

# Improved Bariatric Surgery Outcomes for Medicare Beneficiaries After Implementation of the Medicare National Coverage Determination

Ninh T. Nguyen, MD; Samuel Hohmann, PhD; Johnathan Slone, MD; Esteban Varela, MD; Brian R. Smith, MD; David Hoyt, MD

**Objective:** To compare the outcomes of Medicare beneficiaries who underwent bariatric surgery within 18 months before and after implementation of the national coverage determination (NCD) for bariatric surgery.

**Design:** Analysis of the University HealthSystem Consortium database from October 1, 2004, through September 31, 2007.

**Setting:** A total of 102 academic medical centers and approximately 150 of their affiliated hospitals, representing more than 90% of the nation's nonprofit academic medical centers.

**Patients:** Medicare and Medicaid patients who underwent bariatric surgery to treat morbid obesity.

**Main Outcome Measures:** Demographics, length of stay, 30-day readmission, morbidity, observed-to-expected mortality ratio, and costs.

**Results:** A total of 3196 bariatric procedures were performed before and 3068 after the NCD. After the implementation of the NCD, the volume of gastric banding doubled and the proportion of laparoscopic gastric bypass increased from 60.0% to 77.2%. Patients who underwent bariatric surgery after the NCD benefited from a shorter length of stay (3.5 vs 3.1 days,  $P < .001$ ) and lower overall complication rates (12.2% vs 10.0%,  $P < .001$ ), with no significant differences in the in-hospital mortality rates (0.28% vs 0.20%). Among Medicare patients, there was a 29.3% reduction in the number of bariatric procedures performed within the first 2 quarters after the NCD. However, the number of procedures returned to baseline volume within 1 year and exceeded baseline volume after 2 years of the NCD.

**Conclusion:** The bariatric surgery NCD resulted in improved outcomes for Medicare beneficiaries without limiting access to care for individuals with medical disability.

*Arch Surg.* 2010;145(1):72-78

**Author Affiliations:** Department of Surgery, University of California, Irvine Medical Center, Orange (Drs Nguyen, Slone, Varela, Smith, and Hoyt), and the University HealthSystem Consortium, Oak Brook, Illinois (Dr Hohmann).

**D**URING THE PAST DECADE the number of bariatric operations has exponentially increased with the introduction of laparoscopic bariatric surgery.<sup>1</sup> Data from the Nationwide Inpatient Sample, developed as part of the Healthcare Cost and Utilization Project, showed that the number of bariatric procedures performed in the United States increased from 12 775 in 1998 to 70 256 in 2001.<sup>1</sup> The increase in bariatric surgery resulted in increasing scrutiny by third-party payers and the media with regard to the safety of bariatric surgery. A recent report<sup>2</sup> that examined the outcome of gastric bypass by means of the Washington State Comprehensive Hospital Abstract Reporting System demonstrated that the 30-day mortality was substantially higher (1.9%) than previously reported. Similarly, in another study<sup>3</sup> of 16 155 Medicare beneficiaries who under-

went bariatric surgery, the 30-day mortality rate was 2%. These reports bring into question the safety of bariatric surgery on both regional and national levels. Although the beneficial effects of bariatric surgery have been well documented, the higher perioperative death rate from these recent reports is concerning, particularly for the population of patients with high-risk medical disability.

In February 2006, the Centers for Medicare & Medicaid Services (CMS) expanded the national coverage for bariatric surgery procedures for Medicare beneficiaries. This decision expands coverage that would cover bariatric surgery for patients older than 65 years. The decision also expands coverage to 3 types of bariatric surgery procedures: laparoscopic and open Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and laparoscopic and open biliopancreatic diversion with duodenal switch. The CMS covers these pro-

cedures at high-volume centers (>125 procedures per year) that achieve a low mortality rate and are certified by the American College of Surgeons (ACS) or the American Society for Metabolic and Bariatric Surgery (ASMBS).

With implementation of the CMS bariatric surgery national coverage determination (NCD), important questions arise, such as whether this policy will improve the outcomes for Medicare beneficiaries who undergo bariatric surgery or whether implementation of the NCD will impede access to care for this high-risk patient population.<sup>4</sup> The aim of this study was to answer these questions by the use of a national, clinical database of academic medical centers. We compared the outcomes and volumes of bariatric surgical procedures performed for Medicare beneficiaries within the 18 months before and after implementation of the CMS bariatric surgery NCD.

## METHODS

### DATABASE

The University HealthSystem Consortium (UHC) is an alliance of 102 academic medical centers and approximately 150 of their affiliated hospitals, which represent more than 90% of the nation's nonprofit academic medical centers. The UHC database is an administrative, clinical, and financial database that provides benchmark measures on the use of health care resources for the purpose of comparative data analysis among institutions. The UHC database is a collection of patient-level, discharge abstract data of all inpatients discharged from each institution. The data are based on billing records (UB-04) generated by clinical coders from each academic health center and its affiliate community hospitals. The UHC database contains discharge information with regard to inpatient hospital stays, including patient characteristics, length of stay, 30-day readmission rate, overall and specific postoperative morbidity, observed and expected (risk-adjusted) in-hospital mortality, and inpatient care costs. One of the benefits of the UHC clinical database is the risk-adjusted data for comparison among institutions. In addition, the 3M's All Payer Revised–Diagnosis Related Groups' method is used to assign a level of severity to each patient on the basis of secondary diagnoses (chronic comorbid conditions and complications). The 4 severity classes are minor, moderate, major, and extreme. For example, chronic comorbid conditions, such as diabetes mellitus, would be categorized as moderate severity and recent myocardial infarction as extreme severity. This study meets Health Insurance Portability and Accountability Act compliance because no personal information is included in the reporting of the results. Approval for the use of the UHC patient-level data in this study was obtained from the institutional review board of the University of California, Irvine Medical Center, and the UHC.

In-hospital mortality was defined as the percentage of patients who died before being discharged from the hospital. The UHC database does not include information on deaths that occurred after discharge, unless the patient returns and dies during a subsequent hospitalization. Length of stay was defined as the period from the index procedure to hospital discharge, and 30-day readmission was defined as readmission for any reason within 30 days of discharge after the index procedure. The UHC clinical database provides an estimated cost of patient care using a ratio of cost to charge method. The UHC collects detailed patient charges at the revenue code level and estimates costs by multiplying charges by the cost center–specific ratio of cost to charges from the annual Medicare cost report submitted by individual hospitals.

## DATA ANALYSIS

We analyzed the UHC database for discharge data with regard to all Medicare and Medicaid patients who underwent open or laparoscopic Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and open or laparoscopic biliopancreatic diversion with duodenal switch for the treatment of morbid obesity from October 1, 2004, to September 31, 2007. Medicaid coverage represents individuals and families with low income/resources and people with disabilities. Medicare represents coverage for people 65 years or older or those younger than 65 years with a disability who have been receiving Social Security benefits for at least 24 months from the date of entitlement. Individuals who received both Medicare and Medicaid were included in our analysis because many beneficiaries qualify for both (ie, are dual eligible). All hospitalizations during which these bariatric procedures were performed for the treatment of morbid obesity were identified by means of appropriate diagnosis and procedural codes as specified by the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)*.<sup>5</sup> The principal *International Classification of Diseases, Ninth Revision (ICD-9)*<sup>6</sup> diagnosis codes for obesity and morbid obesity were used (278.0, 278.01, and 278.00), which included a subcategory of obesity and a subclassification of morbid obesity. The principal ICD-9 procedure codes for open Roux-en-Y gastric bypass are 44.31 and 44.39, which include a subcategory of gastroenterostomy without gastrectomy and a subclassification of high gastric bypass. The principal ICD-9 procedure code for laparoscopic Roux-en-Y gastric bypass is 44.38, which included a subcategory of gastroenterostomy without gastrectomy and a subclassification laparoscopic gastroenterostomy. The principal ICD-9 procedure code for laparoscopic adjustable gastric banding is 44.95. The principal ICD-9 procedure code for laparoscopic duodenal switch is 44.68. The secondary diagnosis ICD-9 code for laparoscopic procedures that were converted to open procedures is V64.41; 83 procedures (2.6%) before NCD had this secondary diagnosis, whereas 57 (1.9%) after NCD had it. We analyzed discharge data after October 1, 2004, because the specific ICD-9 procedure code for a laparoscopic procedure was not available before that time. To increase the homogeneity of the cohort, a specific diagnosis-related group for operative treatment of obesity was used (diagnosis-related group code 288), and patients undergoing emergency procedures were excluded.

We compared patient characteristics (age, sex, ethnicity, severity-of-illness class, and comorbidities), perioperative outcomes, in-hospital mortality, observed-to-expected mortality ratio, costs, and volume of bariatric surgical procedures for Medicare and Medicaid patients who underwent bariatric surgery up to 18 months before the CMS bariatric surgery NCD implementation with patients who underwent bariatric surgery up to 18 months after NCD implementation. Data are expressed as mean (SD). Differences in patient characteristics, complications, 30-day readmission rates, and observed in-hospital mortality between the 2 groups were analyzed by the use of Pearson  $\chi^2$  tests. Two-sample *t* tests were performed to determine the differences in length of stay and costs between the 2 groups. Statistical analysis was performed by means of SAS statistical software, version 9.1 (SAS Institute Inc, Cary, North Carolina). *P* < .05 was considered significant.

## RESULTS

### PATIENT CHARACTERISTICS

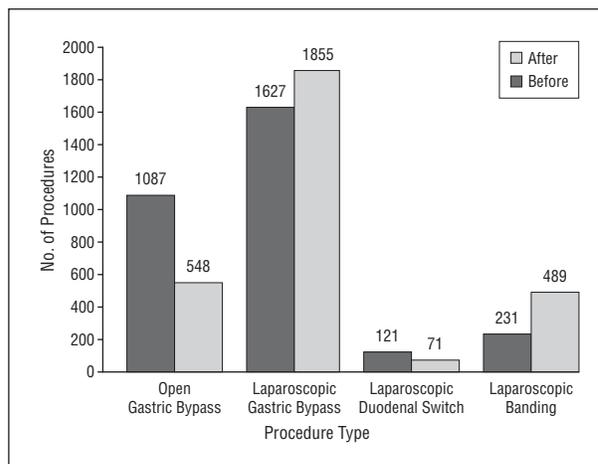
From October 1, 2004, through September 30, 2007, a total of 6264 Medicare and Medicaid patients who met the study criteria underwent bariatric surgery for the treatment of morbid obesity. As indicated in **Table 1**, a total of 3196

**Table 1. Characteristics of Patients Who Underwent Bariatric Surgery Within the 18 Months Before and After Implementation of the Medicare Bariatric Surgery National Coverage Determination (NCD)**

Characteristics	Before Medicare NCD, No. (%) (n=3196 Patients From 60 Institutions)	After Medicare NCD, No. (%) (n=3068 Patients From 45 Institutions)
Age, y		
<18	10 (0.3)	19 (0.6)
18-30	419 (13.1)	399 (13.0)
31-50	1649 (51.6)	1531 (49.9)
51-64	879 (27.5)	826 (26.9)
≥65	239 (7.5) <sup>a</sup>	293 (9.6)
Female sex	2638 (82.5)	2500 (81.5)
Race/ethnicity		
White	2161 (67.6) <sup>a</sup>	1942 (63.3)
African American	623 (19.5)	643 (21.0)
Hispanic	199 (6.2) <sup>a</sup>	255 (8.3)
Asian	9 (0.3)	4 (0.1)
Other or unknown	204 (6.4)	224 (7.3)
Severity class		
Minor	1148 (36.0) <sup>a</sup>	1480 (48.2)
Moderate	1689 (52.9) <sup>a</sup>	1323 (43.1)
Major	305 (9.4) <sup>a</sup>	234 (7.6)
Extreme	54 (1.7) <sup>a</sup>	31 (1.0)
Chronic conditions		
Diabetes mellitus	906 (28.3)	804 (26.2)
Hypertension	1280 (40.1)	1149 (37.5)
Congestive heart failure	130 (4.1)	112 (3.7)
Liver disease	207 (6.5)	188 (6.1)
Chronic pulmonary disease	526 (16.5)	511 (16.7)

<sup>a</sup> $P < .05$  compared with after the NCD ( $\chi^2$  tests).

patients underwent bariatric surgery within the 18 months before implementation of the NCD and 3068 patients underwent bariatric surgery within the 18 months after implementation. The number of institutions that perform bariatric surgery decreased from 60 before implementation of the NCD to 45 after implementation of the NCD. The proportion of females was more than 4 times the proportion of males both before and after implementation of the NCD (82.5% and 81.5%, respectively). The proportion of patients before compared with after implementation of the NCD was statistically different for all 4 levels of severity of illness: minor (36.0% vs 48.2%,  $P < .001$ ), moderate (52.9% vs 42.1%,  $P < .001$ ), major (9.5% vs 7.6%,  $P < .001$ ), and extreme (1.7% vs 1.0%,  $P = .02$ ). More than half of the patients were between 31 and 50 years of age (51.6% before the NCD and 49.9% after the NCD). There were significantly more individuals greater than 65 years of age within the group after the NCD implementation (7.5% vs 9.6%,  $P < .05$ ). The ethnicity distribution was similar for the proportions of African American, Asian, and other or unknown discharges, but the proportion of whites was lower and the proportion of Hispanics was higher after the NCD implementation (67.6% vs 63.3%,  $P = .01$ , and 6.2% and 8.3%,  $P < .001$ , respectively; ethnicity determined by self-report). The proportions of patients with diabetes, hypertension, congestive heart failure, liver disease, and chronic pulmonary disease were not significantly different between the 2 groups.



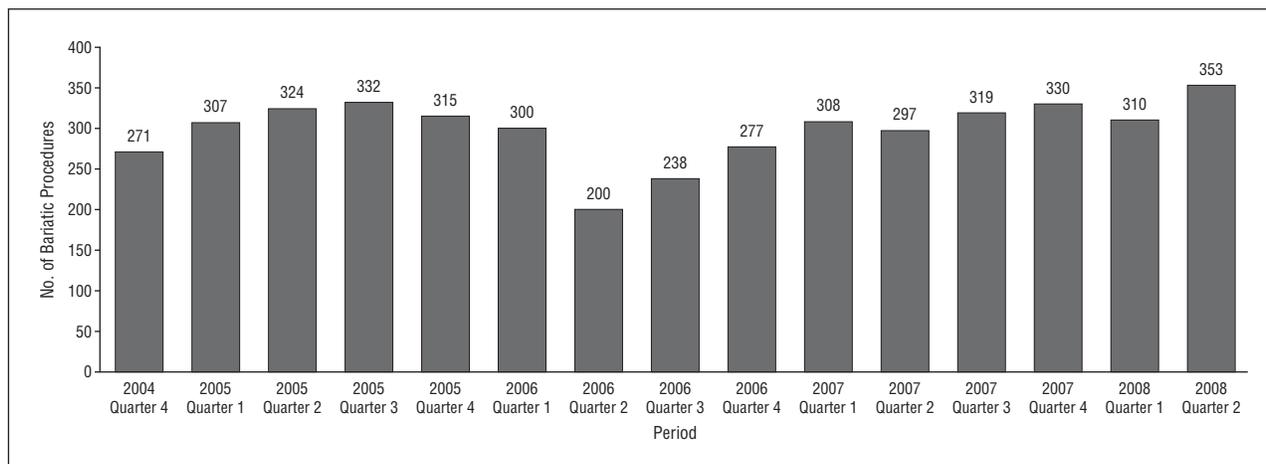
**Figure 1.** Types of bariatric procedures performed before and after implementation of the Centers for Medicare & Medicaid Services bariatric surgery national coverage determination.

### VOLUME OF PROCEDURES AND PERIOPERATIVE OUTCOMES

The type and number of bariatric procedures performed on Medicare beneficiaries (Medicare and Medicaid patients) are depicted in **Figure 1**. After implementation of the NCD, there was a doubling in the volume of laparoscopic gastric banding (231 vs 489 procedures), with a decrease in the volume of gastric bypass (2714 vs 2403 procedures); however, the proportion of laparoscopic gastric bypass procedures increased from 60.0% before the NCD to 77.2% after the NCD.

The number of bariatric procedures performed in Medicare beneficiaries (excluding Medicaid patients) is depicted in **Figure 2**. There was a precipitous decrease in the number of bariatric operations starting in the second quarter of 2006, which coincides with implementation of the NCD. Compared with the volume of bariatric procedures performed within the 2 quarters before implementation of the NCD, there was a 29.1% reduction in the volume of bariatric procedures for the 2 quarters after the NCD. However, the volume of bariatric procedures increased to baseline volume within 1 year after implementation of the NCD and continues to increase and exceed baseline volume, based on data for 3 quarters subsequent to the study period.

The perioperative outcomes for Medicare and Medicaid patients who underwent bariatric surgery up to 18 months before and after implementation of the NCD are given in **Table 2**. The mean length of hospital stay was 3.5 (4.0) days before implementation of the NCD compared with 3.1 (5.3) days after implementation of the NCD ( $P < .001$ ). The 30-day readmission rate was similar between the 2 groups (10.4% before implementation of the NCD and 10.0% after implementation of the NCD). Compared with Medicare and Medicaid patients who underwent bariatric surgery before the NCD, patients who underwent bariatric surgery after the NCD benefited from a lower overall complication rate (12.2% vs 10.0%; odds ratio [OR], 1.24; 95% confidence interval [CI], 1.06-1.45), a significantly lower postoperative pulmonary complication rate (2.4% vs 1.4%; OR, 1.65; 95% CI, 1.13-2.40), and



**Figure 2.** Number of bariatric procedures performed quarterly on Medicare beneficiaries (with the exclusion of Medicaid patients) at US academic medical centers from October 1, 2004, through June 30, 2008.

**Table 2. Outcomes of Bariatric Surgery for Medicare and Medicaid Patients Within the 18 Months Before and After Implementation of the Medicare National Coverage Determination (NCD)<sup>a</sup>**

Outcomes	Before Medicare NCD (n=3196)	After Medicare NCD (n=3068)	OR (95% CI)
Length of hospital stay, mean (SD), d	3.5 (4.0) <sup>b</sup>	3.1 (5.3)	NA
Overall complications	390 (12.2) <sup>c</sup>	307 (10.0)	1.24 (1.06-1.45)
Pulmonary complications	77 (2.4) <sup>c</sup>	43 (1.4)	1.65 (1.13-2.40)
Cardiac complications	3 (0.1)	0 (0.0)	NA
Wound infection	38 (1.2)	25 (0.8)	1.55 (0.92-2.62)
Venous thrombosis or pulmonary embolism	29 (0.9) <sup>c</sup>	12 (0.4)	2.08 (1.07-4.02)
Hemorrhage	61 (1.9)	43 (1.4)	1.37 (0.92-2.03)
Urinary tract infection	6 (0.2)	3 (0.1)	1.68 (0.49-5.75)
30-Day readmission	332 (10.4)	307 (10.0)	1.04 (0.89-1.23)
In-hospital mortality	9 (0.3)	6 (0.2)	1.44 (0.57-4.05)
Observed-to-expected mortality ratio	1.06	0.97	NA
Cost, mean (SD), \$	14 327 (12 191)	14 405 (14 543)	NA

Abbreviations: CI, confidence interval; NA, not applicable; OR, odds ratio.

<sup>a</sup>Data are presented as percentages unless otherwise indicated.

<sup>b</sup> $P < .01$  compared with after the NCD (2-sample  $t$  tests).

<sup>c</sup> $P < .05$  compared with after the NCD ( $\chi^2$  tests).

a lower venous thrombosis or pulmonary embolism rate (0.9% vs 0.4%; OR, 2.08; 95% CI, 1.07-4.02). No significant difference was seen in the in-hospital mortality between groups (0.28% before the NCD vs 0.20% after the NCD). The difference in mean costs between the 2 groups was not significant either (\$14 327 [\$12 191] vs \$14 405 [\$14 543]).

The perioperative outcomes for Medicare-only patients who underwent bariatric surgery within the 18 months before (n = 1847) and after (n = 1639) implementation of the NCD are given in **Table 3**. The mean length of hospital stay was 3.8 (4.3) days before implementation of the NCD compared with 3.1 (3.7) days after imple-

**Table 3. Outcomes of Bariatric Surgery for Medicare-Only Patients Within the 18 Months Before and After Implementation of the Medicare National Coverage Determination (NCD)<sup>a</sup>**

Outcomes	Before NCD (n=1847)	After NCD (n=1639)	OR (95% CI)
Length of hospital stay, mean (SD), d	3.8 (4.3) <sup>b</sup>	3.1 (3.7)	NA
Overall complications	270 (14.6) <sup>c</sup>	170 (10.4)	1.48 (1.21-1.82)
Pulmonary complications	54 (2.9) <sup>c</sup>	28 (1.7)	1.76 (1.10-2.82)
Cardiac complications	2 (0.1)	0 (0.0)	NA
Wound infection	30 (1.6) <sup>c</sup>	11 (0.7)	2.16 (1.10-4.25)
Venous thrombosis or pulmonary embolism	26 (1.4) <sup>c</sup>	10 (0.6)	2.24 (1.07-4.67)
Hemorrhage	44 (2.4)	26 (1.6)	1.51 (0.93-2.47)
Urinary tract infection	4 (0.2)	0 (0.0)	1.78 (0.33-9.71)
30-Day readmission	203 (11.0)	162 (9.9)	1.13 (0.91-1.40)
In-hospital mortality	7 (0.38)	4 (0.3)	1.56 (0.45-5.32)
Observed-to-expected mortality ratio	1.07	0.89	NA
Cost, mean (SD), \$	15 061 (12 324) <sup>b</sup>	14 152 (9746)	NA

Abbreviations: CI, confidence interval; NA, not applicable; OR, odds ratio.

<sup>a</sup>Data are presented as percentages unless otherwise indicated.

<sup>b</sup> $P < .01$  compared with after the NCD (2-sample  $t$  tests).

<sup>c</sup> $P < .05$  compared with after the NCD ( $\chi^2$  tests).

mentation of the NCD ( $P < .001$ ). The 30-day readmission rate was similar between the 2 groups (11.0% before implementation of the NCD and 9.9% after implementation of the NCD). Compared with Medicare patients who underwent bariatric surgery before the NCD, patients who underwent bariatric surgery after the NCD had a lower overall complication rate (14.6% vs 10.4%; OR, 1.48; 95% CI, 1.21-1.82) and significantly lower rates of postoperative pulmonary complications (2.9% vs 1.7%; OR, 1.76; 95% CI, 1.10-2.82), wound infections (1.6% vs 0.7%; OR, 2.16; 95% CI, 1.10-4.25), and venous thrombosis or pulmonary embolisms (1.4% vs 0.6%; OR, 2.24; 95% CI, 1.07-4.67). No significant difference was seen in in-hospital mortality between groups (0.38% before

**Table 4. Outcomes of Bariatric Surgery Within the 18 Months Before and After Implementation of the Medicare National Coverage Determination (NCD), Specifically for Patients With High Severity of Illness Class (Major and Extreme)<sup>a</sup>**

Outcomes	Before NCD (n=359)	After NCD (n=264)	OR (95% CI)
Length of hospital stay, mean (SD), d	7.7 (9.6)	7.2 (16.9)	NA
Overall complications	180 (50.1) <sup>b</sup>	106 (40.2)	1.50 (1.09-2.07)
Pulmonary complications	72 (20.1)	42 (15.9)	1.33 (0.87-2.02)
Cardiac complications	2 (0.6)	0 (0.0)	NA
Wound infection	25 (7.0)	17 (6.4)	1.09 (0.85-2.06)
Venous thrombosis or pulmonary embolism	20 (5.6)	7 (2.7)	2.17 (0.90-4.15)
Hemorrhage	25 (7.0)	10 (3.8)	1.90 (0.90-4.03)
Urinary tract infection	3 (0.8)	0 (0.0)	NA
30-Day readmission	57 (15.9)	3 (1.1)	1.32 (0.83-2.10)
In-hospital mortality	8 (2.2)	5 (1.9)	1.18 (0.38-3.65)
Observed-to-expected mortality ratio	1.12	0.93	NA
Cost, mean (SD)	25 682 (27 896)	25 270 (44 549)	NA

Abbreviations: CI, confidence interval; NA, not applicable; OR, odds ratio.

<sup>a</sup>Data are presented as percentages unless otherwise indicated.

<sup>b</sup> $P < .05$  compared with after the NCD ( $\chi^2$  tests).

the NCD vs 0.24% after the NCD). There was a trend toward improvement of the observed-to-expected mortality ratio from 1.07 before to 0.89 after implementation of the NCD. The mean cost was significantly lower after implementation of the NCD.

Significant differences were found in the baseline characteristics between groups. The group before implementation of the NCD had more patients with a higher severity of illness. To eliminate this important confounding variable, we examined the outcomes of bariatric surgery specifically within a subset of patients with major and extreme (higher) severity of illness (**Table 4**). Compared with Medicare and Medicaid patients with major or extreme severities of illness who underwent bariatric surgery before the NCD, patients who underwent bariatric surgery after the NCD had a lower overall complication rate (50.1% vs 40.2%; OR, 1.50; 95% CI, 1.09-2.07). In addition, because there is an increase in the number of laparoscopic gastric banding procedures after implementation of the NCD, we examined specifically the outcomes of laparoscopic and open gastric bypass procedures performed before and after implementation of the NCD. After implementation of the NCD, Medicare patients (excluding Medicaid patients) who underwent laparoscopic or open gastric bypass benefited from a shorter length of hospital stay and lower overall pulmonary complication rates (**Table 5**).

#### COMMENT

The February 2006 Medicare bariatric surgery NCD expanded bariatric surgery coverage for Medicare beneficiaries to only institutions certified by the ACS or the ASMBS. These institutions must perform at least 125 bariatric operations per year and must have a system in place

**Table 5. Outcomes of Bariatric Surgery Within the 18 Months Before and After Implementation of the Medicare National Coverage Determination (NCD), Specifically for Medicare Patients Who Underwent Laparoscopic or Open Gastric Bypass<sup>a</sup>**

Outcomes	Before NCD (n=1614)	After NCD (n=1230)	OR (95% CI)
Length of hospital stay, mean (SD), d	3.9 (4.0) <sup>b</sup>	3.3 (4.0)	NA
Overall complications	260 (16.1) <sup>c</sup>	155 (12.6)	1.33 (1.07-1.64)
Pulmonary complications	52 (3.2) <sup>c</sup>	25 (2.0)	1.67 (1.03-2.73)
Cardiac complications	2 (0.1)	0 (0.0)	NA
Wound infection	27 (1.7)	12 (1.0)	2.29 (0.91-3.54)
Venous thrombosis or pulmonary embolism	23 (1.4)	4 (0.3)	1.96 (0.90-4.25)
Hemorrhage	29 (1.8)	16 (1.3)	1.24 (0.75-2.03)
Urinary tract infection	3 (0.2)	1 (0.1)	2.29 (0.24-22.03)
30-Day readmission	197 (12.2)	148 (12.0)	1.02 (0.81-1.29)
In-hospital mortality	6 (0.4)	4 (0.3)	1.34 (0.39-4.51)
Observed-to-expected mortality ratio	1.12	1.01	NA
Cost, mean (SD), \$	15 846 (12 435)	15 511 (10 556)	NA

Abbreviations: CI, confidence interval; NA, not applicable; OR, odds ratio.

<sup>a</sup>Data are presented as percentages unless otherwise indicated.

<sup>b</sup> $P < .01$  compared with after the NCD (2-sample  $t$  tests).

<sup>c</sup> $P < .05$  compared with after the NCD ( $\chi^2$  tests).

for bariatric coverage, sufficient hospital and operative equipment to care for morbidly obese patients, appropriate training of surgeons, physicians, and staff in the care of bariatric patients, and a system for long-term follow-up. In this study, we found that after implementation of the CMS bariatric surgery NCD, the mean number of institutions that perform bariatric surgery decreased from 60 to 45 centers, whereas the volume of bariatric surgical procedures remained the same (3196 procedures before vs 3068 procedures after). The mean number of bariatric procedures performed for Medicare beneficiaries increased from 35 procedures per year per institution before the NCD to 45 procedures per year per institution after the NCD. The volume of laparoscopic gastric banding doubled after the NCD, with a decrease in the volume of gastric bypass; however, the proportion of laparoscopic gastric bypass procedures increased from 60.0% before the NCD to 77.2% after the NCD. We also found that Medicare and Medicaid patients who underwent bariatric surgery after implementation of the NCD benefited from a shorter length of hospital stay, lower overall morbidity rate, and a trend toward an improved observed-to-expected mortality ratio. Although there was an immediate reduction in the volume of bariatric procedures performed for Medicare beneficiaries with implementation of the NCD, the procedure volume returned to baseline volume within 1 year and exceeded the baseline volume after 2 years of the NCD implementation. Within the context of this population-based study of academic centers, the CMS bariatric surgery NCD centralized the care of bariatric surgery for Medicare beneficiaries to a smaller group of high-volume centers, increased the volume of laparoscopic gastric bypass procedures, and improved the outcomes with

shorter length of stay and lower complication rates. These benefits occurred without evidence of limiting access to care for patients with medical disability.

In response to the development of centers of excellence by individual third-party payers, the concept of national accreditation of centers of excellence in bariatric surgery was developed by the leadership of the ASMBS.<sup>7,8</sup> Subsequently, the Surgical Review Corporation (SRC) was formed to develop the criteria for acceptance as centers of excellence, and a process for review and approval of these centers was implemented.<sup>9</sup> The SRC accredits both hospitals and surgeons. To date, 387 facilities and 670 surgeons have been accredited by the SRC. The ACS also developed its own accreditation program, the ACS Bariatric Surgery Center Network. Unlike the SRC accreditation program, the ACS program has 2 levels. The level 1 centers provide complete care, with resources devoted to bariatric surgery and high-volume practices performing 125 or more weight-loss operations annually with at least 2 experienced bariatric surgeons. The ACS level 2 centers provide high-quality care, with a lower volume of 25 or more weight loss operations performed annually with 1 or more experienced bariatric surgeons. These level 2 centers are not approved to perform bariatric surgery on high-risk patients, such as male patients with high body mass indexes (>55) and patients with medical disability. Currently, there are 77 approved ACS level 1 centers, 10 outpatient centers, and 35 level 2 centers. Efforts to unify the bariatric surgery accreditation process by these 2 accreditation bodies have been unsuccessful.<sup>10</sup>

In this study, we found that Medicare beneficiaries who underwent bariatric surgery after implementation of the NCD for CMS bariatric surgery benefited from a shorter hospital stay and lower overall morbidity rates. The reasons for improved outcomes are multifactorial. First, there is a clear association between volume and outcome in bariatric surgery. In a study that examined the outcomes of bariatric surgery according to volume, Nguyen et al<sup>11</sup> found that high-volume institutions (>100 procedures per year) had a shorter length of hospital stay, a lower overall complication rate, and a lower cost compared with low-volume institutions (<50 procedures per year). Second, the proportion of laparoscopic gastric bypass procedures increased from 60.0% to 77.2% after the NCD. In a randomized trial of laparoscopic vs open gastric bypass, Nguyen et al<sup>12</sup> found that patients who underwent laparoscopic gastric bypass benefited from a shorter hospital stay, less postoperative pain, reduced wound-related complications, and faster recovery. In this study, there was a precipitous decrease in the number of bariatric operations performed for Medicare beneficiaries immediately after implementation of the NCD because bariatric surgery for this high-risk patient population can only be performed within centers accredited by the ACS or ASMBS. In this study, the number of procedures performed on Medicare beneficiaries returned to baseline volume by the fourth quarter of 2006 and exceeded that of the baseline procedure volume after 2 years of the NCD implementation. This effect of the center of excellence designation on practice trends was reported by Keto and Kemmeter,<sup>13</sup> who noted that their accredited practice had an increase in the Medicare case load, which is an older and higher-risk patient population. Our study answered our original ques-

tion in that the CMS bariatric surgery NCD improved outcomes for Medicare beneficiaries without impeding access to care. Another noteworthy finding from our study is the low in-hospital mortality rate (0.2%-0.3%) for bariatric surgery among Medicare beneficiaries. Our results are in contrast to findings from Flum et al,<sup>3</sup> who reported a 30-day mortality rate of 2% among Medicare beneficiaries as derived from the 1996 to 2002 Medicare Part B database. The low mortality rate in our study may more accurately represent contemporary data derived from 2004 to 2007. However, it only represents in-hospital occurrences and may underestimate the true 30-day mortality rate.

This study has several limitations. The data derived from the UHC only represent in-hospital outcomes without follow-up data. Although data with regard to readmission to the same hospital are identified, any complications or deaths occurring during readmission to a different institution are not captured. The UHC database does not have the patients' weights or body mass indexes for all patients, and these are important factors in computing risk adjustment of outcomes. In addition, the coding of certain complications may be inaccurate because postoperative adverse events can be subjectively defined and may be coded differently (eg, leaks). However, in-hospital mortality and length of stay are accurate end points because they do not require subjective interpretation. This study is also limited to academic centers, and the results may not be generalizable to nonacademic institutions. In recognition of these limitations, this analysis with a large sample size is the first, to our knowledge, to demonstrate that implementation of the CMS bariatric surgery NCD improved outcomes for Medicare beneficiaries who underwent bariatric surgery.

In conclusion, by the use of a large, national clinical database of academic hospitals, this study analyzed the outcomes of Medicare beneficiaries who underwent bariatric surgery and found that the outcomes have improved since the implementation of the Medicare bariatric surgery NCD. Since the implementation of the NCD, the volume of bariatric procedures remained the same, whereas the number of institutions caring for morbidly obese patients decreased from 60 to 45. Concurrently, there was a doubling of laparoscopic gastric banding procedures and an increase in the proportion of laparoscopic gastric bypass procedures from 60.0% to 77.2%. Implementation of the NCD did not impede access to care because the volume of bariatric procedures performed on Medicare beneficiaries returned to baseline volume within 1 year after the NCD implementation and exceeded the baseline volume at 2 years after the NCD implementation. Although we only examined the Medicare beneficiaries population in this analysis, we suspect that the improvement in outcomes will also be extrapolated to the population that is not eligible for Medicare. Currently, there are more than 450 hospitals nationwide that are designated as centers of excellence in bariatric surgery by the ACS or the ASMBS.

**Accepted for Publication:** February 19, 2009.

**Correspondence:** Ninh T. Nguyen, MD, Department of Surgery, University of California, Irvine Medical Center, 333 City Bldg W, Ste 850, Orange, CA 92868 (ninhn@uci.edu).

**Author Contributions:** *Study concept and design:* Nguyen, Slone, Varela, Smith, and Hoyt. *Acquisition of data:* Nguyen and Hohmann. *Analysis and interpretation of data:* Nguyen and Hohmann. *Drafting of the manuscript:* Nguyen, Hohmann, Slone, Varela, Smith, and Hoyt. *Critical revision of the manuscript for important intellectual content:* Nguyen. *Statistical analysis:* Nguyen and Hohmann. *Obtained funding:* Nguyen. *Administrative, technical, and material support:* Nguyen, Slone, Varela, Smith, and Hoyt. *Study supervision:* Nguyen.

**Financial Disclosure:** None reported.

**Previous Presentations:** This study was presented at the Western Surgical Association Annual Meeting; November 12, 2008; Santa Fe, New Mexico.

**Additional Information:** The information contained in this article was based on information from the clinical database provided by the UHC.

## REFERENCES

1. Nguyen NT, Root J, Zainabadi K, et al. Accelerated growth of bariatric surgery with the introduction of minimally invasive surgery. *Arch Surg.* 2005;140(12):1198-1203.
2. Flum DR, Dellinger EP. Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg.* 2004;199(4):543-551.
3. Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA.* 2005;294(15):1903-1908.
4. Livingston EH, Elliott AC, Hynan LS, Engel E. When policy meets statistics: the very real effect that questionable statistical analysis has on limiting health care access for bariatric surgery. *Arch Surg.* 2007;142(10):979-987.
5. World Health Organization. *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).* Geneva, Switzerland: World Health Organization; 1977.
6. World Health Organization. *International Classification of Diseases, Ninth Revision (ICD-9).* Geneva, Switzerland: World Health Organization; 1977.
7. Bradley DW, Sharma BK. Centers of excellence in bariatric surgery: design, implementation, and one-year outcomes. *Surg Obes Relat Dis.* 2006;2(5):513-517.
8. Champion JK, Pories WJ. Centers of excellence for bariatric surgery. *Surg Obes Relat Dis.* 2005;1(2):148-151.
9. Pratt GM, McLees B, Pories WJ. The ASBS bariatric surgery centers of excellence program: a blueprint for quality improvement. *Surg Obes Relat Dis.* 2006;2(5):497-503.
10. Livingston EH. Can't we all get along?: the need to unify our efforts at bariatric surgery center accreditation. *Surg Obes Relat Dis.* 2006;2(5):565-566.
11. Nguyen NT, Paya M, Stevens CM, Mavandadi S, Zainabadi K, Wilson SE. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. *Ann Surg.* 2004;240(4):586-594.
12. Nguyen NT, Goldman C, Rosenquist CJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg.* 2001;234(3):279-291.
13. Keto JL, Kemmeter PR. Effect of center of excellence requirement by Centers for Medicare and Medicaid Services on practice trends. *Surg Obes Relat Dis.* 2008;4(3):437-440.