

Budget Impact and the New AWTTC Template

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Based on a presentation by Eifiona Wood



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All Wales Therapeutics
& Toxicology Centre

Background

- NMG reviews economic evaluations, but not budget impact
- The appraisal of budget impact falls under the AWMSG
- NHS Wales has a limited budget
- Positive recommendations, that have a positive budget impact, result in savings having to be made elsewhere
- Budget impact not same as opportunity cost e.g. if a drug reduces hospital stay by 2 days, beds will be used up by other patients, no money will be released.



Economic Evaluation vs Budget Impact

	Economic evaluation	Budget impact
What is the question?	Is it value for money?	Is it affordable?
What is the time frame?	Usually longer-term (e.g. lifetime)	Short-term (1-5 years)
What inputs are considered?	Clinical evidence, resource use, utilities, costs	Patient numbers, resource use, costs
What are the health outcomes	QALYs	Not considered
Decision rules	Yes	No
Value judgements	Minimal	Yes



AWMSG summary guidelines for appraising medicines

- *“In certain circumstances, AWMSG will also take into consideration the anticipated budget impact...”*
- *“When the AWMSG considers that a medicine has a large impact on NHS resources within a given disease area, it will want to be increasingly more certain of the cost-effectiveness and may require more robust evidence on the clinical effectiveness and cost-effectiveness”*



Uncertainty: Eligible patient numbers

Parameter	Evidence-base
Population, incidence and prevalence of disease, proportion of treated patients	ONS, publications, NICE, StatsWales (QoF disease registers)
Uptake and market share	Company assumptions, market research data



Uncertainty: resource use

- Resource use often lifted from the cost-effectiveness model (uncertainty in the economic model also often relevant to BI model)
- Include drug use, GP visits, outpatient visits, hospital admissions, nurse time
- Data sources: trial data, or may be from clinical expert surveys
- Epidemiology often lacking
- Did company follow ISPOR guidelines for BI analysis?



Uncertainty: resource use

- Resource use savings often reported as “Net cost savings” in ASAR.
 - Resource use usually represented as mean values – these are usually point estimates
 - “Mean differences” in costs, based on resource use differences between interventions
- Data sources not always robust.
 - Often characterised by high degrees of uncertainty, in particular where there is limited data
 - Resource use values are often best “guesstimates”
 - Company-projected uptake may not be verifiable



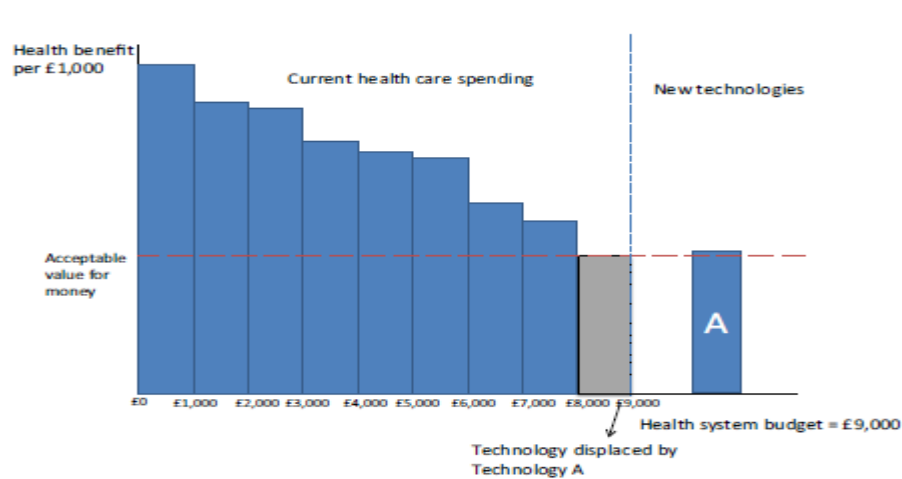
Interpretation: Costs savings money saving vs resource saving

- Money saving – immediate effect on budget
- Resource saving – no immediate effect, though there is potential that savings may be realised at a future point

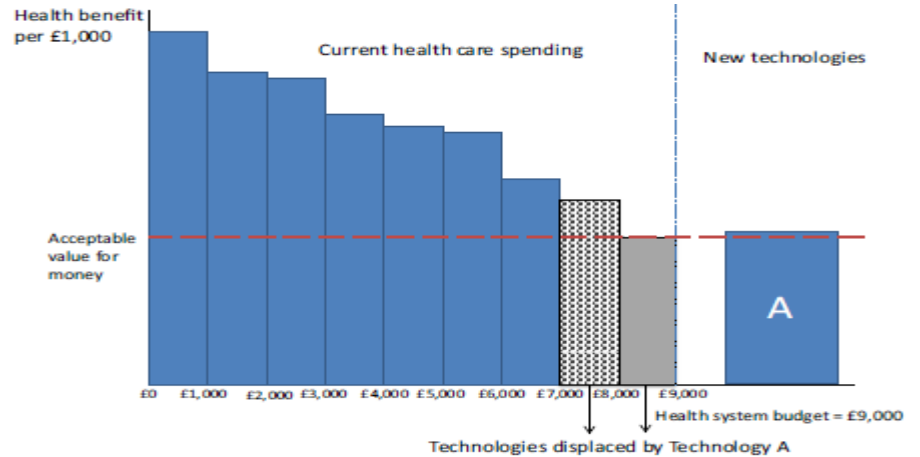
	Old drug, IV antibiotic	New drug, IV antibiotic	Impact	Immediate effect of money saving	Immediate effect of resource saving
Drug costs	£7. 50 per dose £15 per day	£10 per dose £10 per day	£5 per day	✓	-
Resource use	x 2 per day 60 minutes nursing	X 1 per day, 30 minutes nursing	30 minutes nursing time per day	x	✓



Technology displacement



Opportunity costs of small investments



Opportunity costs of large investments

*Source: Woods et al. Pharmacoeconomics 2015 Dec 29.
Assessing the Value of New Treatments for Hepatitis C: Are
International Decision Makers Getting this Right?*



Process for new AWTTC BI template.

- Improve consistency in approach and transparency
- Company downloads template and completes worksheets with data providing full reference to sources
- Template outputs net monetary costs/savings table and net resource use/savings, for years one to five (company copies both of these to form B)



All Wales Medicines Strategy Group

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- [Appraisal process flow diagram & timeline](#)
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Detailed guidance

Explanatory notes and guidance on completion are provided within each worksheet which explain in detail how to complete each part of the template.

Hyperlinks to notes are provided and indicated by [underscored numbers](#) on the left-hand side of the text.

This budget impact template is made up of the following worksheets:

Click on any of the worksheet names below to go directly to that worksheet.

Annual treated patient numbers

This spreadsheet calculates the estimated numbers of patient that will be treated with the new medicine in Wales. Please show all sources of information and calculations to allow reviewers to check assumptions. Please use the column provided and include tables, calculations, graphs and reference sources on right hand side of and below the table .

Medicine acquisition cost

This worksheet allows entry of the acquisition cost of the new medicine for NHS Wales based on the list price or PAS price (where applicable). The acquisition cost must be consistent with the economic model in the AWTTTC submission. Costs should be undiscounted.

Cost per patient

This worksheet allows entry of the costs per patient associated with the new medicine and the existing medicines. The new medicine acquisition costs are autofilled from the 'New medicine acquisition cost' worksheet. Other costs are be entered here for: supportive medicines, administration, diagnosis and monitoring, adverse events, primary care, secondary or tertiary care and personal social services. Each of these cost types are headings which may, or may not be relevant to the medicine under review; there is some overlap here in cost category. Therefore these headings are a guide for the types of costs that AWTTTC seeks information on, rather than a list that needs to be explicitly completed. Costs associated with all existing medicines which are anticipated to be partially or totally displaced by the new medicine are to be entered in the table. Costs per patients on this worksheet are used to provide total costs in the sub-population of patients to be treated in the 'Scenario without new medicine' and 'Scenario with new medicine' sheets.

This worksheet allows entry of resource costs/savings arising from, for example, reduced numbers of outpatient appointments, inpatient stays, theatre sessions. However the costs associated with such items are largely fixed and rarely lead to cash-releasing savings or increased costs; the departments affected might be a little less, or more, busy, but it is likely that the same number of staff will be



only required for orphan/VO or drug for rare diseases

Summary acquisition costs

Net costs	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients (all licensed indications*) - see note below					
Sub-population of eligible patients (indication under consideration)	0			0	0
Uptake of new medicine (%)	0%			0%	0%
Number of patients receiving new medicine allowing for discontinuations	0			0	0
Net medicine acquisition cost	£0			£0	£0
Net supportive medicines costs	£0			£0	£0
Net medicine acquisition costs (savings/costs) - including supportive medicines where applicable	£0			£0	£0

Net costs calculated by subtracting "scenario without new medicine" from "scenario with new medicine"

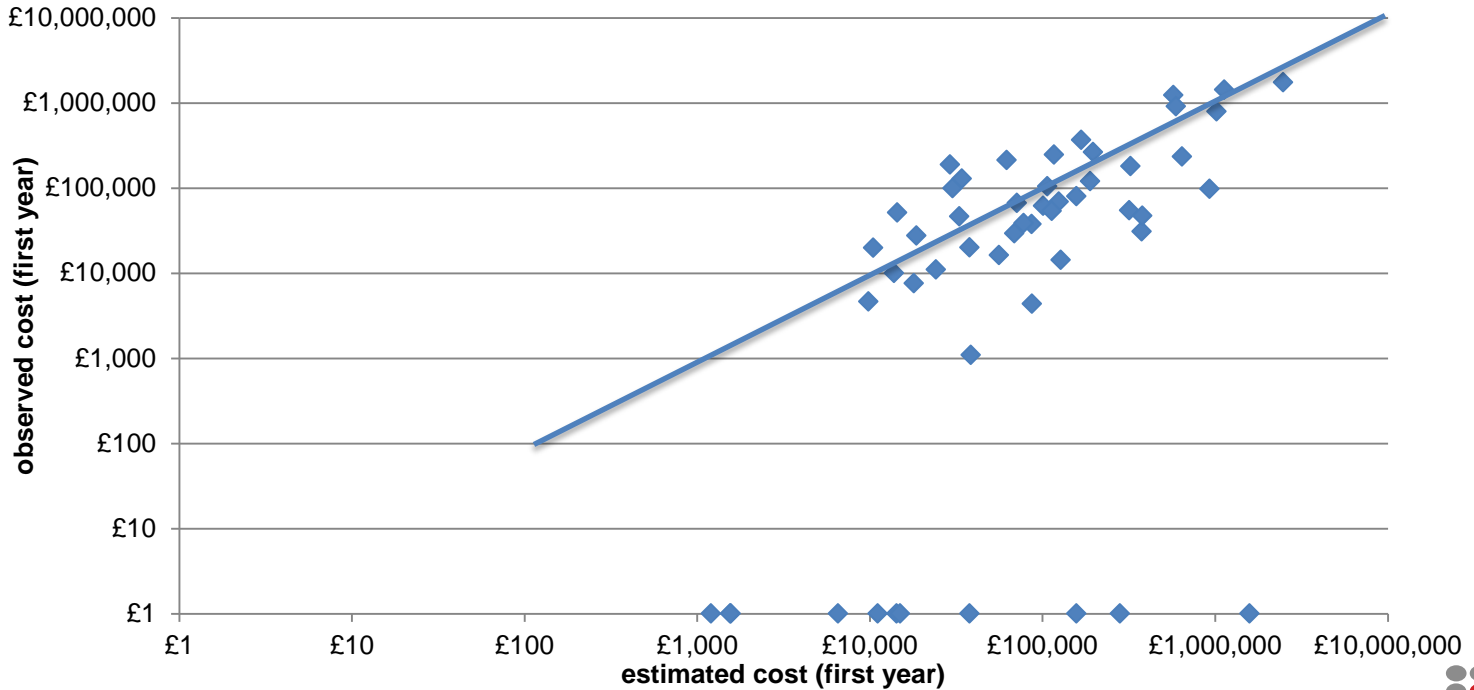


BI monitoring

- Compared company estimates from appraisals since 2005 to NHS prescription data (primary and secondary care data)
- Used acquisition costs (no account of displaced medicines or resource implications)
- Only for medicines which did not have significant use pre-AWMSG approval (less than 20% of total appraised)

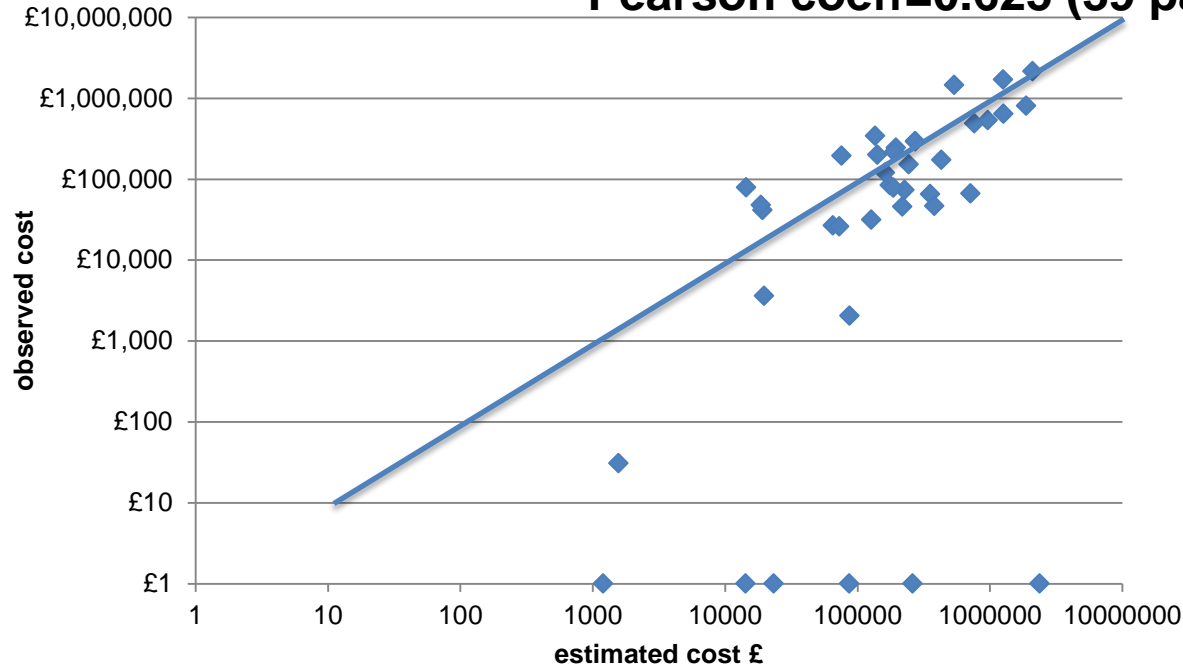


Observed vs estimated cost (first year) (Pearson coeff=0.736 (52 pairs))



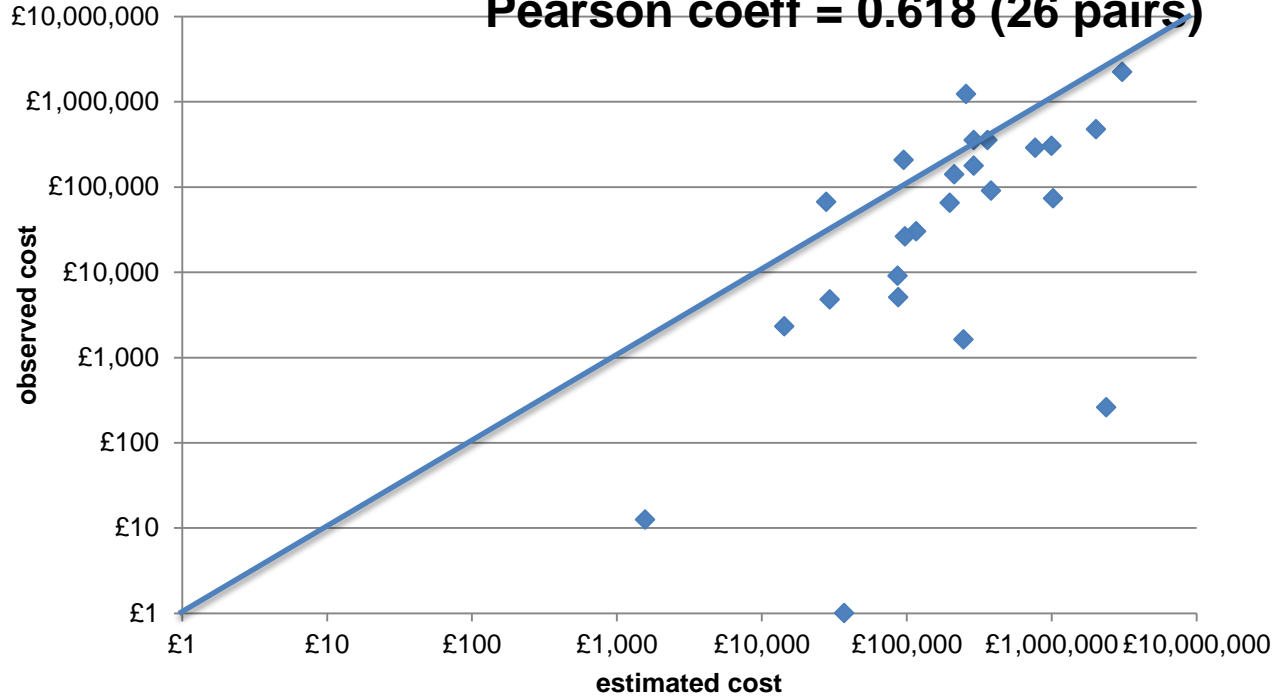
Observed vs estimated costs (second year)

Pearson coeff=0.625 (39 pairs)



Observed v estimated costs (3rd year)

Pearson coeff = 0.618 (26 pairs)



Final messages

- Budget impact analysis is an important part of reimbursement decisions
- Budget impact analysis subject to uncertainty, and potential errors
 - Estimated patient numbers
 - Resource use and unit costs
 - Uncertainty/errors in the economic model often feed through into the BI model
- Money savings are realised differently to resource savings
- Opportunity cost of funding new interventions
 - Positive AWMSG recommendation with positive BI will displace alternative technology
 - How will this impact overall health benefits?



Final messages

- Small budget impact is not in itself a reason to recommend a medicine
- Large budget impact is not in itself a reason to reject a medicine
- Please feedback any issues or suggestions for improvement with new BI template



Thank you



AWTTC
All Wales Therapeutics
& Toxicology Centre



WAPSU
Welsh Analytical
Prescribing Support Unit



WeMeReC
Welsh Medicines
Resource Centre



PAMS
Patient Access to
Medicines Service



WNPU
Welsh National
Poisons Unit



Yellowcard
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