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VIA E-MAIL, FAX & FEDERAL EXPRESS

Mr. Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215-2299

Re: Proposed Revisions to the State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services COMAR 10.24.17

Dear Mr. Parker:

On behalf of Anne Arundel Medical Center ("**AAMC**"), this letter comments on the proposed permanent regulations to replace the State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services in COMAR 10.24.17 (the "**Proposed Chapter**"), in particular the portion of the regulations concerning cardiac surgery.

Thank you for your hard work on the Proposed Chapter, and for shepherding it through multiple drafts and rounds of stakeholder and legislative comment on its way to publication in the Maryland Register. The Proposed Chapter definitely moves Maryland closer to meeting the goal of making cardiac surgery "financially and geographically accessible consistent with efficiently meeting the health care needs of patients" in Maryland. Thank you in particular for your attention to the comments of AAMC throughout this process, and for staff's April 17 memorandum discussing the comments. AAMC offers the following comments on the Proposed Chapter.

§ .03 – Issues and Policies: *Access to Care*

Although the Proposed Chapter discusses access to care and equity of access regarding cardiac surgery in Maryland, that discussion discounts the importance of geographic proximity by asserting – without citation – that "quick access" is not necessary in cardiac surgery and that therefore "access to cardiac surgery services…is not a problem in Maryland…"[1] That assertion contradicts three important factors, and therefore should be revised.

The first factor is that local access correlates with lower in hospital mortality rates. A recent study found that high-risk "patients living near a CABG [coronary artery bypass graft] hospital with acceptable quality...had lower in-hospital mortality rates."[2]

This study is highly probative. Researchers analyzed data from hospitals of a neighboring state (Pennsylvania) for the time period 1995-2005, a period during which new CABG centers were opening.[3] Researchers found that, for high risk patients, mortality rates were 2 to 5 times higher among those that travelled further for CABG.[4] They also found a correlation between travel times and outcomes *excluding* "patients admitting from the emergency room, so as to focus on the health impacts of travel in nonemergency situations."[5] That is, travel time is relevant not only to "care in emergency conditions" but also "for one-time, nonemergent surgical patients". The study postulated that longer travel time may induce more stress, attenuate family support, confound care coordination, and additionally "delay preoperative procedures, impair preoperative education…or reduce the continuity of postoperative care."[6]

The second factor is the growing number of elderly cardiac surgery patients. The Maryland Department of Planning's State Data Center projects that Maryland's population of seniors aged 65 or older will rise ***38%*** in the decade between 2010 and 2020.[7] The same time period will also see an increase of persons aged 45-64.[8] The percentage increase in the senior population will be even greater in Anne Arundel County (~ 42%).[9] [1] "The increasing age of candidates is a distinctive feature of the current cardiac practice….and the number of elderly patients…with disease potentially eligible for surgery is expected to increase." As this aging population increases, cardiac surgery volumes may well increase and adequate access becomes a greater concern. Moreover, Maryland should expect growth in the percentage of elderly patients now recognized as new candidates for cardiac surgery due to new technology, specifically

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[1] Proposed Chapter § .03.

[2] Chou, S., Mary E. Deily, and Suhui Li. "Travel Distance and Health Outcomes for Scheduled Surgery." *Medical Care* 52.3 (2014): 250.

[3] *See Id* at 251.

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] Projections dated January 2014 (accessible at: http://planning.maryland.gov/MSDC/County/stateMD.pdf).

[8] *Id.*

[9] Projections dated January 2014 (accessible at: http://planning.maryland.gov/MSDC/County/anne.pdf).

percutaneous or transapical aortic valve replacement.[10] As the number of elderly patients increase, access issues become an even greater concern particularly in light of increased comorbidities, the need for multispecialty attention, and dependence on family members for this elderly population.

The third factor is policy changes under the new Medicare waiver test, the transition to Global Budget Reimbursement, and the associated transformations underway in care management. To comply with the modernized waiver, the Affordable Care Act and other Medicare initiatives such as Accountable Care Organization (ACOs), care should shift to Maryland hospitals that offer high value to payors and patients. Hospitals operating under a global budget have significant incentives to closely manage the care of their population, and seek the most cost efficient and high quality services. Local area networks will be able to provide coordinated care at low cost with a highly efficient process thereby improving outcomes. In this context, access to local providers and lower cost settings should be encouraged.

AAMC therefore suggests a change to the final paragraph of page 11 of the Proposed Chapter as follows[11]:

> Current geographic access to cardiac surgery services in Maryland does not preclude a finding that a particular regional or demographic disparity in access exists (such as for elderly or high-risk patients), or that new access to a high-value hospital may be advantageous. Metrics that would suggest such a finding could include quality, cost, and outcomes data as they relate to geographic access.

Please note that this suggested language does not press AAMC's previous suggestions regarding regionalization or preference for in-state facilities. Nor does it unequivocally state that any access or outreach issue exists. Rather, the suggested language is prudently agnostic.[12] It balances an assessment of Maryland's health system as a whole with attention to the Commission's mandate to ensure that the system provides **all** Marylanders with financial and geographic access to quality health care services.

§ .04(A)(1)(e) – Publication Schedule for New Cardiac Surgery Programs

[10] *See* Barretto-Filho et al, "Trends in Aortic Value Replacement for Elderly Patients in the United States." *Journal of the American Medical Association* 310:19 (November 20, 2013): 2078. "Between 1999 and 2011, the rate of

surgical AVR for elderly patients in the United States increased" in part "due to growing recognition that the benefits of aortic valve replacement extend to extremes in patient age" and also "earlier, preemptive aortic valve replacement in selected asymptomatic patients." *Id.*

[11] Changes to the Proposed Chapter text are coded herein as follows: Insertions; ~~Deletions;~~ Moves / ~~Moves~~

[12] This agnostic stance would make the Proposed Chapter's access discussion more consistent with the acknowledgement later in the Proposed Chapter [§ .05(A)(5)(a)] that an applicant may seek to "justify establishment of cardiac surgery services....based on inadequate access to cardiac surgery services in a health planning region."

Section .04(A)(1)(e) of the Proposed Chapter states that the Commission will publish a review schedule for establishing cardiac surgery services, but does not give guidance as to the timing of the review schedule. AAMC suggests that the following language be added:

> (e) A review schedule for receipt of letters of intent and applications seeking a CON to establish cardiac surgery services will be published in the Maryland Register for each health planning region where the condition in .04A(1)(d) is met. As with the introduction of new services or other specialized health care services, such review schedule will generally coincide with the review schedule for acute care hospital projects. Publication of a review schedule does not indicate that the Commission has determined an additional provider of cardiac services is needed in a region.

This change would: (1) give guidance to prospective applicants; (2) keep the scheduling rhythm for acute care projects consistent, for the convenience of all participants in the health planning process (including both applicants and reviewers); and (3) parallel the Commission's current practice with respect to the introduction of new services, or other specialized health care services such as neonatal intensive care units.[13]

§ .05(A)(6)(c) – CON Standard for Cardiac Surgery Programs:
Volumes and Diagnostic Cardiac Catheterization

AAMC appreciates that the Proposed Chapter now recognizes that surgical referrals from diagnostic cardiac catheterizations at a facility imperfectly predicts future cardiac surgery volumes at that facility. This is common sense; patients tend not to undergo that diagnostic procedure at a facility unable to perform the cardiac surgery that the diagnosis may prompt.

Section .05(A)(6)(c) of the Proposed Chapter, however, is still at risk of being misread as disqualifying an applicant from demonstrating its ability to meet the 200 case volume threshold unless the referrals from existing catheterization procedures alone amount to more than 200 cases per year, or otherwise at least make up some essential part of the need demonstration.

In that regard, AAMC proposes that § .05(A)(6)(c) of the Proposed Chapter read:

> An applicant's need analysis for a new program shall include current information about the number of patients referred for cardiac surgery following a diagnostic cardiac catheterization at the applicant hospital~~.~~, and ~~address how~~ shall incorporate this information ~~supports~~ into the applicant's demonstration that the proposed new program can generate at least 200 cardiac surgery cases per year.

[13] *See, e.g.,* 41:18 Md. R. 444-446 (April 4, 2014) (specifying identical letter of intent and application due dates for (1) schedule two for acute care hospital projects, and (2) schedule two for neonatal intensive care units).

The new language removes a risk of misinterpretation while still preserving the thrust of the original language. An applicant is still required to produce data regarding referrals from its diagnostic cardiac catheterization. An applicant is also still required to address how this information relates to the applicant's demonstration that it will meet the 200 case volume threshold.

§ .08(C)(2) – Effect of New Projects on Utilization Projections

This section ought to be eliminated because it is more likely to make applicants' utilization projections less accurate. When a new program opens, the program is likely to affect market share and patient migration patterns. That effect will not be captured if there is imposed an arbitrary assumption that those patterns will not change for a year after program opening.

§ .08(G)(1), § .08(H)(1), – Utilization Projection Methodology for Cardiac Surgery:
Use Rate Calculations

AAMC remains concerned that the Proposed Chapter will fail to predict growth in the cardiac surgery use rate accurately.

The Proposed Chapter's method of estimating the target year use rate overweights historical use rates. That is, in calculating the average annual percentage change in cardiac surgery use rates, the Proposed Chapter weights equally (1) the percentage change in use rate from the sixth year before the base year to the fifth year before the base year, and (2) the percentage change in use rate from the most recent two years of data. But in clinical terms, (2) is much more predictive of use rate trends than (1).

AAMC understands too that a linear regression methodology – its initial suggestion to address this issue – may be too complex an alternative. AAMC therefore proposes the following alternative method to replace § .08(G)(1), a method that is more accurate and less complex than the current methodology[14]:

> (a) Calculate the use rate of cardiac surgery for the residents of each health planning region, for ~~each of~~ the ~~six~~ fourth most recent ~~years~~ year and the most recent year of available data for each adult age group, by dividing the total number of surgery cases performed for each adult age group, in each health planning region, by the corresponding population for each health planning region.
>
> (b) Calculate the average annual percentage change in cardiac surgery use rates between the fourth most recent year and the most recent year for each adult age group, in each health planning region, by ~~summing the five percentage changes in use rates calculated for the six-year time period and~~

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[14] This change would also require parallel changes where the "average annual percentage change" and the need projection methodology are defined, such as in § .09 (definitions) and elsewhere in § .08 (e.g., for utilization projections for pediatric surgery).

~~dividing this sum by five.~~ calculating the third root of a fraction, the numerator of which is the use rate in base year, and the denominator of which is the use rate in the fourth most recent year of available data for each adult age group.

(c) Calculate the target year use rate of cardiac surgery cases for each adult age group, in each health planning region, by multiplying ~~one plus~~ the average annual percentage change in the cardiac surgery use rate for each age group, raised to the sixth power, by the corresponding use rate in the base year.

This alternative methodology is less complex. It requires calculation of fewer year-use rate pairings. It replaces five year-to-year calculations of use rate growth with one use rate growth calculation over for the entire historical "look-back" period. It eliminates the intermediate step of "summing" yearly use rate growth percentages garnered from the look-back period.

This alternative makes target year projections more accurate: it shortens the look-back period to a more clinically relevant time period of 4 years rather than 6 years. Under the current methodology, the use rate for a target year would be determined by the vagaries of use rates twelve years prior to that year. Although symmetry – a six-year look-back period for a six-year forward projection – may be aesthetically pleasing, there is no functional rationale for the symmetry. The current "average annual percentage change" variable is not a reflection of the ***actual*** use rate over each of the six prior years, but rather the ***change*** in use rate over that time.

Finally, this methodology subjects the "average annual percentage change" variable to less volatility over historical periods than in the current methodology. The methodology proposed here smooths away year-to-year oscillations during the look-back period. Compounded over six years going forward to the target year, this smoothing can be quite significant.

§ .09 Definition – Cardiac Codes

The definition for *Cardiac Surgery* includes certain procedure codes (based on ICD9 – International Classification of Diseases). AAMC has reviewed these codes and recommends that, to address the continuing evolution of cardiac surgery procedures, the following codes be included in the definition: 35.96, 37.35, 37.36, 39.65 and 39.66.

Your attention to these comments is appreciated. Please feel free to contact me to discuss these comments or request their elaboration or clarification.

Sincerely,

Victoria Bayless
President and CEO

cc: Ms. Paula Widerlite
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Travel Distance and Health Outcomes for Scheduled Surgery

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Background: Changes in the location and availability of surgical services change the distances that patients must travel for surgery. Identifying health effects related to travel distance is therefore crucial to evaluating policies that affect the geographic distribution of these services. We examine the health outcomes of coronary artery bypass graft (CABG) patients in Pennsylvania for evidence that traveling further to a hospital for a one-time, scheduled surgical procedure causes harm.

Methods: We perform instrumental-variable regressions to test for the effect of distance to the admitting hospital on the in-hospital mortality and readmission rates of 102,858 CABG patients in Pennsylvania during 1995–2005, where the instrumental variables are constructed based on the quality of and distance to nearby CABG hospitals.

Results: We found that patients living near a CABG hospital with acceptable quality traveled significantly less and if they were high-risk, had lower in-hospital mortality rates. Readmission rates in general are not affected by patients' travel distance.

Discussion: The positive correlation between travel distance and health outcomes observed by previous studies may reflect the confounding effects of behavioral factors and patient health risks. We found instead that living further from the admitting hospital increases in-hospital mortality for high-risk CABG patients. More research on the possible causes of these effects is necessary to identify optimal policy responses.

Key Words: travel distance, scheduled surgery, hospital quality, outcomes, CABG, regionalization, United States

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Changes in the location and availability of surgical services change the distances that patients must travel for surgery. For example, regionalizing surgical programs or adopting volume-based referral practices so that patients go to higher-volume centers for surgery would increase the distances many travel.[1–3] Conversely, removing regulatory barriers limiting entry of new surgical programs would decrease travel distances if more providers enter the market.[4] Identifying health effects related to travel distance is therefore crucial to evaluating policies that affect the geographic distribution of surgical services, but the causal relationship is difficult to identify because confounding factors such as patients' behavioral patterns and the quality of admitting hospitals are likely correlated with both travel distance and surgical outcomes. In this paper, we use a novel set of instrumental variables to determine whether travel distance affects health outcomes of patients having scheduled coronary artery bypass graft (CABG) surgery in Pennsylvania during the period 1995–2005.

Travel distance may most obviously affect health outcomes if it reduces utilization of preventive care or delays care in emergency conditions.[5,6] However, for one-time, nonemergent surgical patients, greater distances may result in worse health outcomes if they delay preoperative procedures, impair preoperative education of patients and families, reduce the amount of informal care provided by families, or reduce the continuity of postoperative care. Prior literature reveals that preoperative education and family support decrease patients' emotional stress, reduce deterioration of patients' functional and psychological status during the perioperative waiting period, and decrease postoperative complications.[7,8] The benefits of preoperative preparation may be particularly important for high-risk patients: preoperative intensive inspiratory muscle training, for example, can prevent postoperative pulmonary complications in high-risk patients undergoing CABG surgery.[9]

However, identifying the causal relationship between travel distance and health outcomes is difficult because unobserved preferences and characteristics of patients may be correlated with both travel distance and health outcomes. For example, patients may travel further because they have a stronger will to live that helps them achieve better outcomes, or they do so to be treated at "centers of excellence" and thus experience better outcomes.[10–13] In contrast, patients traveling further to seek better hospitals may be sicker and, thus, experience worse outcomes.[14] If, as we hypothesize, the true effect of greater travel distance is to cause harm, then regressing outcomes on travel distance results in coefficients that underestimate the true effect in the former case, biasing estimates toward zero, and overestimate the true effect in the latter case, biasing estimates away from zero. Identification is further complicated because travel distance is often measured with error, which will bias estimates toward zero.

We address these identification problems using a novel instrumental-variable approach that controls for potentially confounding factors and for measurement errors.[15] Our instrumental variables are based on the availability and quality of hospitals near a patient's home because of evidence showing that hospital patients strongly prefer to minimize their travel distance but also care about quality.[16–18] As patients value both hospital quality and less travel, the distance that patients actually travel will be correlated with the quality of nearby hospitals, but the quality of nearby hospitals will have no direct effect on patients' outcomes at their admitting hospitals.

We measure the quality of hospitals using report card grades for CABG surgery providers that have been published by Pennsylvania since the early 1990s. Although measures based on the distance to the closest hospital have been used as exogenous variables in a variety of studies,[19–23] this is, to the best of our knowledge, the first use of both the availability and the report card grades of nearby hospitals to create instrumental variables.

METHODS

Data and Sample

Patient data are from the PHC4 inpatient database, which includes patient sex, age, race, insurance type, diagnostic codes, and residential zip code, whether the procedure was scheduled, whether the patient died in the hospital, and an identification number and zip code for the admitting hospital. Each record also contains a patient identifier that allows us to link patient records from quarter to quarter. Our sample is drawn from the set of patients undergoing isolated CABG surgery (CABG surgery with no other major heart surgery during the same admission) in Pennsylvania hospitals during the period 1995–2005. (Our sample ends in 2005 because we only had data through 2006 and needed the last 12 mo to measure one of our outcomes variables.) Distance from a patient's home to a hospital is the straight-line distance from the centroid of a patient's residential zip code to the hospital's location as computed by the Geographic Information System. Hospital longitudes and latitudes are from the American Hospital Association *Annual Survey of Hospitals*.

We eliminated rural patients because almost all the CABG hospitals are located in more densely populated areas; therefore, the distance/quality trade-offs faced by rural patients may be quite different. We further eliminated patients admitted from the emergency room, so as to focus on the health impacts of travel in nonemergency situations. After eliminating observations missing data for any variable, our sample comprised 102,858 patients.

Outcome Equation

Our main specification is:

$$P(\text{Outcome}_{ijkt}) = a + b_1 * \text{Travel Distance}_{ijkt} + b_2 * P_{ijkt} + b_3 * AH_{kt} + H_k + Y_t + \epsilon_{ijkt} \quad (1)$$

where i is an individual patient residing in zip code j and undergoing s at admitting hospital k in year t, P_{ijkt} and AH_{kt} are vectors of patient and admitting-hospital characteristics, H_k and Y_t are fixed effects for admitting hospital (67 dummies) and year (10 dummies), and ϵ_{ijkt} is the error term.

We estimate the effect of travel distance on 2 different health outcomes, in-hospital mortality and readmission. For mortality, Outcome_{ijkt} is a dummy variable that equals one if the patient died in the hospital, and 0 if not. For readmission, Outcome_{ijkt} is a dummy variable that equals 1 if the patient was readmitted to any hospital during the 12 months following the quarter of their CABG surgery with a diagnosis of ischemic heart disease, congestive heart failure, or post-surgery infection. These conditions capture the most common causes of readmission following CABG surgeries.[24]

Instrumental Variables Estimation

Travel Distance_{ijkt}, the distance between the patient's zip code and the admitting hospital, is our proxy for the actual cost of travel in driving distance and time.[25] We instrument for this variable to control for confounding effects using information about the quality and location of a patient's nearby, as opposed to admitting, hospital. The first stage of the IV estimation is specified as:

$$\text{Travel Distance}_{ijkt} = \alpha + \beta_1 * IV_{jt} + \beta_2 * P_{ijkt} + \beta_3 * AH_{kt} + H_k + Y_t + \varepsilon_{ijkt}, \quad (2)$$

where IV_{jt} represents the instrumental variables, and the other variables are as defined in Eq. (1). The instrumental variables are based on the quality of CABG hospitals available near a patient's home, where CABG hospital quality is measured using the grades from *Pennsylvania's Guide to Coronary Artery Bypass Graft Surgery*, published by the Pennsylvania Health Care Cost Containment Council (PHC4).[26] Although these reports are available to patients, we do not assume that patients select hospitals based on the reported grades. Rather, we use these grades as proxies for patients' perceptions of hospital quality, which may be formed by their own experience, recommendations of their referring cardiologist, or word-of-mouth.[27]

In a report, a hospital receives a grade of "Same as expected" if its actual in-hospital mortality rate falls within a 95% confidence interval (CI) around its predicted mortality rate (a grade referred to in this paper as "as expected"). Hospitals with mortality rates that fall outside of a 95% CI around their predicted rate receive a "Lower than expected" grade, if their mortality rate falls below their 95% CI (a grade referred to here as "superior"), or a "Higher than expected" grade if it falls above (a grade referred to here as "poor"). Mortality rates are risk-adjusted, and hospitals must perform at least 30 isolated CABG procedures on adults in a year to receive a grade.

The report cards have been published at irregular intervals since the first was issued in 1992. The second column of Table 1 identifies the date of the most recent report card for each year in our sample (by quarter when there was >1 grade for the year), with the year in which the data for the report card were collected in parentheses. The next 3 columns of Table 1 show the number of hospitals with each type of grade each year, where the grade is the one most recently reported.

Some CABG operations occurred at hospitals that were not graded because <30 surgeries were performed at a hospital when the report card information was being collected or because the hospital started a CABG program after data for the report card were collected. The number of such facilities increased after December 1996, when Pennsylvania ended the Certificate of Need program that had restricted entry of CABG programs. As the new programs grew to the "gradable" threshold, the number of ungraded CABG providers fell, most sharply in 2002, the first year that report cards based on data collected after the CON regulations ended were issued (see columns 6 and 7 of Table 1).

We assign each hospital its most recent CABG report card grade in each period to measure its quality and add information about hospital locations to create 4 instruments. The first 2 IVs are categorical, measuring location by indicating whether or not at least one hospital of acceptable quality is located within a 10-mile radius of the patient, 10 miles being the median travel distance of our sample. IV1 equals one if there is a graded CABG hospital nearby. IV2 includes IV1 plus its interaction with a dummy variable that equals one if the nearby hospital's grade was average or superior. We expect the estimated coefficients to be negative because a patient likely travels less if a CABG hospital of acceptable quality is nearby.

These IVs identify patients who have a nearby hospital of acceptable quality with which they are likely to be familiar and more comfortable. However, our 10-mile radius is essentially arbitrary, so we also use a second set of IVs that measure location as the distance from the patient to the closest CABG hospital of acceptable quality. IV3 is the distance to the closest graded hospital. IV4 includes both the distance to the closest graded hospital and the distance to the closest hospital with an as-expected or superior grade. We expect the estimated coefficients to be positive because research suggests that patients strongly prefer their closest hospital but are willing to travel further for better quality.[16–18]

The equations were estimated using probit or IV probit (Stata, Version 12; StataCorp. College Station, TX). We assess the endogeneity of travel distance using a Durbin-Wu-Hausman test, under the null hypothesis that travel distance is exogenous.

Control Variables

P_{ijkt} in Eqs. (1) and (2) represents a set of patient characteristics that may affect the patient's health outcome, including dummy variables for patient gender (equals one if male), race (equals one if white), and age category, and whether the patient is covered by Medicare. (Virtually, all other patients are privately insured, with a few uninsured or covered by Medicaid.) We control for differences in patients' illness severity using their Elixhauser comorbidities,[28]

TABLE 1. Pennsylvania CABG Report Cards and Hospitals, 1995–2005

Year	Most Recent Report Card	No. Hospitals With Grades That Were			No. Hospitals That Were		
	Most Recent Report (Years of Data Collection)*	Poor	Average	Superior	Graded	Not Graded	No. CABG Patients†
1995	1st Qtr: 1994 (1992); 2nd–4th Qtr: 1995 (1993)	5	29	3	37	5	11,007
1996	1995 (1993)	5	29	3	37	5	11,611
1997	1995 (1993)	5	29	3	37	8	11,466
1998	1st Qtr: 1995 (1993); 2nd–4th Qtr: 1998 (1994–1995)	4	33	3	40	11	10,888
1999	1998 (1994–1995)	4	33	3	40	13	10,468
2000	1998 (1994–1995)	3	32	3	38	15	9875
2001	1998 (1994–1995)	3	32	3	38	19	9185
2002	1st Qtr: 1998 (1994–1995); 2nd–4th Qtr: 2002 (2000)	4	45	3	52	8	8422
2003	2002 (2000)	4	45	3	52	9	7533
2004	2004 (2002)	7	49	2	58	2	6708
2005	2005 (2003)	3	55	1	59	1	5975

*The report card released in the second quarter of 1998 reflects data from 1994 to 1995. Other report cards are based on data from a single year.
†Patients live in nonrural areas and underwent scheduled CABG procedures.

identified from patients' ICD-9 diagnosis codes at the time they were admitted for surgery. We include separate dummy variables for the top 10 comorbidities and summarize all other comorbidities into a single dummy variable that equals one if the patient had at least one of these conditions. We also include dummies to indicate whether 1, 2, 3, or 4 or more vessels were revascularized, and whether the surgery involved a cardiopulmonary bypass. Although we exclude patients admitted from the emergency room from our sample so as to focus on scheduled surgeries, we include 2 dummies to indicate whether those scheduled surgeries were emergent or urgent. Finally, we control for the season of the patient's surgery (3 dummies) and for the region of their residence (8 dummies).

AH_{kt} in equations (1) and (2) represents a set of admitting-hospital characteristics that may affect the patient's health outcome. These variables are: dummies indicating whether, in the most recent report card, the hospital is graded, the grade is as-expected or the grade is superior, the number of CABG surgeries performed at the hospital in the preceding year, the number of CABG surgeries performed by the operating surgeon in the preceding year, and the hospital size category.

RESULTS

Descriptive statistics are shown in Table 2 for the whole sample and by whether a patient lived near a graded hospital. Travel distance was shorter for patients living near a graded hospital, but the mean patient characteristics show no systematic differences, lending support to our assumption that the grade of the nearby hospital is randomly assigned among patients of different age and severity of illness.

The first-stage estimation results are reported in Table 3, with SEs clustered by admitting hospital. Means and SDs for each IV are reported in column (1). Travel distance has been rescaled from miles to hundreds of miles to make

TABLE 2. Descriptive Statistics by Hospital Quality and Location, and for Sample*

	(1) Whole Sample	(2) No Graded Hospital Nearby	(3) Graded Hospital Nearby
Death	0.020	0.022	0.019
One-year readmission†	0.263	0.263	0.262
Distance to admitting hospital (in hundreds of miles)	0.149 (0.160)	0.233 (0.159)	0.088 (0.131)
Patient characteristics‡			
Male	0.709	0.708	0.710
White	0.874	0.873	0.874
Medicare	0.531	0.515	0.542
Age, 50–59 y	0.192	0.200	0.187
Age, 60–69 y	0.317	0.321	0.314
Age, 70–79 y	0.342	0.328	0.353
Age, ≥ 80 y	0.079	0.074	0.082
Hypertension, uncomplicated	0.516	0.511	0.519
Chronic pulmonary disease	0.134	0.136	0.132
Peripheral vascular disorders	0.096	0.090	0.100
Obesity	0.076	0.076	0.076
Fluid and electrolyte disorders	0.073	0.072	0.073
Hypothyroidism	0.056	0.053	0.057
Diabetes, complicated	0.038	0.038	0.038
Diabetes, uncomplicated	0.224	0.228	0.222
Coagulopathy	0.034	0.035	0.034
Deficiency anemia	0.055	0.053	0.056
Other comorbidities§	0.025	0.023	0.026
1 vessel revascularized	0.140	0.142	0.138
2 vessel revascularized	0.329	0.339	0.322
3 vessels revascularized	0.314	0.310	0.317
4+ vessels revascularized	0.163	0.152	0.171
Cardiopulmonary bypass	0.774	0.784	0.767
Emergency	0.221	0.234	0.212
Urgent	0.280	0.316	0.254
Admitting-hospital characteristics			
Graded	0.925	0.896	0.947
Grades are average	0.776	0.726	0.813
Grades are superior	0.102	0.127	0.083
Lagged surgeon volume	138.806 (57.895)	137.983 (57.705)	139.409 (58.028)
Lagged hospital volume	528.382 (276.14)	538.904 (276.284)	520.669 (275.782)
Bed size between 200 and 400	0.303	0.275	0.323
Bed size above 400	0.638	0.659	0.623

*SDs for continuous variables are reported in parentheses.

†Sample sizes for readmission are smaller. They are 10,000 whole sample, 42,606 no graded hospital nearby, and 58,305 graded hospital nearby.

‡Patient characteristics also include 3 seasonal dummies and 8 regional dummies that are not shown in this table.

§This dummy variable equals 1 if the patient has ≥ 1 of the remaining Elixhauser comorbidities.

the coefficients easier to read. As expected, the coefficients for IV1 and IV2 are negative, for IV3 and IV4 are positive, and all are significant. The F statistics on the joint significance of all 4 IVs are >10, evidence against the possibility that the IVs are only weakly correlated with travel distance to the admitting hospital.[29]

Table 4 shows our main results. Estimates of the marginal effect of travel distance on in-hospital mortality and readmission using Probit are reported in columns 1 and 6; the other columns show the estimated relationships using IV Probit. The estimates in columns 1–5 suggest that patients traveling further for surgery were more likely to die in the hospital. The effect of travel distance on mortality is considerably larger when IV estimation is used (columns 2–5), suggesting that Probit estimates are downward biased because of measurement error or because of the confounding effects from patients with stronger wills to live traveling further or traveling further to a center of excellence. The estimates in columns 6–10 suggest that the correlation between travel distance and the readmission rate is not statistically significant.

Validity of Instrumental Variables

Our results for in-hospital mortality in particular hinge on the quality of our instrumental variables. For example, for the instrumental-variable "Lives near graded hospital" to be valid, it must be correlated with travel distance (as is demonstrated in Table 3) but not correlated with health outcomes. Although we cannot directly test this latter assumption, there is evidence to support its validity. First, health indicators such as age and the prevalence of comorbidities are similar between those patients who live near a graded CABG hospital and those who do not (Table 2), suggesting that there is no obvious selection based on health conditions that would explain the different mortality rates.

Second, if the assumption is true, we can calculate a simple Wald estimate of the effect of travel distance on health outcomes by dividing the decrease in the mortality rate due to being near a graded hospital (the difference between columns 2 and 3 in Table 2, or 0.3 percentage points) and by the decrease in travel distance due to being near a graded hospital (the difference between columns 2 and 3, translated to hundreds of miles, or 0.145).[30] The Wald estimate ($-0.3/-0.145$) indicates that every additional 100 miles of travel is associated with a 0.021 increase in the mortality rate, which is very close to the estimates reported for IV1 and IV2 on Table 4 and suggests that living near a graded hospital is not correlated with observable differences in mortality rates.

Third, if our IVs do capture crucial elements concerning a patient's hospital choice, so that living near a graded hospital leads to shorter travel distances to the admitting hospital, then we would expect to see a larger effect if the hospital has an average or superior grade. Columns 3 and 5 of Table 3 show results consistent with this expectation.

Fourth, including the IVs in the main specification does not change our results, and the IV coefficients are insignificant. Finally, we reestimated the specification as a linear probability model so we could test the relevance of the IVs after the first-stage estimations using a Kleibergen-Paap rank LM test, under the null hypothesis that the instruments are jointly uncorrelated with travel distance,[31,32] and the validity of the IVs using the Hansen's J test, under the null hypothesis that the instruments are jointly exogenous.[31,33] Test results indicated that the IVs are strong and that there is no overidentification problem when using IV2 or IV4.

Patient Severity

We investigate whether traveling further was more harmful for sicker patients by reestimating our equations on subsamples of low-severity (Elixhauser index <2) and high-severity (Elixhauser index ≥ 2) patients. (First-stage results were similar to those on Table 3.) The results in columns 2–5 of Table 5 indicate that travel distance did not affect the mortality of relatively healthy patients, once the effects of endogeneity are controlled. However, for high-severity patients, mortality rates were 2 to 5 times higher among those

TABLE 3. First-stage Results on the Effects of Hospital Grades on Patient Travel Distance†

	(1) Mean (SD)	(2) IV1	(3) IV2	(4) IV3	(5) IV4
Live near graded hospital	0.577 (0.494)	−0.127*** (0.008)	−0.043* (0.023)		
Live near hospital with average or superior grade	0.550 (0.498)		−0.088*** (0.022)		
Distance to the closest graded hospital‡	0.109 (0.093)			0.936*** (0.059)	0.329** (0.162)
Distance to the closest hospital with average or superior grade‡	0.115 (0.096)				0.613*** (0.137)
F statistics on joint significance of instrumental variables		259.5	147.6	253.4	182.2
Sample size	102,858	102,858	102,858	102,858	102,858

†The first-stage estimates an OLS model of patient's actual travel distance. The equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable "Travel distance" are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

‡Values of distance to the closest graded hospital and to the closest hospital with average or superior grade are divided by 100.

*Significant at the 10% level.

**Significant at the 5% level.

***Significant at the 1% level.

TABLE 4. Travel Distance to Admitting Hospital and Health Outcomes†

	Mortality					Readmission				
	(1) Probit	(2) IV1	(3) IV2	(4) IV3	(5) IV4	(6) Probit	(7) IV1	(8) IV2	(9) IV3	(10) IV4
Travel distance	0.008*** (0.002)	0.022*** (0.008)	0.022*** (0.008)	0.014*** (0.004)	0.013*** (0.004)	0.008 (0.012)	0.024 (0.033)	0.021 (0.032)	0.007 (0.025)	0.006 (0.024)
Durbin-Wu-Hausman Test		2.067	2.395	0.489	0.258		0.396	0.291	0.002	0.005
P		0.150	0.122	0.484	0.611		0.529	0.589	0.966	0.943
Sample size	102,858	102,858	102,858	102,858	102,858	100,911	100,911	100,911	100,911	100,911

†Marginal effects of travel distance are reported. Equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable "Travel distance" are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

*Significant at the 10 %level.

**Significant at the 5% level.

***Significant at the 1% level.

TABLE 5. Health Outcomes and Travel Distance to Admitting Hospital, By Patient Severity†

	Mortality					Readmission				
	(1) Probit	(2) IV1	(3) IV2	(4) IV3	(5) IV4	(6) Probit	(7) IV1	(8) IV2	(9) IV3	(10) IV4
Low-severity patients										
Travel distance	0.005** (0.003)	0.001 (0.009)	0.003 (0.009)	0.006 (0.006)	0.006 (0.006)	0.020 (0.018)	0.059* (0.036)	0.055 (0.035)	0.021 (0.032)	0.023 (0.031)
Durbin-Wu-Hausman Test		0.614	0.303	0.0387	0.0435		2.173	1.814	0.003	0.028
P		0.433	0.582	0.844	0.835		0.140	0.178	0.958	0.868
Sample size	57,386	57,386	57,386	57,386	57,386	56,515	56,515	56,515	56,515	56,515
High-severity patients										
Travel distance	0.009*** (0.002)	0.050*** (0.015)	0.048*** (0.014)	0.024*** (0.008)	0.022*** (0.008)	−0.007 (0.016)	−0.016 (0.045)	−0.018 (0.044)	−0.003 (0.037)	−0.007 (0.036)
Durbin-Wu-Hausman Test		9.311	8.963	2.573	1.849		0.0553	0.0843	0.0205	0.000
P		0.002	0.003	0.109	0.174		0.814	0.772	0.886	0.999
Sample size	44,530	44,530	44,530	44,530	44,530	44,396	44,396	44,396	44,396	44,396

†Marginal effects of travel distance are reported. Equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable "Travel distance" are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

*Significant at the 10% level.

**Significant at the 5% level.

***Significant at the 1% level.

who traveled further. Moreover, the Durbin-Wu-Hausman test rejects the hypothesis that travel distance is exogenous for these patients, suggesting that Probit estimation underestimates the true effect of travel distance on severely ill patients because of better outcomes among those who travel further to centers of excellence or who have stronger wills to live.

Columns 6–10 of Table 5 again show that travel distance has little effect on readmission. Although results from IV1 indicate that low-severity patients might be experiencing higher readmission rates, the estimated effect is marginally significant, and travel distance is not significant in the other specifications.

DISCUSSION

We use IVs based on the quality of nearby hospitals to investigate whether traveling further to a hospital for a one-time, scheduled, surgical procedure harms patients. The results of the first-stage estimations imply that the local availability of better quality hospitals was associated with less travel for patients. Estimation of our main specification suggests that in-hospital mortality rates are higher for more severely ill patients who travel further to their admitting hospital. Readmission rates did not appear to be strongly related to travel distance.

The number of CABG surgery centers increased during our sample period because in December 1996, Pennsylvania repealed its Certificate of Need law, which, until then, had restricted the entry of new CABG programs. Consequently, the average distance traveled by severely ill patients in our sample fell by 2.66 miles during our sample period. Multiplying this reduction by the estimated coefficients in Table 5 (0.00022 and 0.0005 when rescaled to represent deaths per additional mile traveled), we concluded that mortality rates fell by 0.0005852 to 0.00133 because of shorter travel distances, a reduction of 4.5%–10.23% (based on a mean mortality of 0.013 for severely ill patients over the sample period).

Our results are in line with those of a very different study that compared predicted to actual outcomes for patients undergoing a number of different types of elective surgeries at the Mayo Clinic, which relied on risk-adjusting to control for confounding effects and which came to the unexpected conclusion that patients who lived closer to the hospital did better than predicted.[14] Such findings contribute to the debate as to the desirability of steering patients to high-volume providers for specialized surgery.[1,3] The mortality effects we found are small but provide evidence that travel distance may negatively affect health outcomes even for the type of complex surgery most likely to benefit from greater regionalization. However, given the potential gains from increased surgical volume and the cost of new programs,[4,34–36] the appropriate policy goal may be to try to improve the quality of care at existing locations rather than increasing the number of providers.[37]

Our analysis has limitations. Although our results about the effects of travel may generalize to other types of scheduled surgery, the specific findings apply to CABG patients in Pennsylvania. Further, our readmission data are confined to readmission in the quarter following surgery and may be missing important readmissions occurring sooner after a patient's operation occurs. This may partly explain why we did not find a precise effect on readmission. We also lack data on whether a patient dies once they have left the hospital, so we are unable to discern the effects of travel on other important patient outcomes such as 7-day or 30-day mortality.

Finally, although our analysis suggests that longer travel distance harms patients, we do not identify the specific causes of harm. Various mechanisms such as psychological stress, lack of family support, and difficulties in coordinating care may explain why outcomes are worse for patients who travel further, but each mechanism calls for a different response, such as providing preoperative care and education at more locations, or supplementing the informal care provided by families by encouraging the use of hospitalists, intensivists, and/or information technology. More research on why travel distance affects health outcomes is necessary before the appropriate policy responses can be determined.

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Trends in Aortic Valve Replacement for Elderly Patients in the United States, 1999-2011 FREE

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ABSTRACT

Importance There is a need to describe contemporary outcomes of surgical aortic valve replacement (AVR) as the population ages and transcatheter options emerge.

Objective To assess procedure rates and outcomes of surgical AVR over time.

Design, Setting, and Participants A serial cross-sectional cohort study of 82 755 924 Medicare fee-for-service beneficiaries undergoing AVR in the United States between 1999 and 2011.

Main Outcomes and Measures Procedure rates for surgical AVR alone and with coronary artery bypass graft (CABG) surgery, 30-day and 1-year mortality, and 30-day readmission rates.

Results The AVR procedure rate increased by 19 (95% CI, 19-20) procedures per 100 000 person-years over the 12-year period (*P*<.001), with an age-, sex-, and race-adjusted rate increase of 1.6% (95% CI, 1.0%-1.8%) per year. Mortality decreased at 30 days (absolute decrease, 3.4%; 95% CI, 3.0%-3.8%; adjusted annual decrease, 4.1%; 95% CI, 3.7%- 4.4%) per year and at 1 year (absolute decrease, 2.6%; 95% CI, 2.1%-3.2%; adjusted annual decrease, 2.5%; 95% CI, 2.3%-2.8%). Thirty-day all-cause readmission also decreased by 1.1% (95% CI, 0.9%-1.3%) per year. Aortic valve replacement with CABG surgery decreased, women and black patients had lower procedure and higher mortality rates, and mechanical prosethetic implants decreased, but 23.9% of patients 85 years and older continued to receive a mechanical prosthesis in 2011.

Conclusions and Relevance Between 1999 and 2011, the rate of surgical AVR for elderly patients in the United States increased and outcomes improved substantially. Medicare data preclude the identification of the

causes of the findings and the trends in procedure rates and outcomes cannot be causally linked. Nevertheless, the findings may be a useful benchmark for outcomes with surgical AVR for older patients eligible for surgery considering newer transcatheter treatments.

Aortic valve disease in the United States is a major cardiovascular problem that is likely to grow as the population ages.[1-5] Aortic valve replacement is the standard treatment even for very elderly patients despite its risks in this age group.[6] With transcatheter aortic valve replacement emerging as a less invasive option,[7-9] contemporary data from real-world practice are needed to provide a perspective on the outcomes that are being achieved with surgery.

Changes in practice during the past decade are partly due to growing recognition that the benefits of aortic valve replacement extend to extremes in patient age.[10,11] There is also a recommendation for consideration of earlier, preemptive aortic valve replacement in selected asymptomatic patients[12] and strong guidance that bioprostheses rather than mechanical valves be used for patients 65 years or older.[13,14] There is also uncertainty about the benefit of performing coronary artery bypass graft (CABG) surgery during aortic valve replacement in patients with stable coronary disease.[8,15,16] Previous studies have indicated that rates of aortic valve replacement are increasing and outcomes are improving[17-20] but do not provide population-based rates and long-term follow-up.[17-20]

We therefore studied aortic valve replacement among Medicare fee-for-service beneficiaries between 1999 and 2011. We calculated trends in rates of surgical aortic valve replacement and outcomes defined as mortality, readmission, and length of stay. In addition, we compared the outcomes of patients who had CABG surgery and aortic valve replacement with those who had replacement alone and assessed rates of use of mechanical prostheses, which generally are not recommended for patients 65 years or older in the absence of another reason for anticoagulation.[21,22] Because variation in patterns of care and outcomes across subgroups may indicate opportunities for quality improvement, we also calculated these trends by age, sex, and race.

METHODS

Institutional review board approval for this study was obtained through the Yale University Human Investigation Committee. We identified all Medicare fee-for-service patients from January 1, 1999, to December 31, 2011, using the inpatient administrative data from the Centers for Medicare & Medicaid Services (CMS). We identified patients who underwent aortic valve replacement based on the principal discharge diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* codes 35.21 [aortic valve surgery replacement with bioprosthesis], and 35.22 [aortic valve surgery replacement with mechanical prosthesis]; eTable 1 in the Supplement). We excluded 566 patients who underwent aortic valve repair, 37 412 who underwent aortic valve replacement with concomitant mitral valve surgery, and 4007 who underwent tricuspid valve surgery from the years 1999 to 2011, and 2961 who had endocarditis as their principal diagnosis. For a small group of patients who had more than 1 aortic valve replacement during any of the study years—a proportion that decreased over time (n=389, or 1.5% in 1999 and 44 or 0.1% in 2011)—we selected the first procedure. We linked aortic valve replacement data with Medicare denominator files to obtain mortality information and to determine the eligibility of the beneficiaries and their length of time in the fee-for-service program.

We collected data on patients' age, sex, race, and common comorbidities. Race was determined from the Medicare denominator files, which used patient-reported data from the Social Security Administration.[23] We selected 21 comorbidities in categories of cardiovascular disease (hypertension, diabetes mellitus, atherosclerotic disease, unstable angina, prior myocardial infarction, prior heart failure, peripheral vascular disease, stroke, non–stroke cerebrovascular disease), geriatric conditions (dementia, functional disability, malnutrition), and miscellaneous (renal failure, chronic obstructive pulmonary disease, pneumonia, respiratory failure, liver disease, cancer, major psychiatric disorders, depression, and trauma) based on the method used by CMS for profiling hospitals for acute myocardial infarction and heart failure.[24,25] We identified comorbidities from diagnosis codes of all patient hospitalizations for any cause, primary or secondary, up to 1 year before the initial hospitalization for aortic valve replacement. Comorbidity data from 1998 were used for patients who underwent an aortic valve replacement in 1999.

We calculated person-years for each beneficiary to account for new enrollment, disenrollment, or death during an index year. For each year, we linked person-year data with aortic valve replacement hospitalization data to obtain rates of aortic valve replacement by dividing the total number of aortic valve replacements by the corresponding person-years of beneficiaries.[26] Using CABG codes (*ICD-9*, 36.1x), we determined the proportion of aortic valve replacement performed with and without CABG surgery (eTable 1 in the Supplement). We also determined the type of aortic valve replacement performed using codes for replacement with bioprosthesis and replacement with mechanical prosthesis, as described above.

In-hospital mortality was defined as deaths occurring during the index aortic valve replacement-specific hospitalization. To standardize the follow-up period, we used 30-day and 1-year mortality rates, defined as the rate of deaths due to all causes that occurred within 30 days or 1 year from the first procedure date during the index hospitalization for aortic valve replacement. We divided length of stay into 2 phases: *preprocedure length of stay*, defined as the difference in days between the procedure and admission dates, and *postprocedure length of stay*, defined as the difference in days between the discharge and procedure dates. We defined 30-day readmission as rehospitalizations for all causes occurring within 30 days from the date of discharge, using November 30, 2011, as the final date of discharge for complete follow-up.[26,27]

We express the rate of aortic valve replacement per 100 000 person-years, the rates of mortality and readmission as percentages, and length of stay as median (interquartile range) days. We used the Mantel-Haenszel χ^2 test to determine the statistical significance of temporal changes in observed outcomes and patient characteristics. To evaluate changes in rates of aortic valve replacement, we fit a mixed-effects model with a Poisson link function and state-specific random intercepts, adjusting for age, sex, and race. To estimate changes in the rates of mortality (30-day and 1-year), we used the same mixed model with a logit-link function and hospital-specific random intercepts, adjusting for patient age, sex, race, and comorbidities. To assess change in rates of 30-day readmission, we constructed a Cox proportional hazards model with death as a censoring event and adjusting for age, sex, race and comorbidity. We used the method developed by Lin et al[28] to check the adequacy of the Cox regression model and found the proportional hazards assumption was satisfied.

All models included an ordinal time variable ranged from 0 to 12, corresponding to the years 1999 to 2011, to represent the annual changes in outcomes. The incidence rate ratio (RR) of the time variable was used to represent the age-, sex-, and race-adjusted annual changes in the aortic valve replacement rate, and the odds ratio (OR) and hazard ratio (HR) of the time variable were used to represent the age-, sex-, and race-comorbidity–adjusted annual changes in mortality and readmission rates, respectively. We repeated models for age, sex, and race subgroups.

Dr Wang performed all analyses using SAS version 9.2 (SAS Institute Inc). Statistical tests were 2-sided at a significance level of .05.

RESULTS

The final sample consisted of 409 591 889 records, representing 82 755 924 beneficiaries aged 65 years or older with at least 1 month of enrollment in Medicare fee-for-service during the study period (2 542 827 477 person-years). Patient age, sex, and race remained mostly unchanged over time but several comorbidities were more commonly coded, including hypertension (51.8% in 1999, 65.7% in 2011), diabetes mellitus (21.0% in 1999, 27.7% in 2011), and renal failure (2.4% in 1999, 10.4% in 2011). Atherosclerotic disease (60.7% in 1999, 57.2% in 2011) and history of heart failure (18.4% in 1999, 17.6% in 2011) were reported less frequently (P <.001 for trend) (Table 1 and eTable 2, in the Supplement).

Table 1. Characteristics of Patients Hospitalized for Aortic Valve Surgery, 1999-2011

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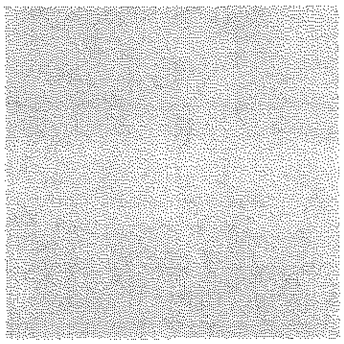
Rates of aortic valve replacement increased by 19 (95% CI, 19-20) procedures per 100 000 person-years between 1999 and 2011 (93 in 1999, 112 in 2011; *P* <.001 for trend); the rate of aortic valve replacement without CABG surgery increased (40 in 1999, 64 in 2011; increase, 24 [95% CI, 23-24] procedures per 100 000 person-years; *P* <.001 for trend) and the rate of aortic valve replacement with CABG surgery decreased (53 in 1999, 48 in 2011; decrease, 5 [95% CI, 4-5] procedures per 100 000 person-years; *P* < .001 for trend). Procedure rates increased in all age, sex, and race strata, most notably in patients 75 years or older (Table 2 and eTable 3, in the Supplement). The findings did not change substantially after accounting for age, sex, race, and state.

Table 2. Hospitalization Rates for Aortic Valve Surgery, 1999-2011



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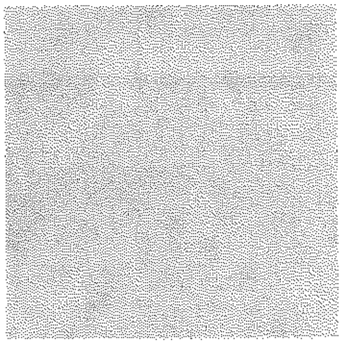
The age-, sex-, and race-adjusted change was 1.6% (95% CI, 1.0%-1.8%; incidence RR, 1.016 [95% CI, 1.01-1.018]) increase per year for all aortic valve replacement procedures, 4.1% (95% CI, 3.9%-4.2%; incidence RR, 1.041 [95% CI, 1.039-1.042]) increase per year for aortic valve replacement without CABG surgery, and 0.5% (95% CI, 0.2%-0.6%; incidence RR, 0.995 [95% CI, 0.994-0.998]) decrease per year for aortic valve replacement with CABG surgery. The direction of change was similar by age, sex, and race strata except for a small increase in rates of aortic valve replacement with CABG surgery among patients 75 years or older (eFigure, eTable 4 in the Supplement).

Between 1999 and 2011, 30-day mortality rates decreased an absolute 3.4% (95% CI, 3.0%-3.8%) for all aortic valve replacement, an absolute 3.1% (95% CI, 2.6%-3.7%) for aortic valve replacement without CABG surgery, and an absolute 3.2% (95% CI, 2.6%-3.8%) for aortic valve replacement with CABG surgery. One-year mortality rates also decreased by an absolute 2.6% (95% CI, 2.1%-3.2%) for all aortic valve replacements, 2.2% (95% CI 1.5% to 3.0%) for aortic valve replacement without CABG surgery, and 2.4% (95% CI 1.6% to 3.2%) for aortic valve replacement with CABG surgery. The decreases were similar among all age, sex, and race strata (Table 3 and eTable 5, in the Supplement) and did not change substantially after accounting for patient characteristics and hospital. Age-, sex-, and race-comorbidity–adjusted decreases in 30-day mortality rates were 4.1% (95% CI, 3.7%-4.4%) per year (OR, 0.959; 95% CI, 0.956-0.963) for overall aortic valve replacement, 4.7% (95% CI, 4.2%-5.3%) per year (OR, 0.953, 95% CI, 0.947-0.958) for aortic valve replacement without CABG, and 3.4% (95% CI, 2.9%-3.8%) per year (OR, 0.966; 95% CI, 0.962-0.971) for aortic valve replacement with CABG surgery. Similarly, the age-, sex-, and race-comorbidity–adjusted decreases in 1-year mortality rates were 2.5% (95% CI, 2.3%-2.8%) per year (OR, 0.975; 95% CI, 0.972-0.977) for all aortic valve replacement, 2.8% (95% CI, 2.3%-3.2%) per year (OR 0.972, 95% CI, 0.968-0.977) for aortic valve replacement without CABG surgery, and 2.1% (95% CI, 1.7%-2.5%) per year (OR, 0.979; 95% CI, 0.975-0.983) for aortic valve replacement with CABG surgery. The decreases were seen among all age, sex, and race strata with the exception of a nonstatistically significant estimate of no change in 1-year mortality among nonwhite nonblack women undergoing aortic valve surgery with CABG surgery (eFigure, eTables 6 and 7 in the Supplement). Although decreases in mortality were comparable within sex and race strata, women nevertheless had higher 30-day and 1-year mortality than men, and black patients had higher mortality than white patients in every study year.

Table 3. Outcomes of Aortic Valve Replacement Surgery, 1999-2011



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Median length of stay was unchanged (Table 3 and eTable 5, in the Supplement). Thirty-day readmission rates decreased slightly for aortic valve replacement procedures overall and with and without CABG surgery (Table 3). Age-, sex-, and race-comorbidity–adjusted decreases in 30-day readmission rates were 1.1% (95% CI, 0.9%-1.3) per year (HR, 0.989; 95% CI, 0.987-0.991) for overall aortic valve replacement, 1.3% (95% CI, 1.1%-1.6%) per year (HR, 0.987, 95% CI, 0.984-0.989) for aortic valve replacement without CABG surgery and 0.8% (95% CI, 0.5%-1.1%) per year (HR, 0.992; 95% CI, 0.989-0.995) for aortic valve replacement with CABG surgery (eFigure, eTable 8 in the Supplement).

Use of bioprostheses in aortic valve replacement increased from 44.1% in 1999 to 72.7% in 2011 ($P < .001$). Conversely, mechanical prosethetic implants decreased from 55.9% to 27.3% ($P<.001$). Among age, sex, and race strata in 2011, use of bioprostheses was highest for patients who were 85 years or older, men, and white (eTable 9 in the Supplement). In 1999, 46.2% of patients 85 years or older received a mechanical prosthesis, decreasing to 23.9% in 2011.

DISCUSSION

Our study describes a national increase in the rates of aortic valve replacement and a reduction in mortality, readmission, and length of stay for Medicare beneficiaries undergoing the procedure from 1999 through 2011. Rates of aortic valve replacement without CABG surgery increased while rates of aortic valve replacement with it decreased, but adjusted annual decreases in 30-day mortality were comparable for either procedure. Mechanical aortic valve prostheses continued to be used in about a quarter of elderly patients in 2011.

Several studies have investigated this topic with less contemporary cohorts, but direct comparison between our results and those of other studies is difficult because other studies looked at smaller cohorts and few provided a comprehensive national perspective or reported standardized short- and long-term outcomes.[8,18,19,29,30] Goodney et al,[31] using Medicare data from 1994 to 1999, reported that in-hospital mortality for aortic valve replacement (54% performed with CABG surgery) was 8.8%, ranging from 6% to 13%. Lee et al,[19] using the Society of Thoracic Surgeons database, showed that operative mortality for aortic valve replacement decreased from 5.6% during the years 1993-1997 to 4.4% during the years 2003-2007. Brown et al[18] focused on aortic valve replacement without CABG surgery in the Society of Thoracic Surgeons database and reported higher survival rates, with age-, sex-, and race-comorbidity–adjusted operative mortality decreasing from 3.5% to 2.4% between 1997 and 2006. Our data set extended to 2011, and we found higher mortality for patients undergoing aortic valve replacement without CABG surgery (6.6% in 1999 and 3.5% in 2011), which we believe is likely due to the older age of our population and our use of 30-day (rather than in-hospital) mortality as an outcome measure. In addition to providing more contemporary estimates, our study provides longer-term (1-year) mortality outcomes, data on readmission, and outcomes from centers that may not have been captured in Society of Thoracic Surgeons data.

Across all years of observation, we found lower procedure rates and higher mortality in black patients than in white patients. Racial differences in aortic valve disease or black patients being referred at a later stage of illness and having less access to the procedure may be factors.[32-36] Similarly for women, procedure rates were lower and mortality was higher. A report from the Society of Thoracic Surgeons database of patients undergoing aortic valve replacement without CABG surgery described a similar finding: fewer patients undergoing the procedure were women (43% women vs 57% men) and mortality was higher among women (2006 mortality: 3.2% in women, 2.1% in men).[19] We could not determine reasons for any differences from the Medicare data set, but they point to a worthwhile direction for future investigation. Encouragingly, mortality rates declined among all subgroups from 1999 to 2011, although residual differences persisted.

There are several potential explanations for the increase in the use of aortic valve replacement among older adults, including better access to specialized health care centers and enhanced awareness of the therapeutic benefit of aortic valve replacement independent of patient age among health care professionals.[11] The increase in age and comorbidities among patients undergoing aortic valve replacement suggest that the recommendation to perform preemptive aortic valve surgery earlier in the disease course had not taken hold during the study period. Although the largest increase in rates of aortic valve replacement occurred in those aged 85 years or older, a group in which the rate of 1-year mortality was 17.5% by 2011, these patients still underwent surgery less commonly than those aged 75 through 84 years, despite the known increasing prevalence of aortic stenosis with advancing age.[1] This finding suggests that there is a significant residual population of very elderly patients with aortic stenosis for whom transcatheter aortic valve replacement may emerge as a common treatment modality. In that context, our findings could provide a useful benchmark of outcomes with surgical aortic valve replacement among eligible patients who may also be considering transcatheter aortic valve replacement.

Approximately 50% of aortic valve replacement procedures were performed with CABG surgery, and we could not determine from our data whether the decrease in aortic valve replacement with CABG surgery over time reflected changing coronary anatomy among the study population (eg, lower prevalence of lesions amenable to surgical revascularization), an increasing use of preprocedural or postprocedural percutaneous coronary intervention, or some other factor. The treatment of chronic coronary artery disease in the setting of aortic valve replacement is uncertain and evolving.[15] CABG surgery continues to be performed during aortic valve replacement in cases of anatomical coronary obstruction. Future studies are needed to investigate whether the current practice of aortic valve replacement plus CABG surgery for patients with stable coronary artery disease is preferable to other strategies such as aortic valve replacement plus watchful waiting, aortic valve replacement plus percutaneous coronary intervention (hybrid procedure), or transcatheter aortic valve replacement plus percutaneous coronary intervention.[8]

Previous studies reported a progressive shift toward the use of bioprostheses in the aortic position, but rates of use of mechanical prostheses are still quite high.[17,18,37] The debate surrounding the optimal prosthesis for elderly patients remains unresolved.[30,38,39] In similar instances of clinical uncertainty, some experts recommend shared decision making.[40] The 1998 guidelines for managing valvular heart disease from the American Heart Association and the American College of Cardiology recommended the use of bioprosthetic valves in the aortic position for patients 65 years or older.[13,38,39] Our administrative data, however, lacked detailed information that could explain the high rate of use of mechanical prostheses. Small native aortic valve annulus or preexisting clinical conditions for anticoagulation may represent some appropriate uses of mechanical prostheses in the elderly. The high rates of mechanical prostheses that we observed in 2011 raise concern about whether this practice is in the best interest of patients.

This study has several limitations. First, our findings are observational and multiple factors may have accounted for the observed trends (eg, patient selection, health care system changes, secular changes). We cannot determine the underlying causes due to the limitations of administrative data. Second, our mortality adjustment models used comorbidity information based on administrative data and did not include some relevant clinical information that could have improved the modeling process, such as patient functional status, left ventricular function, the pathological process associated with aortic valve dysfunction, previous cardiac surgery, or the distinction between elective or urgent aortic valve replacement.[41] Third, we used Medicare claims data to infer trends in the type of surgery performed (bioprosthetic implant or mechanical prostheses). Because we used codes for the primary diagnosis, aortic valve disease may have been misclassified as the primary diagnosis in cases of aortic dissection or aneurysm with concomitant aortic valve disease. However, this would represent a very small number of patients. Fourth, our cohort was limited to Medicare fee-for-service beneficiaries, and thus we cannot comment on trends among patients enrolled in Medicare managed care programs or among patients younger than 65 years. Because more patients have enrolled in Medicare managed care programs over time,[42] the Medicare fee-for-service population may have changed and therefore affected the observed trends. However, we are reporting rates that take into account any change in the denominator over the years. Finally, the use of inpatient claims limited our ability to include comorbidity information in our procedure rate model, so we were therefore unable to estimate the influence of changes in patient comorbidity on patient selection for an aortic valve replacement.

CONCLUSIONS

We found an increase in rates of aortic valve replacement and an improvement in mortality and other outcomes among Medicare beneficiaries over a 12-year period. Rates of aortic valve replacement with CABG surgery decreased, older patients are still receiving mechanical prostheses despite recommendations to the contrary, and women and black patients experienced higher mortality than men and white patients. These findings may provide a useful benchmark for outcomes of aortic valve replacement surgery for older patients eligible for surgery considering newer transcatheter treatments.

ARTICLE INFORMATION

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