

# Access of Care for TAVR

Steven L. Goldberg, MD

Director Structural Heart Disease

Tyler Heart Institute

Community Hospital of the Monterey Peninsula

# Disclosures

- I have no conflict of interest to disclose

# Volume requirements for TAVR

- PCI volumes
- Surgical volumes
- TAVR volumes

# Dynamic Tension

Volume Requirements as a  
surrogate for quality versus  
Access to Care



# Standards for Major Healthcare Policy Decisions

- Data driven versus Opinion?
  - Where is the data that the performance of 400 PCI's per year has any beneficial impact on the performance of TAVR?
  - Is this not an artificial hoop to jump through that limits smaller hospitals from providing a proven, beneficial therapy?
  - Where does this number come from – what studies have been done validating this criteria?
  - Who is driving these decisions? Is there any representation from smaller hospitals? If not, who is protecting the interest of patients treated at those institutions?
  - CABG outcomes assumed to be related to hospital volumes - but some data suggests it is poorly related to hospital volumes
    - Shahian et al. J Thorac Cardiovasc Surg 2001;122:53-64
- Assume for a moment there is a statistically significant, but clinically small, difference in outcome when the procedure is limited to larger hospitals compared to smaller volume hospitals\*, is it not important to ensure that the drop in Access to Care doesn't numerically overwhelm the small difference in outcome?
  - \*"10% of the observed variation in surgeon-specific mortality rates (for CABG) is attributable to a case volume effect". Nugent and Plume J Thorac Cardiovasc Surg 2001;122:6-7

# Why do patients go to smaller hospitals?

- Geography
- Cultural
- Efficiency
  - Documented higher satisfaction rates of patients treated at smaller hospitals than larger hospitals
    - Does Hospital Size Affect Patient Satisfaction?  
McFarland, Daniel C. DO; Shen, Megan Johnson PhD; Parker, Patricia PhD; Meyerson, Sandra RN; Holcombe, Randall F. MD, MBA  
[Miscellaneous] Quality Management in Health Care. 26(4):205-209, October/December 2017.

# 2018<sup>EDITION</sup> AHA HOSPITAL STATISTICS<sup>TM</sup>

> A COMPREHENSIVE REFERENCE FOR ANALYSIS AND  
COMPARISON OF HOSPITAL TRENDS

|   |         |
|---|---------|
| Total Number of All U.S. <b>Registered</b> <sup>1</sup> Hospitals       | 5,534   |
| Number of U.S. <b>Community</b> <sup>2</sup> Hospitals *                | 4,840   |
| Number of Nongovernment Not-for-Profit Community Hospitals              | 2,849   |
| Number of Investor-Owned (For-Profit) Community Hospitals               | 1,035   |
| Number of State and Local Government Community Hospitals                | 956     |
| Number of Federal Government Hospitals                                  | 209     |
| Number of Nonfederal Psychiatric Hospitals                              | 397     |
| <b>Other</b> <sup>3</sup> Hospitals                                     | 88      |
| Total Staffed Beds in All U.S. <b>Registered</b> <sup>1</sup> Hospitals | 894,574 |

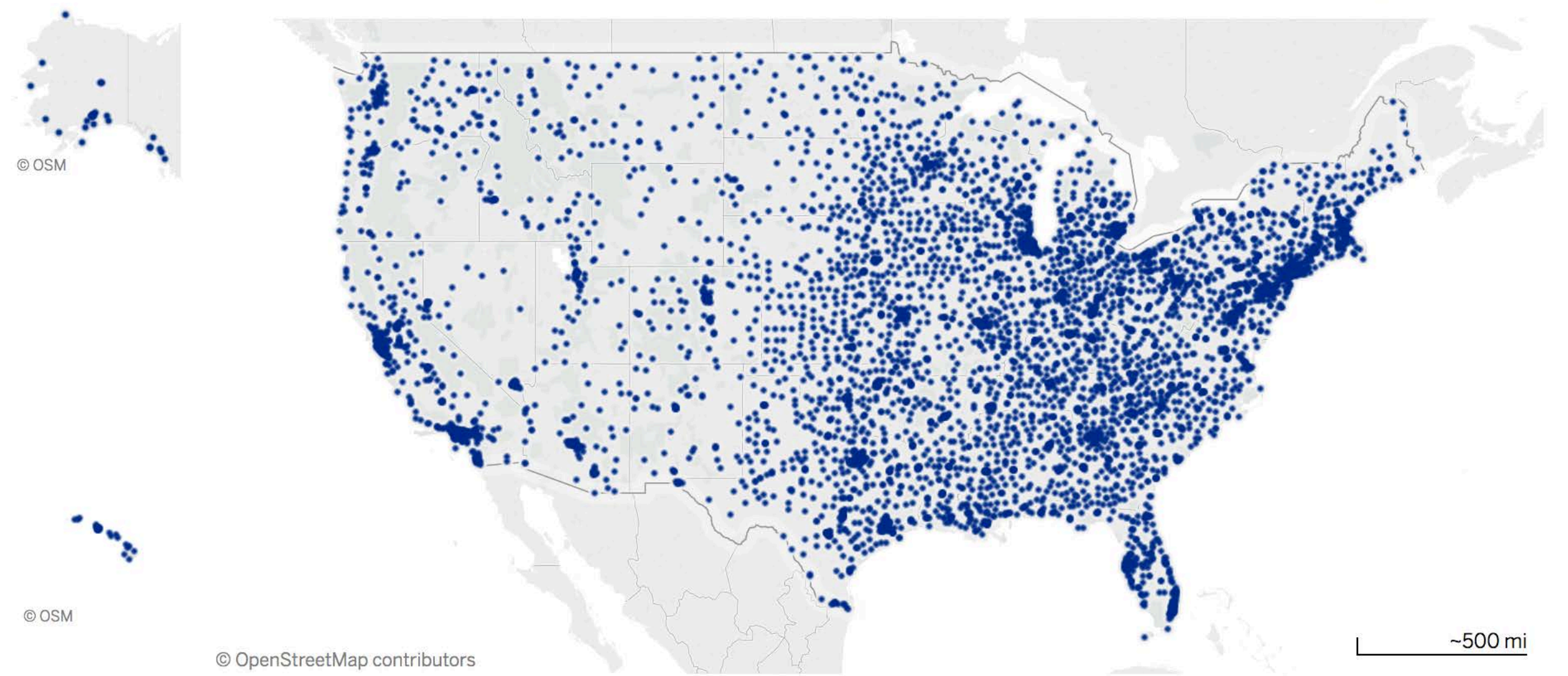
\*Includes larger hospitals and academic institutions

# Map of Registered Hospitals in the United States

Data source: 2016 AHA Annual Survey Database

[Learn more about hospital data from AHA](#)

5,534  
Hospitals



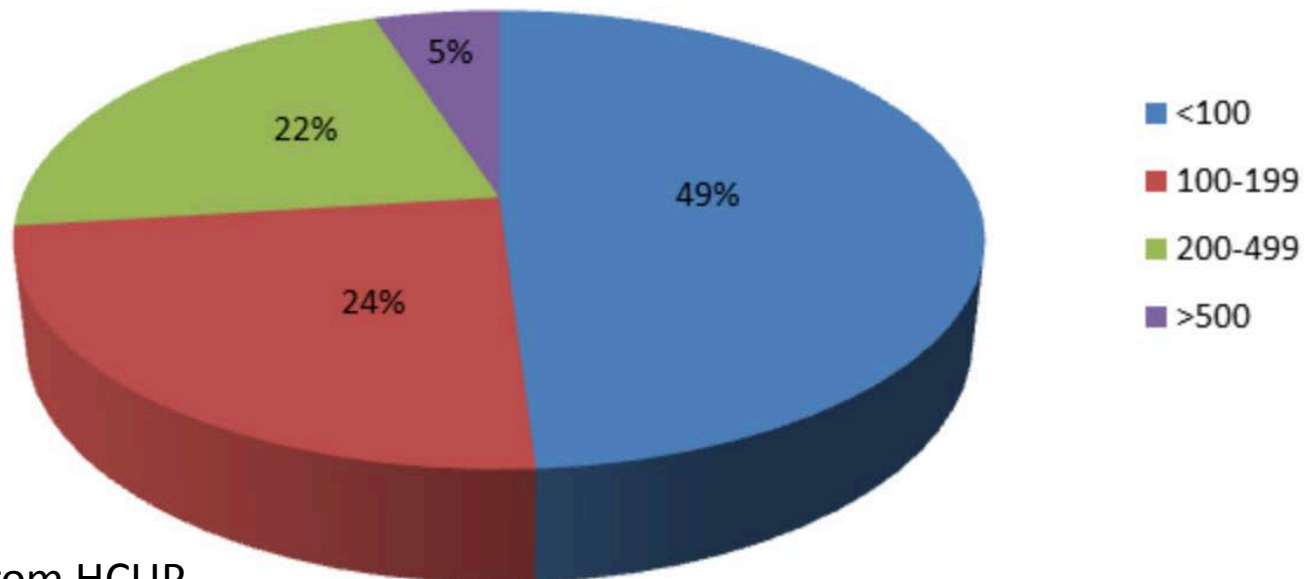


# Hospital sizes and geographies

|  |       |
|--|-------|
| Number of Rural Community <sup>2</sup> Hospitals | 1,825 |
| Number of Urban Community <sup>2</sup> Hospitals | 3,015 |

## US Hospitals By Bed Size , 2005

n=6009



Data from HCUP

The 5% are making decisions for everybody, even though there are 4-5 X as many hospitals potentially large enough for TAVR, but somewhat small programs

# Impact of smaller hospitals – Valve surgery

- From California OSHPD\* 2016 data
  - < 500 bed hospitals (n = 158): 9304 patients
  - > 500 bed hospitals (n = 16): 2756 patients
- So 3-4 times more valve surgeries are done in smaller hospitals – is there appropriate representation for these hospitals?

\*Office of Statewide Health Planning and Development

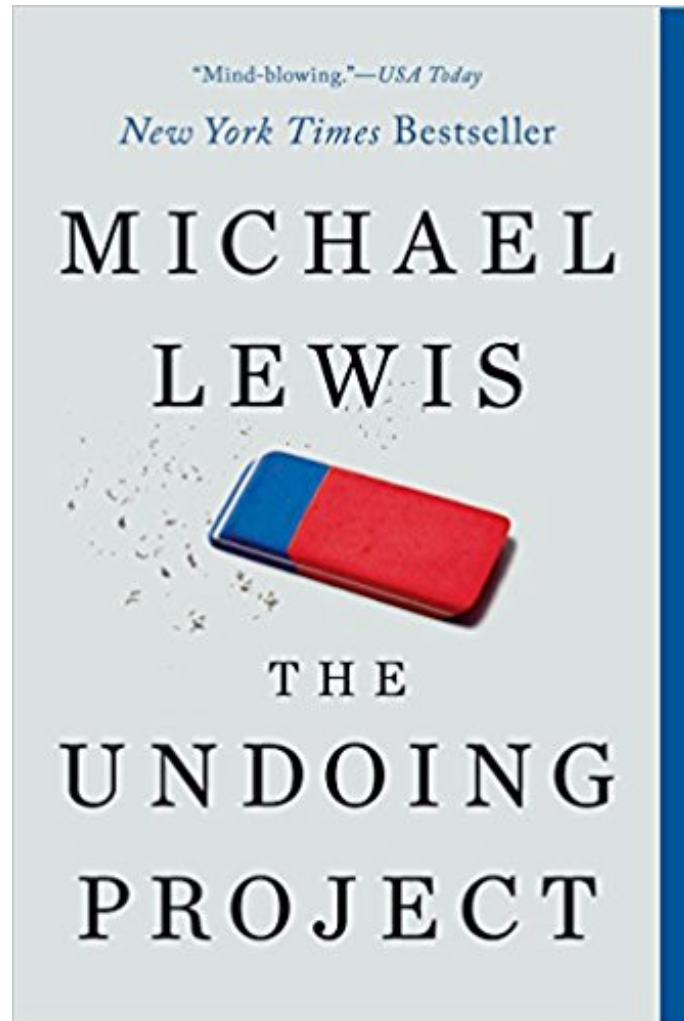
# Consider TAVR patients

- Frequently elderly and/or debilitated
  - Traveling carries challenges, including medical risk, fatigue, costs
  - Support system affected by traveling – time off from work (or inability to take off from work), in addition to costs
  - Need to travel is often used as a reason not to pursue TAVR by symptomatic elderly patients (personal experience)
- Minority populations under-represented in TAVR population
  - 4% of TAVR's are done in African-Americans, who comprise ~12-13% of the US population (US Census Bureau)

# Arguments used to justify volume requirements for TAVR

- For PCI volume requirements – no data provided linking PCI volume to TAVR outcomes – all arguments are theoretic
  - Is it appropriate for major policy decisions to be made based upon theoretic arguments, especially when there is under-representation of the interests of critical stake-holders?
- For TAVR volume requirements, there is data, but there are many confounders. The data is worthy of hypothesis generation, but perhaps not of sufficient quality to make major policy decisions
  - Concern for confirmation bias which may inflate the quality and value of the data

# Confirmation bias



- Even the most sophisticated and knowledgeable scientists are still prone to fall victim to confirmation bias – the tendency to interpret data to fulfill one's incoming impressions

# Assessment of risk between large and small volume TAVR hospitals in TVT registry

- “If anything, patients undergoing TAVR in the **highest sequential volume category** had an even greater burden of high-risk features than those in the **lowest volume category**. For example, the fourth volume category had higher STS-predicted risk of mortality, increased frequency of New York Heart Association functional class III to IV heart failure symptoms, longer 5-meter walk times, increased frequency of atrial fibrillation, and a greater proportion of patients with severely lowered ejection fraction. “

Carroll et al., Procedural Experience for Transcatheter Aortic Valve Replacement and Relation to Outcomes  
The STS/ACC TVT Registry JACC 2017

| TABLE 2 Patient Characteristics |                         |  |   |  |   |          |          |
|---------------------------------|-------------------------|--|---|--|---|----------|----------|
|                                 | Overall<br>(N = 42,988) | Cases 1-30<br>(n = 10,653<br>[in 395 sites]) | Cases 31-71<br>(n = 10,880<br>[in 319 sites]) | Cases 72-137<br>(n = 10,676<br>[in 215 sites]) | Cases 138-602<br>(n = 10,779<br>[in 119 sites]) | p Value* | p Value† |
| Age, yrs                        | 83 (78-88)              | 84 (78-88)                                   | 84 (78-88)                                    | 83 (77-88)                                     | 83 (77-88)                                      | <0.001   | <0.001   |
| <75                             | 7,144 (16.6)            | 1,629 (15.3)                                 | 1,728 (15.9)                                  | 1,867 (17.5)                                   | 1,920 (17.8)                                    | <0.001‡  | <0.001‡  |
| 75-84                           | 16,829 (39.1)           | 4,061 (38.1)                                 | 4,327 (39.8)                                  | 4,185 (39.2)                                   | 4,256 (39.5)                                    |          |          |
| 85-94                           | 18,273 (42.5)           | 4,769 (44.8)                                 | 4,646 (42.7)                                  | 4,446 (41.6)                                   | 4,412 (40.9)                                    |          |          |
| ≥95                             | 742 (1.7)               | 194 (1.8)                                    | 179 (1.6)                                     | 178 (1.7)                                      | 191 (1.8)                                       |          |          |
| Female                          | 21,025 (49.0)           | 5,367 (50.4)                                 | 5,384 (49.5)                                  | 5,137 (48.2)                                   | 5,137 (47.8)                                    | <0.001   | <0.001   |
| Race                            |                         |  |   |  |   | 0.005    | 0.005    |
| White                           | 40,474 (94.2)           | 10,006 (93.9)                                | 10,283 (94.5)                                 | 10,027 (93.9)                                  | 10,158 (94.2)                                   |          |          |
| Black                           | 1,611 (3.7)             | 436 (4.1)                                    | 370 (3.4)                                     | 407 (3.8)                                      | 398 (3.7)                                       |          |          |
| Asian                           | 468 (1.1)               | 91 (0.9)                                     | 124 (1.1)                                     | 123 (1.2)                                      | 130 (1.2)                                       |          |          |
| Other                           | 435 (1.0)               | 120 (1.1)                                    | 103 (0.9)                                     | 119 (1.1)                                      | 93 (0.9)  |          |          |
| Mean STS PROM score             | 6.6 (4.4-10.1)          | 6.5 (4.4-10.0)                               | 6.6 (4.3-9.9)                                 | 6.5 (4.3-10.0)                                 | 6.8 (4.4-10.5)                                  | <0.001   | <0.001   |

**And yet, no comment is made that the patients in the lowest volume category were more elderly!?!**

# Does the TVT registry confirm less optimal results in smaller volume programs?

- The analysis included the initial experience of hospitals – including larger volume hospitals (but characterized in early stages as small volume programs), so the analysis is confounded by the learning curve component
- The analysis focuses on early TAVR commercial experience, which is already outdated
  - Greater universal understanding of complications and avoidance techniques
  - Greater sophistication in pre-procedure imaging
  - Newer generation valves
- The statistics are “murky”
  - Cribier et al: “Using sophisticated analytic approaches (that, we must confess, are way beyond the understanding skills of a vast majority of cardiologists, like us)...”

# Suggested conclusions from TVT registry analysis

- The data is of interest, but is inconclusive
  - It is reasonable to believe that the data may not be currently relevant in light of confounder of learning curve, and advances in TAVR
- Relying upon these preliminary data to justify public policy decisions seems to be - arguable (at the least)
  - Shouldn't it be a clear message, not "way beyond the understanding skills of a vast majority of cardiologists, like us" (Cribier in editorial on manuscript)
- The downside of accepting and acting on these preliminary and confounded data will be a restriction to access of care



# Surgical volumes

- Surgical volumes are in a state of flux, due to the increasing acceptance of TAVR, which is likely to become even more of an issue if/when low risk surgical patients become acceptable for TAVR
- This creates a dynamic tension where patients may be funneled to surgery, to allow for large enough surgical volumes to allow a TAVR program - which is internally inconsistent
- Currently, it is known that patients evaluated at hospitals with surgical programs but no TAVR are less likely to undergo TAVR, due either to referral of higher risk patients to surgery, or to avoid treatment of symptomatic aortic stenosis altogether – access limitation

# Conclusions

- Maintaining or establishing volume requirements limits access of care to patients with established benefits to TAVR
- Most key opinion leaders come from larger hospital systems, so have a potential inherent bias and conflict of interest over this issue
  - Establishing a voice for smaller, less vocal hospitals is important in establishing major policy decisions, especially since those hospitals care for a significant percentage of US patients – over three times the volume of large hospitals