TECHNICAL APPENDIX FOR:
Cost-Effectiveness of Bariatric Surgical Procedures for the Treatment of Severe Obesity

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Overview

The cost-effectiveness model was divided into 2 parts: 1) a decision analytic model, including the surgical procedure and the first five years post-surgery; and 2) an empirical "natural history" model for the non-surgical control population and surgical population beyond the fifth year following surgery. This supplement describes in more detail the inputs and methods used to complete each section. The simulation model was implemented in Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA) with substantial parts of the analysis done in SAS 9.2 (SAS Institute, Cary, NC) and STATA 11.0 (StataCorp, College Station, TX).

Decision Tree

Each of the three surgical procedures considered in this study was simulated to estimate clinical outcomes, costs, and utilities from the initial procedure date to five years post-procedure. We divided the first set of outcomes to identify death within 30 days of the procedure, early, and late complications of each surgical procedure. The first set of branches aimed to identify mortality within the first 30 days and has two states: 1) Death within the first 30 days after the procedure or 2) Alive up to 30 days after the procedure. Those subjects alive at 30 days after the procedure were further divided based on the presence of early complications. Early complications were defined as the presence of readmission within 30 days of surgery or an initial prolonged length of stay (PLOS). PLOS was defined as 1 standard deviation above the mean length of stay during the procedure, which was 12, 5, and 3 days for ORYGB, LRYGB, and LAGB, respectively, in the Medicare database.

There were four initial decision branches: 1) No Surgical Intervention, 2) ORYGB, 3) LRYGB, and 4) LAGB. Each of these branches—except for "No Surgical Intervention", which utilized the natural history model—has subsequent clinical pathways during the first five years, representing the probability of the most relevant events (i.e. death) associated with the surgical procedures at every year.

Inputs

Clinical Events and Mortality

We used the following CPT-4 codes to identify the procedures: 43846, 43847, 43621, 43631, 43633, 4431, 4439 for ORYGB; 43644, 43645, 43844, 43659, S2085, 4438 for LRYGB; and 43770, S2082, 4495 for LAGB.

The data for complications and mortality were derived directly from the Medicare database, where patients undergoing each specific procedure were identified. We validated our preliminary analyses to support the assumption that patients with readmissions or PLOS during the first 30 days after the procedure had a higher probability of complications, health resource use, costs, and mortality, with the data published by Encinosa and colleagues [1,2].

Mortality in the 0-30 day and 31-365 day periods post procedure were measured as unadjusted rates from the Medicare database. In years 2-5, annual mortality rates were computed as a function of age, sex and BMI (see Lifetime Natural History Model below for more details). BMI changes post procedure were derived from Picot et al. (2009) [3].

Direct Medical Costs

We estimated annual direct medical costs after a bariatric procedure using a generalized linear model (GLM) with a gamma distribution and log link function. The link function was validated using a Box-Cox regression and the outcome distribution was validated using the Modified Park Test [4]. Our method addressed the fact that costs had a lower bound of zero in some periods and a positively skewed distribution. The GLM method has been widely used and recommended in the analysis of costs exhibiting these characteristics. The decision analytic model requires the quantification of costs for those subjects who survive during the entire period, as well as the costs for those subjects who die during the first five years after surgery. We use both Medicare and MarketScan® data for the former and Medicare data for the latter. All cost data were adjusted to 2010 dollars using the Consumer Price Index (CPI) obtained from the Bureau of Labor Statistics.

In the GLM, we included procedure type (ORYGB, LRYGB, and LAGB), complications (death within 30 days, alive with complications, alive without complications), age, and gender as adjustment variables. We performed this analysis separately for each of the periods of the decision tree model—0-30 days, 31 days – 1 year, Year 2, Year 3, Year 4, and Year 5 (Tables 5-10).

Utilities

Utilities and changes in BMI associated with each procedure were drawn from published sources— specifically from the report published by Picot and colleagues [3] and individual clinical trials assessing the quality of life and changes in utility following the first 30 days after procedures. Utilities for subsequent periods were modeled using the Medical Expenditure Panel Survey (MEPS) data from years 2000-2006. We converted the physical and mental summary components of the SF-12 to EQ-5D scores using the algorithm described in Franks, et al. (2003) [5]. We then estimated adjusted utility values using GLM, assuming a log link and gamma distribution. Because EQ-5D scores were between 0 and 1 and the distribution of EQ-5D scores was left-skewed, we used a reflective transformation to allow for estimation using GLM. We verified the validity of the link function using the Box-Cox test and of the outcome distribution using the Modified Park test. We did not employ a two-part model because EQ-5D scores were derived from the estimated model in Franks, et al. (2003) and the resulting distribution of EQ-5D scores did not exhibit a spike at one. Our GLM model adjusted for BMI, age and gender. A squared term for BMI was not statistically significant. Given the coefficients from the GLM, we computed predicted utility scores conditional on specified covariate values. Predicted utilities were generated for each procedure in years one through five, post-surgery. BMI values post-surgery were derived from a systematic review by Picot and colleagues [3]. We also used this systematic review to provide an adjustment for utilities in the first 30 days post-surgery for those who experienced post-surgical complications (Tables 1, 2, and 3).

<u>Lifetime Natural History Model</u>

Patients who did not have a bariatric procedure followed a natural history pathway; hence, by definition, they enter the lifetime natural history model immediately (i.e., five years earlier than a similar surgical procedure patient). All other patients are transitioned from the decision-tree model after five years. The natural history model was driven by the estimated trajectory of BMI values over time. Given the BMI values, we then predicted outcomes at each period to complete the cost-effectiveness analysis.

Inputs

BMI Trajectory Model

Longitudinal data from Group Health (GH) [6] tracked BMI values for over 60,000 individuals who have reached a BMI of 35 kg/m^2 or greater during the period 2005-2010. To estimate BMI as a function of time (days), we used Generalized Estimating Equations (GEE) with an identity link and normal distribution. In our model, we included linear and quadratic terms for time, while adjusting for baseline BMI, age and sex. The specific model we estimated was:

$$BMI_{i,t} = \ b_0 + b_1 AGE_0 + b_2 BMI_0 + b_3 SEX + t \ \ \beta_1 + \beta_2 AGE_0 + \beta_3 BMI_0 + \beta_4 SEX \ \ +$$

$$t^2 \ \ \gamma_1 + \gamma_2 AGE_0 + \gamma_3 BMI_0 + \gamma_4 SEX \ \ + e_{i,t} \quad [1]$$

For each subject, time 0 (baseline) was defined as the first period in which BMI was greater or equal to 35 in our data. To address the irregular frequency of BMI measurements across patients, intensity of provider visit weights were estimated an applied to the GEE estimation of (1). For more details, see Wong, et al. (2012) [7]. The estimated model was used to predict BMI at a given age conditional on survival. Because the length of follow-up in the GH sample was six years, we adjusted baseline characteristics at six-year intervals when we generated predicted trajectories.

Survival

Survival probabilities were obtained from static life tables stratified by BMI and Sex. We constructed these life tables by estimating the 5-year probability of death from a logistic regression model. We estimated 5-year death as a function of Sex, BMI, squared BMI, Age, squared Age as well as interactions for Sex/Age, Sex/BMI and BMI/Age. Data were from the NCHS National Health Interview Survey between the 1997 and 2000. Respondent were linked to the National Death Index allowing for mortality follow-up through December 31, 2005. Analogous to Schauer, et al. (2010) [8], our modeling focused on respondents with a BMI of 25 and above, excluding respondents below this threshold. The logistic model used 5-year death as the dependent outcome because of the limited very low incidence of death annually. Predicted 5-year death probabilities were used to calculate equivalent one-year probabilities through appropriate translations between instantaneous rates and probabilities. Consistent with previous literature, our results showed that death probabilities were higher among males and increase with age and BMI. Also, the increase in mortality risk due to obesity decreased with age. These predicted death probabilities were used to generate life expectancy given sex, age, and BMI using standard life table methods.

Direct Medical Cost and Utility

Direct medical costs and health utilities were estimated using data from MEPS between 2000 and 2006. Given the predicted BMI and survival probability in each period, we estimated costs using a two-part model [9,10] to address the high proportion of MEPS respondents with zero costs. The first part of the two-part model estimated the probability of non-zero costs using a Probit model. We then estimated the second part of the two-part model using a GLM across the sample of respondents with non-zero costs. The GLM model was estimated assuming a square root link and gamma distribution, while adjusting for BMI, squared BMI, age and gender. A Box-Cox test and Modified Park test were used to verify the validity of the selected link and distribution. Predicted costs, conditional on BMI, age and gender, were calculated by weighting the expected value from the GLM model by the predicted probability of non-zero costs derived from the Probit model. Health utilities used in the natural history model were derived using methods described in the Decision Tree section. We applied MEPS sampling weights to cost and utility regressions in order to adjust the sample to reflect the U.S. population according to the Current Population Survey.

Expected costs from the two-part model were calculated by weighting expected costs conditional on non-zero costs by the likelihood of non-zero costs:

$$\mathrm{E}(COST \mid X) = \mathrm{Prob}(COST > 0) * \mathrm{E}(COST \mid COST > 0, X). \; [2]$$

where *X* includes BMI, age and gender. The marginal effect of BMI on costs is obtained by taking the derivative of (2):

$$\frac{\partial \mathrm{E}(COST \mid X)}{\partial BMI} = \mathrm{Pr}(COST > 0) * \frac{\partial \mathrm{E}(COST \mid COST > 0, X)}{\partial BMI} + \mathrm{E}(COST \mid COST > 0, X) * \frac{\partial \mathrm{Pr}(COST > 0)}{\partial BMI}. \; [3]$$

Marginal effects for age and gender were computed analogously.

Table 1. Simulation Parameters for LAGB

	Value	Source
General Characteristics		
Number of Procedures	9,886	CMS/Medicare
Probability of post procedure hospitalization (<31 days)	5.30%	CMS/Medicare
Probability of Early Death (0-30 days)	0.10%	CMS/Medicare
Cost of Early Death (0-30 days)	$ 26,418	Regression (Table 5)
Mortality (31d-365d)	0.21%	CMS/Medicare
Mortality (Year 2)	0.52%	Regression (Table 4)
Mortality (Year 3)	0.58%	Regression (Table 4)
Mortality (Year 4)	0.63%	Regression (Table 4)
Mortality (Year 5)	0.68%	Regression (Table 4)
Post Procedure Hospitalization		
Total Cost (<31 days)	$ 31,095	Regression (Table 5)
Total Cost (31-365 days)	$ 20,429	Regression (Table 6)
Total Cost (Year 2)	$ 13,238	Regression (Table 7)
Total Cost (Year 3)	$ 13,232	Regression (Table 8)
Total Cost (Year 4)	$ 10,061	Regression (Table 9)
Total Cost (Year 5)	$ 3,526	Regression (Table 10)
Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.70	Picot, et al. (2009)
Utility (31-365 days)	0.75	Regression (Table 11)
Utility (Year 2)	0.73	Regression (Table 11)
Utility (Year 3)	0.70	Regression (Table 11)
Utility (Year 4)	0.67	Regression (Table 11)
Utility (Year 5)	0.65	Regression (Table 11)
Subtotal: Expected Cost of With Hospitalization	$ 93,352	
Subtotal: Expected Utility of With Hospitalization	4.15	
No Post Procedure Hospitalization		
Total Cost (<31 days)	$ 14,159	Regression (Table 5)
Total Cost (31-365 days)	$ 7,835	Regression (Table 6)
Total Cost (Year 2)	$ 8,551	Regression (Table 7)
Total Cost (Year 3)	$ 7,917	Regression (Table 8)
Total Cost (Year 4)	$ 6,291	Regression (Table 9)
Total Cost (Year 5)	$ 2,685	Regression (Table 10)

Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.75	Picot, et al. (2009)
Utility (31-365 days)	0.75	Regression (Table 11)
Utility (Year 2)	0.73	Regression (Table 11)
Utility (Year 3)	0.70	Regression (Table 11)
Utility (Year 4)	0.67	Regression (Table 11)
Utility (Year 5)	0.65	Regression (Table 11)
Subtotal: Expected Cost of Without Hospitalization	$ 49,434	
Subtotal: Expected Utility of Without Hospitalization	4.20	
Total Expected Open Band Cost	$ 51,736	
Total Expected Open Band Utility	4.19	

Table 2. Simulation Parameters for LRYGB

	Value	Source
General Characteristics		
Number of Procedures	18,341	CMS/Medicare
Probability of post procedure hospitalization (<31 days)	9.90%	CMS/Medicare
Probability of Early Death (0-30 days)	0.28%	CMS/Medicare
Cost of Early Death (0-30days)	$ 31,142	Regression (Table 5)
Mortality (31d-365d)	0.49%	CMS/Medicare
Mortality (Year 2)	0.42%	Regression (Table 4)
Mortality (Year 3)	0.46%	Regression (Table 4)
Mortality (Year 4)	0.51%	Regression (Table 4)
Mortality (Year 5)	0.57%	Regression (Table 4)
Post Procedure Hospitalization		
Total Cost (<31 days)	$ 36,655	Regression (Table 5)
Total Cost (31-365 days)	$ 24,753	Regression (Table 6)
Total Cost (Year 2)	$ 14,673	Regression (Table 7)
Total Cost (Year 3)	$ 14,218	Regression (Table 8)
Total Cost (Year 4)	$ 8,992	Regression (Table 9)
Total Cost (Year 5)	$ 1,558	Regression (Table 10)
Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.70	Picot, et al. (2009)
Utility (31-365 days)	0.78	Regression (Table 11)
Utility (Year 2)	0.74	Regression (Table 11)
Utility (Year 3)	0.73	Regression (Table 11)
Utility (Year 4)	0.70	Regression (Table 11)
Utility (Year 5)	0.67	Regression (Table 11)
Subtotal: Expected Cost of With Hospitalization	$ 102,682	
Subtotal: Expected Utility of With Hospitalization	4.27	
No Post Procedure Hospitalization		
Total Cost (<31 days)	$ 16,691	Regression (Table 5)
Total Cost (31-365 days)	$ 9,494	Regression (Table 6)
Total Cost (Year 2)	$ 9,478	Regression (Table 7)
Total Cost (Year 3)	$ 8,507	Regression (Table 8)
Total Cost (Year 4)	$ 5,622	Regression (Table 9)

Total Cost (Year 5)	$ 1,221	Regression (Table 10)
Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.75	Picot et al. (2009)
Utility (31-365 days)	0.78	Regression (Table 11)
Utility (Year 2)	0.74	Regression (Table 11)
Utility (Year 3)	0.73	Regression (Table 11)
Utility (Year 4)	0.70	Regression (Table 11)
Utility (Year 5)	0.67	Regression (Table 11)
Subtotal: Expected Cost of Without Hospitalization	$ 53,119	
Subtotal: Expected Utility of Without Hospitalization	4.32	
Total Expected Lap Bypass Cost	$ 57,950	
Total Expected Lap Bypass Utility	4.30	

Table 3. Simulation Parameters for ORYGB

	Value	Source
General Characteristics		
Number of Procedures	14,358	CMS/Medicare
Probability of post procedure hospitalization (<31 days)	15.70%	CMS/Medicare
Probability of Early Death (0-30 days)	1.08%	CMS/Medicare
Cost of Early Death (0-30days)	$ 38,577	Regression (Table 5)
Mortality (31d-365d)	1.28%	CMS/Medicare
Mortality (Year 2)	0.42%	Regression (Table 4)
Mortality (Year 3)	0.46%	Regression (Table 4)
Mortality (Year 4)	0.51%	Regression (Table 4)
Mortality (Year 5)	0.57%	Regression (Table 4)
Post Procedure Hospitalization		
Total Cost (<31 days)	$ 45,406	Regression (Table 5)
Total Cost (31-365 days)	$ 33,500	Regression (Table 6)
Total Cost (Year 2)	$ 19,045	Regression (Table 7)
Total Cost (Year 3)	$ 18,781	Regression (Table 8)
Total Cost (Year 4)	$ 15,814	Regression (Table 9)
Total Cost (Year 5)	$ 7,571	Regression (Table 10)
Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.70	Picot, et al. (2009)
Utility (31-365 days)	0.78	Regression (Table 11)
Utility (Year 2)	0.74	Regression (Table 11)
Utility (Year 3)	0.73	Regression (Table 11)
Utility (Year 4)	0.70	Regression (Table 11)
Utility (Year 5)	0.67	Regression (Table 11)
Subtotal: Expected Cost of With Hospitalization	$142,192	
Subtotal: Expected Utility of With Hospitalization	4.24	
No Post Procedure Hospitalization		
Total Cost (<31 days)	$ 20,675	Regression (Table 5)
Total Cost (31-365 days)	$ 12,849	Regression (Table 6)
Total Cost (Year 2)	$ 12,302	Regression (Table 7)
Total Cost (Year 3)	$ 11,237	Regression (Table 8)

Total Cost (Year 4)	$ 9,887	Regression (Table 9)
Total Cost (Year 5)	$ 5,764	Regression (Table 10)
Cost of Death (All Periods)	$ 38,049	CMS/Medicare
Utility (0-31 days)	0.75	Picot, et al. (2009)
Utility (31-365 days)	0.78	Regression (Table 11)
Utility (Year 2)	0.74	Regression (Table 11)
Utility (Year 3)	0.73	Regression (Table 11)
Utility (Year 4)	0.70	Regression (Table 11)
Utility (Year 5)	0.67	Regression (Table 11)
Subtotal: Expected Cost of Without Hospitalization	$ 75,547	
Subtotal: Expected Utility of Without Hospitalization	4.29	
Total Expected Open Bypass Cost	$ 85,498	
Total Expected Open Bypass Utility	4.24	

Table 4: Regression results from mortality model.

	Coefficient	**Std. Err**	**P-Value**
BMI	0.065	0.030	0.030
Squared BMI	1.0E-04	2.8E-04	0.715
Age	0.036	0.014	0.009
Squared Age	5.0E-04	7.93E-05	< 0.001
Male (1=yes)	-0.192	0.324	0.553
Male*BMI	0.006	0.008	0.451
Male*Age	0.007	0.003	0.011
BMI*Age	-2.6E-04	2.5E-04	0.294
Constant	-8.361	0.807	< 0.001
N	89,606		

Logistic regression results estimating the probability of 5-year death among individuals from the National Health Interview Survey in years 1997 to 2000.

Table 5: GLM regression results for direct medical costs in the 0-30 day period post-procedure.

	Coefficient	Std. Err	P-Value
Age	0.0002	0.0002	0.1808
Male (1=yes)	-0.0499	0.0048	< 0.0001
LAGB (1=yes)	-0.3786	0.0058	< 0.0001
LRYGB (1=yes)	-0.2141	0.0048	< 0.0001
ORYGB	Reference Category		
Alive w/Rehospitalization (1=yes)	0.1630	0.0250	< 0.0001
Alive w/o Rehospitalization (1=yes)	-0.6237	0.0242	< 0.0001
Constant	10.5997	0.0266	< 0.0001
N	46,988		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 6: GLM regression results for direct medical costs in the 31-365 day period post-procedure.

	Coefficient	**Std. Err**	**P-Value**
Age	-0.0039	0.0005	< 0.0001
Male (1=yes)	-0.0223	0.0144	0.1214
LAGB (1=yes)	-0.4946	0.0171	< 0.0001
LRYGB (1=yes)	-0.3026	0.0140	< 0.0001
ORYGB	Reference Category		
Alive w/o Rehospitalization (1=yes)	-0.9583	0.0210	< 0.0001
Constant	10.6483	0.0395	< 0.0001
N	44,170		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 7: GLM regression results for direct medical costs in year 2 post-procedure.

	Coefficient	Std. Err	P-Value
Age	-0.0027	0.0007	< 0.0001
Male (1=yes)	0.0192	0.0180	0.2877
LAGB (1=yes)	-0.3637	0.0224	< 0.0001
LRYGB (1=yes)	-0.2608	0.0166	< 0.0001
ORYGB	Reference Category		
Alive w/o Rehospitalization (1=yes)	-0.4370	0.0275	< 0.0001
Constant	10.008	0.0488	< 0.0001
N	30,125		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 8: GLM regression results for direct medical costs in year 3 post-procedure.

	Coefficient	Std. Err	P-Value
Age	-0.0020	0.0009	0.0179
Male (1=yes)	-0.0045	0.0226	0.8422
LAGB (1=yes)	-0.3502	0.0327	< 0.0001
LRYGB (1=yes)	-0.2783	0.0202	< 0.0001
ORYGB	Reference Category		
Alive w/o Rehospitalization (1=yes)	-0.5136	0.0356	< 0.0001
Constant	10.0102	0.0623	< 0.0001
N	19,957		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 9: GLM regression results for direct medical costs in year 4 post-procedure.

	Coefficient	Std. Err	P-Value
Age	-0.0004	0.0011	0.0758
Male (1=yes)	-0.0527	0.0297	0.7037
LAGB (1=yes)	-0.4522	0.0540	< 0.0001
LRYGB (1=yes)	-0.5645	0.0272	< 0.0001
ORYGB	Reference Category		
Alive w/o Rehospitalization (1=yes)	-0.4696	0.0484	< 0.0001
Constant	9.8312	0.0815	< 0.0001
N	12,923		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 10: GLM regression results for direct medical costs in year 5 post-procedure.

	Coefficient	Std. Err	P-Value
Age	0.0006	0.0018	0.7302
Male (1=yes)	-0.1838	0.0498	0.0002
LAGB (1=yes)	-0.7641	0.2342	< 0.0001
LRYGB (1=yes)	-1.5811	0.0911	< 0.0001
ORYGB	Reference Category		
Alive w/o Rehospitalization (1=yes)	-0.2727	0.0981	0.0054
Constant	9.2023	0.1463	< 0.0001
N	5,147		

Costs modeled using bariatric patients from Medicare claims during the period 2004 to 2008.
Total medical costs modeled using GLM with a gamma distribution and log link.

Table 11: Regression results from GLM utility model.

	Coefficient	**Std. Err**	**P-Value**
BMI	0.031	7.5E-04	< 0.001
Age	0.024	2.7E-04	< 0.001
Female (1=yes)	0.245	0.010	< 0.001
Constant	-4.263	0.027	< 0.001
N	122,609		

Health utility modeled using individuals from the Medical Expenditure Panel Survey from 2000 to 2006.
GLM model assumes a gamma distribution and log link.

A reflective transformation was applied to EQ-5D scores in order to allow for GLM estimation.

Table 12: Regression results from two-part model estimating total medical expenditure.

	Probit (First Part)			GLM (Second Part)		
	Coefficient	**Std. Err**	**P-Value**	**Coefficient**	**Std. Err**	**P-Value**
BMI	0.009	0.004	0.020	-1.797	0.540	0.001
Squared BMI	6.73E-06	5.99E-05	0.911	0.037	0.008	< 0.001
Age	0.023	3.38E-04	< 0.001	0.906	0.025	< 0.001
Female (1=yes)	0.569	0.011	< 0.001	6.979	0.952	< 0.001
Constant	-0.392	0.063	< 0.001	41.666	8.496	< 0.001
N	129,644			106,790		

Medical expenditure modeled using individuals from the Medical Expenditure Panel Survey from 2000 to 2006.
The probability of non-zero costs model in the first part.
Total medical costs in the second part modeled using GLM with a gamma distribution and square root link.