Negotiating the Relationship between Price and Volume:
Implications for ICER Calculations in Heterogeneous Treatment Populations

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Purpose

- Restricting reimbursement to subgroups of the licensed population and engaging in price negotiations with producers are two methods payers are increasingly employing to optimise the use of new technologies
- However together these have implications for ICER calculations which the literature has not considered to date.
- For the purposes of this analysis we consider subgroups as representing stratified analysis of a licensed indication or analysis of populations for different treatment indications.

The purpose of this study is to describe a new method for incremental cost-effectiveness ratio (ICER) calculations in the presence of heterogeneity and price negotiations.

Methods-Novel Method

- In scenarios where an intervention is cost-effective in one subgroup ($Subgroup_1$) and fails to be cost effective in another ($Subgroup_2$), a decision may be made to restrict reimbursement to the Cost-effective subgroup
- However if it is profit maximising to do so, producers may be willing to negotiate a lower price for reimbursement in the full population to generate increase sales.
- It has been previously shown that stratified analysis is more appropriate than a weighted average approach if reimbursement can be restricted to subgroups[1]. Therefore traditional stratified ICER calculations would only consider the incremental costs and gains of the new intervention in the remaining subgroup.
- We propose a broader incremental comparison where the additional cost-savings from the reimbursed subgroup $Subgroup_1$ (that would be generated by a price reduction) are included in the calculation of the ICER of the new intervention to reduce the incremental costs.
- Components included in the incremental analysis for the second subgroup under different methods are presented in **Figure 1.**

Methods - Simulation Study

- The implications of the new method are illustrated through the use of a simulation study.
- We propose that a new medicine "DrugA" is available to treat two diseases, 'Yellow' and 'Blue'.
- We assume a greater rate of disease progression and a larger treatment effect in 'Yellow' compared to 'Blue'.
- A hypothetical simple Markov Model was created compatible with these assumptions **(Figure 2 and Table1 and 2)**

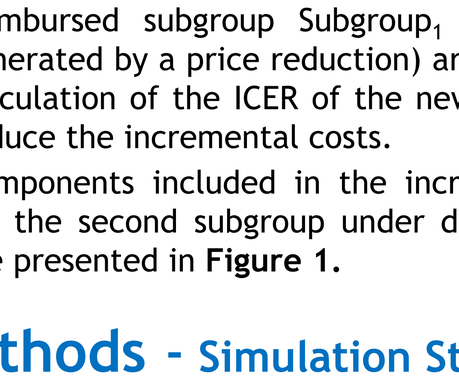

Figure 2. Markov Model Health States and Transitions

Methods-Simulation Study(Cont.)

- We assume a cost effectiveness threshold of €45,000/Quality Adjusted Life Year (QALY).
- An incremental cost-effectiveness analysis was conducted versus standard of care for both diseases at a cost of €13,000/patient/year
- Assuming DrugA is reimbursed for 'Yellow', another incremental analysis is conducted in a scenario at a cost of €11,000/patient/year if reimbursement is extended in both 'Yellow' and 'Blue'.
- ICERs are calculated under the traditional stratified approach and the novel approach. Weighted Average ICERS are presented for comparison purposes.

Table 1. Model Parameters associated with Health States

Parameter		Health State		
		Well	Sick	Dead
Initial Population Distribution		1000	0	0
Health State Costs		€1000	€500	0
Utility Values		1	0.8	0
Progression Transition Probabilities				
Well	Yellow	Balance	0.100	0.050
	Blue	Balance	0.090	0.045
Sick	Yellow		Balance	0.100
	Blue		Balance	0.090
Dead	Yellow			1
	Blue			1

Table 2. Other Model Parameters

Parameter	Value	
	Yellow	Blue
DrugA Treatment Effect*	0.5	0.6
Standard of Care Cost	€0	€0
Initial Annual DrugA Cost/ Patient	€13,000	€13,000
Negotiated Annual DrugA Cost/Patient	€11,000	€11,000
Cycle Length	1 year	
Discount Rate	5%	

*Remaining Proportion of baseline risk of progression after treatment with Drug A

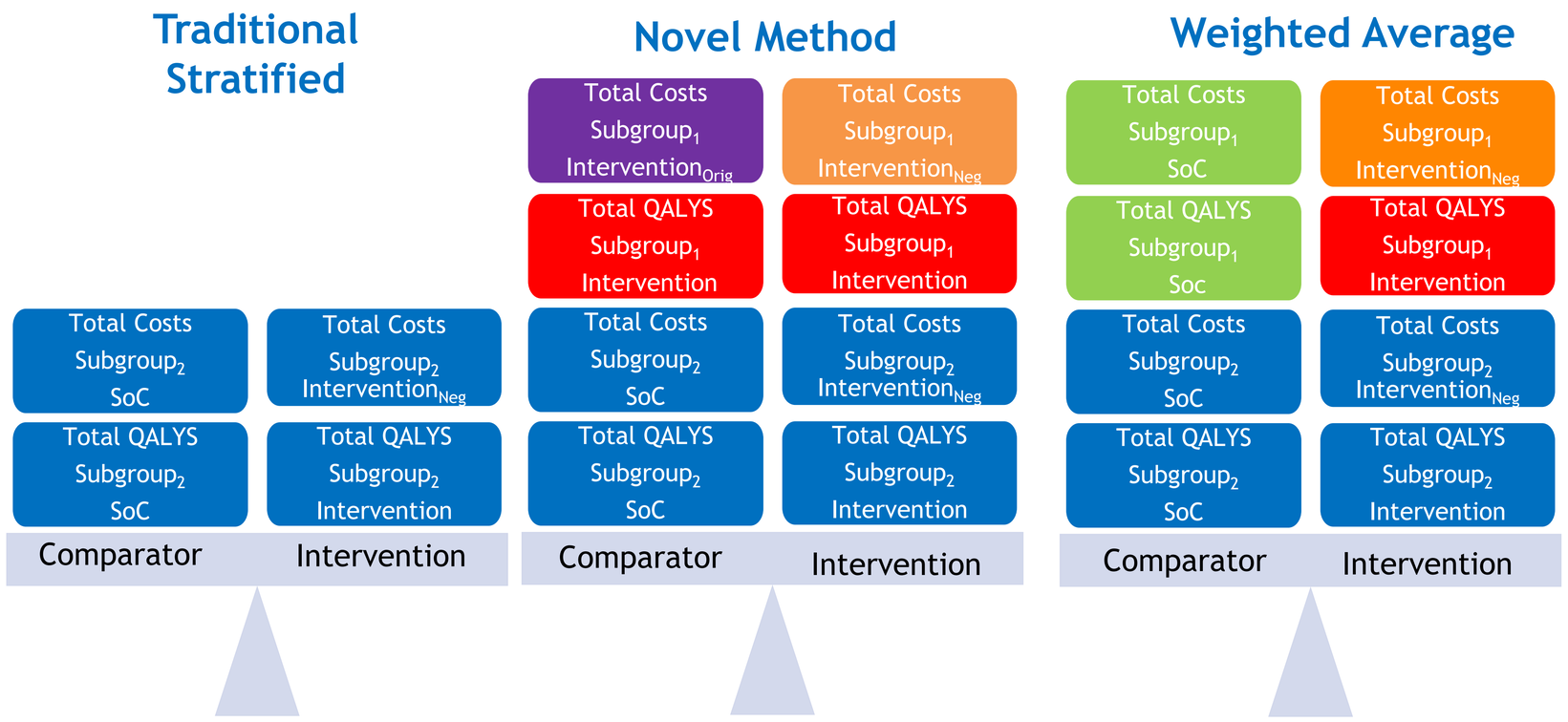

Figure 1. Components included in the incremental cost-effectiveness analysis of Subgroup 2 under different methods after price negotiations. Assumption: Intervention is more cost effective in subgroup 1 than subgroup2 and is already reimbursed in Subgroup1
$Intervention_{Neg}$,Negotiatied Intervention Cost; $Intervention_{Orig}$, Original Intervention Cost; QALYS, Quality Adjusted Life Years; SoC, Standard of Care;

Results

Drug A is offered for reimbursement at €13,000/patient /year

ICER (€/QALY)		
Yellow	Blue	Weighted Average
€43,305	€56,091	€49,678

- ICER for yellow disease is below the cost-effectiveness threshold and reimbursed ✓
- Drug A is not reimbursed for Blue Disease ✗

*Calculation breakdown shown in Table3

Producer offers a reduced price of €11,000/patient/year if reimbursement is extended to the blue population

Blue Disease ICER (€/QALY)		
Traditional Stratified	Novel Method	Weighted Average
€47,607	€38,815*	€42,198

- Under the Traditional Stratified method Drug A would not be reimbursed for Blue ✗
- Under the novel method when the incremental gains from the price reduction in the yellow population are taken into account the ICER falls to €38,815/QALY for blue. As this falls below the cost-effectiveness threshold it would be reimbursed. ✓

Figure 3. Simulation study negotiation assumptions and reimbursement outcome results under traditional stratified, novel and weighted average approaches

Table 3. ICER Calculations for Blue under Novel Method at Negotiated Price of €11,000

	Current		Negotiated		Incremental
Costs	TC Yellow Drug A @€13,000	€163,138,461	TC Yellow Drug A@€11,000	€139,540,169	-€23,598,292
	TC Blue SoC	€6,821,424	TC Blue Drug A@€11,000	€134,607,768	€127,786,344
	Total Costs	€169,959,885	**Total Costs**	€274,147,937	€104,188,052
QALYs	TQ Yellow Drug A	10,979	TQ Yellow Drug A	10,979	0
	TQ Blue SoC	7,890	TQ Blue Drug A	10,574	2684
	Total QALYs	18,869	**Total QALYs**	21,554	2684
ICER					€38,815

ICER, Incremental Cost Effectiveness Ratio; QALYs, Quality Adjusted Life Years; TC, Total Costs; TQ, Total QALYs

Conclusions

- Novel Method has the potential to change conclusions regarding the cost effectiveness of interventions
- This method should be employed when decision making is linked to price negotiations and when reimbursement can be restricted to subgroups
- Impact of novel method may be considerable given the increasing prevalence of these scenarios

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[1]Coyle D, Buxton MJ, O'Brien BJ. Stratified cost-effectiveness analysis: a framework for establishing efficient limited use criteria. Health Econ. 2003;12(5):421-427