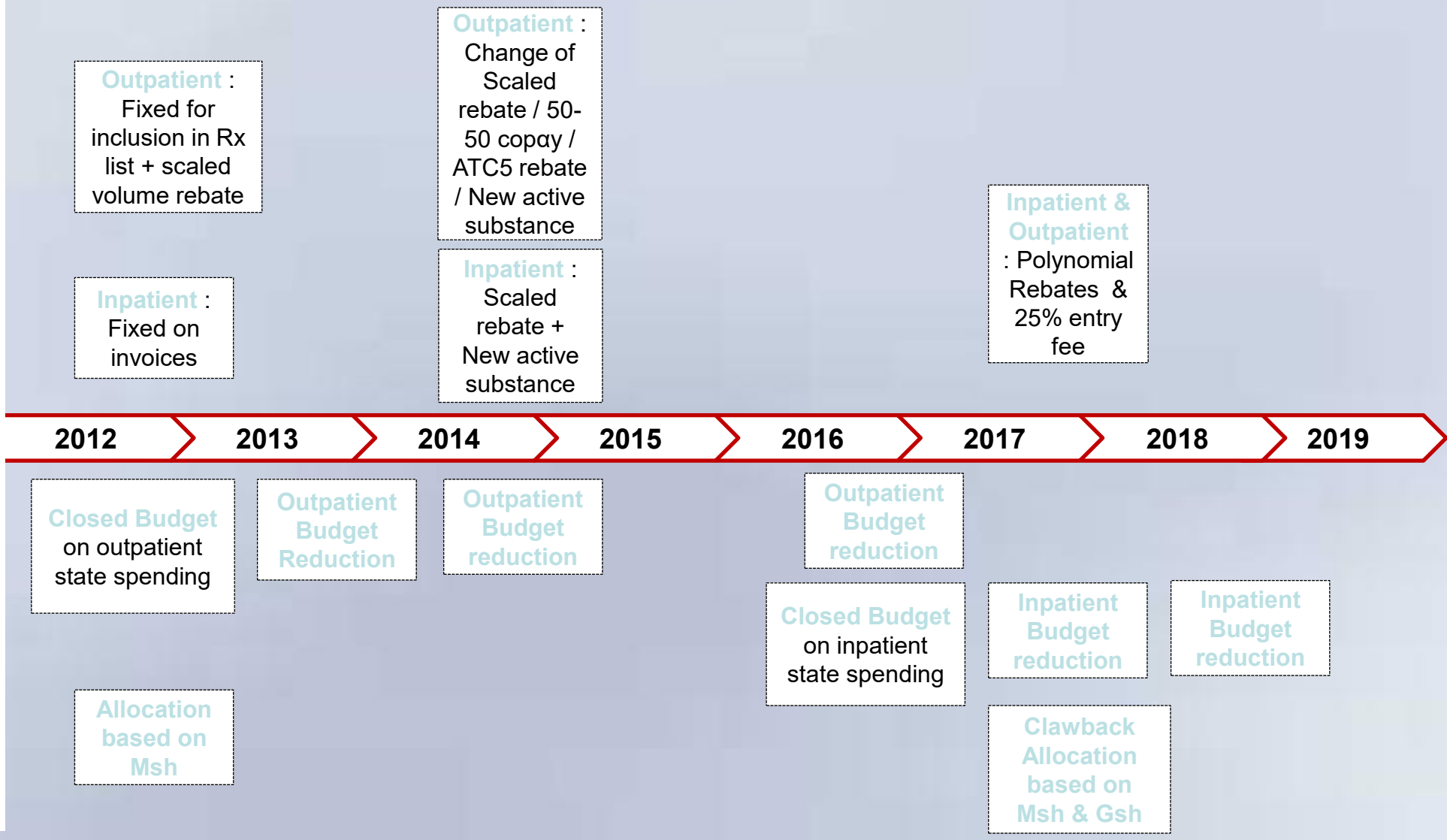
1 Health Technology Assessment
- Independent government commission assesses comparative therapeutic value of new drug

2 Maximum Allowable Price
- Agency determines maximum price consistent with HTA
- New products enter five-year contract with no price increase and capped sales volume
- Manufacturers pay rebates if total sales volume exceeds contract

3 Negotiated Prices
- Agency negotiates confidential discounts of 10% to 30% off maximum allowed price
- Hospitals negotiate additional discounts from manufacturers when competing products exist

4 Price Decreases over Time
- Agency usually decreases prices after five years
- High-priced drugs in each class lowered over time toward lowest-price drugs in class

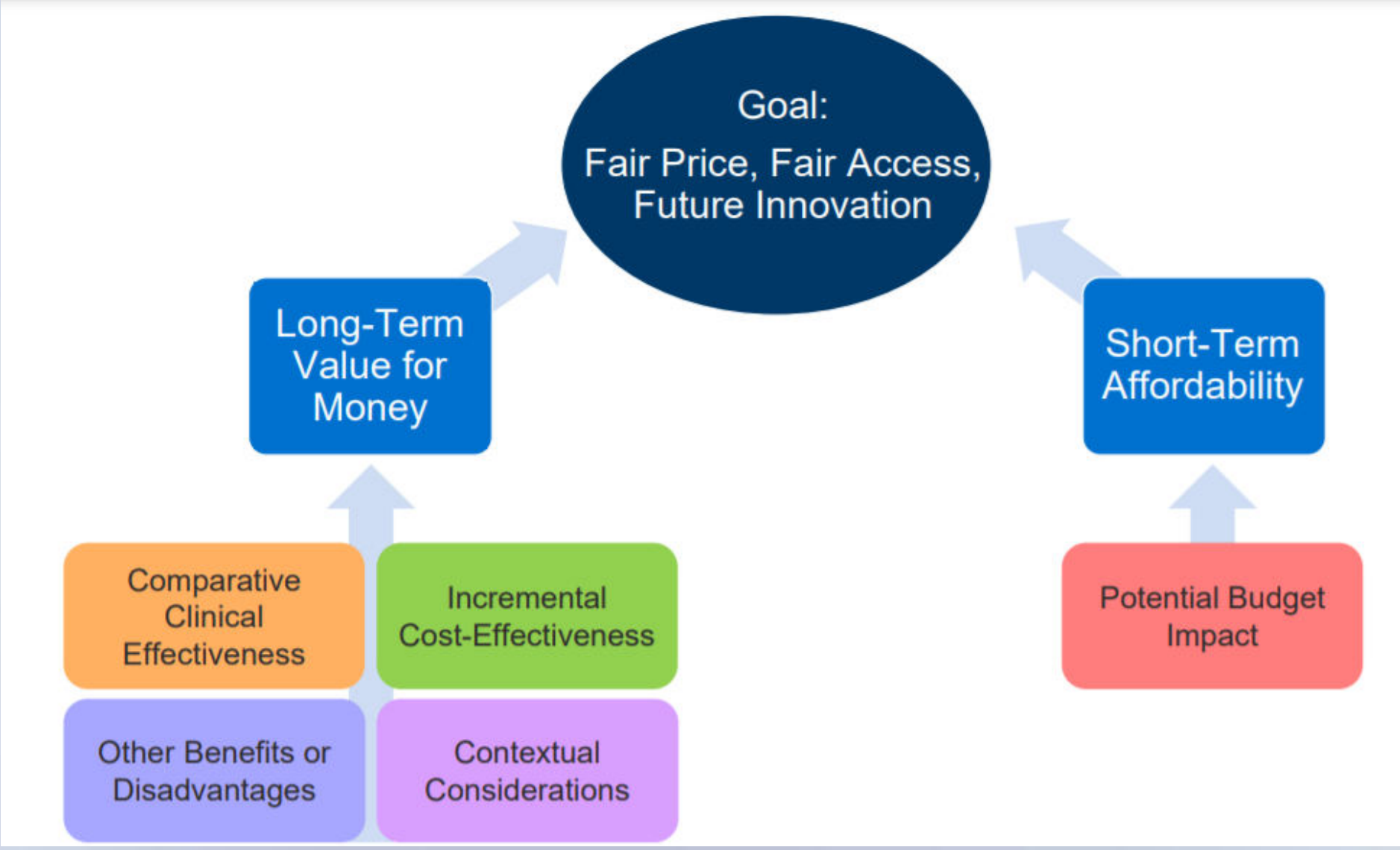
5 Annual Spending Cap
- Parliament sets budget for total drug spending growth
- All manufacturers pay back share of revenue if total spending exceeds the target



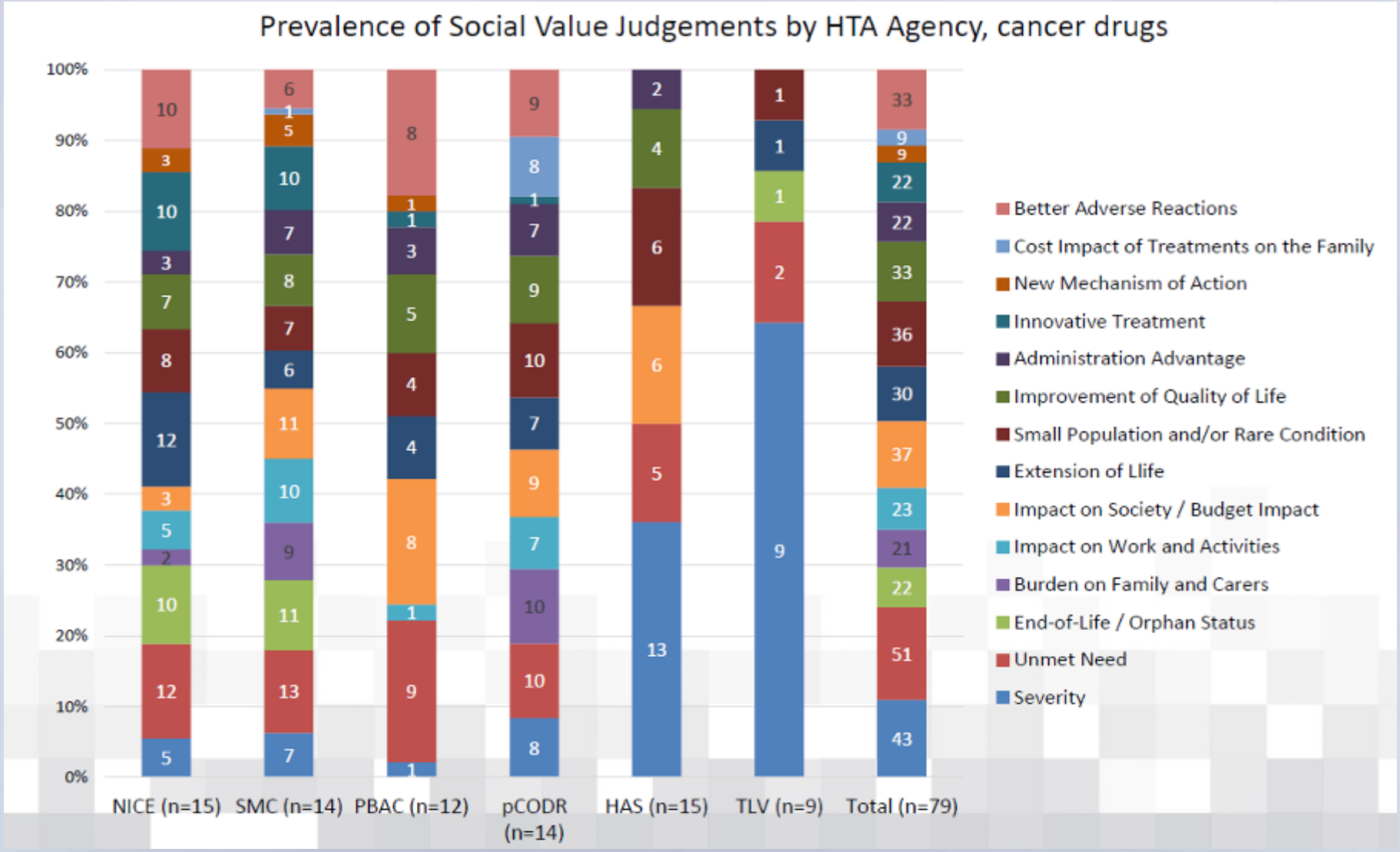
Mechanisms to manage affordability

1. Discounts and revenue caps
2. Targeting the highest value patient groups
3. Managed entry agreements
4. Pay-for-performance
5. Annualisation
6. Credit market solutions
7. And more….
8. Combination of the above

Purchasing Medical Innovation



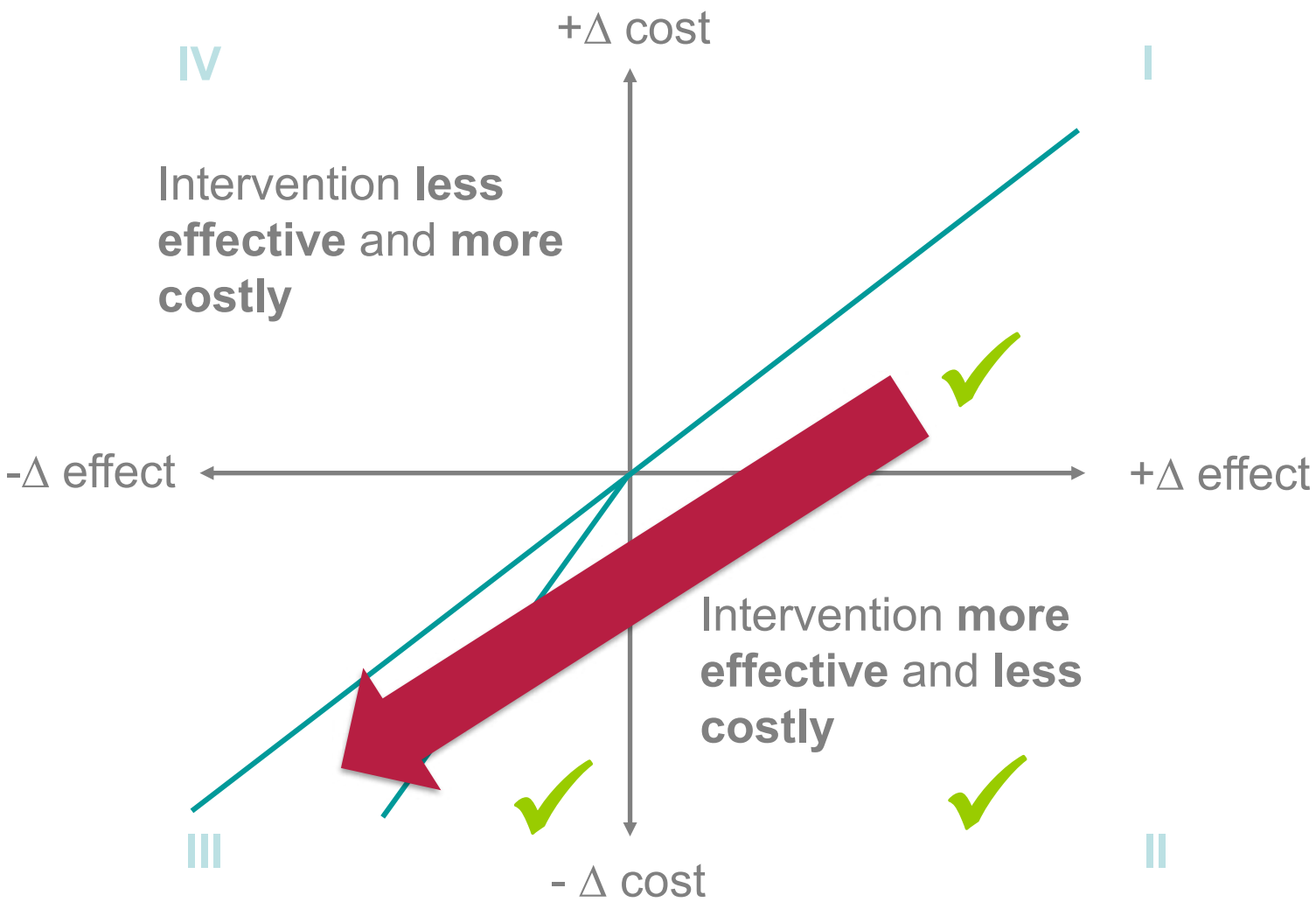
“Value” dimensions adopted by HTA & Negotiation Organizations



Source: Angelis and Kanavos, *Social Science & Medicine* 2017

The cost effectiveness plane

Difference in effect and cost of an option relative to its comparator



Purchasing Medical Innovation

McKinsey & Company

Strategy & Corporate Finance Practice

Innovation in a crisis: Why it is more critical than ever

Prioritizing innovation today is the key to unlocking postcrisis growth.

by Jordan Bar Am, Laura Furstenthal, Felicitas Jorge, and Erik Roth

Purchasing Medical Innovation