



Bariatric Outcomes and Obesity Modeling

Study Meeting

09.17.10

REPORT DOCUMENTATION PAGE

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study sought to (1) define the clinical impact and economic burden of bariatric surgical procedures, and (2) estimate the cost-effectiveness and budgetary impact of obesity treatments when compared to no surgical intervention. We developed a cost-effectiveness model and a payer-based budget and fiscal impact tool to compare bariatric surgical procedures to non-operative approaches for maorbid obesity. Use of these economic models based on data from the Department of Defense (DOD) population found that all evaluated surgical interventions were cost-effective compared to non-surgical interventions. These economic assessments models can inform helath policy decisions related to obesity.					
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Study Objectives

David Flum, MD, MPH, Co-Principal Investigator

Sean Sullivan, PhD, Co-Principal Investigator

OBJECTIVE 1 -

- ◆ Cost and Burden of Obesity Care
 - ◆ Quantify the burden of non-surgical costs across the U.S.
 - ◆ Quantify the burden of surgical costs across the U.S.

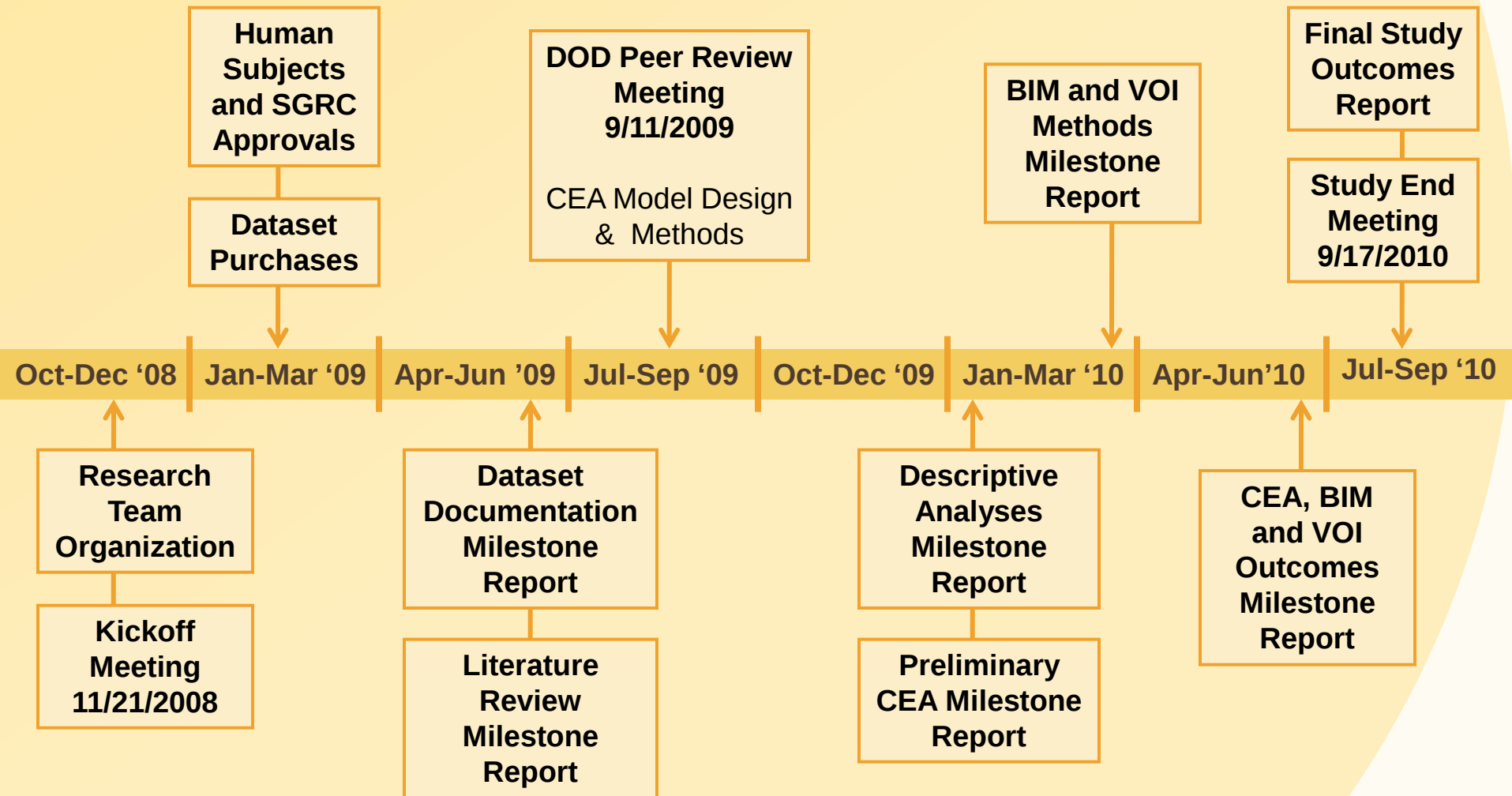
OBJECTIVE 2-

- ◆ Economic Assessment & Policy Planning
 - ◆ Macro-economic assessment of the development of healthcare policy related to obesity
 - ◆ Micro-economic tool to compare and contrast surgical care to non-surgical care based on patient characteristics
 - ◆ Undertake uncertainty and probabilistic sensitivity analysis, as well as value of information (VOI) computations, as appropriate

Study Milestones

Allison Rhodes, MS

BOOM STATEMENT OF WORK



Cost-Effectiveness and Budgetary Impact Models

Bruce Wang, PhD

CONSTRUCTING TWO ECONOMIC MODELS

- ✘ Cost-Effectiveness Model: Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action.
- ✘ Budget Impact Model: The purpose of a Budget Impact Analysis (BIA) is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints.

COST-EFFECTIVENESS MODEL OVERVIEW

- ✗ Two parts: 1) Decision Tree and 2) Natural History Model
- ✗ Results: Bariatric Surgery is cost-effective compared to no intervention

SIMPLICITY IN END-USER INTERFACE

Select Patient for Simulation:

Gender	☐ Male ☒ Female	2
Age		40
BMI		42

Other inputs:

Discount Rate (Cost)	0.0%
Discount Rate (QALY)	0.0%
Threshold (\$/QALY)	\$ 100,000

OUTCOMES

Intermediate Outcomes (5 years later)

Intervention:	Patient Age	BMI	Costs	QALYs
Lap RYGB	45	29.40	\$ 64,910.01	4.92
Lap Band	45	33.60	\$ 68,626.00	4.78
Open RYGB	45	29.40	\$ 77,563.49	4.92

Lifetime Outcomes

Intervention	None	Lap RYGB	Lap Band	Open RYGB
Costs	\$ 407,936.36	\$ 420,589.35	\$ 433,445.79	\$ 433,242.82
QALY	40.61	45.06	43.98	45.06
Expected Age of Death	77	82	81	82
ICER		2,840.35	7,563.95	5,680.81
Net Benefit		432,819.62	311,740.74	420,166.14

ICER plane

Graphs

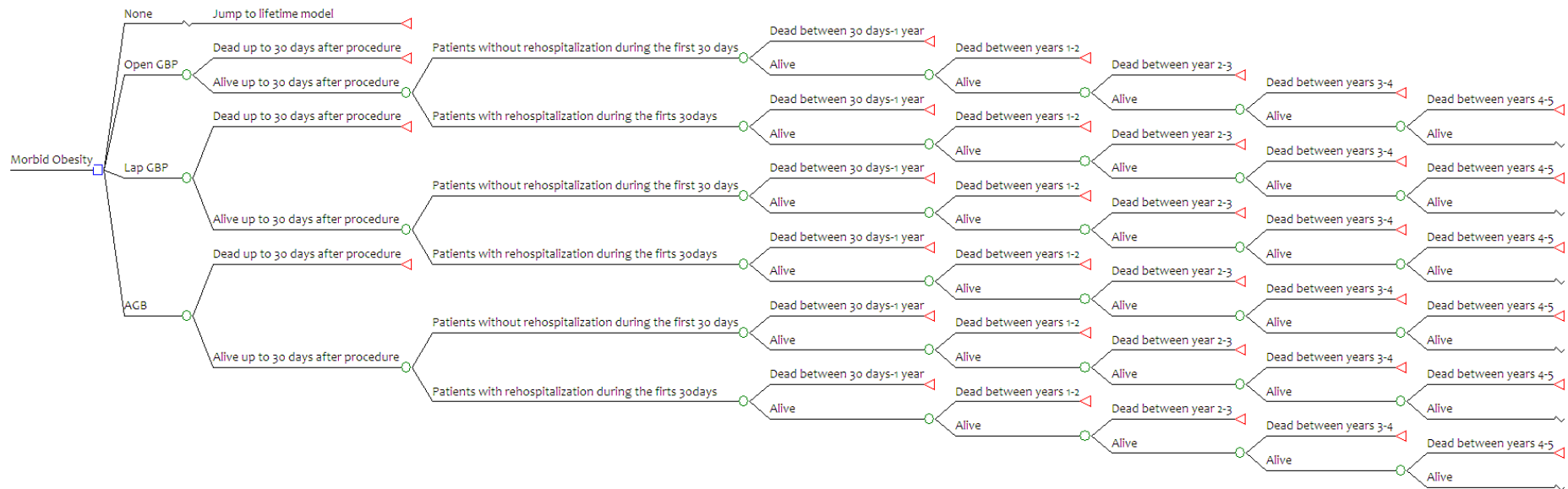
Source: BOOM Research

COMPLEXITY IN BACK-END ENGINE

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Probabilistic?																
2	0		Raw Results									Incremental	Results				
3																	
4			40.61	407,936.36	45.06	420589.35	43.98	433445.79	45.06	433242.82		4.45	12652.98	3.37	25509.42	4.45	25306.46
5																	
6			None		Lap RYGB		Band		Open RYGB			Lap RYGB		Band		Open RYGB	
7			QALYs	Cost	QALYs	Cost	QALYs	Cost	QALYs	Cost		QALYs	Cost	QALYs	Cost	QALYs	Cost
8	1		12.38	81,896.76	17.71	137150.90	16.92	152828.15	17.86	148334.29		5.33	55254.14	4.54	70931.39	5.48	66437.52
9	2		12.38	81,896.76	17.73	137370.64	16.95	149952.47	17.91	146318.10		5.35	55473.88	4.57	68055.71	5.53	64421.34
10	3		12.38	81,896.76	17.73	138010.80	16.92	153619.48	17.87	145695.80		5.35	56114.04	4.54	71722.72	5.49	63799.04
11	4		12.38	81,896.76	17.64	138254.70	17.03	147820.46	17.89	147930.12		5.26	56357.94	4.65	65923.70	5.50	66033.36
12	5		12.38	81,896.76	17.69	138104.66	17.04	148491.95	17.83	147125.93		5.31	56207.90	4.66	66595.19	5.45	65229.17
13	6		12.38	81,896.76	17.75	137963.10	17.02	149117.88	17.79	148304.02		5.36	56066.34	4.64	67221.12	5.41	66407.26
14	7		12.38	81,896.76	17.69	139159.17	17.00	149674.47	17.90	145568.35		5.31	57262.41	4.62	67777.71	5.52	63671.59
15	8		12.38	81,896.76	17.75	137308.83	17.00	148072.93	17.92	144401.36		5.37	55412.07	4.62	66176.17	5.54	62504.60
16	9		12.38	81,896.76	17.70	139398.26	16.98	151094.36	17.90	146003.25		5.32	57501.50	4.60	69197.60	5.51	64106.49
17	10		12.38	81,896.76	17.70	139726.40	17.01	150459.94	17.90	146654.35		5.32	57829.64	4.62	68563.18	5.51	64757.59
18	11		12.38	81,896.76	17.70	138511.99	17.04	147662.94	17.86	146680.86		5.32	56615.23	4.66	66566.18	5.48	64784.10
19	12		12.38	81,896.76	17.75	137335.20	17.00	150380.34	17.90	146208.23		5.37	55438.44	4.61	68483.58	5.52	64311.47
20	13		12.38	81,896.76	17.69	140288.61	17.05	147448.76	17.91	145924.71		5.31	58391.85	4.67	65552.00	5.53	64027.95
21	14		12.38	81,896.76	17.70	139343.86	17.05	147129.91	17.90	145490.05		5.32	57447.10	4.67	65233.15	5.52	63593.29
22	15		12.38	81,896.76	17.73	137679.45	17.00	150045.35	17.90	145008.22		5.34	55782.69	4.62	68148.59	5.52	63111.46
23	16		12.38	81,896.76	17.73	137616.31	17.03	147965.42	17.89	146407.81		5.35	55719.55	4.65	66068.66	5.50	64511.05
24	17		12.38	81,896.76	17.69	138837.02	17.04	148011.01	17.92	144855.58		5.31	56940.26	4.66	66114.24	5.53	62958.81
25	18		12.38	81,896.76	17.71	139207.03	17.04	147799.64	17.87	147057.26		5.33	57310.27	4.66	65902.88	5.49	65160.50
26	19		12.38	81,896.76	17.73	137902.17	17.00	150046.82	17.88	148572.45		5.35	56005.41	4.62	68150.06	5.49	66675.69
27	20		12.38	81,896.76	17.68	140689.72	17.03	147986.29	17.83	149310.89		5.30	58792.96	4.65	66089.53	5.44	67414.13
28	21		12.38	81,896.76	17.73	137525.41	16.95	150611.00	17.88	146199.93		5.35	55628.65	4.56	68714.24	5.50	64303.17
29	22		12.38	81,896.76	17.71	138761.25	17.04	147724.62	17.91	144884.97		5.32	56864.49	4.66	65827.86	5.53	62988.21
30	23		12.38	81,896.76	17.68	138210.79	17.00	147568.80	17.91	146408.92		5.30	56314.03	4.61	65672.04	5.53	64512.16
31	24		12.38	81,896.76	17.73	138196.47	17.04	147356.03	17.90	145604.96		5.35	56299.71	4.66	65459.27	5.52	63708.20
32	25		12.38	81,896.76	17.69	138673.98	16.96	150997.01	17.87	145271.01		5.31	56777.21	4.58	69100.25	5.49	63374.25
33	26		12.38	81,896.76	17.72	138971.01	17.00	148239.87	17.86	148194.02		5.34	57074.25	4.62	66343.11	5.48	66297.26
34	27		12.38	81,896.76	17.75	137406.94	17.03	148355.59	17.88	148296.96		5.37	55510.17	4.65	66458.83	5.50	66400.20
35	28		12.38	81,896.76	17.70	138519.64	17.00	149821.73	17.92	144496.42		5.32	56622.88	4.62	67924.97	5.53	62599.66
36	29		12.38	81,896.76	17.74	138822.17	17.00	148173.32	17.87	146691.09		5.36	56925.41	4.62	66276.56	5.48	64794.33
37	30		12.38	81,896.76	17.74	139659.03	17.04	149386.44	17.91	146707.78		5.36	57762.27	4.65	67489.68	5.53	64811.02
38	31		12.38	81,896.76	17.68	140111.58	16.91	148038.57	17.91	145695.97		5.30	58214.82	4.53	66141.81	5.53	63799.21

Source: BOOM Research

DECISION TREE FOR FIRST 5 YEARS

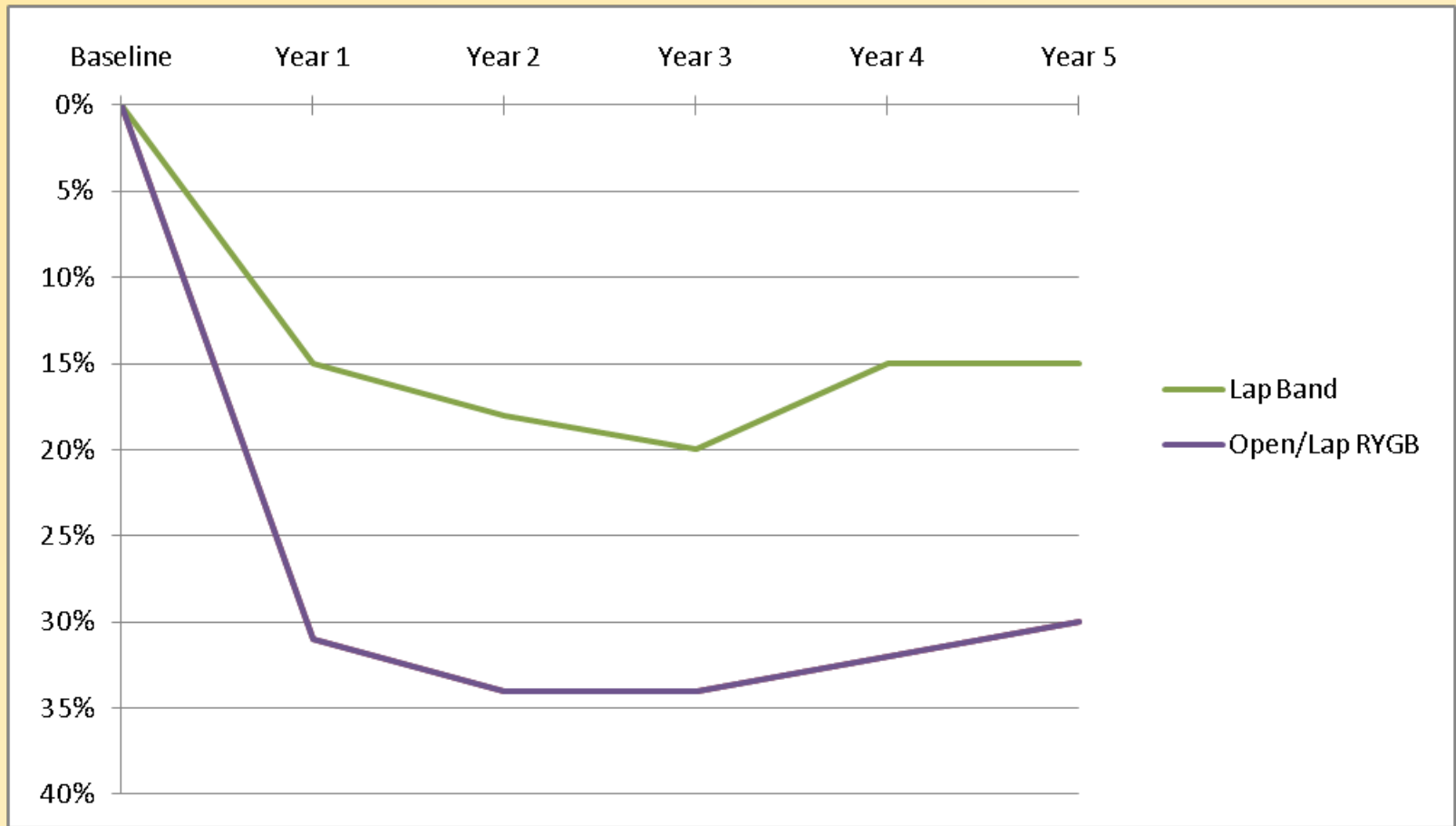


Source: BOOM Research

MANY DATA SOURCES FOR DECISION TREE

- ✗ Mortality and complication rates from Centers for Medicare & Medicaid Services (CMS)
- ✗ Annual costs from Group Health Cooperative (GHC)
- ✗ Death costs from CMS
- ✗ Utilities from Medical Expenditure Panel Survey (MEPS)
- ✗ BMI trajectory from Picot et al (HTA, 2009)

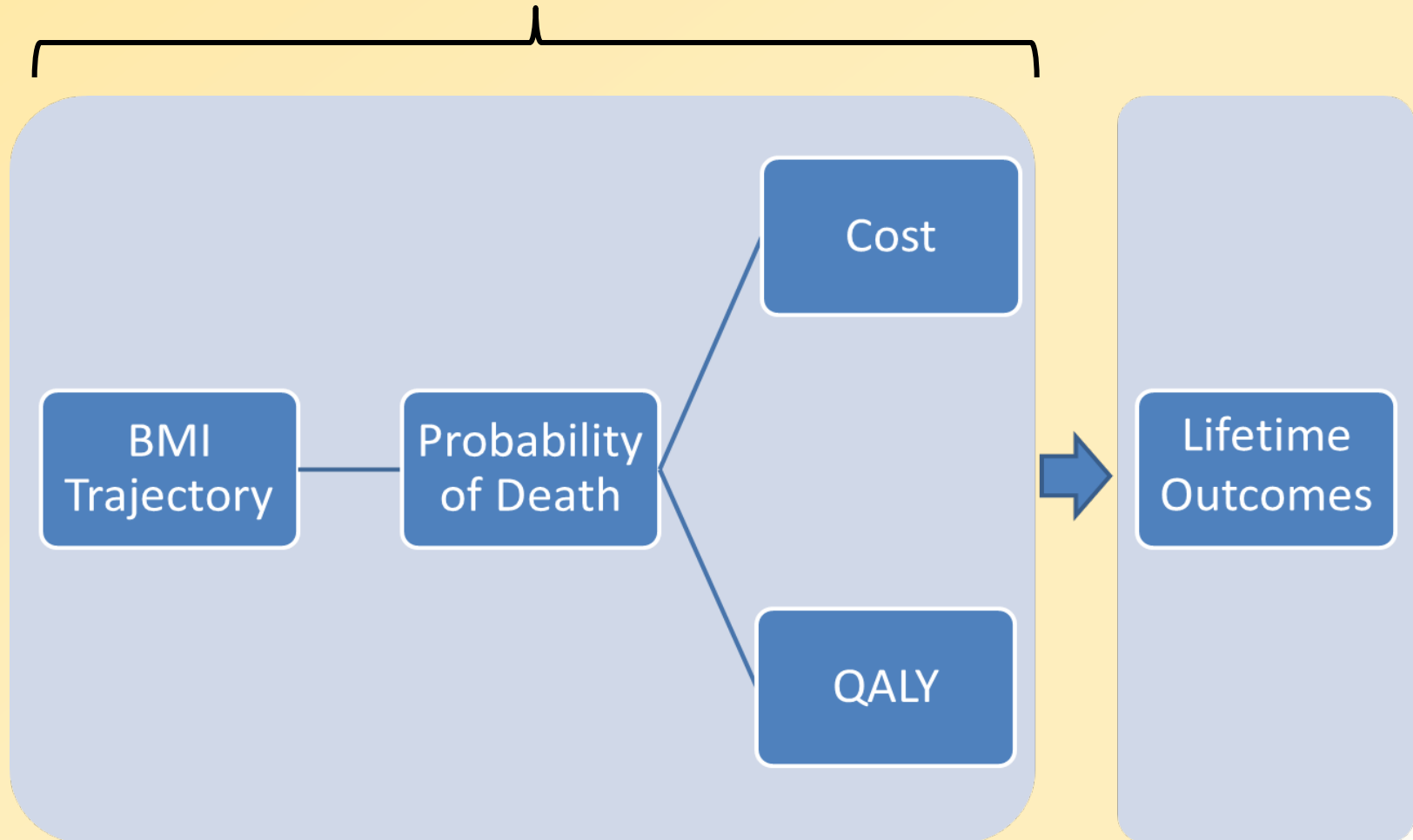
BMI LOSS IS NON-LINEAR



Source: Picot et al (HTA, 2009)

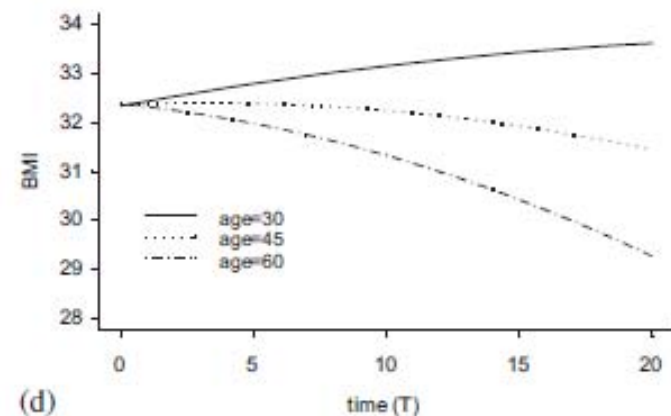
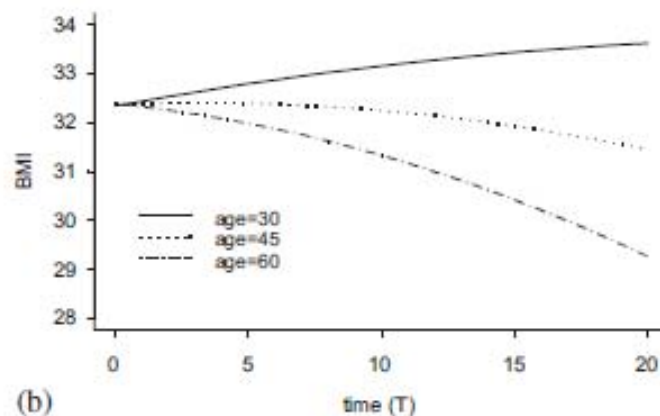
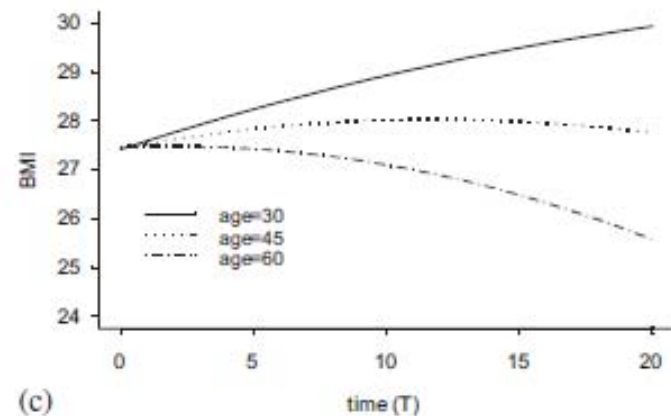
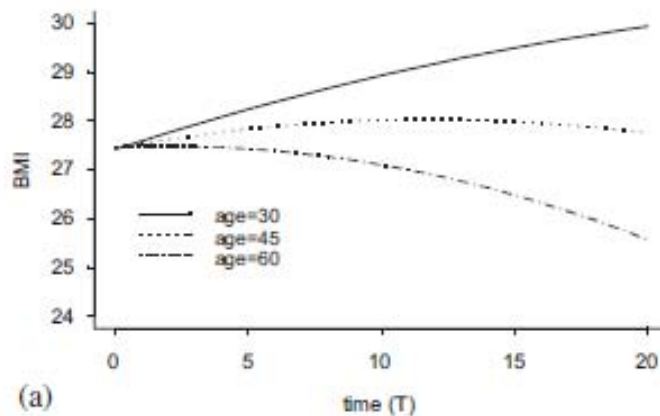
NATURAL HISTORY MODEL OVERVIEW

ANNUAL ESTIMATES



Source: BOOM Research

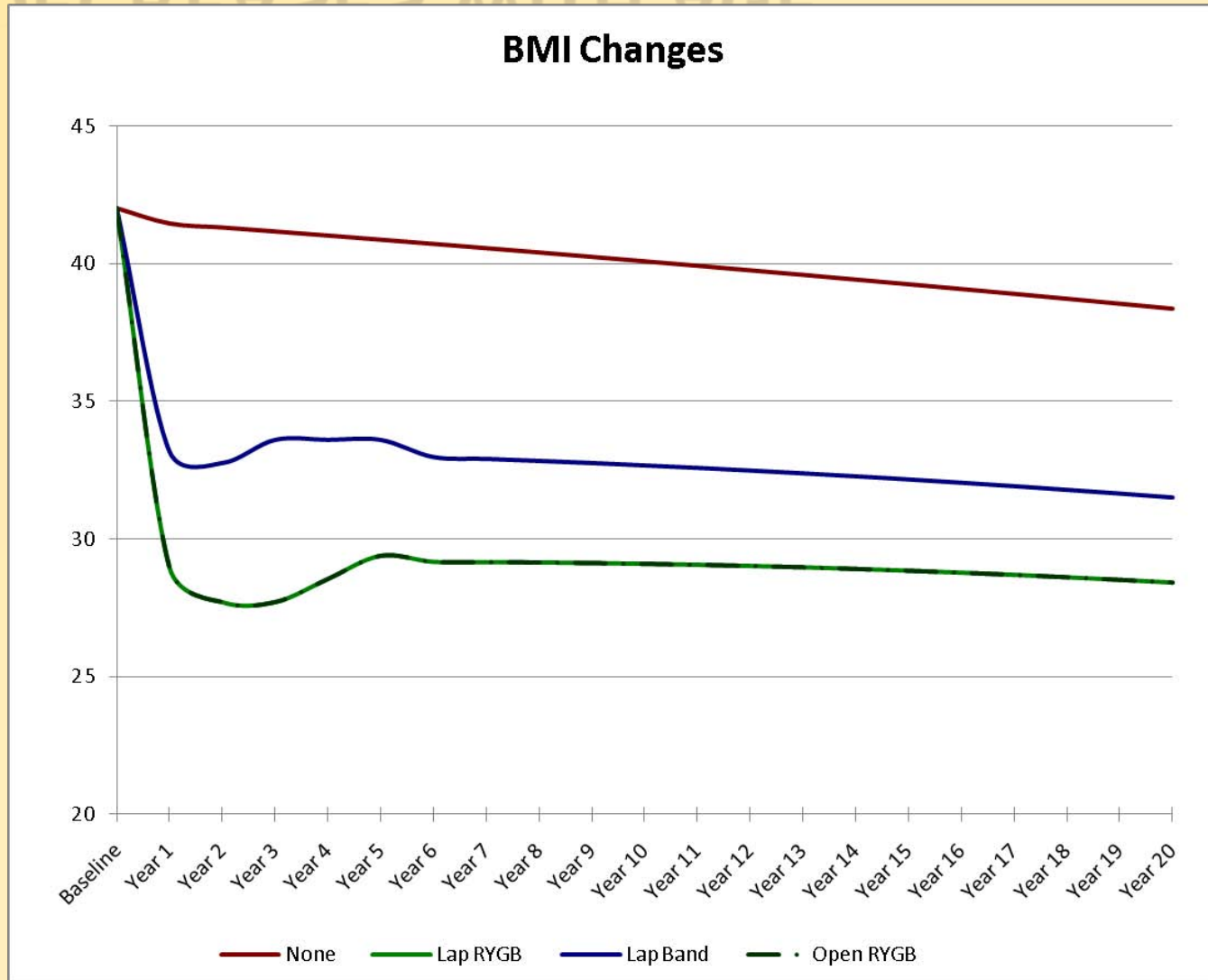
BMI TRAJECTORY FROM HEO (2003)



(a) for men with baseline BMI 27.5; (b) for men with baseline BMI 32.5; (c) for women with baseline BMI 27.5; (d) for women with baseline BMI 32.5.

Source: Heo et al (Stat. Med., 2003)

BMI DECREASES WITH AGE



- For a Female, Age 45, BMI = 42

Source: BOOM Research

SURVIVAL MODELED FROM NHIS-NDI

- Statistical analysis adapts the methods from Schauer 2010.
- Logistic regression model is used to predict the 5-year probability of death.
- Independent variables include BMI, age, sex and interactions for sex-BMI, sex-age and BMI-age.
- Predicted death probabilities are used to generate life expectancy at any given age, sex and BMI.
- Life expectancy is computed using standard life table techniques

DEATH INCREASES WITH BMI



Source: BOOM Research

COST AND UTILITIES FROM MEPS

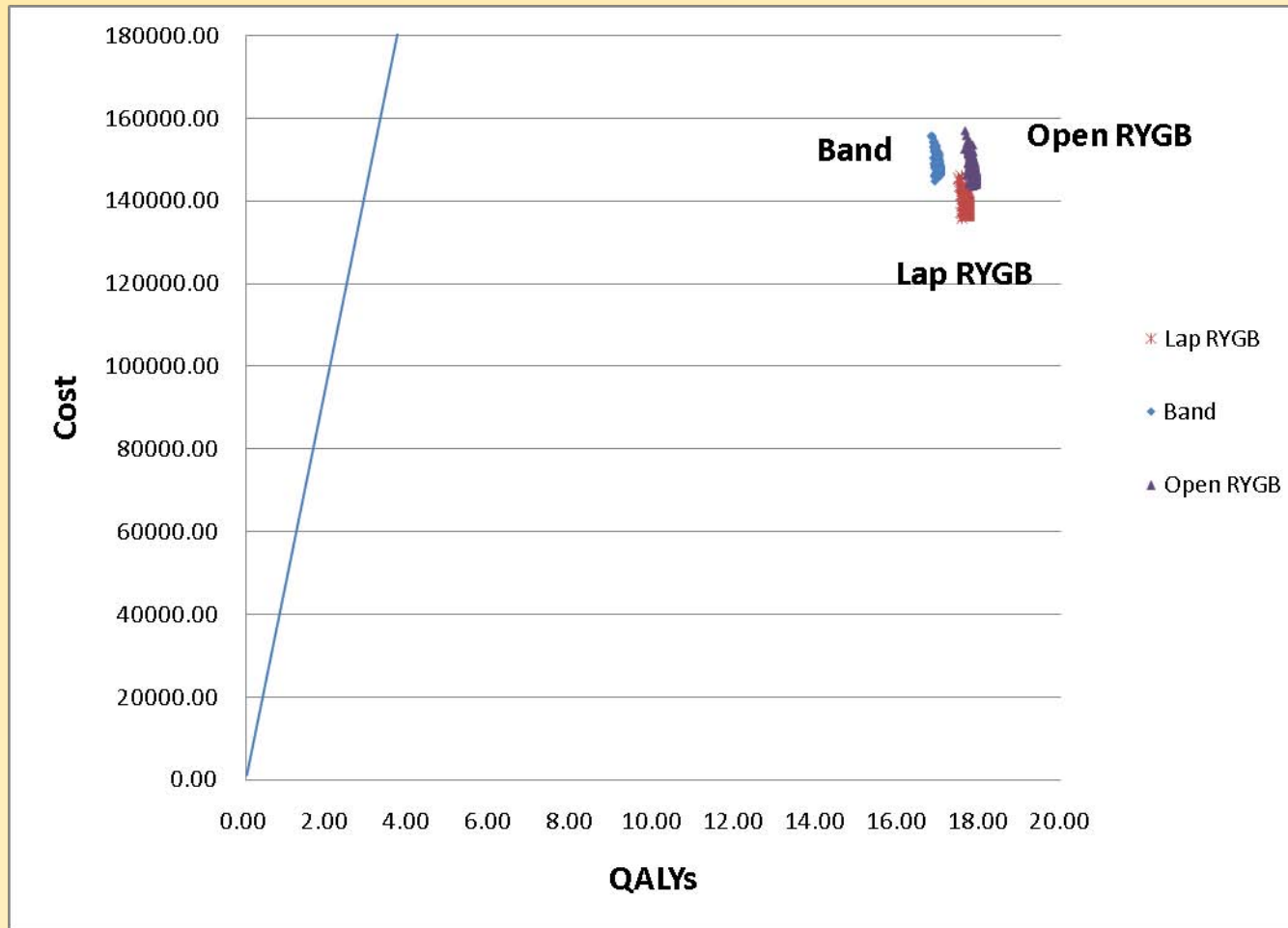
- ✗ Average annual medical costs were positively associated ($p < 0.01$) with:
 - ↑ BMI (+\$362 per 5 BMI unit increase),
 - ↑ Age (+\$118 for each year of age), and
 - Gender (+\$547 for females).
- ✗ Utility values negatively associated ($p < 0.01$) with:
 - ↑ BMI (-0.0246 per 5 BMI unit increase),
 - ↑ Age (-0.0036 for each year of age), and
 - Gender (-0.0355 for females).

PREDICTED LIFETIME OUTCOMES FOR A 45-YEAR OLD FEMALE

BMI	Cost	QALY	Expected Age of Death
25	\$ 155,443	21.26	83
35	\$ 168,965	20.04	80
45	\$ 182,149	18.81	77

Source: BOOM Research

RESULTS: EACH PROCEDURE COST-EFFECTIVE



Source: BOOM Research

VALIDATION AND SENSITIVITY ANALYSIS

- ✗ Probabilistic Sensitivity Analysis
- ✗ Model originally done in Excel
- ✗ Reproduced in SAS 9.2
- ✗ Allows for powerful simulations of large populations

GAINS ASSOCIATED WITH BMI REDUCTION

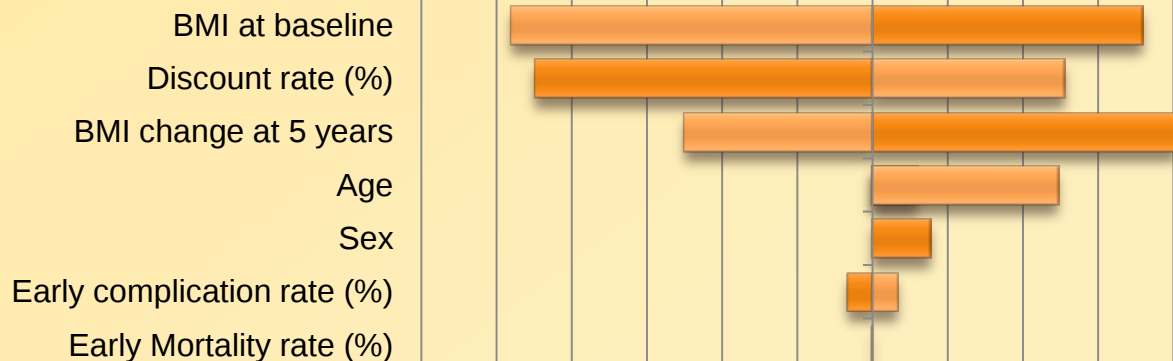
	Cost	QALY	Life-Years
Current Population	\$ 135,246	20.80	36.10
10% BMI Reduction	\$ 134,313	20.90	36.30
20% BMI Reduction	\$ 133,368	20.99	36.50
30% BMI Reduction	\$ 132,412	21.08	36.70
40% BMI Reduction	\$ 131,444	21.18	36.90
50% BMI Reduction	\$ 131,400	21.21	37.10
<i>Reduction only in those above 30 BMI</i>			

Source: BOOM Research

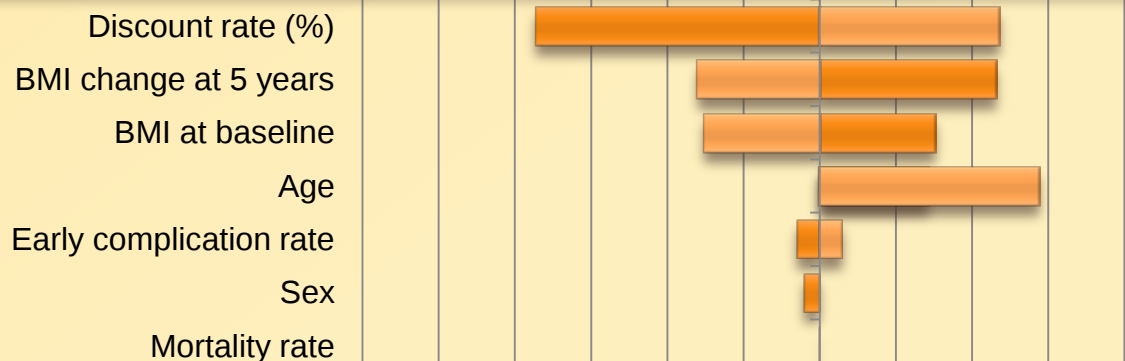
ONE-WAY SENSITIVITY ANALYSIS

Variables	Reference values	Minimum	Maximum
Early Mortality rate (%)	0.23	0	0.5
Early complication rate (%)	2.5	0	5
Sex	F	M	F
Age	45	18	70
BMI change at 5 years (%)	20% AGB or 30% GB	-10%	+10%
Discount rate (%)	3	0	5
BMI at baseline	45	35	70

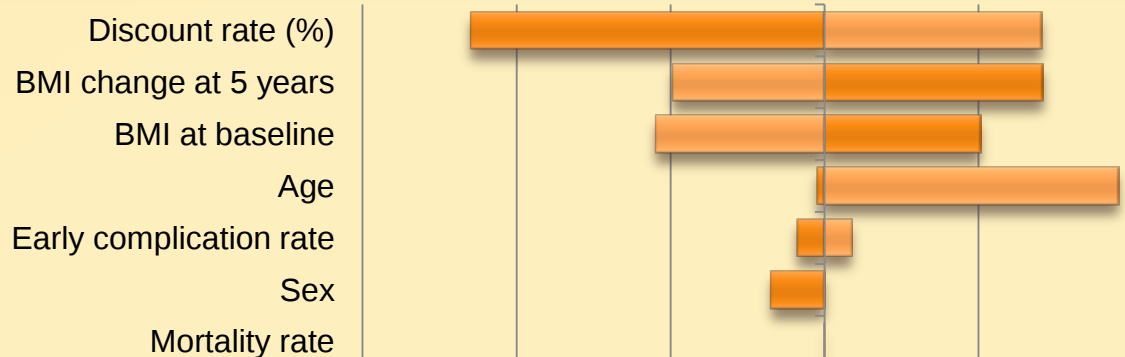
AGB



Lap GB



Open GB



(12,000.00) (8,000.00) (4,000.00) - 4,000.00 8,000.00

ICER

PREVIOUS RESULTS

Author	Year	Population	Perspective	Interventions	ICER
Siddiqui,A., et al.	2006	Morbidly obese and super obese patients	NA	Open By-pass surgery vs. Laparoscopic By-pass Surgery	NA LGBP dominates
Van Mastrigt,G. A. et al.	2006	Morbidly obese with co-morbidity	Societal	Vertical banded gastroplasty (VBG) vs. Lap band	€36,834 Lap band dominates
Ackroyd,R. et al.	2006	Morbidly obese and type-2 diabetes, in Germany, UK and France	Payer	AGB and GBP vs no intervention	Germany: €-1,305 for AGB €-2,208 for GBP France: €1,379 for AGB €-4,000 for GBP UK £3,251 for AGB £2,599 for GBP
Salem,L. et al.	2008	Morbidly obese without obesity-related comorbidities	Payer	AGB and LRYGB and no intervention	\$8,878 for AGB \$14,680 for LRYGB
Campbell et al.	2010	Morbidly Obese US	Payer	AGB and LRYGB and no intervention	\$/LY \$9,300 for AGB \$10,600 for LRYGB

AGB: Adjustable gastric banding

LRYGB: laparoscopic Roux-en-Y gastric bypass

A Financial Model of Bariatric Surgery for Morbid Obesity

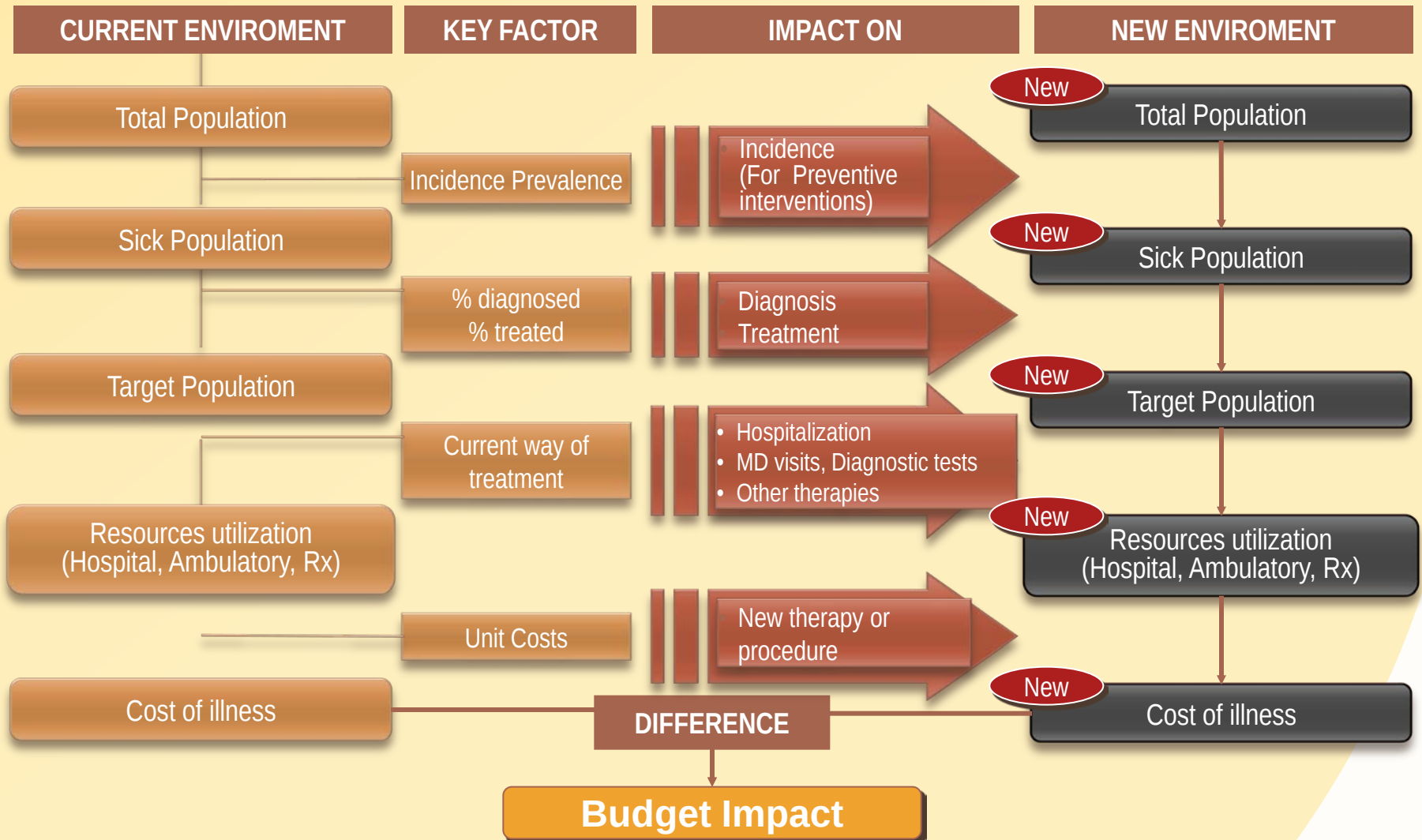
Rafael Alfonso-Cristancho, MD, MSc

WHAT IS A BUDGET IMPACT ANALYSIS?

“The purpose of a Budget Impact Analysis is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints.”

A Budget Impact Model (BIM) was developed to perform this analysis

HOW THE BIM IS DEVELOPED?



OPEN COHORT



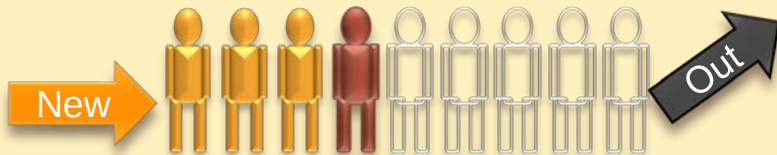
T0



T1

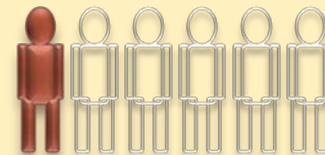
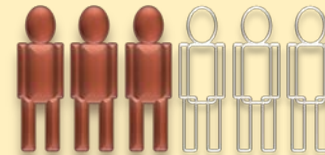


T2



T3

CLOSED COHORT



BUDGET IMPACT MODEL

Population

Procedures

Costs

Results

PATIENTS ELIGIBLE FOR BARIATRIC SURGERY IN GIVEN YEAR*

		Females		Males		Total	
		N	%	N	%	N	%
 	BMI >35&<40 with comorbidities	30,553	5.7%	13,087	2.8%	43,639	4.4%
	BMI >40	29,979	5.6%	9,636	2.1%	39,615	4.0%
	Total number of patients	60,532	11.4%	22,723	4.9%	83,254	8.3%

* Based on a hypothetical closed cohort of 1 million subjects with the same age, gender and BMI distribution as reported by NHANES



POPULATION*

✖ U.S. General Population

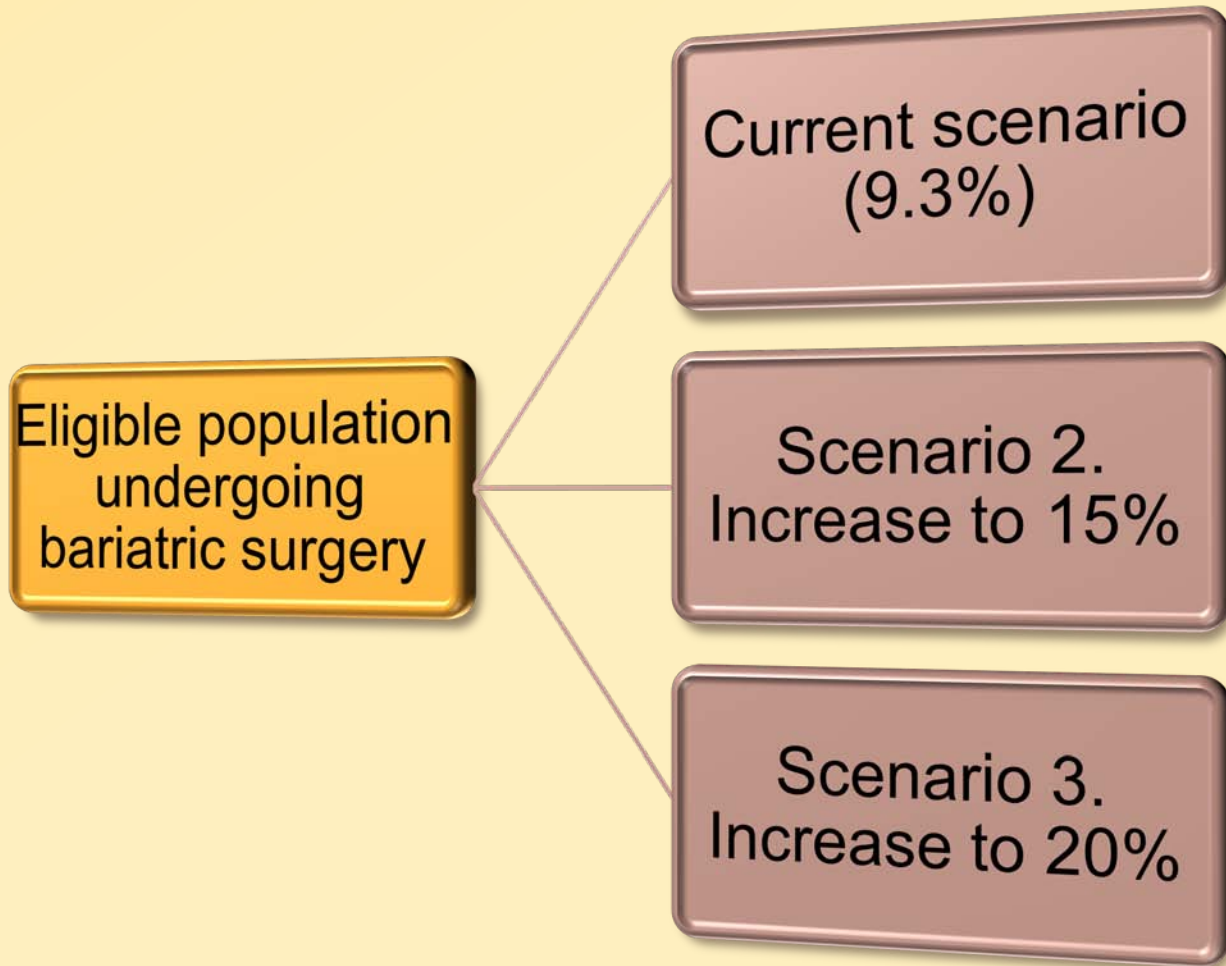
- ✖ Approx. 307 million (July 2009)
- ✖ 5.7% of adult population (Approx. 14 million people) had a BMI > 40 kg/m² (NHANES)
- ✖ 171,000 bariatric surgeries were performed in 2005 (ASBS)

✖ TRI-CARE

- ✖ Approx. 9.4 million beneficiaries (DEERS)
- ✖ Air Force (AF) Active Duty (AD) (2001-2007): 608,939
 - + Had bariatric surgery: 49 (< 0.01%)
 - + Had morbid obesity and no bariatric surgery: 4,430 (0.7%)
- ✖ AF beneficiaries (not AD anytime from 2001-2007): 1,575,257
 - + Had bariatric surgery: 6,964 (0.5%)
 - + Had morbid obesity and no bariatric surgery: 63,863 (4.1%)

**Closed cohort*

SCENARIOS FOR ANALYSIS



PROCEDURE MIX

AF reference population

% of bariatric
surgery for
eligible
patients

Scenario 1
(9.3% -
current)

Scenario 2
(15%)

Scenario 3
(20%)

Procedures

N

%

N

%

N

%

Lap RYGB

4,208

60

6,684

60

8,912

60

AGB

701

10

1,114

10

1,485

10

Open RYGB

2,104

30

3,342

30

4,456

30

Sleeve

-

-

-

-

-

-

**Biliopancreatic
Div**

-

-

-

-

-

-

Total

7,013

100

11,140

100

14,853

100

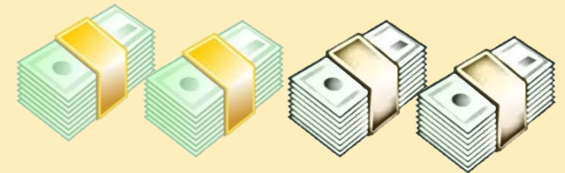
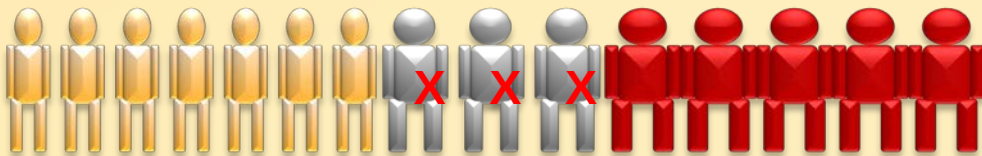
- AD+Beneficiaries:
2,184,196

- ✖ Approx. 75,306 (3.4%)
with morbid obesity

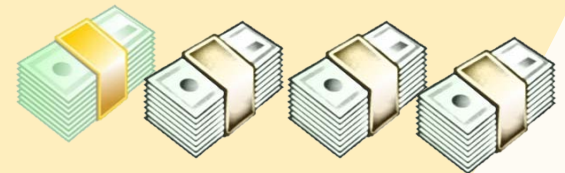
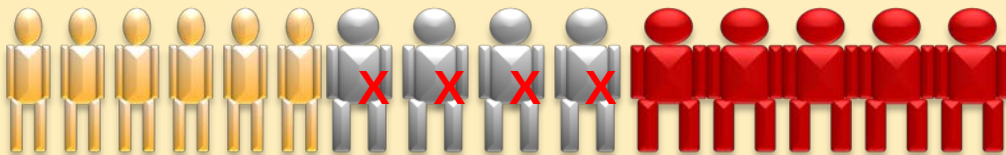
- Only 9.3% of morbidly
obese underwent
bariatric surgery .

HOW MUCH DOES OBESITY COST?

HOW MUCH DOES BARIATRIC SURGERY COST?

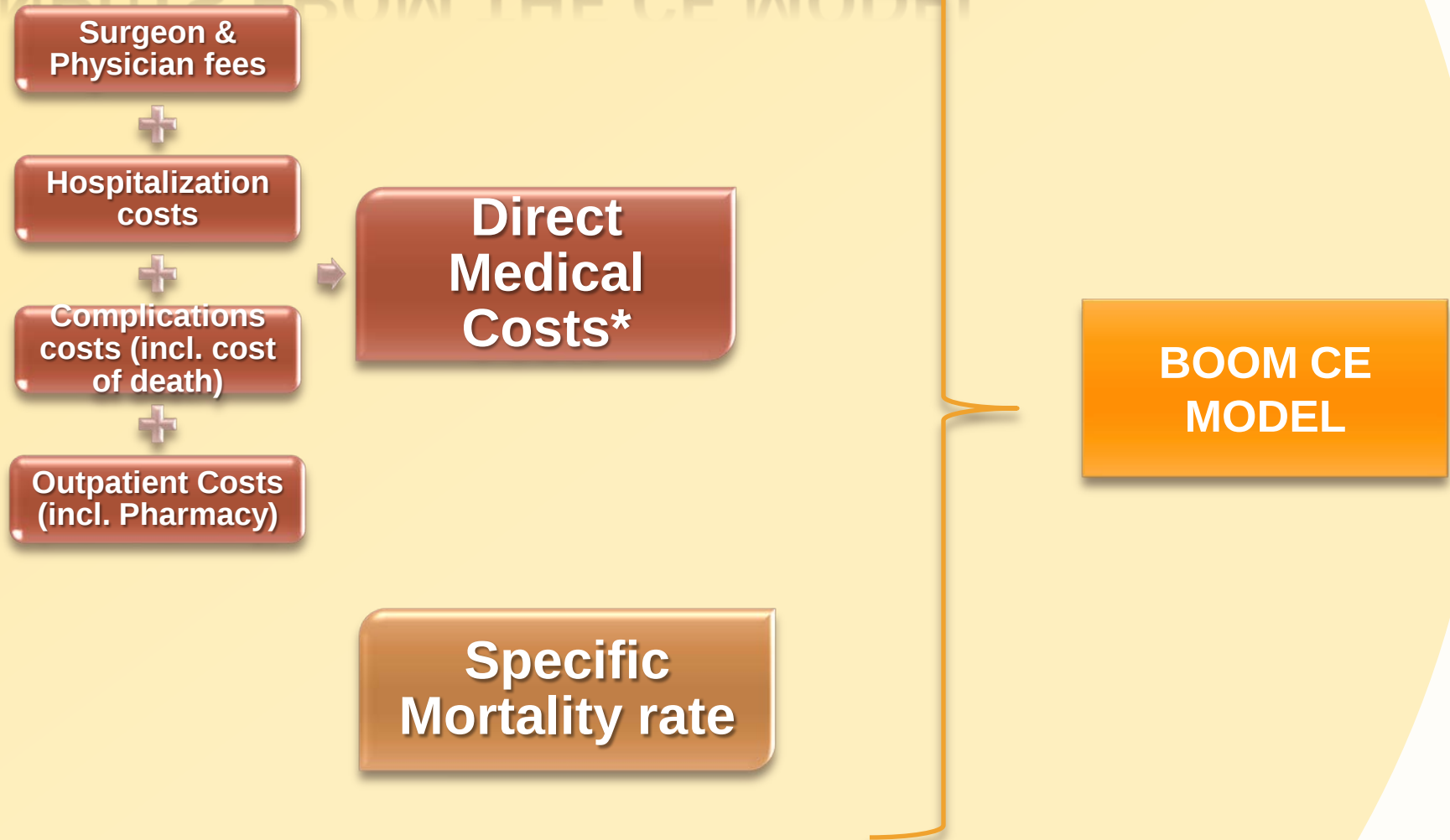


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INPUTS FROM THE CE MODEL



DIRECT MEDICAL COSTS (SELECTED YEARS)

Average Annual Direct Medical Costs

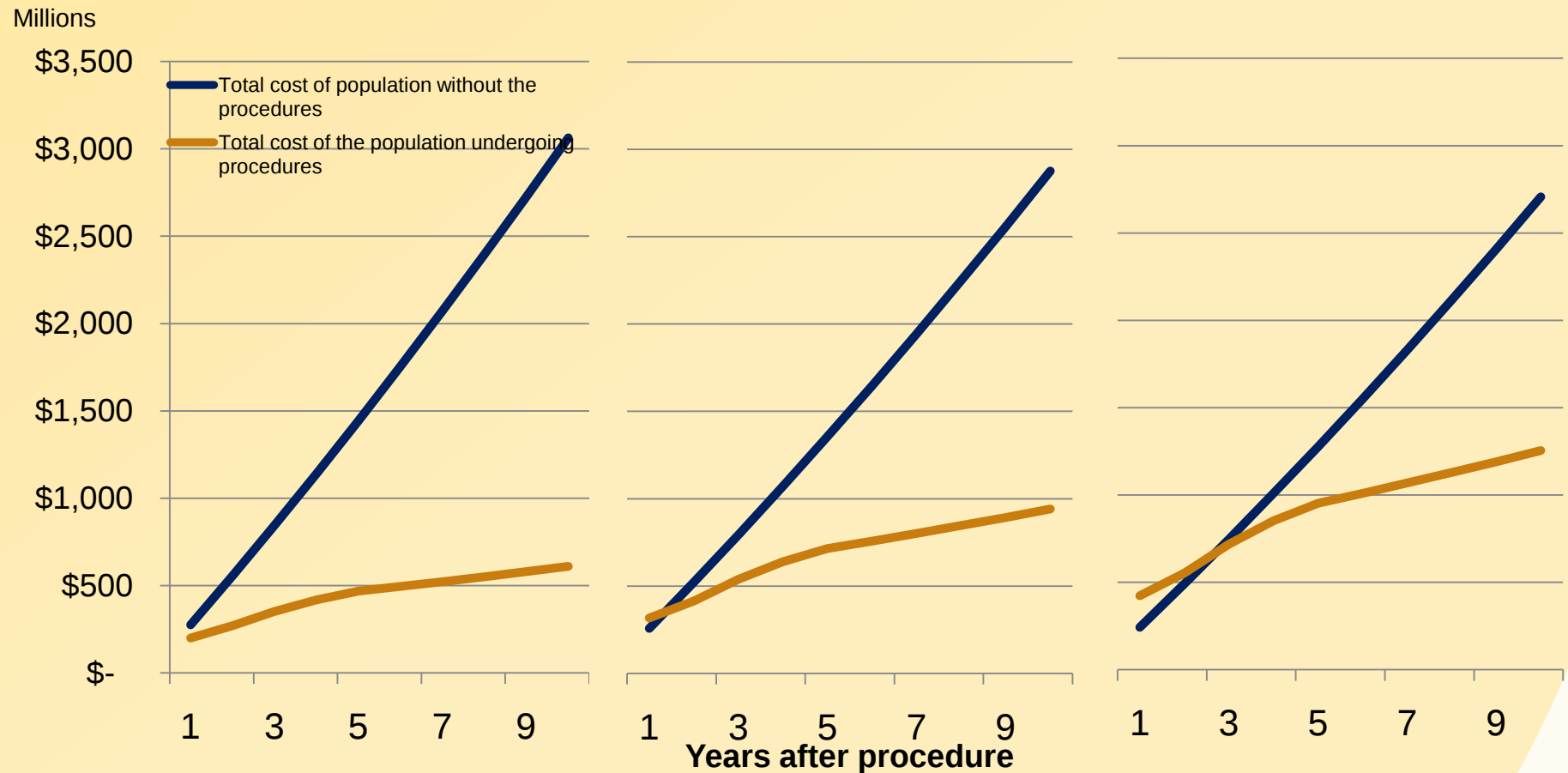
	Year 1	Year 3	Year 5	Year 7	Year 9	Year 10
None	\$ 4,101	\$ 4,314	\$ 4,525	\$ 4,736	\$ 4,945	\$ 5,048
Lap RYGB	\$ 30,222	\$ 10,451	\$ 5,378	\$ 3,928	\$ 4,159	\$ 4,274
Lap Band	\$ 19,133	\$ 15,653	\$ 10,526	\$ 4,194	\$ 4,416	\$ 4,526
Open RYGB	\$ 30,176	\$ 13,237	\$ 9,403	\$ 3,928	\$ 4,159	\$ 4,274



DIRECT MEDICAL COSTS BY SCENARIO BY YEAR (SELECTED YEARS)

		Total cost of the population without the procedures	Total cost of the population undergoing procedures	Total plan costs	Incremental PMPY
Scenario 1 (9.3% Current)	Year 1	\$ 274,855,100	\$ 199,961,200	\$474,816,300	\$ 79
	Year 5	\$ 302,967,900	\$ 47,141,300	\$350,109,200	\$ 7
	Year 10	\$ 337,441,800	\$ 30,006,300	\$367,448,100	\$ (3)
Scenario 2 (15%)	Year 1	\$ 257,988,400	\$ 317,637,900	\$575,626,300	\$ 126
	Year 5	\$ 284,376,000	\$ 74,883,900	\$359,259,900	\$ 12
	Year 10	\$ 316,734,400	\$ 47,664,900	\$364,399,200	\$ (4)
Scenario 3 (20%)	Year 1	\$ 242,812,600	\$ 423,517,200	\$666,329,800	\$ 167
	Year 5	\$ 267,648,000	\$ 99,845,100	\$367,493,100	\$ 16
	Year 10	\$ 298,103,000	\$ 63,553,200	\$361,656,100	\$ (5)

RESULTS: CUMULATIVE PLAN COST BY INTERVENTION



CONCLUSIONS

- ✘ In the three scenarios examined, the Incremental PMPY becomes negative after year five, leading to savings in direct medical costs .
- ✘ By the end of the 10-year period, the highest cumulative costs are for the scenario where no one receives surgery.
- ✘ The results are driven by the number of subjects receiving each of the different procedures and the costs associated with each one over time.
- ✘ The model allows for customization of each parameter to provide useful estimates for the decision-maker: nevertheless, additional benefits not included in the model--such as increased life expectancy, quality of life, and productivity, among others--should be considered during the decision-making process.

AGB Survey Study

David Flum, MD, MPH, Co-Principal Investigator

AGB SURVEY STUDY

- ✘ Objective: To capture the semi quantitative and use/frequency of follow-up care for AGB patients.
- ✘ Surveyed 1,571 patients who had AGB between April 1, 2007 and July 1, 2008 at four sites in Washington State
- ✘ Patients completed the AGB Health Survey and EQ5D
- ✘ Response: 502 surveys (32% response)

Patients
with AGB
who
answered
the survey

N=502

Gastric
Band
adjusted
since
placement

Yes: 485
(96.6%)

No: 13 (2.6%)

Missing: 4
(0.8%)

Number of
times
adjusted
during last
year

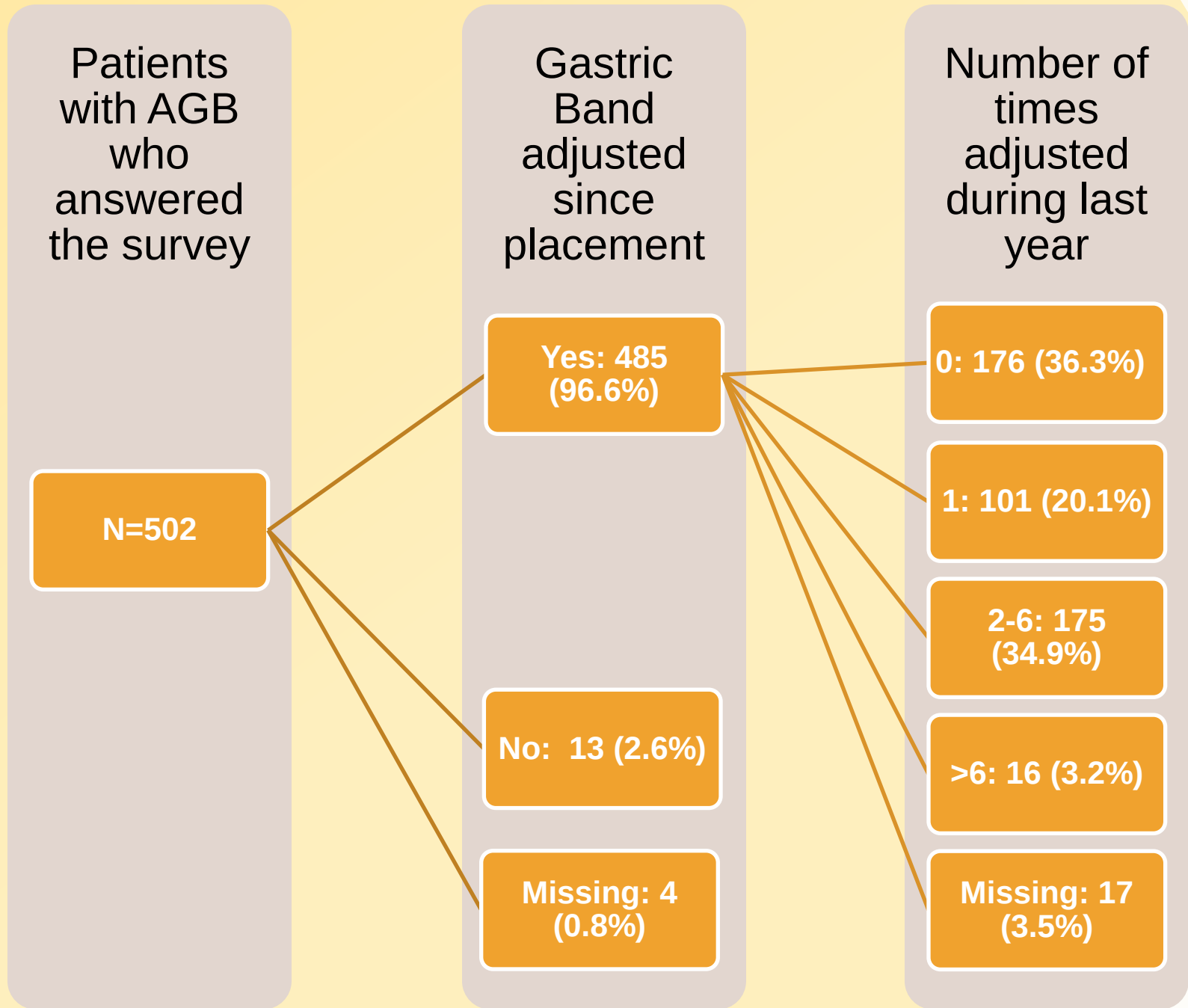
0: 176 (36.3%)

1: 101 (20.1%)

2-6: 175
(34.9%)

>6: 16 (3.2%)

Missing: 17
(3.5%)



Patients
with AGB
who
answered
the survey

N=502

Any
additional
operations
related to
the original
AGB

Band/port-
tubing
revision:
18 (3.6%)

Band
Replacements:
12 (2.4%)

Band removal:
20 (4.0%)

Conversion to
other BS: 11
(2.2%)

Other: 12
(2.4%)

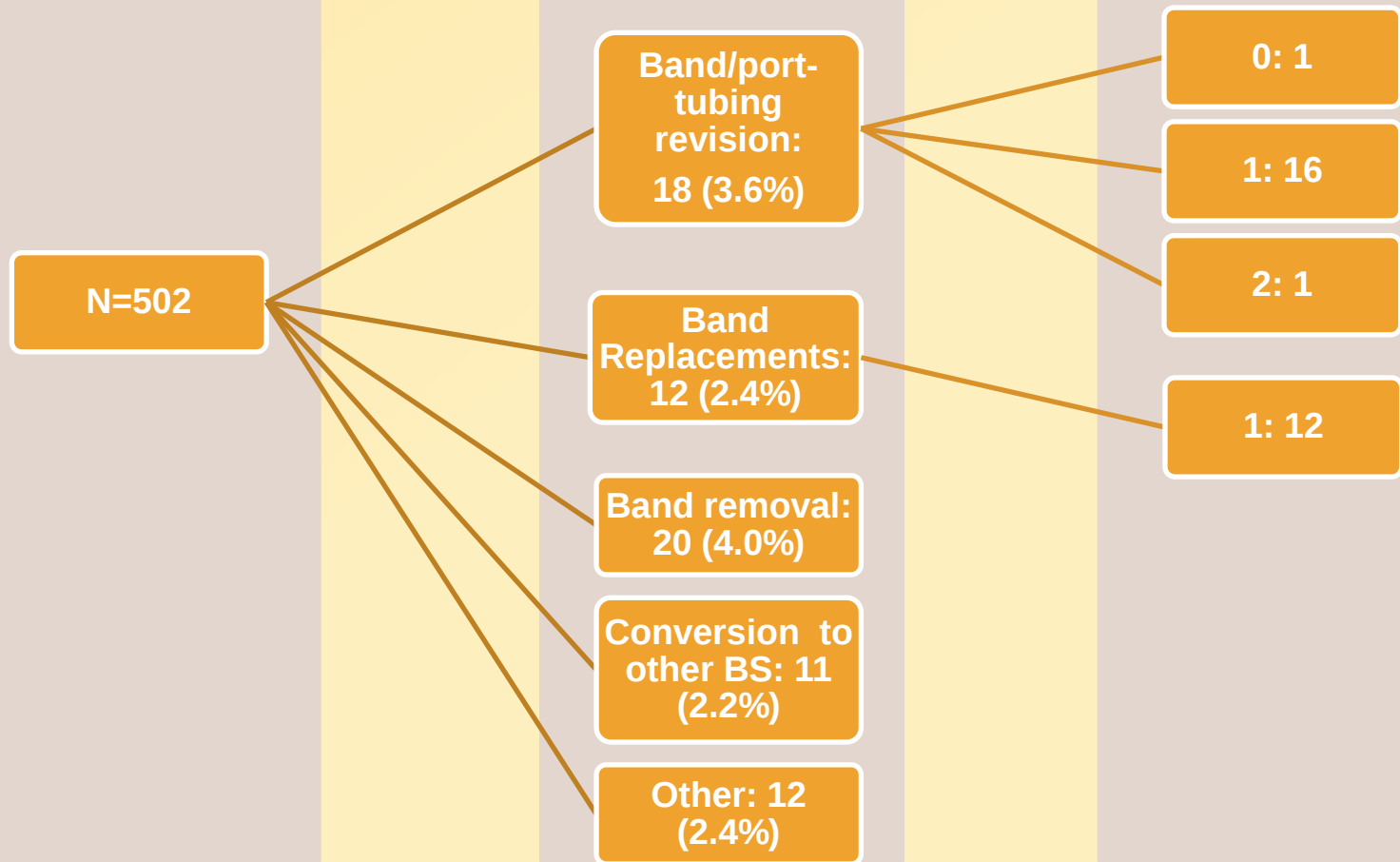
Number of
...

0: 1

1: 16

2: 1

1: 12



Research Outcomes

David Flum, MD, MPH, Co-Principal Investigator

Sean Sullivan, PhD, Co-Principal Investigator

PRESENTATIONS AND PUBLICATIONS

- ✗ **Projecting the economic outcomes of obesity using a natural history model.** Poster presented at ISPOR - International Society for Pharmacoeconomics and Outcomes Research: 15th Annual International Meeting. *May 15-19, 2010. Atlanta, GA*
- ✗ **Budget Impact Analysis of Bariatric Surgery for Morbid Obesity.** Presentation at AFMS Medical Research Symposium. *August 24-26, 2010. Arlington, VA*
- ✗ **The Impact of Medicare's Accreditation-based National Coverage Decision on the Use, Safety and Cost of Bariatric Surgery Among Medicare Beneficiaries.** *Publication prepared for Health Affairs and Annals of Surgery*

Implications for DOD Policy