

Budget Impact Analysis

Lotte Steuten, PhD MSc

Associate Member, Hutchinson Institute Cancer Outcomes Research

Fred Hutch

Associate Professor, School of Pharmacy

University of Washington

Founder & CSO, Panaxea - a health economic research firm

Aims

- I. Introduction to Budget Impact Analysis (BIA)
- II. Description of a six step process for BIA
- III. Presentation of the six steps, using an example
- IV. Hands-on exercise
 - Guided example
 - Start your own BIA!

I. Introduction to BIA

Why perform a BIA?

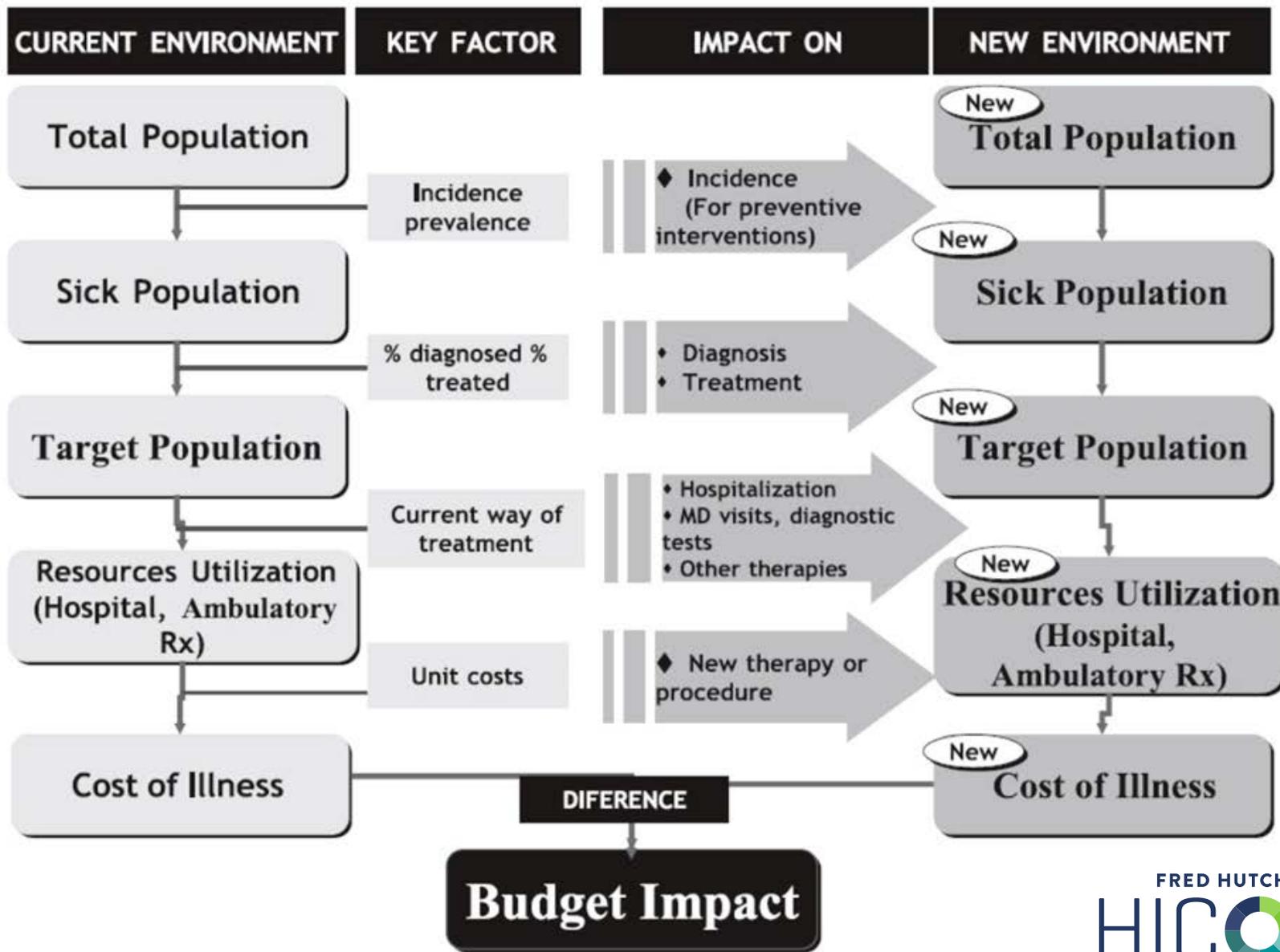
- BIA is an essential part of a comprehensive economic assessment of a health care technology
- BIA is increasingly required, along with cost-effectiveness analyses (CEA), prior to formulary approval, reimbursement or otherwise getting your product/service paid for in the market

Why perform a BIA?

- BIA provides a valid computing framework that allows users to see how different assumptions about the diffusion of a new technology in the health plan will result in:
 - Changes in the mix of treatments used for a specific condition
 - Changes in the cost of treating a specific condition
- BIA is useful for budget planning and forecasting
 - The results of the BIA will vary depending on the decision maker perspective
- It is not a measure of value!

Why Will a New Intervention Impact a Health Plan Budget?

- New intervention may be higher cost than current interventions
- New intervention may result in reduced condition costs because of clinical benefits to the patient
 - Reduced condition costs may offset the higher cost of the new intervention
- Timing of the changes in intervention and condition cost will impact the timing of the budget changes



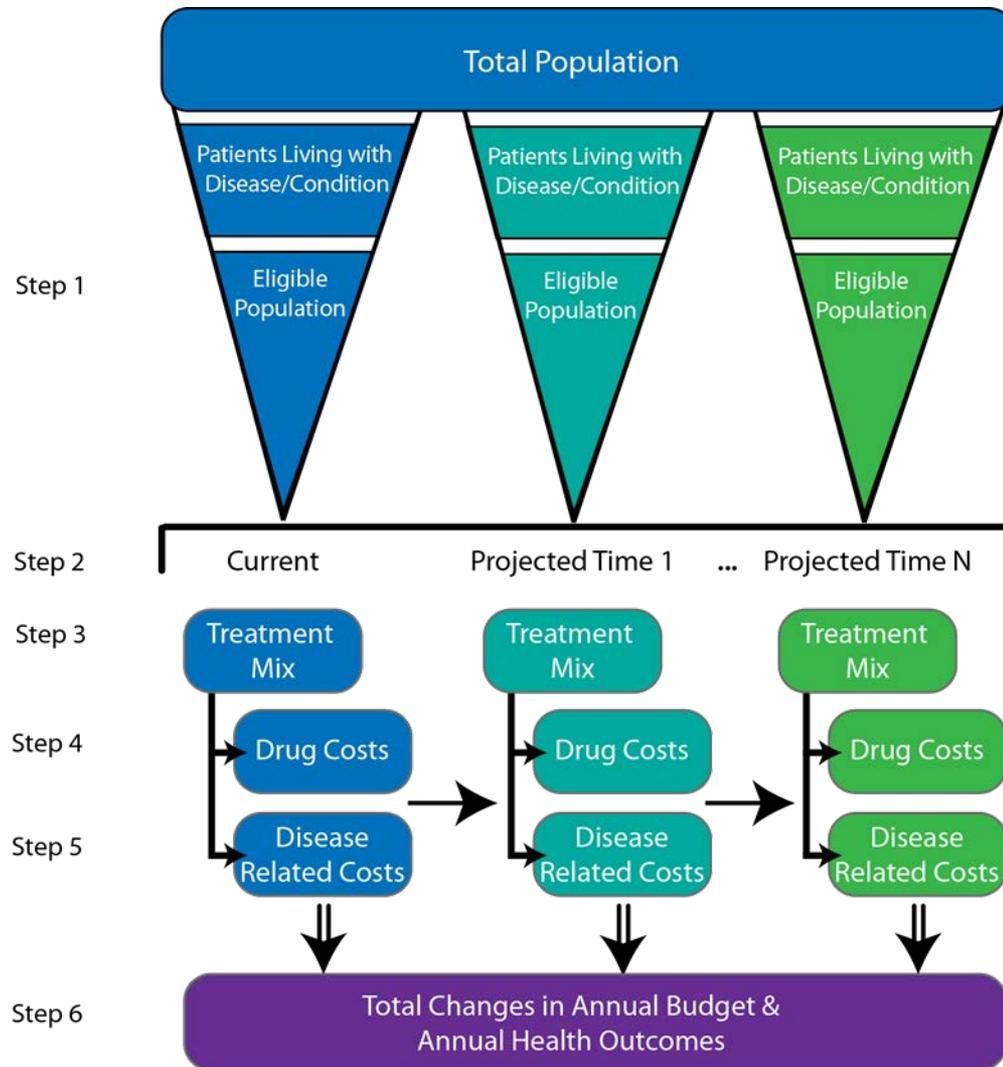
CEA versus BIA

Analysis Approach	Population Studied	Time Span	Example Outcome Measure	Value to Decision Makers
Cost-Effectiveness Analysis	One-year incidence cohort or representative individual	Disease Duration	Incremental: <ul style="list-style-type: none"> • lifetime costs • years/QALYs • cost per LY/QALY gained 	Resource allocation decisions among different treatments
Budget Impact Analysis	All people with disease in one year time period	1-5 Year/Annual	Change in: <ul style="list-style-type: none"> • health care costs • mortality or morbidity • cost per member per month • cost per treated member per month 	<ul style="list-style-type: none"> • Budget planning • Reaching target health outcomes

LY = Life Year; QALY = Quality-Adjusted Life Year

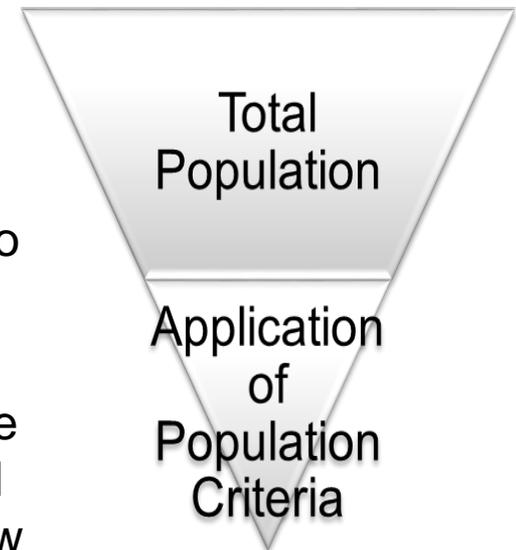
II. Description of a six step process for BIA

Six Steps for Estimating the Budget Impact



Step 1: Characterize Population

- Starting with the health plan population, determine all who will be impacted by new intervention each year
 - Include all with the condition for which the new product is indicated, who are diagnosed and currently being treated
 - Consider any additional people with condition who might enter treatment because of the availability of the new drug
 - Consider whether only patients newly entering the treatment population will take the new drug or will those already taking other drugs switch to the new drug



Step 1: Characterize Population (*Cont.*)

- Subdivide population by disease severity or stage where appropriate
- Allow population size and severity or stage to change over time where appropriate
- Use epidemiology, natural history and clinical trial data in a disease progression model where appropriate to characterize population

Time 1



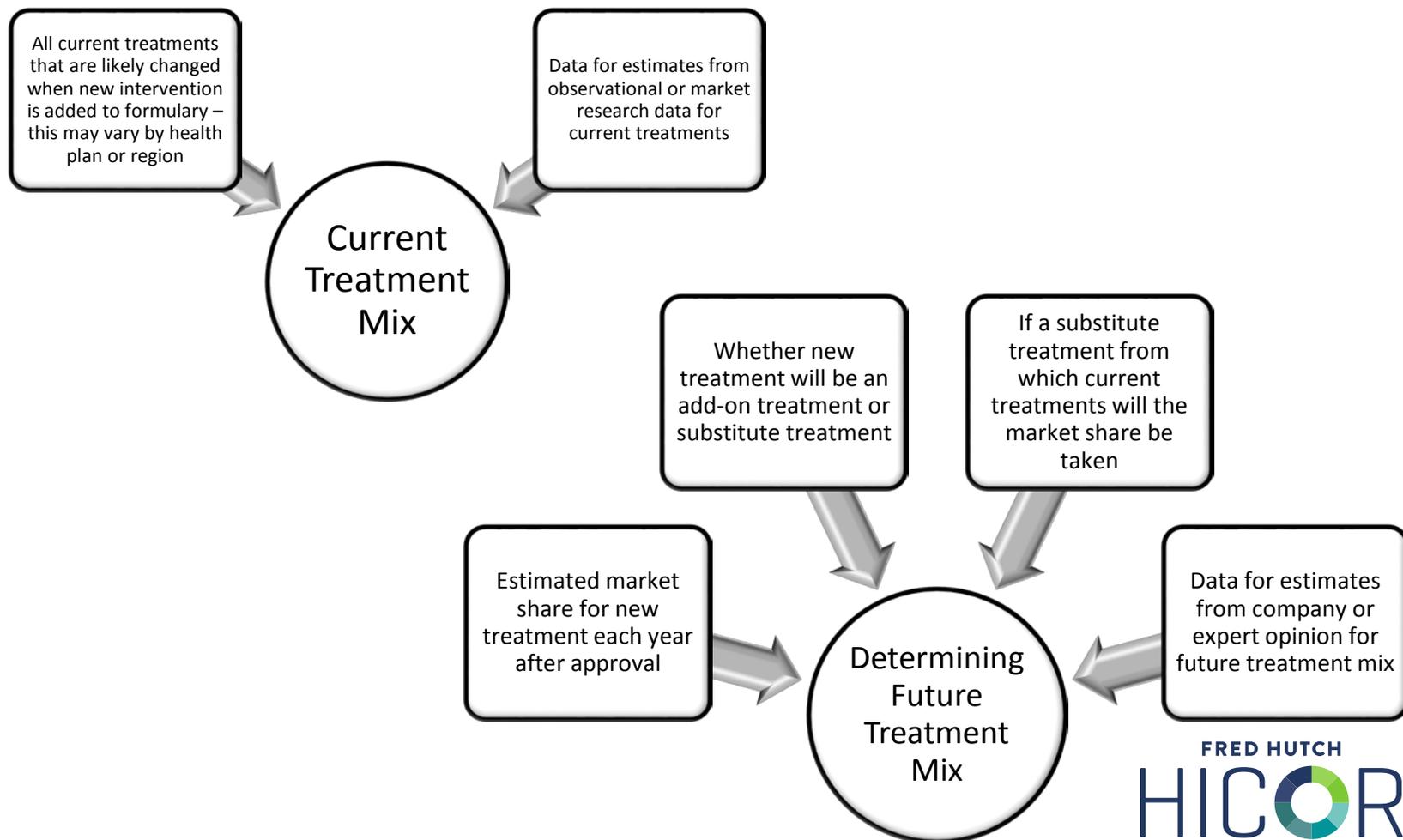
Time N



Step 2: Select Time Horizon

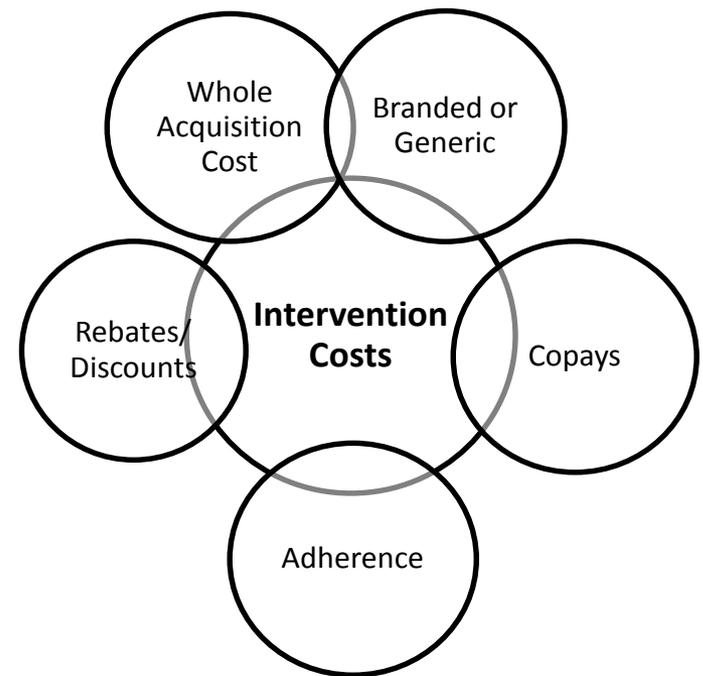
- Remember decision makers have short term horizons (maybe only 1 year)
 - Program model to allow for some flexibility so that decision maker may choose from 1 to 5 years
- Longer time horizons might be useful in some cases but only when population and treatments are likely to remain stable.

Step 3: Current and Future Treatment Mix



Step 4: Estimate Intervention Costs

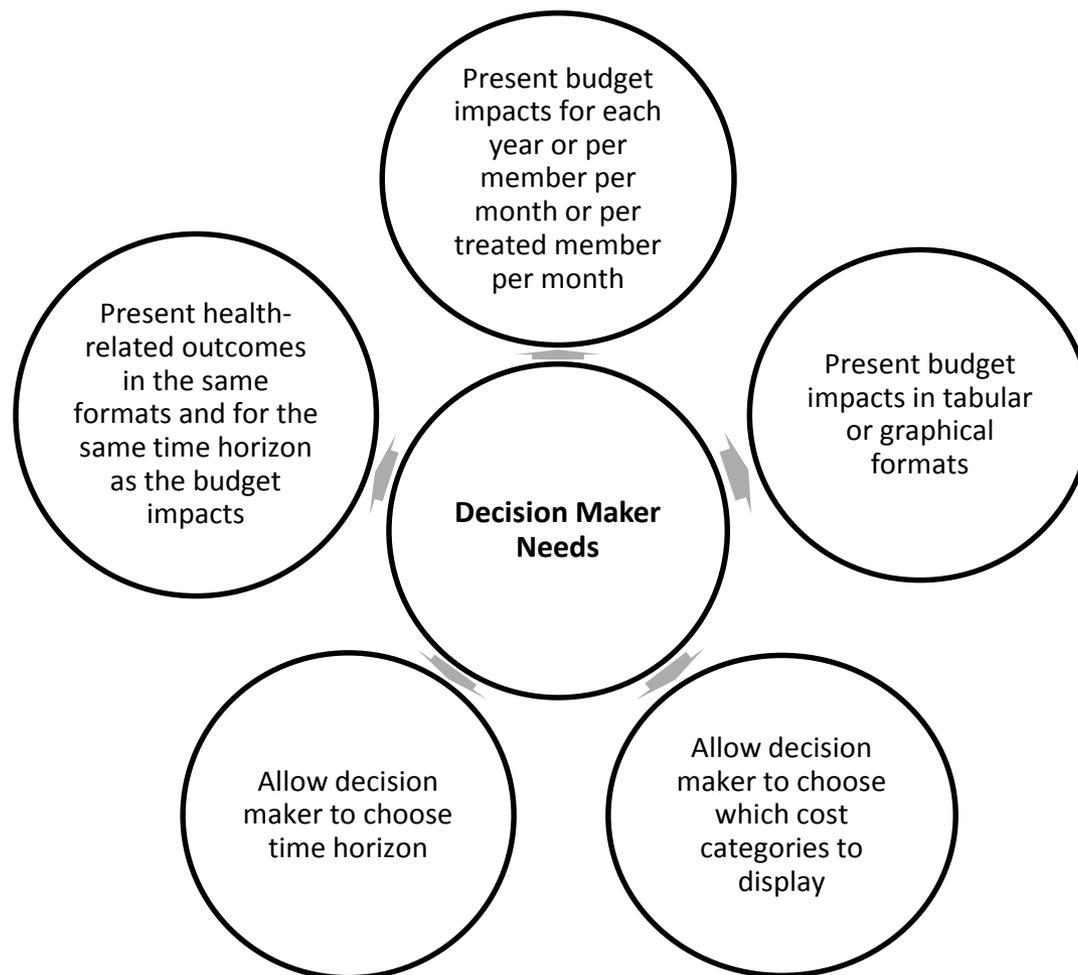
- Use wholesale acquisition costs for default values but allow user to enter their own acquisition costs
- Account for loss of patent protection if this is occurring in the chosen time horizon
- In the US, program the model to allow for discounts and co-pays
- Consider the impact of adherence on drug costs – but also need to consider impact of adherence on disease outcomes



Step 5: Estimate Changes in Disease-Related Costs

- For an acute disease
 - Use data from clinical trials to estimate changes in disease outcomes and associated costs
- For a chronic disease
 - Use a disease progression model and effectiveness estimates that are used for CEA
 - Consider the full treatment pathway
- Consider including changes in costs of treatment of other conditions when life expectancy is increased

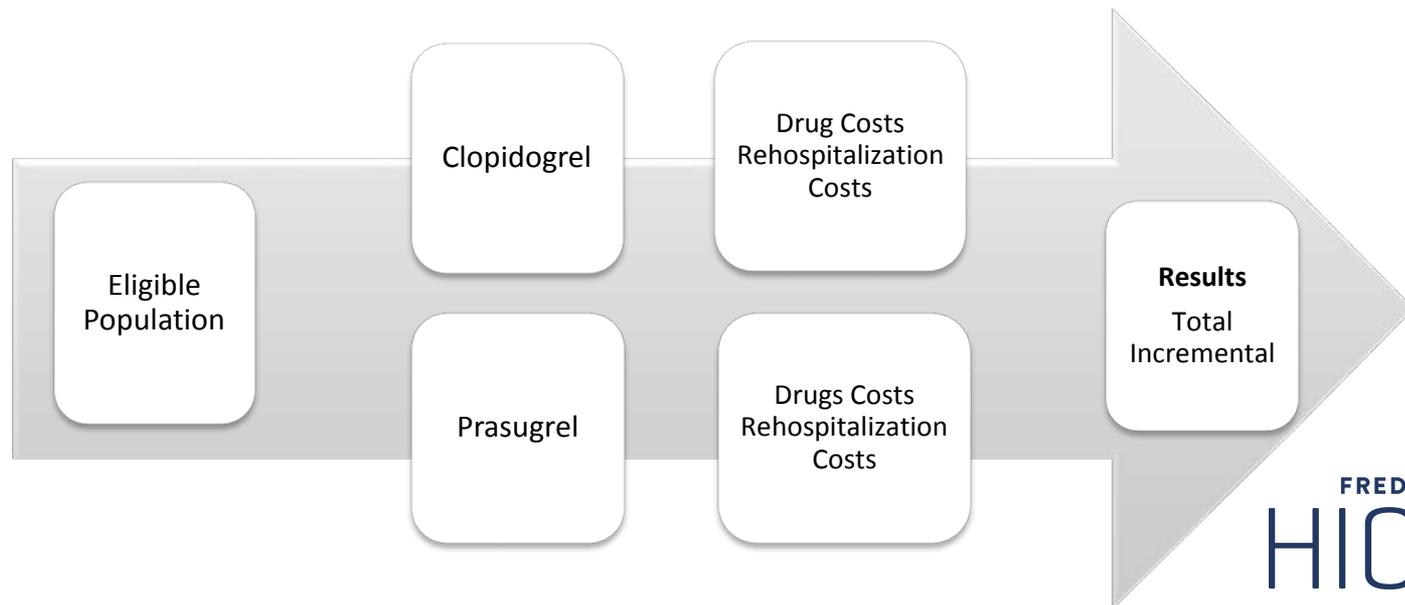
Step 6: Present Budget Impacts and Health Outcomes



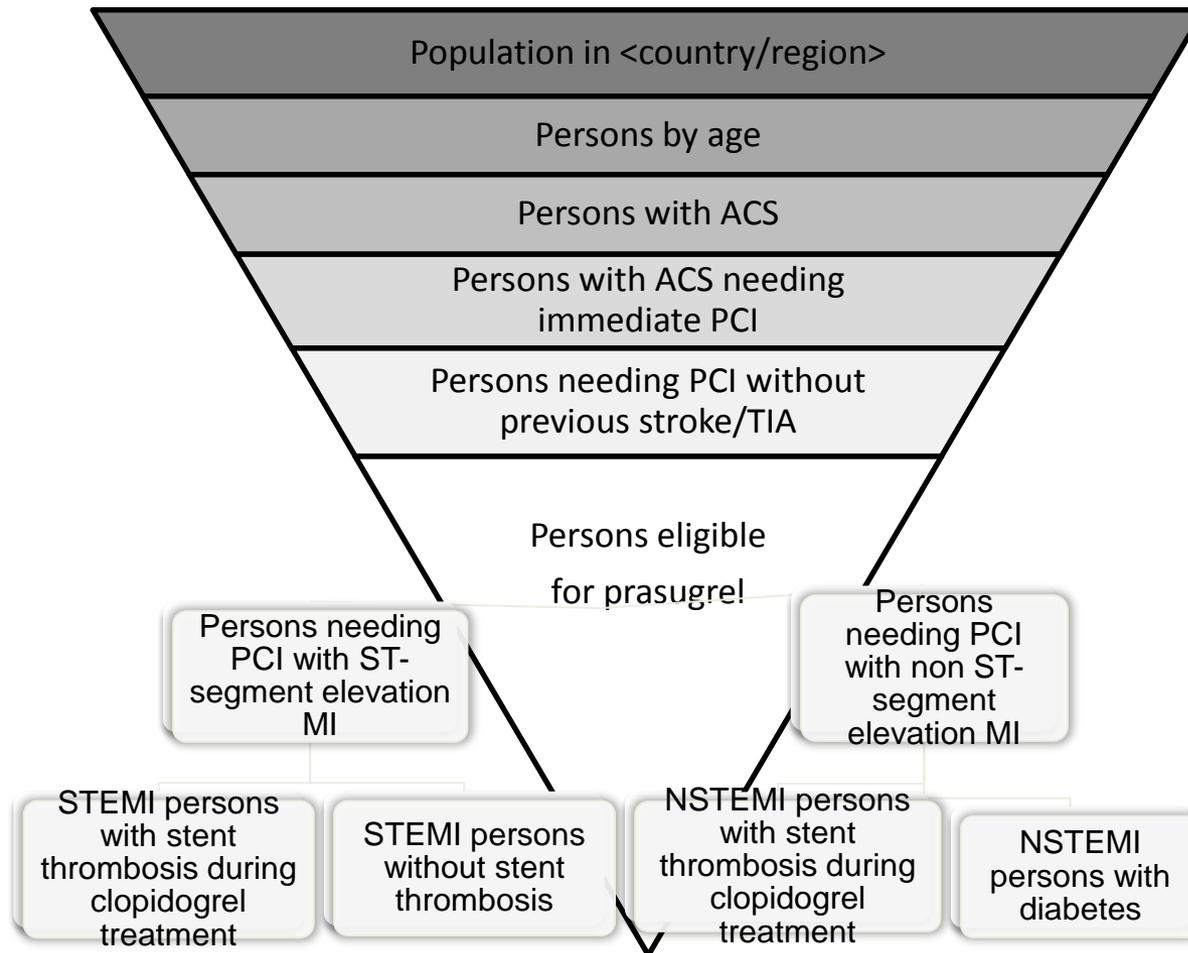
III. Presentation of the six steps, using an example

Static Model: Prasugrel

- Patients with acute coronary syndrome (ACS) needing Percutaneous Coronary Intervention (PCI)
- Time horizon: 1-year
- Disease cost is proxied by 1-year rehospitalization
- No discounting



Step 1: Characterize Population



*Adapted from NICE model. NICE template was edited and embellished

Step 1: Characterize Population

Population	Population Size	Source
England & Wales Population	50,542,505	Office for National Statistics population estimates by primary care organisation 2006.
Persons with ACS per year	233,614	Published estimate
Persons with ACS needing immediate PCI	37,430	British cardiovascular intervention society audit returns (2007)
Persons needing PCI without previous stroke/TIA	35,933	TRITON trial of prasugrel
Persons needing PCI with ST-segment elevation MI	8,839	British cardiovascular intervention society audit returns (2007)
STEMI persons with stent thrombosis during clopidogrel treatment	208	TRITON trial of prasugrel
STEMI persons without stent thrombosis	8,632	
Persons needing PCI with non-ST segment elevation MI	27,093	British cardiovascular intervention society audit returns (2007)
NSTEMI persons with stent thrombosis during clopidogrel treatment	637	
NSTEMI persons with diabetes	4,630	

ACS=acute coronary syndrome, MI=myocardial infarction, PCI=percutaneous coronary intervention, NSTEMI=non-ST elevation MI, STEMI=ST elevation MI, TIA=transient ischemic stroke

Step 2: Select Time Horizon

- One year time horizon
- Present results for current year
- Present results for future years with projected uptake: year 2, year 3, year 4, and year 5

Step 3: Current and Future Treatment Mix

- Current mix: clopidogrel only (without prasugrel)
- Projected mix: clopidogrel with slow uptake of prasugrel over time
 - Patients with stent thrombosis automatically switch to prasugrel
 - STEMI patients and NSTEMI patients with diabetes will have slow uptake

Step 3: Current and Future Treatment Mix

Parameter	Current Year	Year 2	Year 3	Year 4	Year 5
STEMI w Stent Thrombosis					
Prasugrel	0%	100%	100%	100%	100%
Clopidogrel	100%	0%	0%	0%	0%
STEMI					
Prasugrel	0%	20%	30%	50%	70%
Clopidogrel	100%	80%	70%	50%	30%
NSTEMI w Stent Thrombosis					
Prasugrel	0%	100%	100%	100%	100%
Clopidogrel	100%	0%	0%	0%	0%
NSTEMI with Diabetes					
Prasugrel	0%	20%	30%	50%	70%
Clopidogrel	100%	80%	70%	50%	30%

Source: Assumption

Step 4: Estimate Drug Costs

- Clopidogrel
 - STEMI:
 - Patients ≤ 75 years of age: loading dose of 300 mg + 75 mg QD for 12 months
 - Patients > 75 years of age: 75 mg QD for 12 months
 - NSTEMI:
 - Loading dose of 300 mg + 75 mg QD for 12 months
- Prasugrel
 - Patients ≥ 75 years of age or < 60 kg in weight: loading dose of 60 mg + 5 mg QD for 12 months
 - All other patients: loading dose of 60 mg + 10 mg QD for 12 months

Step 4: Estimate Drug Costs

- Static model so patients are not assumed to age through the model
- No allowances for generic forms

Parameter	Value	Source/Assumption
Clopidogrel		
Loading dose 300 mg	£5.04	British national formulary 57 ed (2009)
75 mg 30-tablet pack	£37.83	
Prasugrel		
Loading dose 60 mg	£10.20	Price of prasugrel as in manufacturers submission (2009).
10 mg 28-tablet pack*	£47.56	

*Cost is weighted to allow for 5 mg for patients weighing under 60 kg or age 75+ years. Proportion is based on annual incidence numbers for people aged 35 to 74.

Step 5: Estimate Changes in Disease-Related Costs

- Patients on prasugrel in clinical trial versus clopidogrel had a lower rehospitalization rate in year 1 after ACS/PCI
 - Number of rehospitalizations
 - Cost of rehospitalization

Parameter	Value	Source/Assumption
Rehospitalization rate for clopidogrel patients	0.377	Mahoney et al (2010)
Reduction in rate of rehospitalization with prasugrel	0.0087	Daiichi-Sankyo (2009) Eli Lilly and Company Ltd STA submission
Cost of rehospitalization	£5,345	NHS mandatory tariff 2009/10 and reference costs 2007–08

Step 6: Present Budget Impact and Health Outcomes

- Present annual outcomes
 - Drug costs
 - Re-hospitalization costs
 - Total costs
 - Number of hospitalizations
- Incremental change from year to year
 - Increase in drug budget
 - Decrease in other medical cost budget
 - Change in total cost budget
 - Hospitalization avoided

Step 6: Present Budget Impact and Health Outcomes

- Budget impact as reported by NICE

Parameter	Annual Change
Increase in Drug Budget	£1,735,881
Reduction in Rehospitalization Costs	£470,360
Increase in Total Costs	£1,265,521
Reduction in Rehospitalizations	88

Step 6: Present Budget Impact and Health Outcomes

Total annual results

Parameter	Current Year	Year 2	Year 3	Year 4	Year 5
Drug Costs					
Clopidogrel	£6,447,553	£4,849,271	£4,243,112	£3,030,794	£1,818,477
Prasugrel	£0	£2,197,631	£3,031,096	£4,698,027	£6,364,958
Total	£6,447,553	£7,046,901	£7,274,208	£7,728,821	£8,183,434
Increase in Drug Budget		£599,348	£826,655	£1,281,268	£1,735,881
Rehospitalization Costs	£28,424,710	£28,264,360	£28,200,220	£28,077,285	£27,954,350
Change in Rehospitalization Costs		-£160,350	-£224,490	-£347,425	-£470,360
Total Costs	£34,872,263	£35,311,261	£35,474,428	£35,806,106	£36,137,784
Increase in Total Costs		£438,998	£602,165	£933,843	£1,265,521
Number of Rehospitalization	5318	5288	5276	5253	5230
Rehospitalizations Avoided		30	42	65	88

Step 6: Present Budget Impact and Health Outcomes

Number of treated members = 14,107

Per treated member per month

Parameter	Current Year	Year 2	Year 3	Year 4	Year 5
Drug Costs					
Clopidogrel	£486.18	£365.66	£319.95	£228.54	£137.12
Prasugrel	£0.00	£165.71	£228.56	£354.26	£479.95
Total	£486	£531	£549	£583	£617
Increase in Drug Budget		£45	£62	£97	£131
Rehospitalization Costs	£2,143.38	£2,131.29	£2,126.46	£2,117.19	£2,107.92
Change in Rehospitalization Costs		-£12	-£17	-£26	-£35
Total Costs	£2,630	£2,663	£2,675	£2,700	£2,725
Increase in Total Costs		£33	£45	£70	£95

Step 6: Present Budget Impact and Health Outcomes

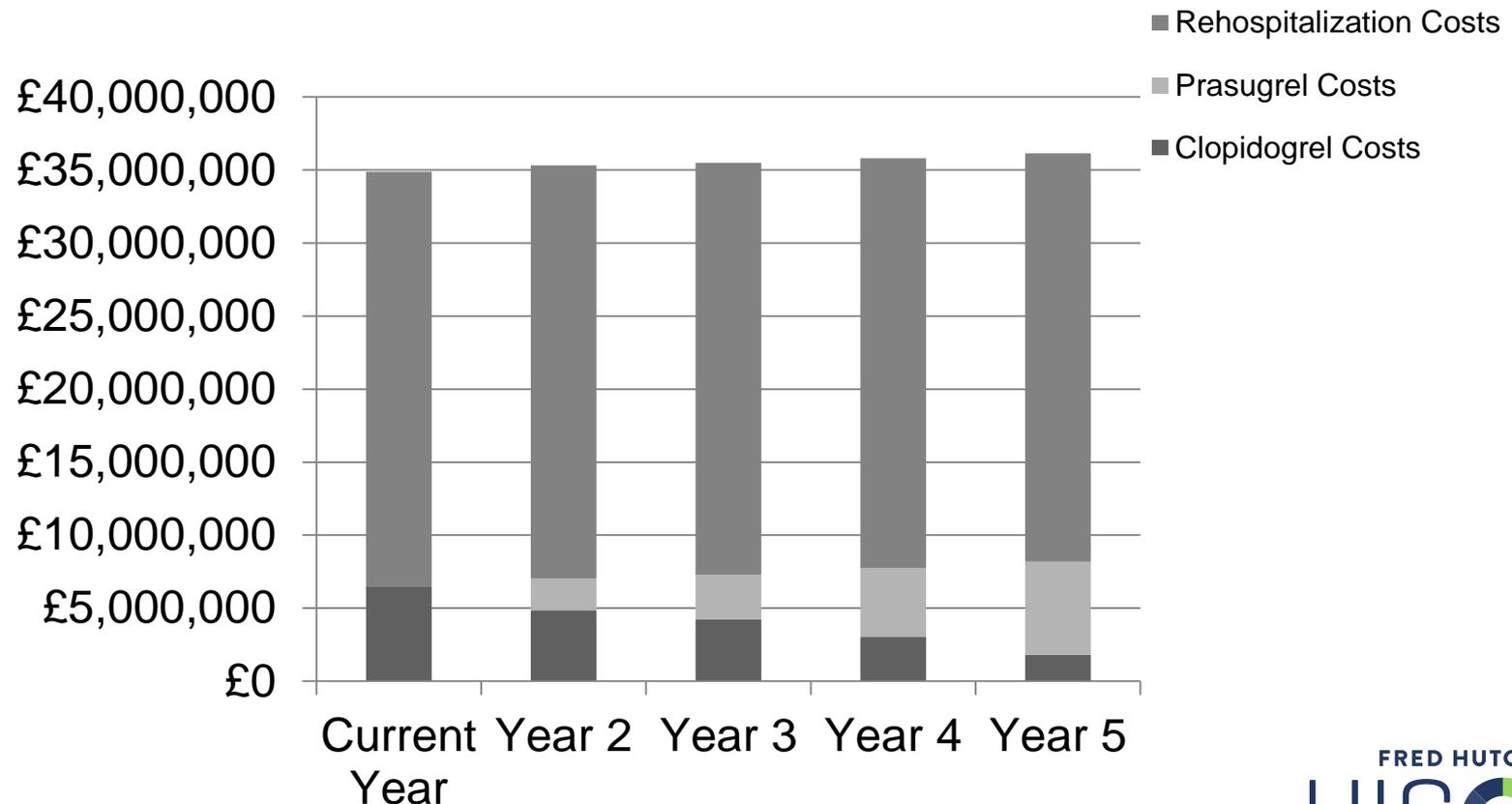
Number of members = 50,542,505

Per member per month

Parameter	Current Year	Year 2	Year 3	Year 4	Year 5
Drug Costs					
Clopidogrel	£0.128	£0.096	£0.084	£0.060	£0.036
Prasugrel	£0.000	£0.043	£0.060	£0.093	£0.126
Total	£0.128	£0.139	£0.144	£0.153	£0.162
Increase in Drug Budget		£0.012	£0.016	£0.025	£0.034
Rehospitalization Costs	£0.5624	£0.5592	£0.5580	£0.5555	£0.5531
Change in Rehospitalization Costs		-£0.0032	-£0.0044	-£0.0069	-£0.0093
Total Costs	£0.6900	£0.6986	£0.7019	£0.7084	£0.7150
Increase in Total Costs		£0.0087	£0.0119	£0.0185	£0.0250

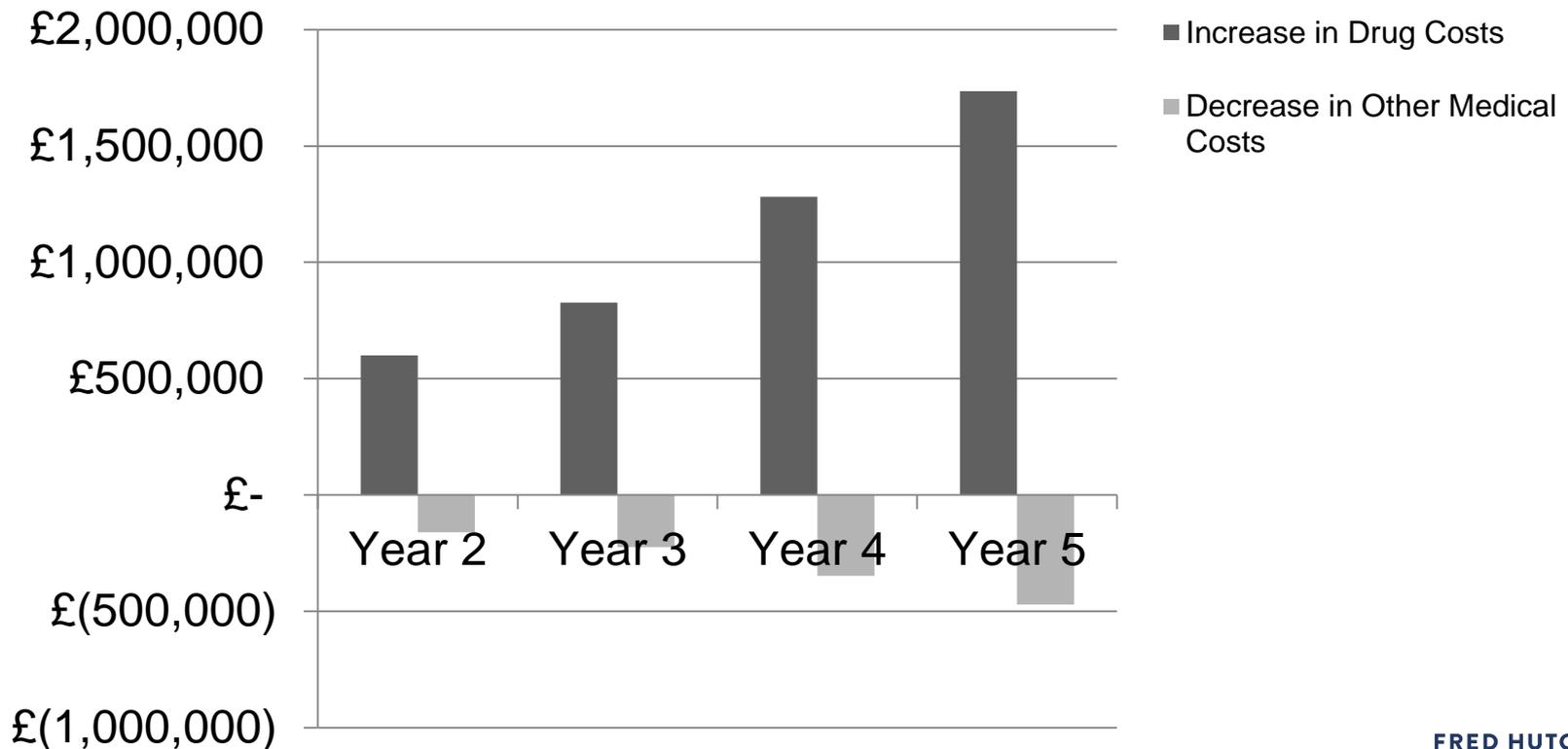
Step 6: Present Budget Impact and Health Outcomes

- Change in annual total budget over time



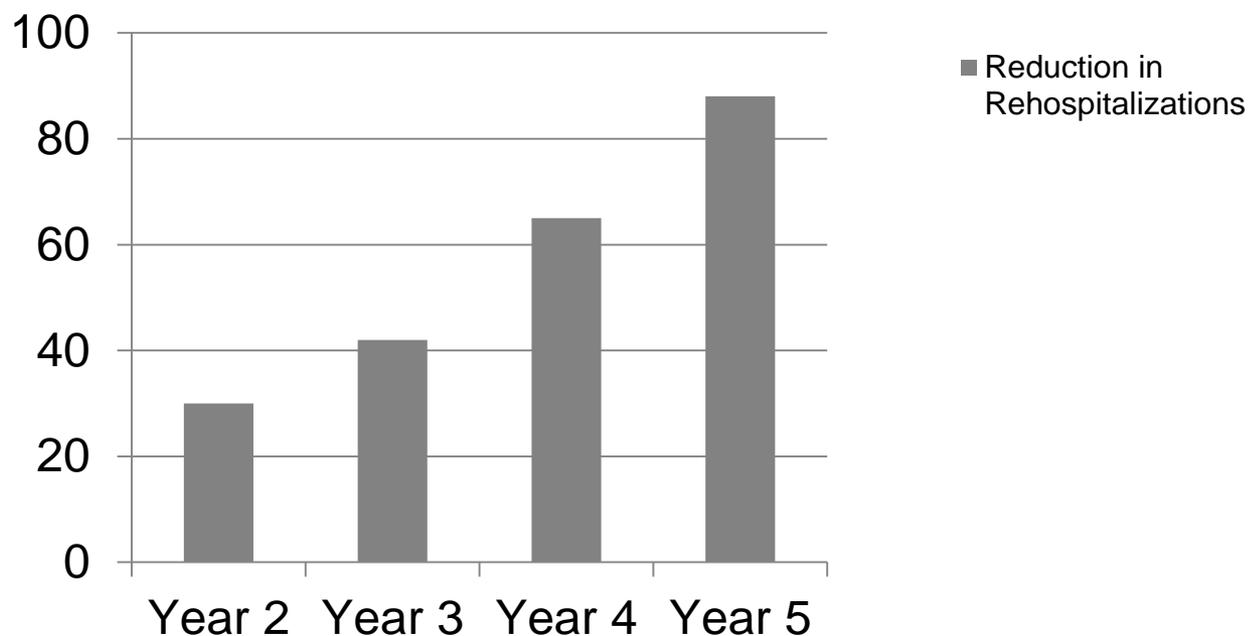
Step 6: Present Budget Impact and Health Outcomes

- Change in costs from current year



Step 6: Present Budget Impact and Health Outcomes

- Change in rehospitalizations from current year



Questions so far?

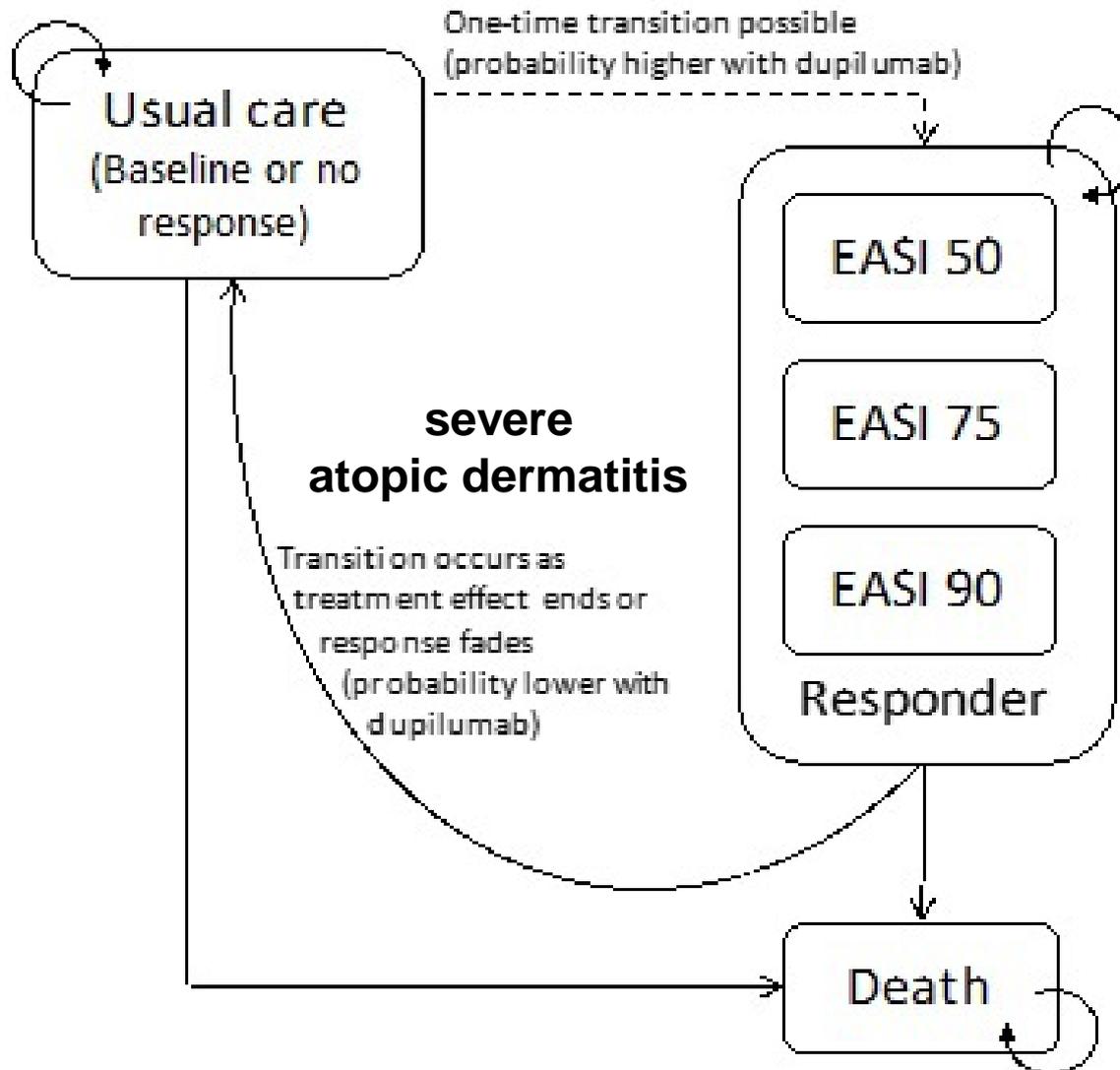
When Do We Need a Dynamic Model?

- A dynamic budget impact model is needed when the new intervention has one or more of the following impacts:
 - Reduces disease-related mortality
 - Reduces disease-related complications
 - Reduces the rate of disease progression
 - Changes the duration of treatment
- However, if these effects are small or the impacts occur within a short period of time (≤ 1 year) a static model can still be used.

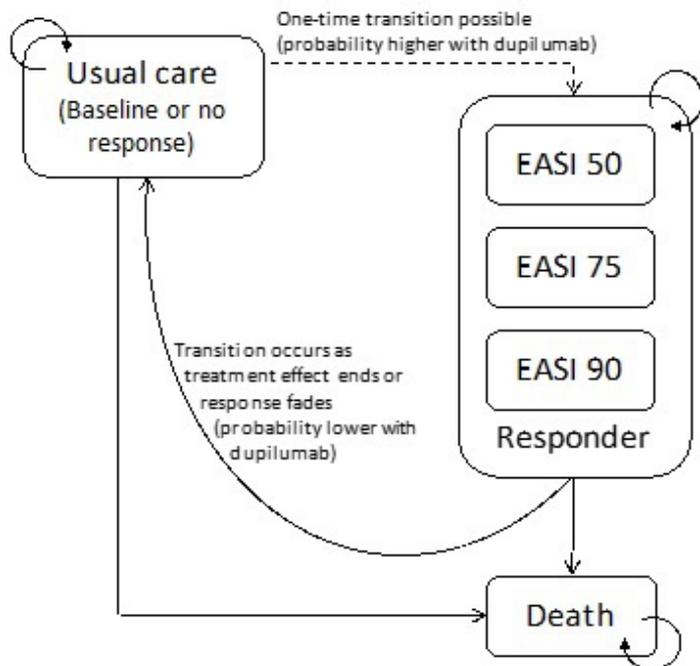
How Do We Develop a Dynamic Budget Impact Model?

- Create a natural history model for a cohort with the disease of interest, or
 - Use the same disease progression model as used for the cost-effectiveness model
 - Simplify the model if possible
- Run the model allowing for a new disease cohort to enter the population each year

Example Dynamic Model Dupilumab



Example



	Year 1 cohort		Year 2 cohort		Year 3 cohort		Year 4 cohort		Year 5 cohort	
	Dupilimab	Standard of Care	Dupilimab	Standard of Care	Dupilimab	Standard of Care	Dupilimab	Standard of Care	Dupilimab	Standard of Care
Year 1	\$41,988	\$11,175								
Year 2	\$36,318	\$11,587	\$41,988	\$11,175						
Year 3	\$34,766	\$11,588	\$36,318	\$11,587	\$41,988	\$11,175				
Year 4	\$33,306	\$11,567	\$34,766	\$11,588	\$36,318	\$11,587	\$41,988	\$11,175		
Year 5	\$31,930	\$11,544	\$33,306	\$11,567	\$34,766	\$11,588	\$36,318	\$11,587	\$41,988	\$11,175
Total	\$178,308	\$57,461	\$146,378	\$45,916	\$113,073	\$34,349	\$78,306	\$22,762	\$41,988	\$11,175

Summary of Issues to Consider for BIA

- Relevant costs and time horizon for particular budget holder
- Acute or chronic disease and timing of changes in costs
- Static or dynamic model
- Eligible patient population
- Disease related costs