

Does Volume in a Pediatric Cardiac Surgery Program Impact the Results?

Jeffrey P. Jacobs, MD

Professor of Surgery and Pediatrics, Johns Hopkins University

Director, Andrews/Daicoff Cardiovascular Program

Surgical Director of Heart Transplantation

Johns Hopkins All Children's Hospital

The STS/EACTS Latin America Cardiovascular Surgery Conference

Cartagena, Colombia

Hilton Cartagena

Presented Thursday November 15, 2018, 11:24 AM – 11:36 AM



Disclosure

- **Chair, STS Workforce on National Databases**
- **Chair, CHSS Committee on Quality Improvement and Outcomes**
- President, Southern Thoracic Surgical Association
- Editor-In-Chief, Cardiology in the Young
- Co-Chair, World Congress of Pediatric Cardiology and Cardiac Surgery 2021

- **This slide set does not represent the official opinion of any of the organizations listed on this slide**

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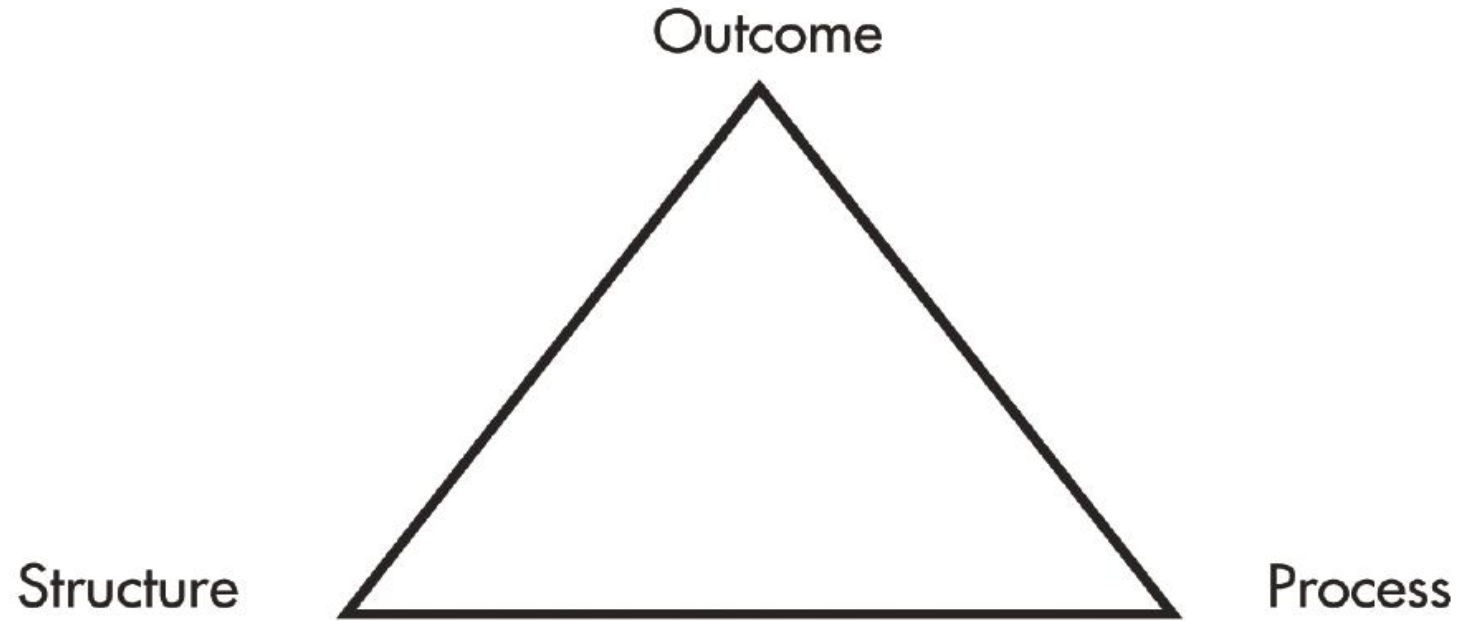
YES

Definition of Quality

- ♥ **how good or bad something is**
- ♥ a characteristic or feature that someone or something has : something that can be noticed as a part of a person or thing
- ♥ a high level of value or excellence

[<http://www.merriam-webster.com/dictionary/quality>]. Accessed November 10, 2015

Donabedian's Triad



Donabedian A. **Evaluating the quality of medical care**. Milbank Mem Fund Q. 1966;44(Suppl):166–206.

Michael Porter

The Healthcare Value Equation

$$\text{Value} = \frac{\text{Quality}}{\text{Cost}}$$

value defined as the health outcomes achieved per dollar spent

Michael E. Porter, Ph.D. Perspective. **What Is Value in Health Care?** N Engl J Med 2010; 363:2477-2481



46th Annual Meeting

Presidential Address

October 22, 2018

A light blue, 3D-style map of the United States is centered on the slide. The map has a white border and a slight shadow, giving it a sense of depth. The text "Rational Regionalization" is overlaid on the map in a bold, yellow, sans-serif font.

Rational Regionalization

Carl Lewis Backer
President

Congenital Heart Surgeons' Society

First Ad hoc Regionalization Committee Meeting



San Diego Jan 2015

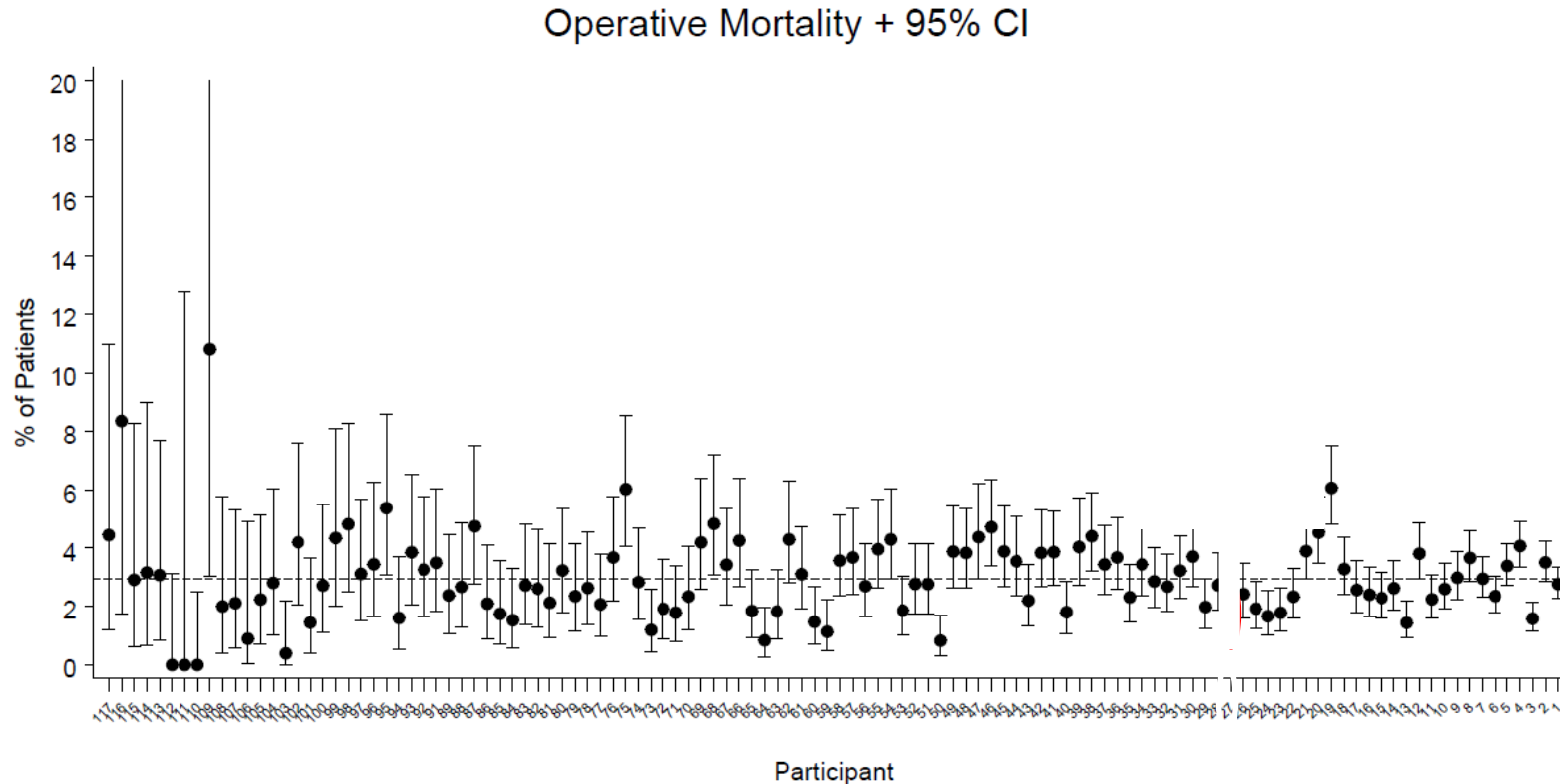
Is this Variation in Mortality Acceptable?

STS Congenital Heart Surgery Data Summary
All Patients

Participant 50005
STS Period Ending 12/31/2017

Duke Clinical Research Institute

Figure 1: All Patients, Operative Mortality, Last 4 years (Jan 2014 - Dec 2017)
All Patients



Dotted line on graph represents overall value for the STS: 2.94%

Note: Caution should be taken when interpreting this graph because this graph reports outcome data without considering case mix and without incorporating any complexity stratification. In the following pages these data will be analyzed (and reported in similar graphs) with incorporation of case mix analysis and complexity stratification.

Can We Improve This Variation?

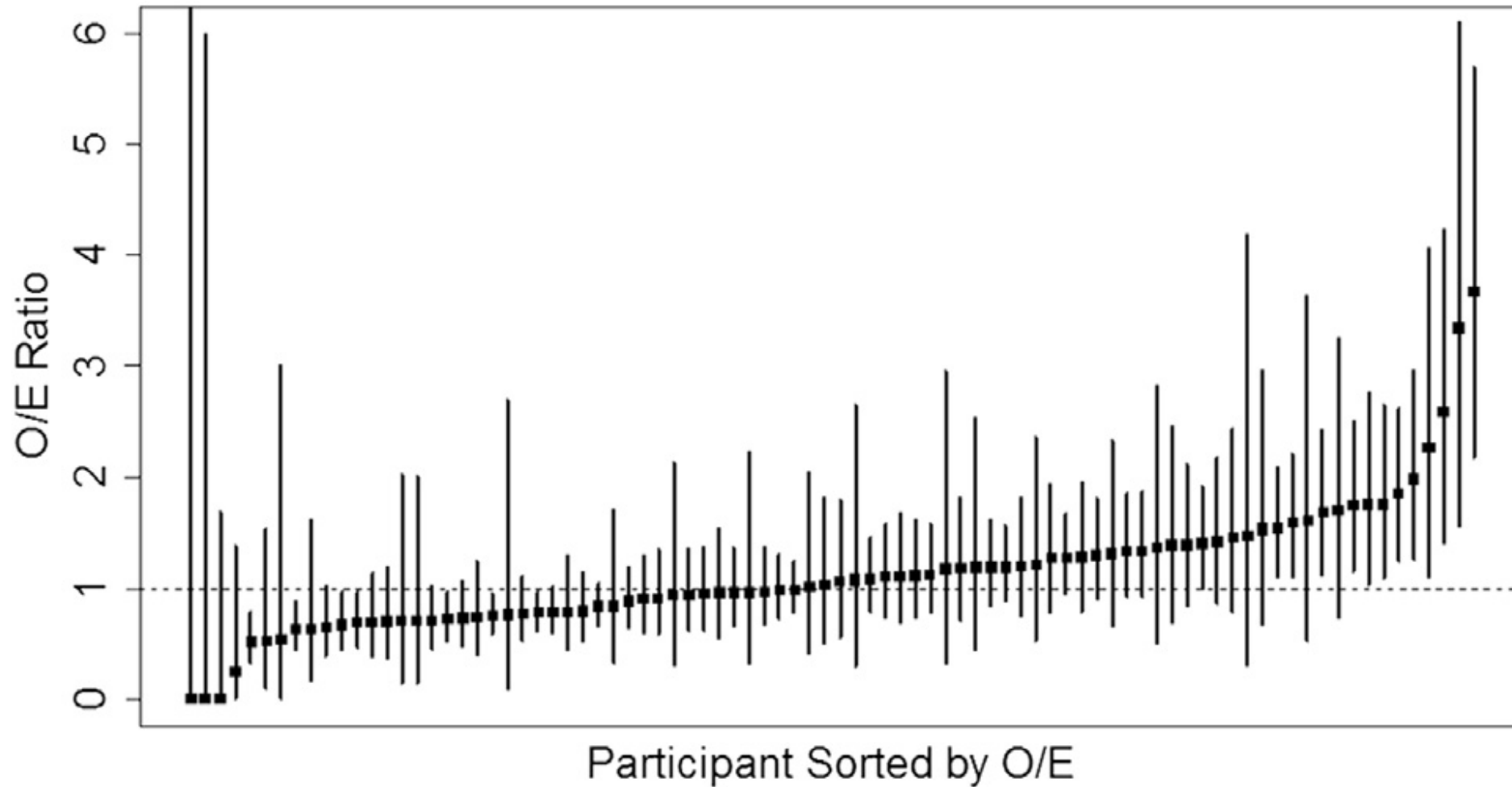



Fig. 1. Distribution of hospital-specific observed-to-expected (O/E) ratios for operative mortality with 95% confidence intervals (gray lines)

The Other Issue is Public Scrutiny



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Breaking: Some Palm Beach County beaches to remain closed because of red tide

CNN puts St. Mary's infant heart surgery deaths at 3x national average

Updated June 03, 2015
By [Sonja Isger](#), Palm Beach Post Staff Writers

WEST PALM BEACH — St. Mary's Medical Center, in response to a blistering [CNN report](#), insisted Tuesday that the infant mortality rate in its pediatric open heart surgery unit is "consistent" with the national average and blasted the cable news station for trying to mislead the public through skewed arithmetic.

In a yearlong investigation, CNN reported that the mortality rate at St. Mary's was three times above the national average, with eight infant deaths since the program started in late 2011.

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St. Mary's closes disparaged pediatric heart surgery program

LOCAL By [John Pacenti](#) - Palm Beach Post Staff Writer    

Updated: 8:24 p.m. Monday, August 17, 2015 | Posted: 7:47 p.m. Monday, August 17, 2015

WEST PALM BEACH — St. Mary's Medical Center stood by its pediatric cardiothoracic surgery program despite a scathing CNN investigation and grave concerns by some of the most renowned doctors in the highly specialized field.

On Monday, St. Mary's pulled the plug.

"After much consideration, we have made the decision to permanently close our Pediatric Cardiothoracic Surgery Program," the hospital said in a statement. "We are proud of the work that has been done and the lives that have been saved."

In the end, the Tenet Healthcare hospital couldn't sustain the program after CNN reported **nine infants had died** in four years — a mortality rate that experts said was partly due to the program not attracting enough patients to be proficient. After the CNN story, the program's demise became a fait accompli.

About the Author

 **JOHN PACENTI**  

Popular in News

 **Border Patrol arrests 14 near Palm Springs Home Depot**

MGH halts a pediatric program

Heart surgeries on hold after errors

By Liz Kowalczyk

Globe Staff / April 17, 2009

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Text size - +

Massachusetts General Hospital has suspended its pediatric cardiac surgery program after two babies recently suffered serious complications following errors made during open-heart surgery.

Discuss
 COMMENTS ()

The Harvard teaching hospital had expanded the small program and taken on more complex cases after hiring a heart surgeon two years ago to operate solely on children. But that plan has not worked out as hoped, and hospital executives

said they shut down the program last week, at least temporarily.

State public health officials began investigating the two cases after Mass. General notified them on Tuesday that the hospital had stopped taking young heart surgery patients and was evaluating whether to reopen the program.

Dr. David Torchiana, head of the Massachusetts General Physicians Organization, said both babies survived their operations, although one suffered neurological damage. That child, who was operated on at the end of January, has since been transferred to Children's Hospital Boston. The second infant had surgery in March and is still at Mass. General and recovering well, Torchiana said. In both cases, technical errors were made during the surgeries, Torchiana said, though he declined to go into detail because of what he called patient privacy concerns.

The hospital's decision to expand its program, and now to suspend it, goes to the core of a long-standing debate in pediatric medicine: should hospitals run small surgery programs or should care be consolidated in a few large programs, where physicians and nurses can sharpen their skills by caring for large numbers of



UK hospital and Kentucky Children's Hospital on the University of Kentucky campus in Lexington, Ky., on Sept. 11, 2012. Herald-Leader

EDUCATION

Internal review of UK's pediatric heart surgery program doesn't say why it was closed



By Linda B. Blackford - lblackford@herald-leader.com



October 17, 2013 07:20 PM

Updated September 04, 2015 12:28 PM



An internal review of the University of Kentucky's pediatric cardiothoracic surgery program does not address why the program was voluntarily shut down last fall, despite numerous calls for transparency from affected parents, some of whose children died.



You are in: Health: Background Briefings: **The Bristol heart babies**

Thursday, 29 November, 2001, 17:41 GMT

THE BRISTOL HEART BABIES

- Front Page
- World
- UK
- UK Politics
- Business
- Sci/Tech
- Health
- Background Briefings
- Medical notes



Bristol surgeon loses High Court bid

A High Court bid by a surgeon at the centre of the Bristol heart babies scandal to force the Health Secretary to hear an appeal has failed.

Also:

- ▶ Bristol 'had double normal death rates'
- ▶ Bristol baby surgeon breaks down
- ▶ Surgeon: 'I was unlucky to lose patients'



'Up to 100 babies died needlessly'

Up to 100 babies may have died needlessly after undergoing complex heart surgery at Bristol Royal Infirmary, it has been claimed.

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You are in: In Depth: **The Bristol babies inquiry**

THE BRISTOL BABIES INQUIRY

Monday, 6 January, 2003, 11:31 GMT

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Talking Point

Country Profiles

In Depth

Programmes

KEY NEWS STORIES



Heart scandal 'could happen again'

The official report into the Bristol Royal Infirmary tragedy blames a "club culture" among surgeons and warns it could be repeated elsewhere.

- ▶ Bristol whistle-blower speaks out
- ▶ Report findings at a glance
- ▶ Report recommendations at a glance
- ▶ What the doctors got wrong
- ▶ Bristol: Parents' reaction
- ▶ Inquiry chief's 'blame culture' warning
- ▶ GMC president: 'We let parents down'

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- ▶ BBC Radio news latest
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MORE AUDIO VIDEO NEWS

THE BRISTOL BABIES TIMELINE

CLICKABLE GUIDE

Bristol history



Operation guide



A parent's story



...and Inquiry



National Health Service England



“Safe and Sustainable” – Response to Bristol

A new vision for Children’s
Congenital Heart Services in England

Massive survey/study of physicians,
hospitals, public and policy makers

\$20 million study: 234 pages

(published 2011)

NHS Proposal for Regionalization

THE EVIDENCE FOR 500 PROCEDURES PER CENTRE

The proposed standards also require that each Specialist Surgical Centre should ideally perform at least 500 paediatric procedures per year. This is based on each of the four surgeons carrying out approximately 125 operations per year to ensure that enough surgery to maintain their skills and so that round the clock cover can be provided at every centre.

Many studies suggest that larger caseloads tend to perform better operations and achieve better outcomes. Countries that have reviewed their planning and delivery of paediatric cardiac surgery include Sweden in 2000¹⁵, Canada in 2002, Australia in 2004¹⁶, The Netherlands in 2009¹⁷ and Germany in 2010¹⁸. Common themes throughout each of these studies are clear:

Sources: The Relationship between Hospital Surgical Case Volumes and Mortality Rates in paediatric Cardiac Surgery: a National Sample 1988-2005. Karl F Welke et al 2009. The relationship between paediatric cardiac surgery mortality and hospital case volume: a national database study.

In recent years major concerns around their own congenital

¹⁵ Lundström, NR, Bergg *Cardiology*, 2000, 21:35.

¹⁶ Queensland Government

¹⁷ Commission for Paediatric Document translated from

¹⁸ Federal Ministry of Justice measures over cardiac Security Statute Book (S) by London Translation



The proposed standards also require that each Specialist Surgical Centre should ideally perform at least **500 paediatric procedures per year**. This is based on **each of the four surgeons carrying out approximately 125 operations per year** to ensure that they perform enough surgery to maintain their skills and so that round the clock cover can be provided at every centre.

developing a recommendation for the minimum number of paediatric surgical procedures that a Specialist Surgical Centre staffed with four surgeons must meet, the Working Group considered the findings of the European Association for Cardio-Thoracic Surgery¹⁹. Whilst acknowledging that the available research evidence does not identify an exact cut-off point between what is a too small, adequate or optimal a case load' it suggested a minimum caseload of 125 surgical procedures each year for a full time surgeon.

Paediatric Heart Surgery Committee on

NHS Proposal for Regionalization

WHAT WOULD HAPPEN IN THE FUTURE?



LARGER CENTRES OF SURGICAL EXCELLENCE

It is important that each centre is big enough to cope, yet small enough to care. Larger centres would be safer and deliver better results for children. Urgent care could be provided when required 24 hours a day seven days a week and would reduce the risk of cancellations. In future surgical teams at all centres would see enough children to maintain and develop vital skills, and end the risk of children with particularly complex or rare conditions being seen by surgeons insufficiently experienced in the procedures needed. Expert care for children before and after heart surgery is vital. Paediatric Intensive Care Unit (PICU) consultants with skills in critical care for children with heart conditions would be available 24 hours a day.



CENTRES WOULD HAVE FOUR SURGEONS AND APPROPRIATE SURGICAL TEAMS

Working together in a team of four gives surgeons time to cover other responsibilities such as ward rounds, outpatient clinics, research, teaching or taking annual leave. As there is a growing trend for clinicians to specialise in particular procedures it is important to concentrate this expertise within larger teams.

Appendix 6 shows that the numbers of children with congenital heart disease requiring heart surgery is expected to remain roughly the same. **SAFE AND SUSTAINABLE** has considered population needs and is satisfied that it is unnecessary to increase the number of surgeons to plan for future demand.



MEETING THE STAFF

Parents of babies and children awaiting surgery or an interventional procedure would have the opportunity to visit the centre and meet the staff who will be responsible for their child's care. This should include meeting the surgeon or interventionist who would be undertaking the procedure.



INTERVENTIONAL CARDIOLOGY

For some congenital heart conditions interventional procedures are replacing surgical procedures as the primary form of treatment. Interventional cardiology is becoming more complex and presents a degree of risk to the child as devices are inserted into the child's heart. It is for this reason that should a complication arise the proposed new standards require interventional cardiology to only be carried out in Specialist Surgical Centres so that a congenital cardiac surgeon can assist if required.



WE WOULD LIKE YOUR VIEWS.

To what extent do you support or oppose:

- The need for 24/7 care in each of the Specialist Surgical Centres?
- The proposal that, in the future, interventional cardiology should be provided only by designated Specialist Surgical Centres?

61

62

KEY STANDARDS



 500

Ideally 500 children's heart operations would be carried out every year in each Specialist Surgical Centre with a minimum of 400 operations



24/7

Round the clock cover seven days a week would be provided – a consultant surgeon and specialist team available at all times



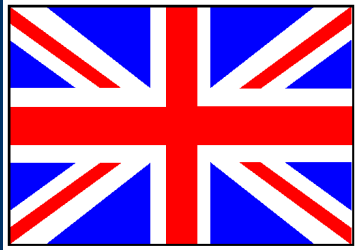
4

Each Specialist Surgical Centre would have a minimum of 4 full-time consultant congenital heart surgeons

Recommend Reducing the number of Centers from 11 to 7



Applying the NHS Formula to the USA



- **US Population 325 million**
- 100 Congenital Cardiac Operations/
year per 1 million population
- **32,500 operations predicted / year**
(30,130 in STS database 2017)
- 500 cases / center
- **Predict need for 65 centers**
(116 U.S. programs in STS database)



The NHS response
to Bristol recommended
REGIONALIZATION:
Based on Evidence that
**Higher Volume in a Pediatric
Cardiac Surgery Program
Improves Outcomes**

What is the evidence that
**Higher Volume in a Pediatric
Cardiac Surgery Program
Improves Outcomes**



Centralization of pediatric heart surgery in Sweden

N.R. Lundström, H. Berggren, G. Björkhem, P. Jögi, J. Sunnegårdh

University Hospital, Sweden and Sahlgrenska University Hospital, Göteborg, Sweden

Abstract

In Sweden, which has a population of 8.9 million people, **pediatric heart surgery was previously performed in four cities.** After a long, difficult process, **centralization of pediatric heart surgery to two centers was achieved in 1993.** **The overall 30-day mortality for open-heart surgery on infants and children of 9.5% before the centralization (1988-1991) was reduced to 1.9% in 1995-1997.** A causal relationship between the mortality rates before and after the centralization is impossible to prove. Heart surgery was concentrated to the two centers with the lowest surgical mortality, and the reduction in surgical mortality was observed over a short period of time which makes it likely that the centralization of the surgical activity promoted the improved results. During the later time period the amount of more complex surgery was clearly increased compared to that performed previously.

The complex relationship between pediatric cardiac surgical case volumes and mortality rates in a national clinical database

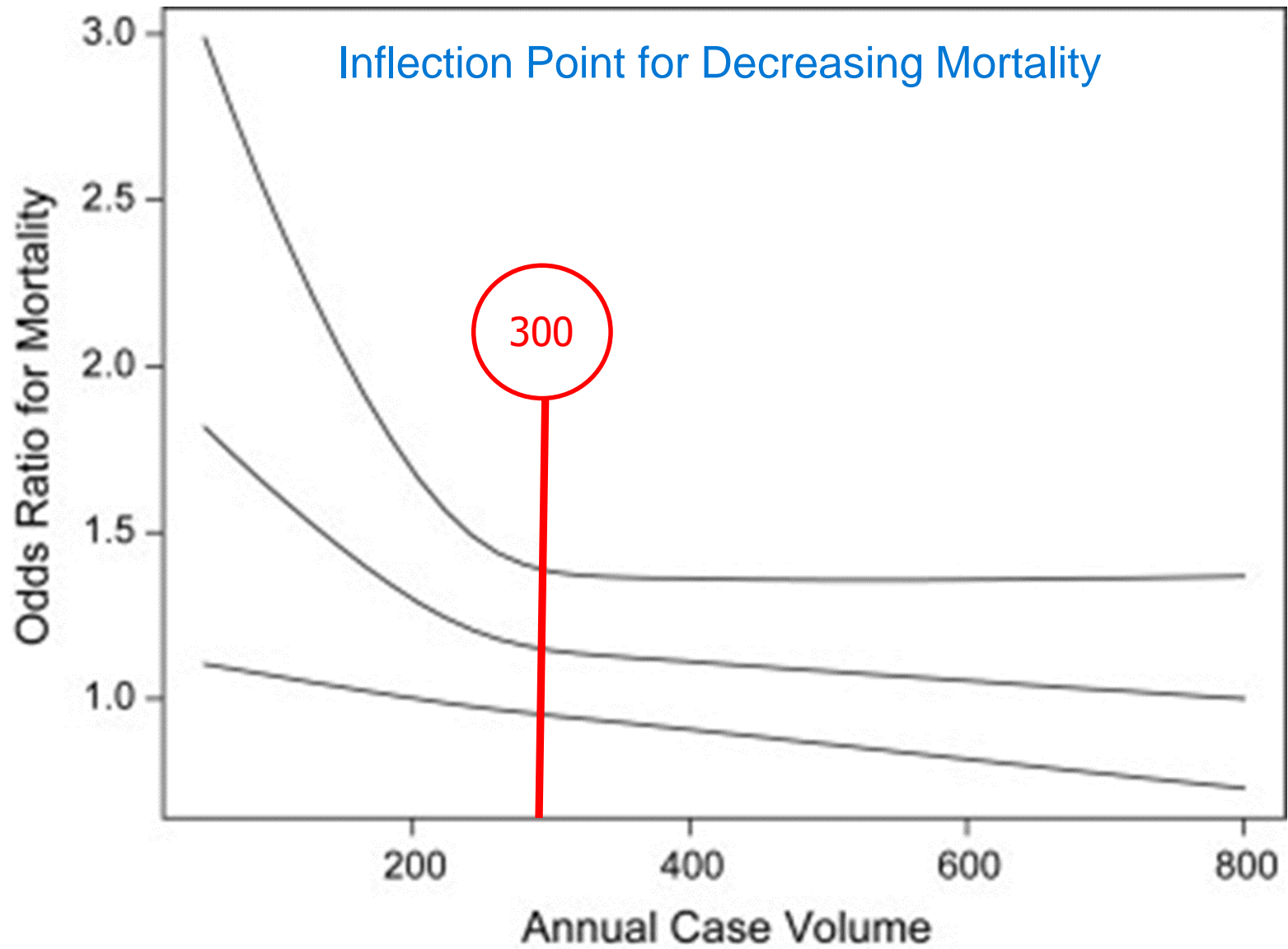
Karl F. Welke, MD, Sean M. O'Brien, PhD, Eric D. Peterson, MD, MPH, Ross M. Ungerleider, MD, MBA, Marshall L. Jacobs, MD, and Jeffrey P. Jacobs, MD

Objective: We sought to determine the association between pediatric cardiac surgical volume and mortality using sophisticated case-mix adjustment and a national clinical database.

Methods: Patients 18 years of age or less who had a cardiac operation between 2002 and 2006 were identified in the Society of Thoracic Surgeons Congenital Heart Surgery Database (32,413 patients from 48 programs). Programs were grouped by yearly pediatric cardiac surgical volume (small, <150; medium, 150-249; large, 250-349; and very large, \geq 350 cases per year). Logistic regression was used to adjust mortality rates for volume, surgical case mix (Aristotle Basic Complexity and Risk Adjustment for Congenital Heart Surgery, Version 1 categories), patient risk factors, and year of operation.

Results: With adjustment for patient-level risk factors and surgical case mix, there was an inverse relationship between overall surgical volume as a continuous variable and mortality ($P = .002$). When the data were displayed graphically, there appeared to be an inflection point between 200 and 300 cases per year. When volume was analyzed as a categorical variable, the relationship was most apparent for difficult operations (Aristotle technical difficulty component score, >3.0), for which mortality decreased from 14.8% (60/406) at small programs to 8.4% (157/1858) at very large programs ($P = .02$). The same was true for the subgroup of patients who underwent Norwood procedures (36.5% [23/63] vs 16.9% [81/479], $P < .0001$). After risk adjustment, all groups performed similarly for low-difficulty operations. Conversely, for difficult procedures, small programs performed significantly worse. For Norwood procedures, very large programs outperformed all other groups.

Conclusion: There was an inverse association between pediatric cardiac surgical volume and mortality that became increasingly important as case complexity increased. Although volume was not associated with mortality for low-complexity cases, lower-volume programs underperformed larger programs as case complexity increased.



Can Regionalization Decrease the Number of Deaths for Children Who Undergo Cardiac Surgery? A Theoretical Analysis

Ruey-Kang R. Chang, MD, MPH, and Thomas S. Klitzner, MD, PhD

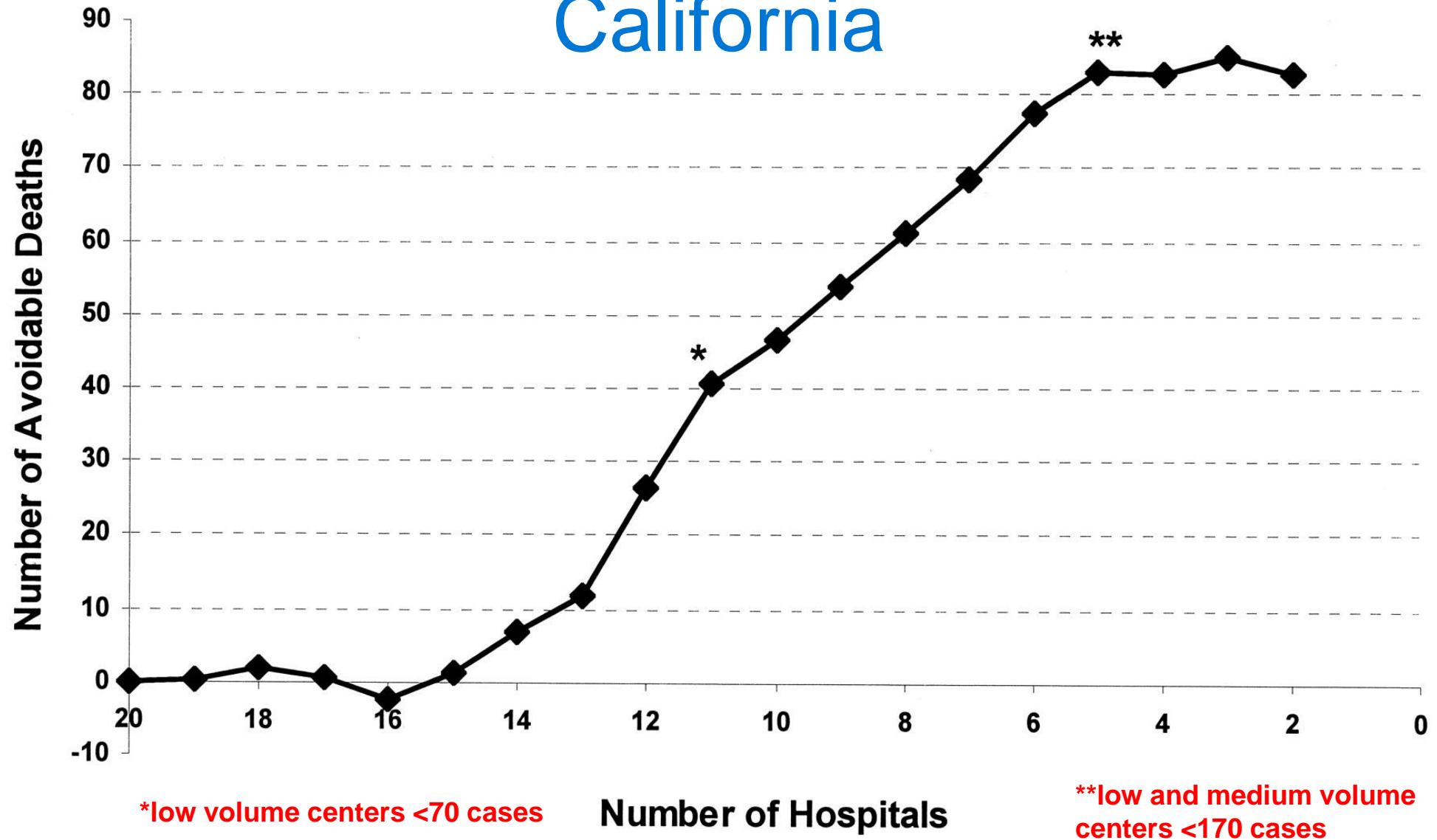
ABSTRACT. Objective: The association between high case volumes and better patient outcomes has been demonstrated for many surgical procedures and medical treatments, including surgery for children with congenital heart disease. To simulate the effects of regionalization of pediatric cardiac surgery, we assessed the impact of reducing the number of pediatric cardiac centers on surgical mortality and patient's travel distance.

Methods. This study used abstracted statewide hospital discharge data from **California from 1995 to 1997**. Case volume and in-hospital mortality for pediatric cardiac surgeries at each hospital were calculated. All hospitals that performed ≥ 10 pediatric cardiac surgeries in 1995 to 1997 were included in the analysis. To simulate regionalization, we "closed" the hospital with the lowest case volume and redistributed patients from this hospital to the nearest remaining hospitals. The number of in-hospital deaths was then recalculated using the original mortality rate of each remaining hospital multiplied by its new case volume. A multivariate logistic regression was conducted to determine the odds ratios of mortality of various types of surgery compared with closure of ventricular septal defect. This result was used for adjusting for the case-mix of the hospitals. Regionalization simulation analysis was repeated, and the number of deaths was recalculated using this adjustment of hospital case-mix. We also examined the increase in travel distance of patients to the hospitals as a result of the regionalization simulation.

Results: In California, 6592 children underwent cardiac surgeries in 1995 to 1997 with 352 in-hospital deaths (overall mortality rate: 5.34%). A quadratic regression model demonstrated that a high surgical volume was associated with a low mortality rate. We found demarcations between low- and medium-volume hospitals at 70 cases per year and medium- and high-volume hospitals at 170 cases per year. With adjustment for hospital case-mix, we found that 41 deaths could be avoided when all patients from low-volume hospitals were referred, and 83 deaths could be avoided when all patients from low- and medium-volume hospitals were referred to high-volume hospitals (overall mortality rate decreased to 4.08%). The average travel distance for pediatric cardiac surgery was 45.4 miles, which increased by 12.7 miles when all surgeries were referred to high-volume hospitals. When only the 733 high-risk patients were referred from low- and medium-volume hospitals to high-volume hospitals, 49 deaths could be avoided, yielding an overall mortality rate of 4.60%.

Conclusions: Theoretical regionalization of pediatric cardiac surgery is associated with a reduction in surgical mortality from 5.34% to 4.08% when all cases were referred to high-volume hospitals, or decrease to 4.60% when high-risk cases were referred. **Although regionalization is associated with an important decrease in the number of deaths, it also increases the travel distance for patients.** Additional studies on the costs and benefits of regionalization are needed to determine the best strategies to improve outcomes for children who undergo cardiac surgery.

California



Higher Programmatic Volume in Neonatal Heart Surgery Is Associated With Lower Early Mortality



Andrzej Kansy, MD, PhD, Christine zu Eulenburg, PhD, Georgios Sarris, MD, PhD, Jeffrey P. Jacobs, MD, PhD, Jose Fragata, MD, PhD, Zdzislaw Tobota, MD, Tjark Ebels, MD, PhD, and **Bohdan Maruszewski, MD, PhD**

Children's Memorial Health Institute, Warsaw, Poland; Athens Heart Surgery Institute, Athens, Greece; University Medical Center Groningen, Groningen, Netherlands; Johns Hopkins All Children's Heart Institute, St. Petersburg, Florida; Hospital de Santa Marta, Lisbon, Portugal; and Cardiothoracic Surgery, University of Amsterdam, Netherlands

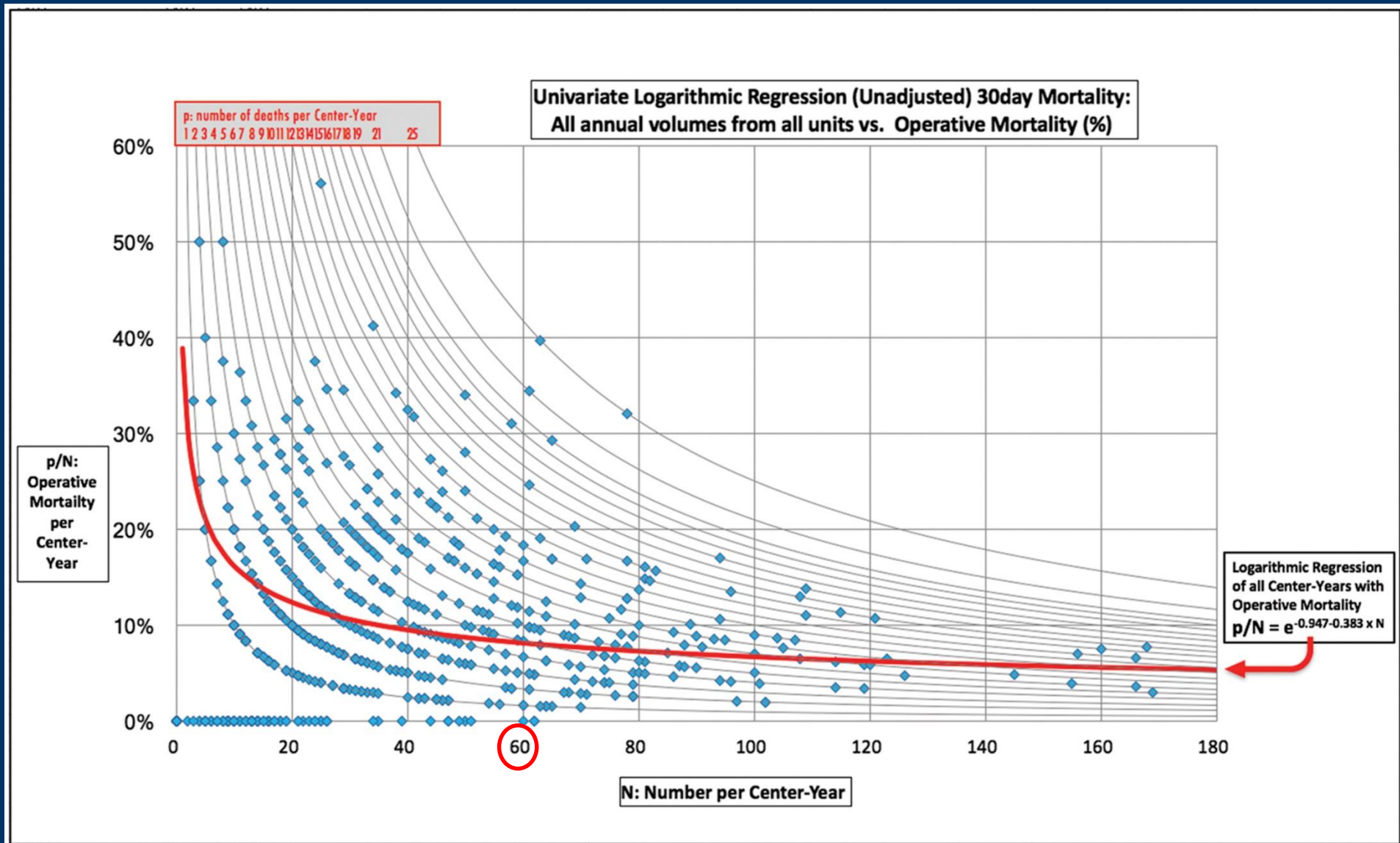
Background. The early results of congenital heart surgery in neonates remain a challenge. We sought to determine the nature of the association between annual center volume of neonatal cardiac surgery and operative mortality using a multicenter cohort.

Methods. The dataset consists of 27,556 neonatal procedures performed between 1999 and 2015 in 90 centers participating in the European Congenital Heart Surgeons Association database. Centers with mean annual volume load of six or more that submitted data for at least 3 consecutive years were included. World Bank annual gross national index per capita was utilized as an indicator of temporal national affluence. Multilevel logistic regression was used to create a model including the significant risk factors and to calculate odds ratios for operative mortality. Iterative modeling of the dataset incrementally excluding centers with lower annual caseload was used to identify the relationship between annual volume and mortality.

Results. In the model thus calculated including The Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery (STAT) mortality score, operative weight and age, noncardiac genetic anomalies, and annual volume of operations were independent risk factors for operative mortality in the analysis of the entire cohort. In the model containing these variables, annual gross national index and year of surgery were not significantly associated with mortality. In the Iterative process, annual volume ceased to be a risk factor when units operating on fewer than 60 neonates annually were excluded.

Conclusions. In neonatal congenital heart surgery, the **risk of operative death decreased with the increase of volume load. The cutoff point in this cohort was a mean annual volume of 60 neonatal operations per year.**

Neonatal Operative Mortality by Center Volume



Optimal Structure of a Congenital Heart Surgery Department in Europe*



- At least 3 fully trained surgeons per center
- Minimum surgical case load 125 operations/surgeon/year
- Optimal activity should be over 250 patients/year (4-6 million population base)

*Approved by the European Congenital Heart Surgeons Association
Eur J Cardiothorac Surg 2003;24:343-351



Regionalization: International Perspective

Sweden Regionalization

- (4 \rightarrow 2 centers): 9 million people
- Mortality \downarrow 9.5% \rightarrow 1.9%

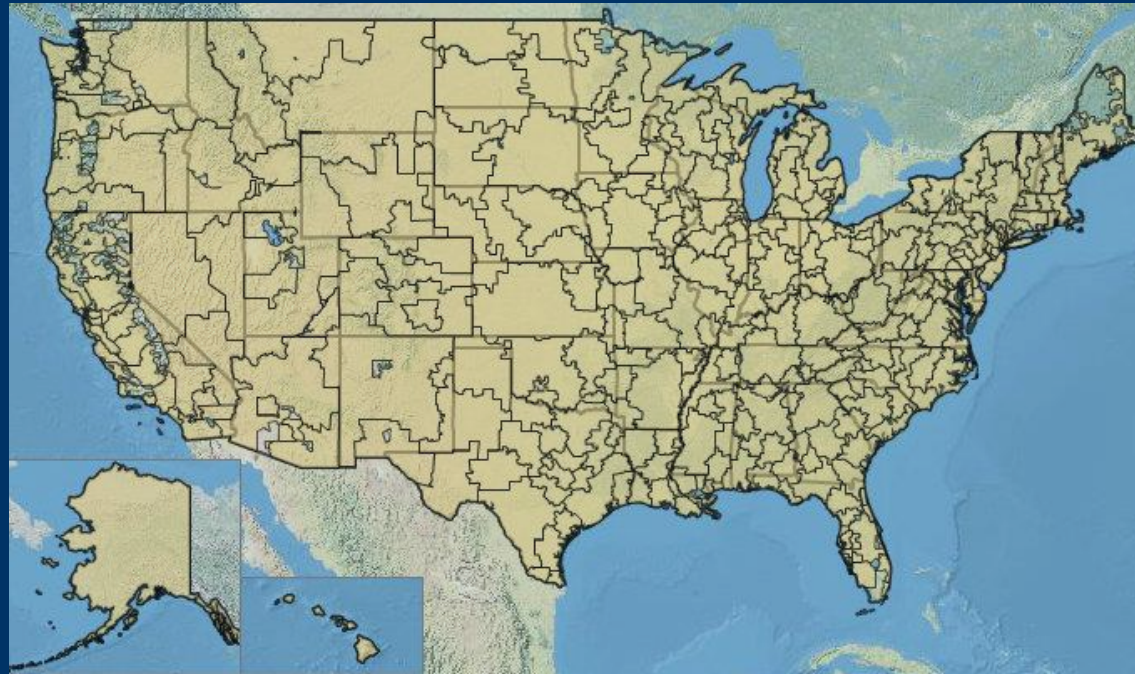
England: NHS Proposal

- 4 surgeons / center
- 125 operations / surgeon / year
- 500 cases / center

European Congenital Heart Surgeons Association:

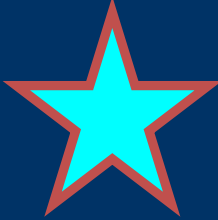

- 3 surgeons / center
- 125 operations / surgeon / year
- 60 neonatal operations / year / center

What Can We Learn about Regionalization from the STS Database?



Data source: <https://publicreporting.sts.org/>

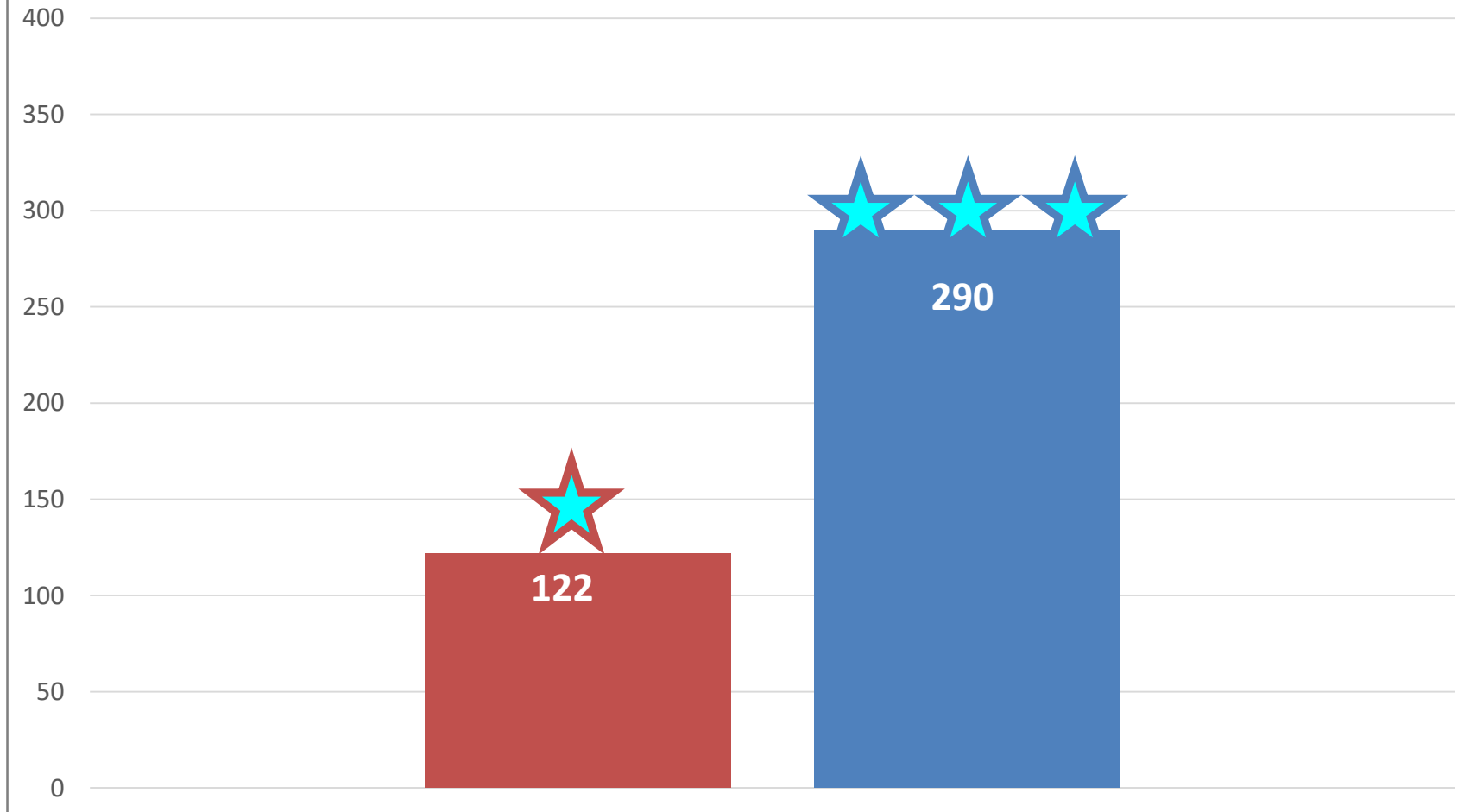
Data Presented by Carl Backer during his CHSS Presidential Address on October 15, 2018.

What is the Median Annual Volume
of Cases at 1-Star 
versus
3-Star Programs? 

Data source: <https://publicreporting.sts.org/>

Data Presented by Carl Backer during his CHSS Presidential Address on October 15, 2018.

Median Annual Volume of Surgical Cases 2014 - 2017



Data source: <https://publicreporting.sts.org/>

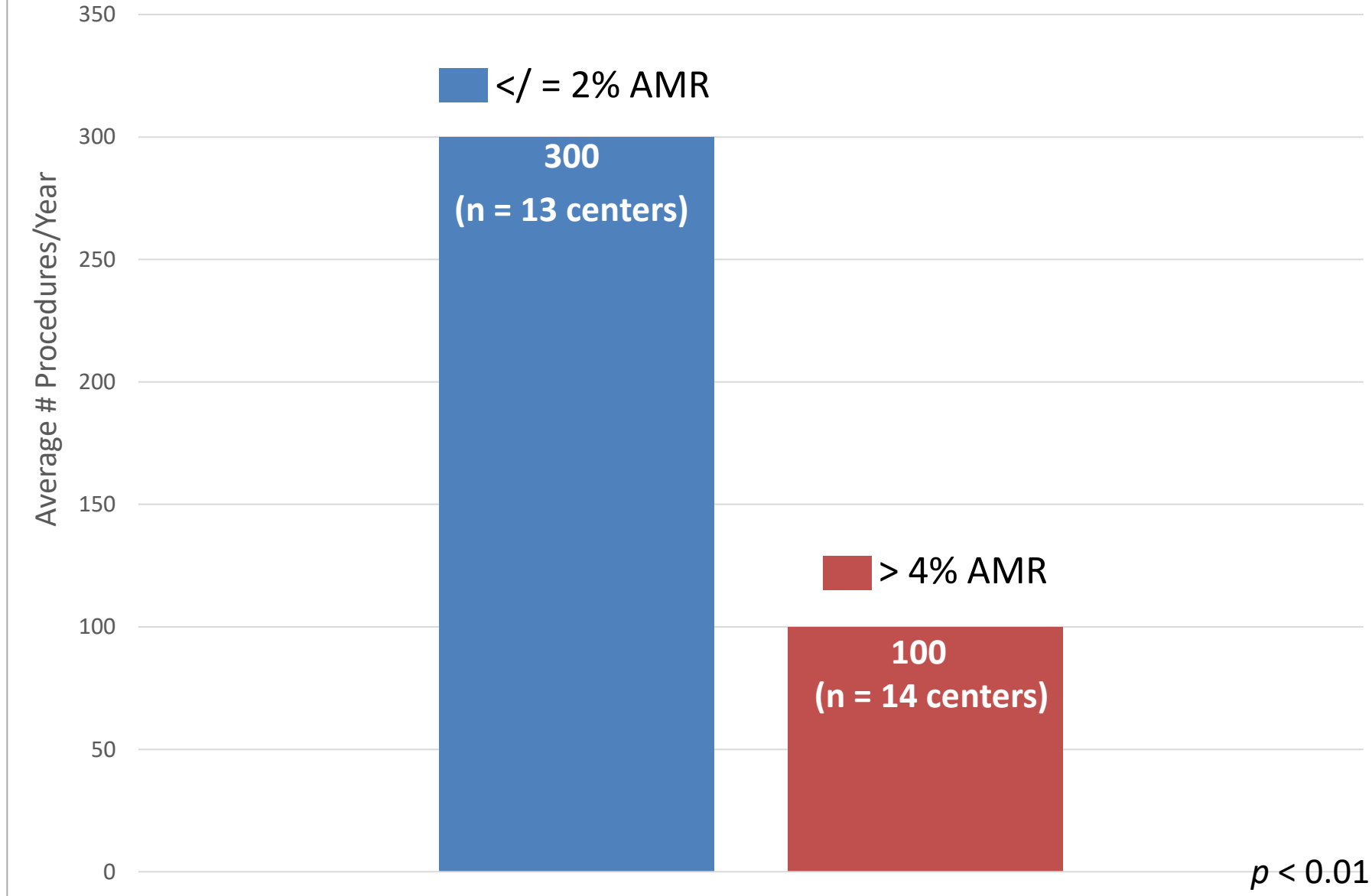
Data Presented by Carl Backer during his CHSS Presidential Address on October 15, 2018.

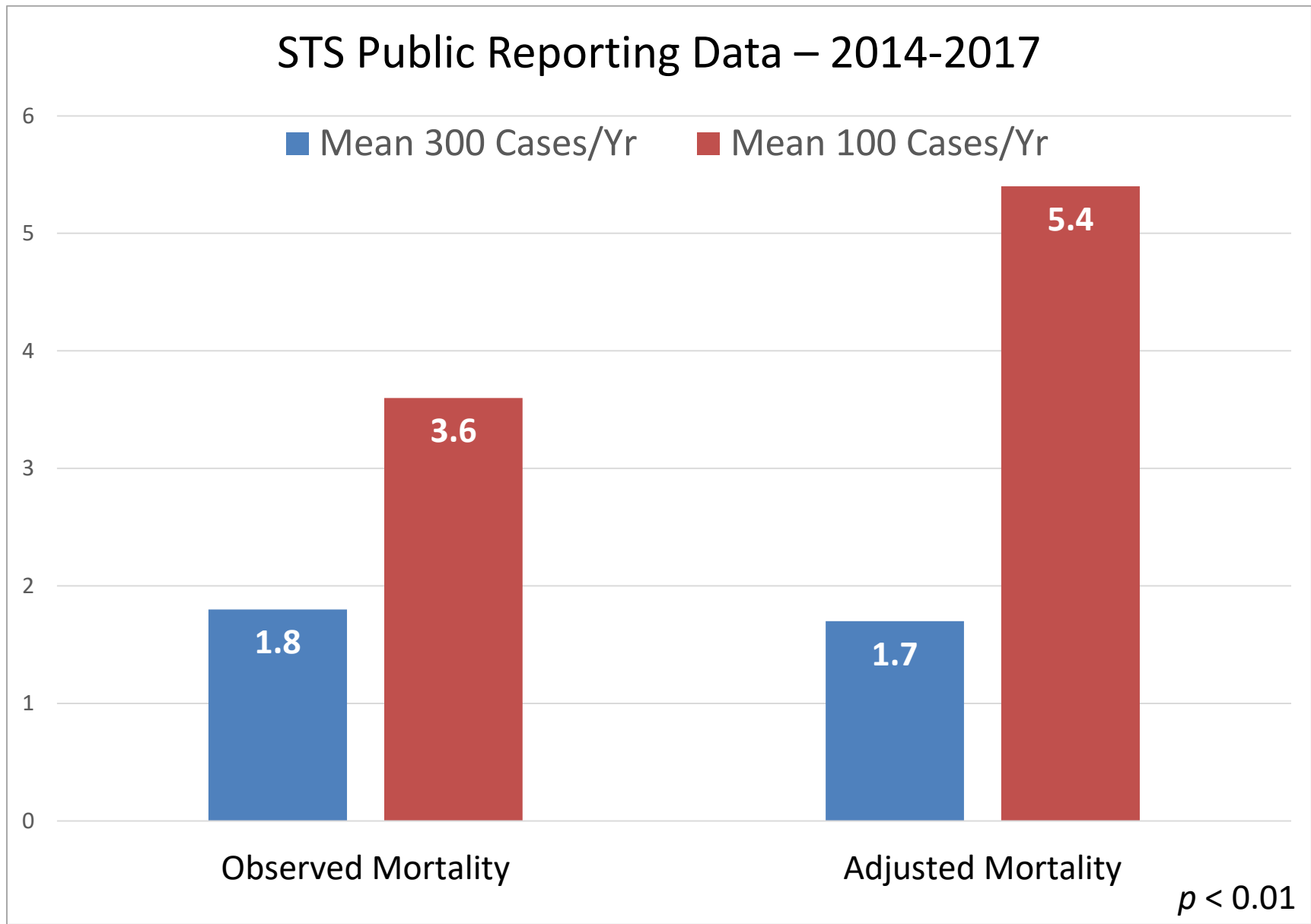
What is the Median Annual
Surgical Case Volume of
Low Mortality (<2%)
versus
High Mortality (>4%) Programs?

Data source: <https://publicreporting.sts.org/>

Data Presented by Carl Backer during his CHSS Presidential Address on October 15, 2018.

STS Public Reporting Data – 2014-2017





Mortality Difference Accentuated when Adjusted for Case Complexity

Does Volume in a Pediatric Cardiac Surgery Program Impact the Results?

Jeffrey P. Jacobs, MD

Professor of Surgery and Pediatrics, Johns Hopkins University

Director, Andrews/Daicoff Cardiovascular Program

Surgical Director of Heart Transplantation

Johns Hopkins All Children's Hospital

Does Volume in a Pediatric Cardiac
Surgery Program Impact the Results?

YES

“**Science** tells us what we can do;

Guidelines what we should do; &

Registries what we are actually doing.”

Lukas Kappenberger MD

Heart Rhythm Society Policy Conference

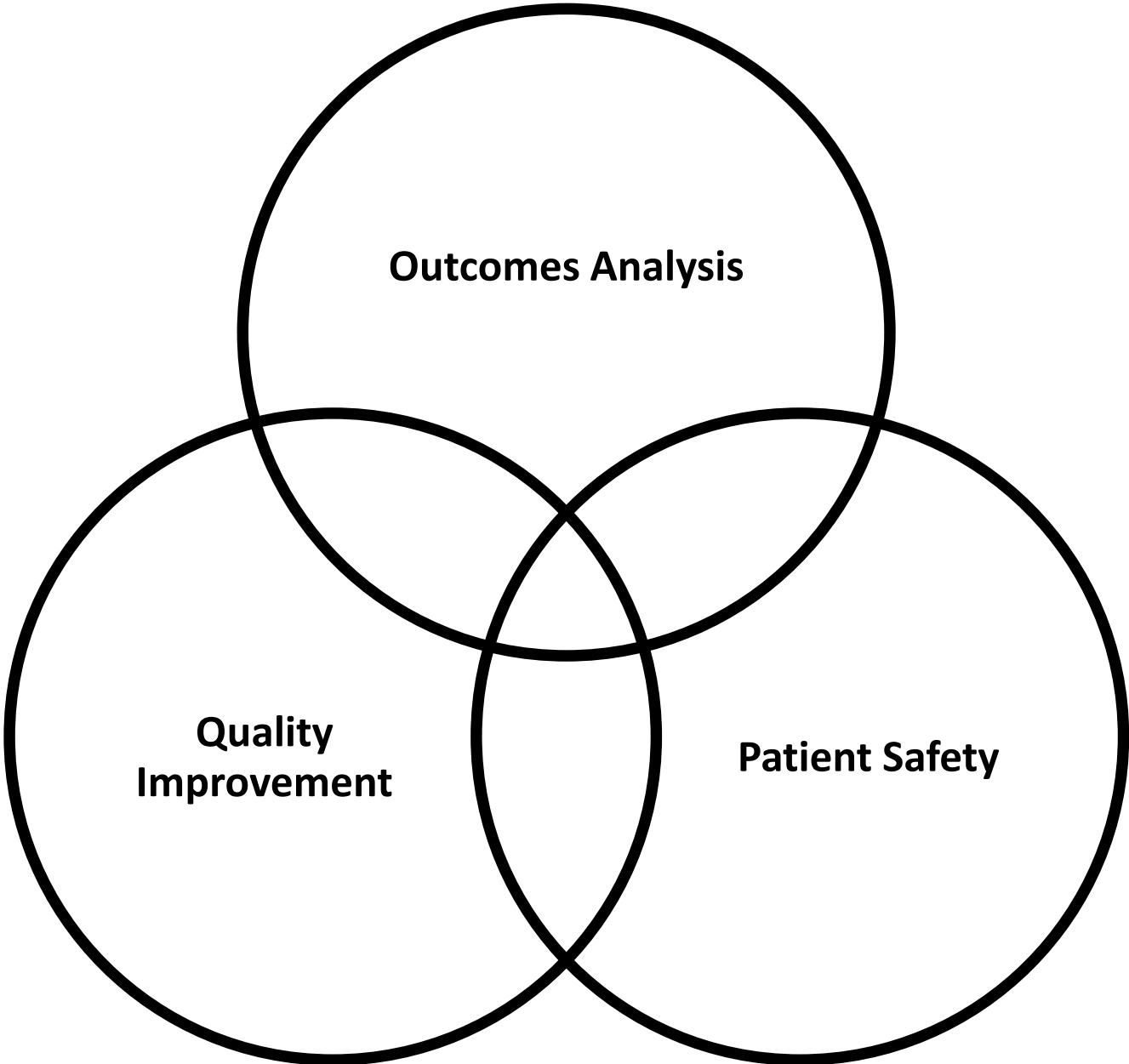
Washington DC 2005



“Without data
you’re just
another person
with an opinion.”

- W. Edwards Deming,
Data Scientist





Outcomes Analysis

**Quality
Improvement**

Patient Safety