Triangulating Developers, Regulators and Payers to Reap Rewards and Address Challenges with Curative Therapies

MARK SCULPHER, Professor of Health Economics, University of York, York, UK
ANIRBAN BASU, Stergachis Family Endowed Professor, University of Washington, Seattle, WA, USA
ADRIAN TOWSE, Director of the Office of Health Economics, London, UK
SHELBY REED, Professor in Population Health Sciences, Duke University, Durham, NC, USA

Motivation

- Pipeline of potentially-curative therapies has (only just) begun production
  - Significant health gains
  - Large up-front costs and potential long-term savings
- Value frameworks may or may not be up to the task
  - Limited data
  - Methodological challenges
- New financing mechanisms may be needed

Themed Section in *Value in Health*

Value of Curative Therapies

- Health technology assessment
- Methodological issues
- Regulatory issues
- Financing mechanisms

Co-edited by Don Husereau and Shelby Reed

Speakers

Mark Sculpher MSc, PhD, Professor of Health Economics, University of York, York, UK
- HTA perspective

Anirban Basu, PhD, Stergachis Family Endowed Professor, University of Washington, Seattle, WA, USA
- Heterogeneity in assessing value

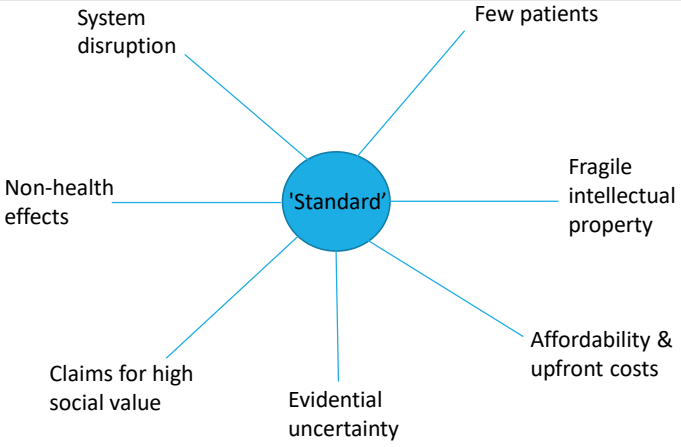
Adrian Towse, MA, MPhil, Director of the Office of Health Economics, London, UK
- Payment mechanisms

TRIANGULATING DEVELOPERS, REGULATORS AND PAYERS TO REAP REWARDS AND ADDRESS CHALLENGES WITH CURATIVE THERAPIES

MARK SCULPHER, PHD

PROFESSOR OF HEALTH ECONOMICS
CENTRE FOR HEALTH ECONOMICS
UNIVERSITY OF YORK, UK

Complexity in evaluation



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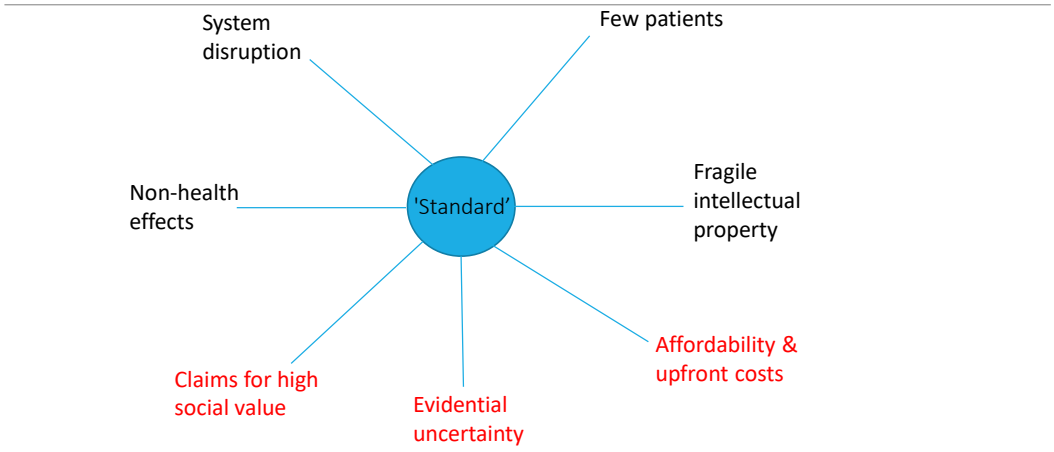
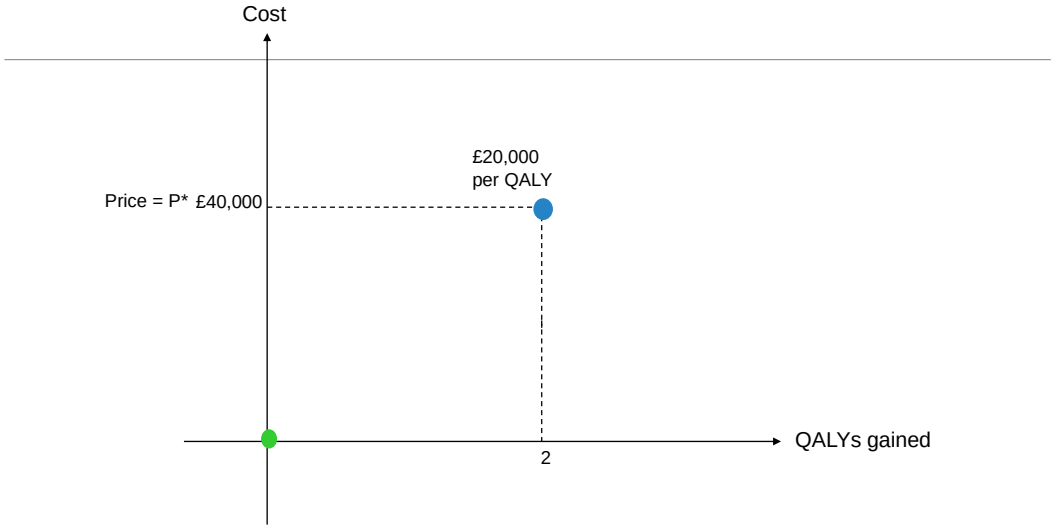


Cost-effectiveness and affordability



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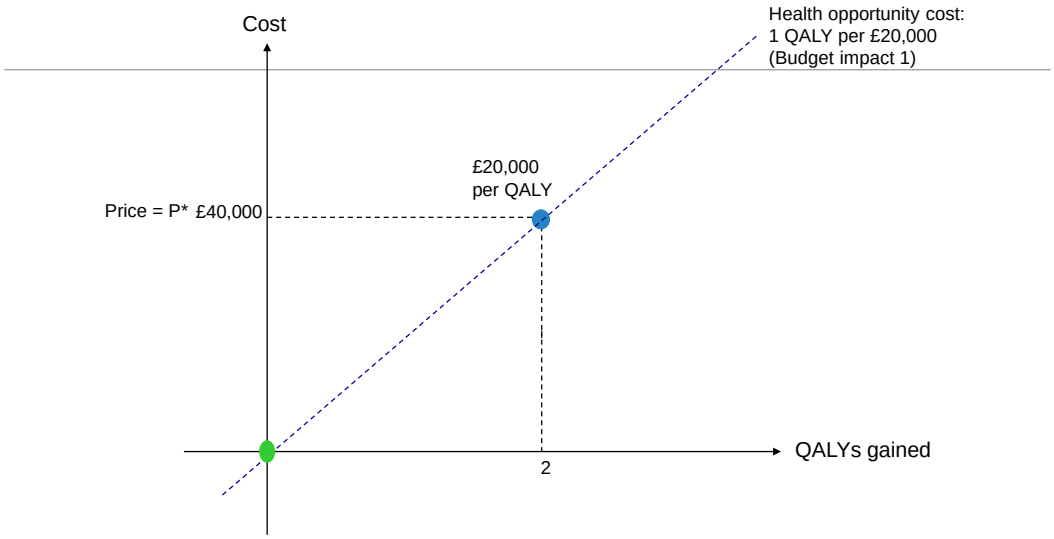

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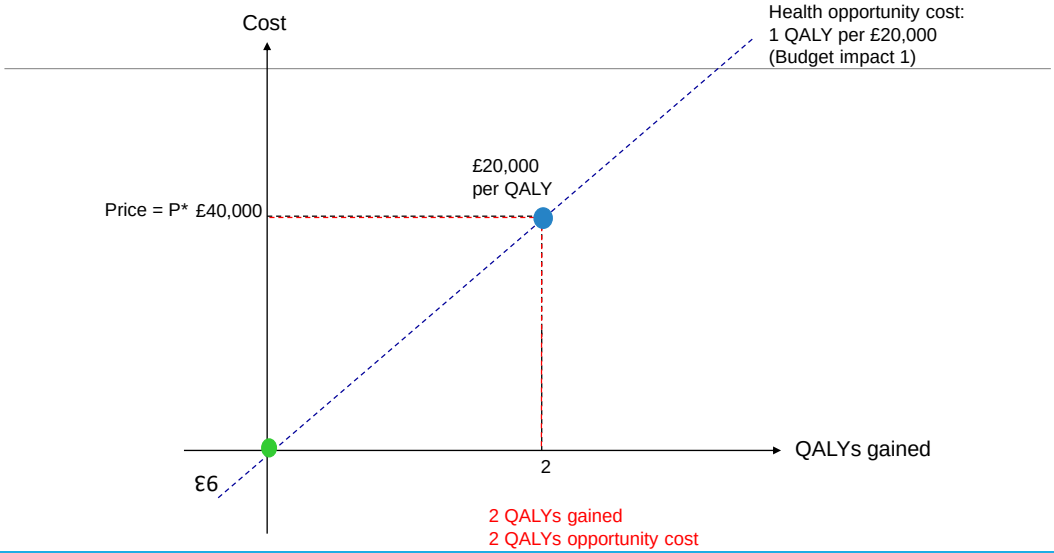

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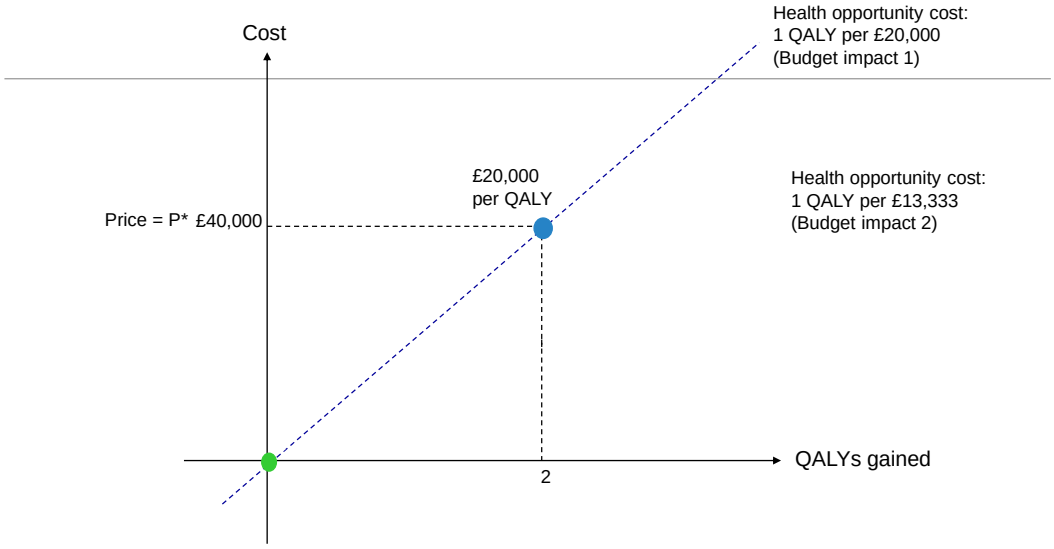

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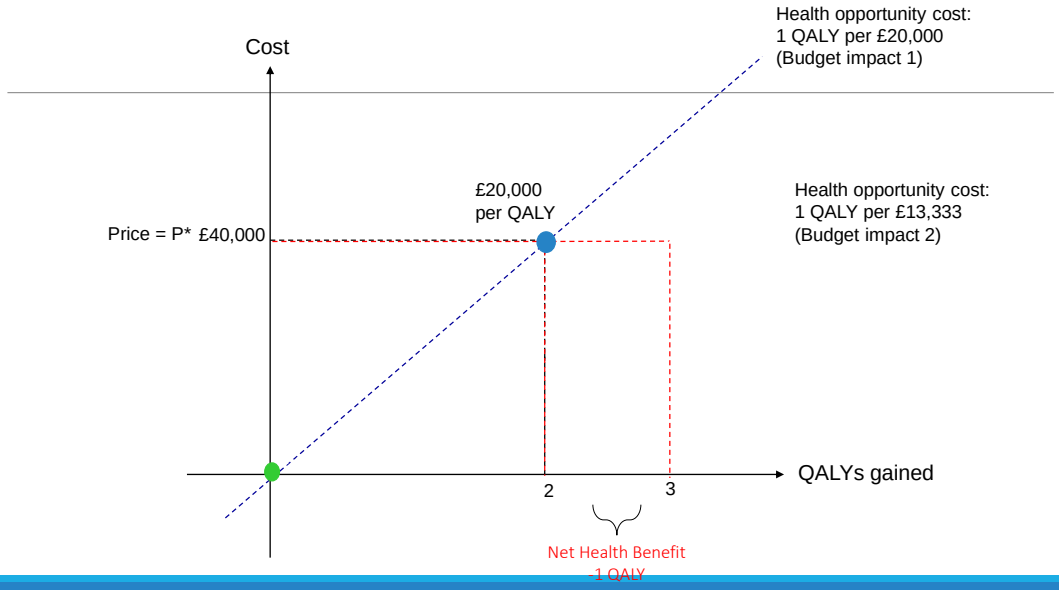


Estimating opportunity cost by budget impact

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

ELSEVIER

Resolving the "Cost-Effective but Unaffordable" Paradox: Estimating the Health Opportunity Costs of Nonmarginal Budget Impacts

James Lomas, MSc, PhD[1,*], Karl Claxton, MSc, PhD[1,2], Stephen Martin, MSc, PhD[2], Marta Soares, MSc, PhD[1]

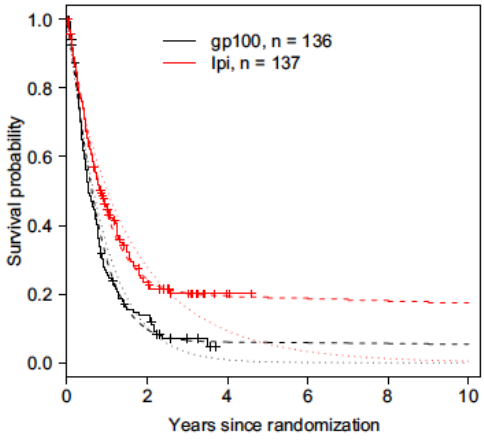
[1]Centre for Health Economics, University of York, UK; [2]Department of Economics and Related Studies, University of York, UK

Lomas *et al.* *Value in Health*, 2018, 21:266-275

Evidential uncertainty – example of oncology

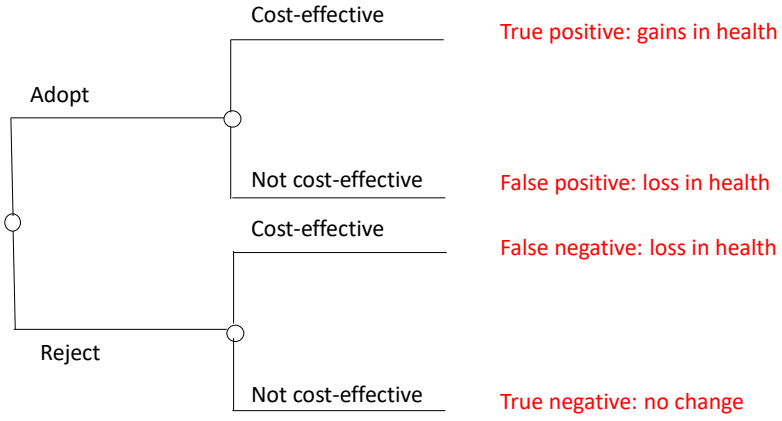
- Mortality risk in delayed event
- Plateau in OS
- Long-term OS treatment effect
- Long-term OS
- Separation in OS curves
- PFS as a surrogate for OS

Example in oncology



Othus et al. Value in Health 2017;20:705-9

Decision uncertainty and its implications



Dealing with uncertainty

Analysis
- Magnitude and cost of uncertainty
- Key uncertainties
- Feasibility & timing of research
- Irrecoverable costs
- Impact of price changes

Policy responses
- Fund
- Reject
- Price reduction
- Risk-sharing
- Fund only in research
- Fund with research

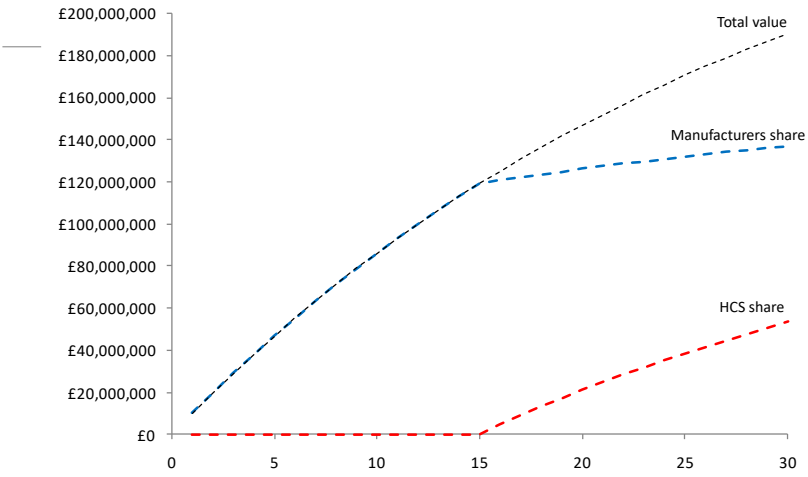
Should we value putative cures differently?

- **Product A**
- 2 life-years gained
- Good QoL
- Die of disease

Versus

- Product B
- 2 life-years gained
- Good QoL
- Die of other causes

Sharing value over time



Conclusions

Evaluation challenges not unique to 'cures'

The toolkit exists, needs to be used

Always need for further development

- Survival modelling
- Policy responses to uncertainty
- Policy responses to high upfront costs

Principles of value-based pricing remain

Thank you!

mark.sculpher@york.ac.uk

https://www.york.ac.uk/che/

@MJSculpher

Incorporating evidence on effect-heterogeneity in CEA

ANIRBAN BASU
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@basucally

THE CHOICE INSTITUTE
School of Pharmacy

Background

- **Cost-effectiveness analysis is beginning to play a major role in decision-making for private and some public plans in the US**

CVS Caremark is initiating a program that allows clients to exclude any drug launched at a price of greater than $100,000 per QALY from their plan. The QALY ratio is determined based on publicly available analyses from the

Criticisms

September 12, 2018

Mr. Larry J. Merlo
President and Chief Executive Officer
CVS Health
One CVS Drive
Woonsocket, Rhode Island 02895

Dear Mr. Merlo:

Therefore, we request that you reconsider this decision. CVS Health's stated purpose is "helping people on their path to better health." Reliance on cost-effectiveness thresholds like ICER's falls short of this purpose, replacing deeply personal, individual health care decisions with an opaque algorithm based on average study results that do not address the needs of different patients and special populations.

Premise

- Relying on average cost-effectiveness of a new technology has been criticized in the presence of heterogeneity

- Consider three issues in this talk:
  - Stochastic (first-order) uncertainty vs variability
  - Implication for learning by doing
  - Demand-weighted cost-effectiveness analysis
    - Its relationship to indication-based pricing

Stochastic (first-order) uncertainty vs variability

- Stochastic (first-order) uncertainty
  - Represents uncertainty in subject-level outcomes that is entirely due to chance.
  - E.g. even if you specify that subjects have a 5% chance of death, for any single individual at any point in time, either he dies and stay alive.
- This uncertainty is due to pure randomness (e.g. flipping a coin) – UNPREDICTABLE
- Cannot be used as a basis to allocate resources

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Stochastic (first-order) uncertainty vs variability

- Variability
  - PREDICTABLE differences in outcomes and costs for subgroups determined by subject characteristics
- Important for resource allocation
  - Heterogeneity may also arise due to system characteristics and also individual preferences
- Efficient allocation of resources should try to directly incorporate variability in decision-making

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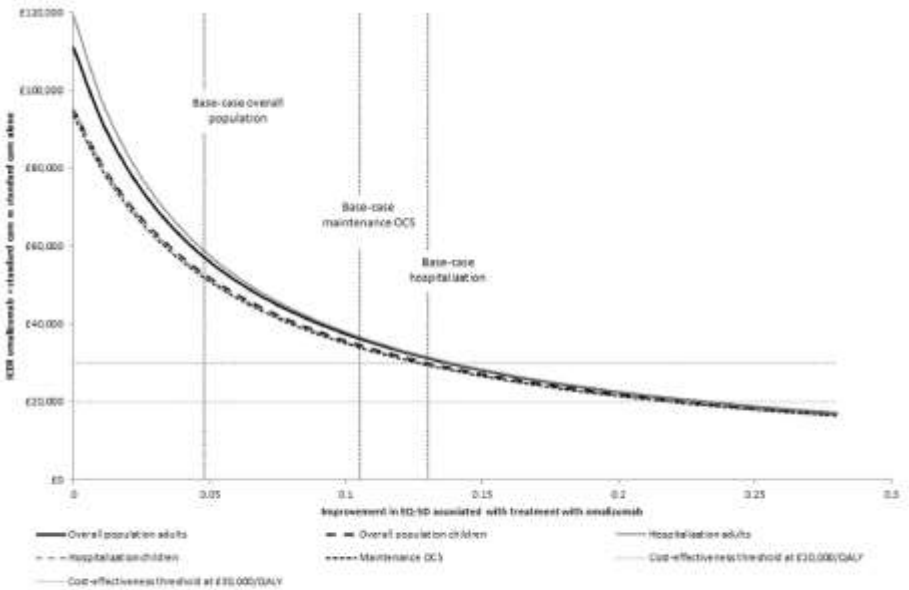

Fig. 2 – Effect of improvements in health-related quality of life on the cost-effectiveness of omalizumab. The subgroups with three or more exacerbations are not shown because the curves overlap the other subgroups and the overall population. EQ-5D, EuroQol five-dimensional questionnaire; ICER, incremental cost-effectiveness ratio; OCS, oral corticosteroid; QALY, quality-adjusted life-year.

Faria et al VIH 2014


NICE

NICE guidance

Omalizumab for treating severe persistent allergic asthma

Technology appraisal guidance
Published: 24 April 2013
nice.org.uk/guidance/ta278

7

1 Guidance

1.1 Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older:

- who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), **and**
- only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme.

https://www.nice.org.uk/guidance/ta278/

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Learning-by-Doing

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Learning-by-Doing:
Transition of Stochastic Uncertainty to Variability

9

> Physician and patients learn from the random variation in outcomes

> Develop algorithms to identify subgroups with higher/lowed than average outcome

> Should resource allocation be generous up-front to allow for learning?

- Fundamentally a trade-off between current health & costs and future health
- Depends on expected quality-of-learning and the rate of learning
- Empirical evidence suggest that learning exists but far from perfect.

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HEALTH ECONOMICS
Health Econ. **23**: 359–373 (2014)
Published online 9 October 2013 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/hec.2996

HETEROGENEITY IN ACTION: THE ROLE OF *PASSIVE* PERSONALIZATION IN COMPARATIVE EFFECTIVENESS RESEARCH

ANIRBAN BASU[a,*], ANUPAM B. JENA[b], DANA P. GOLDMAN[c], TOMAS J. PHILIPSON[d] and ROBERT DUBOIS[e]
[a]*Department of Health Services, University of Washington, Seattle and the National Bureau of Economic Research, Cambridge MA, Seattle, WA, USA*

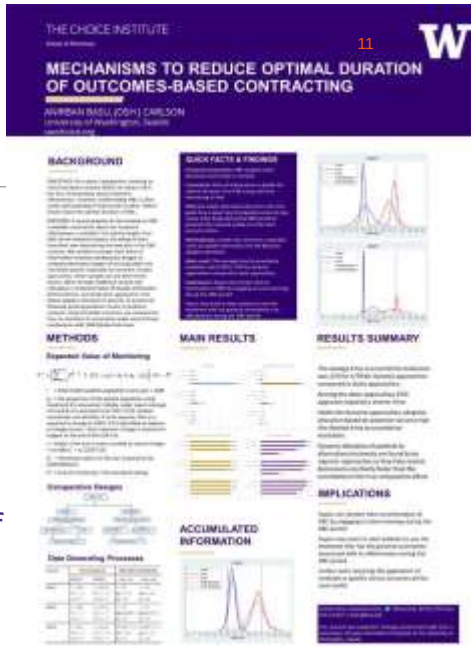
Table II. Predicted impact of generic group atypical antipsychotic drugs (AADs) compared with branded group AADs on average number of hospitalizations in 12 months following initiation of therapy

	All hospitalizations	Schizophrenia-related hospitalizations
Group	Mean (95% CI)	Mean (95% CI)
All patients (ATE)	0.35 (0.02, 0.67)	−0.07 (−0.28, 0.10)
Patients initiating therapy with generic group (TT)	0.17 (−0.17, 0.44)	−0.15 (−0.38, −0.03)
Patients initiating therapy with branded group (TUT)	0.61 (0.29, 1.05)	0.002 (−0.13, 0.22)
TT—ATE	−0.18 (−0.13, −0.28)	−0.08 (−0.04, −0.12)

ATE, average treatment effect; TT, effect on the treated; TUT, effect on the untreated.

Structured learning-by doing

- **Centralized learning from doing**
  - Learning during the outcomes-based agreement
  - Tuesday Poster 3:00 – 7:00 pm
- **Needs structure**
  - Determine time for learning
  - Select methods to learn faster
  - Have explicit decision-making tied to the end of learning period



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Demand-weighted CEA

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Demand-weighted cost-effectiveness

> **Evidence on variability is important even if**

- **there is no learning-by-doing**
- **there is no opportunity to implement sub-group-based coverage**

ORIGINAL ARTICLE

New Metrics for Economic Evaluation in the Presence of Heterogeneity: Focusing on Evaluating Policy Alternatives Rather than Treatment Alternatives

David D. Kim, PhD, Anirban Basu, PhD
Medical Decision Making 2017

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ICER for Alternative Treatments

Typical ICER compares Treatment A vs B

$$ICER = \frac{E(C_A) - E(C_B)}{E(Q_A) - E(Q_B)} = \frac{E(\Delta C_{AB})}{E(\Delta Q_{AB})}$$

$$= \frac{\sum\left(P_j E(\Delta C_{AB,j})\right)}{\sum\left(P_j E(\Delta Q_{AB,j})\right)} \qquad j = 1, 2, 3$$

P_j = Size of Subgroup j

- Suppose, clear evidence on variability in ICER across subgroups.

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ICER for Alternative Treatments

- ICER comparing potential realized value of Treatment A vs B

$$ICER = \frac{\sum_j [P_j \cdot D_j \cdot E(\Delta C_{AB,j})]}{\sum_j [P_j \cdot D_j \cdot E(\Delta Q_{AB,j})]} \quad (4)$$

- D_j: the rate of adoption of treatment A in the population subgroup j

- Similar to "Volume weighted price" across indications

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ICER for Alternative Policies

- The Rate of the uptake is endogenous to the policy
- So ICER should be comparing two coverage policies – Policy *k* vs Status quo

$$ICER = \frac{\sum_j [P_j \cdot D_{jk}(f_k) \cdot E(\Delta C_{AB,j}) \cdot f_k]}{\sum_j [P_j \cdot D_{jk}(f_k) \cdot E(\Delta Q_{AB,j})]}$$

f_k: a fraction of the incremental costs under a policy k borne by a payer

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Table 1 Illustration of Traditional and Modified ICERs and INMBs under a Health-Care Sect

Parameter	Males	Females	Overall
Total costs per patient under Statin + Fibrate, $	$107,021	$107,023	-
Total costs per patient under Statin Only, $	$98,131	$98,131	-
Total incremental costs per patient, $	$8,890	$8,892	-
Total QALYs per patient under Statin + Fibrate, $	9.468	9.308	-
Total QALYs per patient under Statin Only, $	9.200	9.200	-
Total incremental QALYs per patient, $	0.268	0.108	-
Subgroup-specific ICER	$33,130/QALY	$82,562/QALY	-
Subgroup-specific INMB[a]	$3,170	-$4,032	
Subgroup size (P_j)	0.533	0.467	
Traditional population ICER (eq. 3)			$46,000/QALY
Population NMB per patient from statin monotherapy[b]			$315,869
Adoption of Statin + Fibrate under status quo (f_k = 0.80), D_j	0.072	0.043	
Modified population ICER (f_k = 0.80, eq. 7)			$41,733/QALY
Status-quo policy NMB per patient (f_k = 0.80, eq. 8)			$315,910
Adoption of Statin + Fibrate under Policy 2 (f_k = 1.0), D_j^c	0.075	0.045	
Modified population ICER under Policy 2 (f_k = 1.0, eq. 7)			$41,766/QALY
Policy 2 NMB per patient (f_k = 1.0, eq. 8)			$315,911
Adoption of Statin + Fibrate under Hypothetical Policy,[d] D_j	0.23	0.023	
Population ICER under Hypothetical Policy[d] (eq. 7)			$34,848/QALY
Hypothetical Policy[d] NMB per patient (eq. 8)			$316,214

18

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Future Work in CEA

- To use demand weighted CEA at launch
  - Can we develop reliable estimates for *evidence elastic of demand?*
    - *Discrete choice experiments*
    - *Retrospective analysis*
    - Validated prediction model for technology diffusion
- CEA at 5 year assessment
  - Direct estimate from real-world use.

Crossroads

Decision makers focus of population averages because of the lack of reliable evidence on heterogeneity

Manufacturers argue that there is no incentive to generate evidence on heterogeneity

Conclusions

- Are we are failing to produce the necessary evidence of heterogeneity of effects, which can improve value in the society, by not providing sufficient reward incentive for such information.

> Importantly to create an environment that respects and rewards evidence on heterogeneity.

> Laying a clear path of incorporating reliable evidence on heterogeneity in third-party assessor's base analysis. This includes

  - **not reporting population average cost-effectiveness results when there are distinct differences in subgroup-specific results,**
  - **experimenting with demand weighted cost-effectiveness approaches.**

F4: Triangulating Developers, Regulators, and Payors to Reap Rewards and Address Challenges with Curative Therapies Payment Mechanisms and Handling Uncertainty

Adrian Towse[1] and Elisabeth Fenwick[2]

[1] Director of the Office of Health Economics

[2] Senior Director, Modelling and Meta-Analysis, Pharmerit International

ISPOR Barcelona 2018

Office of Health Economics Research

Agenda

What do we know about payer willingness to embrace new payment models for curative therapies?

Handling uncertainty – avoiding a bias against curative therapies

Fitting both parts together – a recipe for progress?

Agenda

What do we know about payer willingness to embrace new payment models for curative therapies?

Handling uncertainty – avoiding a bias against curative therapies

Fitting both parts together – a recipe for progress?

Payer willingness to embrace new payment models for curative therapies? Remarks based on three papers

Hampson, G., Towse, A., Pearson, S., Dreitlein, W., Henshall, C. 2017. Gene therapy: evidence, value and affordability in the US health care system. J Comp Eff Res. Nov 16. https://doi.org/10.2217/cer-2017-0068

Karlsberg-Schaffer, S., Messner, D., Mestre-Ferrandiz, J., Tambor, E. and Towse, A., 2018. Paying for Cures: Perspectives on Solutions to the "Affordability Issue". Value in Health, 21(3), pp.76-279. DOI: https://doi.org/10.1016/j.jval.2017.12.013.

Towse, A. and Mauskopf. 2018, Affordability of New Technologies: The Next Frontier, *Value in Health*. DOI: https://doi.org/10.1016/j.jval.2018.01.011.

Discussions with payers

- None of the US payers saw extraordinary measures as needed to pay for "cures"
- Costs dealt with via policy and competition
- Do not want to legitimise increased funding for drugs
- Likewise European payers – we got through….
  - Discounts, revenue caps limiting returns on R&D to "reasonable" or "affordable" levels

Payers are reluctant to adopt amortisation, although may sign up to outcomes-based agreements

Trade off is the signal payers want to send about R&D

Higher the share of social return going to the innovator in the patent period, the stronger are the incentives to find additional "cures" but greater affordability pressures

Having similar maximum revenue caps across different diseases where the social value of a cure may be very different sends the signal that payers are indifferent between them. Is this an acceptable consequence?

In the Hep C "cures" market, competition was a key driver of discounts. Evidence of a competitive R&D supply side. But will this happen in the subsequent areas of curative therapies?

Affordability (non-marginal budget impact) matters. But pragmatic approaches are needed. Need to avoid bias against cures.

Agenda

What do we know about payer willingness to embrace new payment models for curative therapies?

Handling uncertainty – avoiding a bias against curative therapies

Fitting both parts together – a recipe for progress?

Handling uncertainty – avoiding a bias against curative therapies

For simplicity we focus on one aspect of uncertainty – duration of treatment effect.

We consider whether the way in which uncertainty is handled should, or does, differ as between a one-off curative therapy and a repeat dose curative therapy which requires regular administration, but achieves the same expected health gain

If mechanisms for handling uncertainty in economic evaluations and in payer / HTA decision making processes create a bias against a one-off curative therapy (for example by accepting a lower price for a cure as compared to a repeat treatment for an equivalent health effect) this would send inefficient incentives.

If, however, the consequences of, and nature of the uncertainty associated with a one-off curative therapy is different to that of a repeat dose curative therapy then we need to send appropriate differential incentives for R&D.

Our main assumptions

We have a prevalence of 8000 patients,

General (background) mortality rate of 0.05% per month

Curative therapy with either the one-off or regular dose gives an expected discounted gain of 5.51 QALYs, and stops disease mortality

Current ineffective treatment generates 0.2 QALYs and costs $740 per month but has no impact on the disease mortality rate of 0.5% per month

Both curative treatments have an ICER of $40,000 per QALY, within the payer threshold ICER of $50,000 per QALY, i.e. they are cost-effective

The one-off therapy costs $296K and the regular dose therapy costs $4.5K per annum, with the same discounted cost of $296K

Time horizon is 50 years and we discount costs and outcomes at 5%

Annual monitoring costs are $120 per patient

The effectiveness of the curative therapy falls from 100% in year 1 to 92% in year 30.

What we are exploring

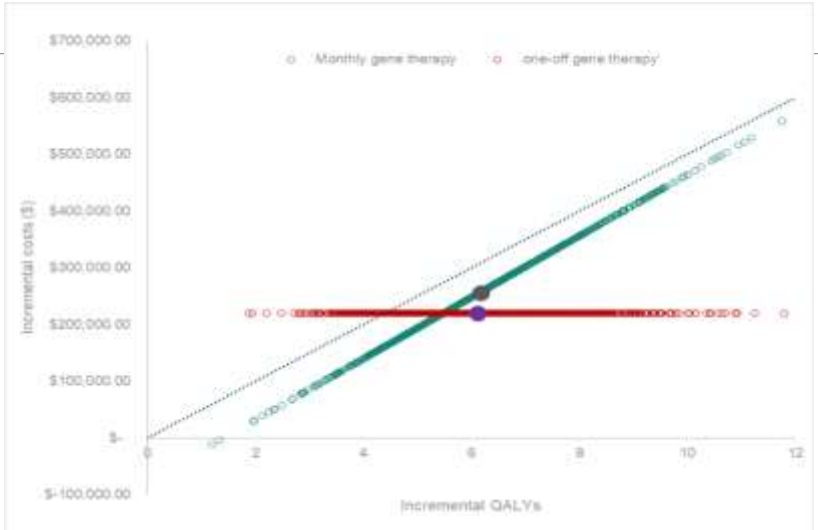
We compare the uncertainty associated with the one-off and repeat dose curative therapies, if evidence emerges that the treatment has stopped working

- With both we can stop treating new patients
- With repeat dose we can also discontinue treatment for existing patients

We look at the impact of introducing for the one-off treatment

- Outcomes based payments
- Annuity payments

Uncertainty on the (incremental) cost-effectiveness plane



Observations

With the one-off, it is the iterations where the treatment is least effective (i.e. the duration of effect is shortest) which are not cost-effective

With the repeat dose, it is the complete opposite

The introduction of an outcomes based payment or annuity payment changes the profile of the one-off to resemble repeat dose

In a VoI calculation we can:

- treat the outcomes-based approach as equivalent to coverage with evidence development or OWR;
- expect that the alternative of delay is not preferred and adopt with no new evidence is only preferred if no outcomes-based arrangement is possible

CEAC and EVPI for one-off curative therapy

CEAC and EVPI for repeat dose curative therapy

Outcomes versus annuity payment

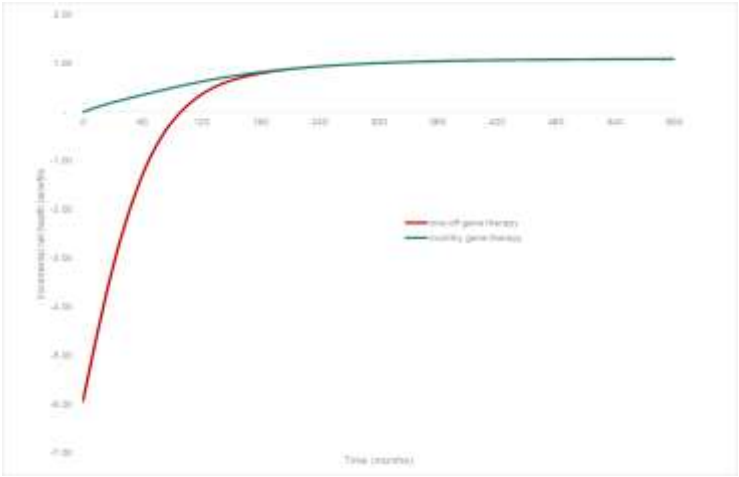
Annuity payment is £26,276 per annum, pay each year patient is alive

Outcomes based payment is £57,499 per annum, for each year patient remains cured.

Why the difference? The cure rate is not 100%. So manufacturer "needs" more per annum in an outcomes-based payment in order to receive the same revenue as when paid upfront for the one-off.

A subject for negotiation?

Net Health Effect per patient



Net Health Effect per patient

Illustrates the initial investment by the payer if a one-off cure is used

But not clear it adds anything to the ICER and the CEAC and EVPI illustrations…other than to look scary

But the key issue is expected value (for a risk neutral payer) and the costs and benefits of investing in uncertainty reduction

The profile of repeat dose indicates (as above) that an outcomes based scheme is likely to be a good investment

Introducing an expensive comparator

Steve Pearson and ICER have highlighted the challenge of an expensive cost-ineffective comparator

If our comparator cost $7,400 instead of $740 per month, the price for one-off (at an ICER of $40K) would rise to $1.06m, an increase of more than $750K

One option would be to only reward based on a cost-effective comparator. This would reduce the price of the comparator to roughly $8 per month and so reduce the value of the curative therapy from $296K to $218K.

But what are we trying to achieve?

- Incentivising saving costs of ineffective comparators
- Some sort of share of cost-savings but the health gain goes to the innovator in the patent period?

Agenda

What do we know about payer willingness to embrace new payment models for curative therapies?

Handling uncertainty – avoiding a bias against curative therapies

Fitting both parts together – a recipe for progress?

Fitting both parts together – a recipe for progress?

Payers don't want new payment mechanisms other than outcomes-based agreements

One-off treatments, paid for as one-off, present affordability issues

There is high uncertainty for the payer with one-off treatments and genuine issues around discontinuation with one-off versus repeat dose

Outcomes-based agreements overcome bias against one-off curative treatments by:

- addressing the large amount of uncertainty and
- reducing the affordability challenge

THANK YOU FOR YOUR ATTENTION

To enquire about additional information and analyses, please contact Professor Adrian Towse at atowse@ohe.org

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It’s time for you to ask questions.