

CHSS Paper: Standardizations and Implications for Regionalization of Care

RDB Jaquiss, MD

Assistant to Nicolas Madsen, MD and Jean Storey, MSN, RN, NEA-BC

Children's Health System of Texas

Dallas

Disclosure

- I have no disclosure relevant to this presentation

Objectives and Guardrails

- Vigorously defend surgical volume as *an* important factor in center designation.
- Vigorously defend regionalization as *one of several* methods of QI
- Suggest that we have a cognitive bias vis-à-vis the “bell curve”
- Lament unfortunate rhetorical techniques which employ straw-man arguments and statistical disingenuity
- Propose quality improvement initiatives built on the CHSS standards

All this while trying to....

- Not enlarge my enemies list or impugn motives

What would you do if I showed you a way to produce a four-fold reduction in your STS Mortality Rate?

Evidence-Based Referral Results in Significantly Reduced Mortality After Congenital Heart Surgery

Steven W. Allen, MD*; Kimberlee Gauvreau, ScD†; Barry T. Bloom, MD‡; and Kathy J. Jenkins, MD, MPH

ABSTRACT. *Objective.* Significant interinstitutional variation in mortality after congenital heart surgery has been demonstrated. Noting an association between reduced mortality and higher volume, a center with a small annual case volume began in August 1998 to selectively refer to high-volume surgical centers based on published or "apparent" low mortality rates for specific cardiac lesions. This study was undertaken to evaluate the effect of evidence-based referral in this practice.

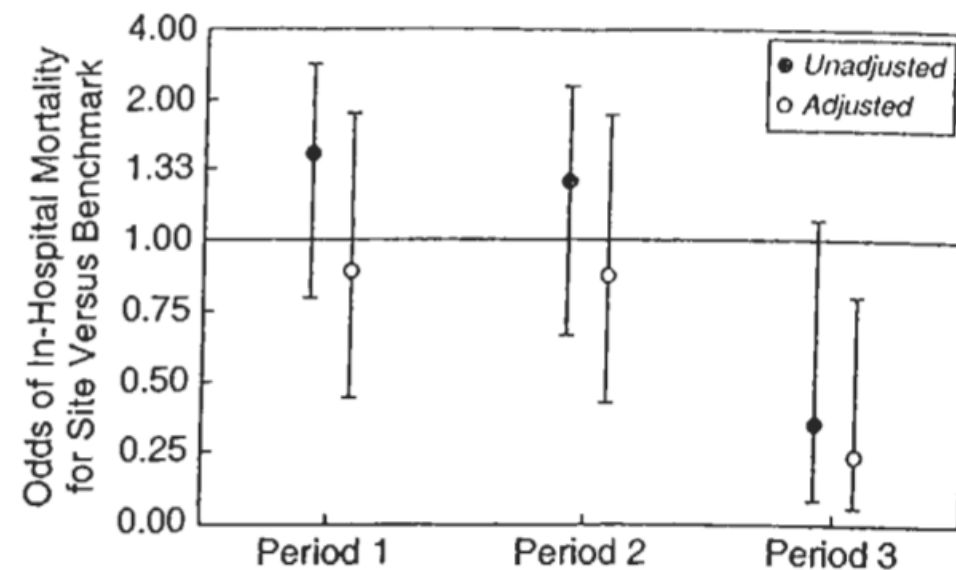
Design, Setting, and Participants. A retrospective cohort comparison over a 10-year period for a small Midwestern pediatric cardiology practice. The institutional database was retrospectively reviewed for children (<18 years) undergoing surgery from August 1992 to July 2002. Data were divided into 3 time periods (August 1992 to July 1995, period 1; August 1995 to July 1998, period 2; and August 1998 to July 2002, period 3). Hospital discharge abstract data from 5 states (California, Illinois, Massachusetts, Pennsylvania, and Washington) in 1992, 1996, and 1998 provided contemporaneous benchmark data. Risk adjustment was performed using multivariate regression in Congenital Heart Surgery Registry, age at surgery, prematurity, and structural anomaly were entered in a logistic regression model to compare adjusting for case-mix differences.

Results. A total of 514 congenital heart lesions were identified from August 1992 to July 2002 (98.6%) were assigned to a risk category. Unadjusted in-hospital mortality rates for congenital heart surgery were 6.4% in period 1, 5.9% in period 2, and 4.8% in period 3. Unadjusted mortality rates for congenital heart surgery were 6.4% in 1992, 4.8% in 1996, and 4.8% in 1998. Risk adjusted mortality was compared to benchmark data in periods 1 and 2, but not in period 3 (odds ratio = 0.24) were demonstrated.

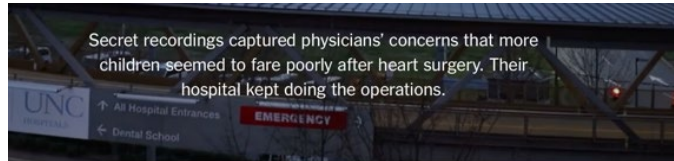
Conclusions. Evidence-based referral to high-volume pediatric cardiac centers for congenital heart surgery resulted in a reduction in mortality after congenital heart surgery. *Pediatrics* 2003;112:200-206.

Surgical results for congenital heart disease (CHD) have dramatically improved over the last 25 years.¹⁻³ Many low-complexity operations are approaching survival rates of 100%,^{4,5} and in some institutions even the most complex lesions have low mortality.⁶ Improvements in diagnostic techniques, anesthesia, perfusion, postoperative care and surgery have altered the natural history of these conditions. However, there remains marked institutional variability in the surgical outcome of patients with CHD.^{5,6}

In response to the recently demonstrated relationship between institutional volume and outcome for CHD surgery,^{1,4-6} a small Midwestern practice with ~50 cases per year instituted a practice change in August 1998. Cases were selectively referred to high-volume (>300 cases/year) surgical centers based on published or "apparent" low mortality rates for specific cardiac lesions (evidence-based referral). After 4



Wasn't That From a Bygone Era?



Doctors Were Alarmed: 'Would I Have My Children Have Surgery Here?'

BY ELLEN GABLER MAY 31, 2019

The Palm Beach Post

REAL NEWS STARTS HERE

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

By Sonja Isgur

Posted Jun 3, 2015 at 12:01 AM
Updated Jun 3, 2015 at 1:07 PM

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.

Colorado News and Denver News: The Denver Post

Hospitals shield mortality rates

By Allison Sherry
Denver Post Staff Writer

March 2, 2001 - Hospital death rates, like those from Children's Hospital that became public this week, are usually seen only by doctors and hospital officials - not their patients.

But it wasn't always that way.

A legislative-appointed group, dubbed the Health Data Commission, used to scrutinize hospital expenses, mortality rates and prices for care. The fledgling group was disbanded in 1994 after bickering with hospital administrators about the subjectivity of its findings. In the end, the state legislature decided to cut its funding.

"The data is helpful internally, but it's less useful in a public document," said Peg O'Keefe, vice president of the Colorado Hospital Association. "People ask their physician what they recommend. There doesn't seem to be a great deal of inter- Screenshot

After CNN investigation, a push to halt child heart surgery at some hospitals

By Elizabeth Cohen, CNN Senior Medical Correspondent
© 9 minute read - Updated 11:27 AM EST, Wed January 13, 2016

f X e



From 2011 to 2015, nine babies died after heart surgery at St. Mary's Medical Center in Florida. This baby, Jaehoon Desamours, went in organ failure after surgery there, but was transferred to another hospital and survived.

Tearing at Children's Heart

The controversy that has shaken Children's Hospital to its core

By Nina Shapiro
Monday, October 9, 2006 12:00am NEWS & COMMENT



TEN-YEAR-OLD DARIUS SOLEIMAN didn't know that the operation he was scheduled to have would end his life. All he knew was that it was going to make him normal again, that it would, at last, relieve him of the congenital heart condition that left him unable to keep up with his schoolmates on the playground. He

alt.
the date on his calendar, June
rew in a wish list for gifts after

Babies die; hospital halts heart surgeries


By Elizabeth Cohen, Senior Medical Correspondent

Updated 10:50 AM ET, Sun August 4, 2013



Johns Hopkins promised to elevate All Children's Heart Institute.
Then patients started to die at an alarming rate.

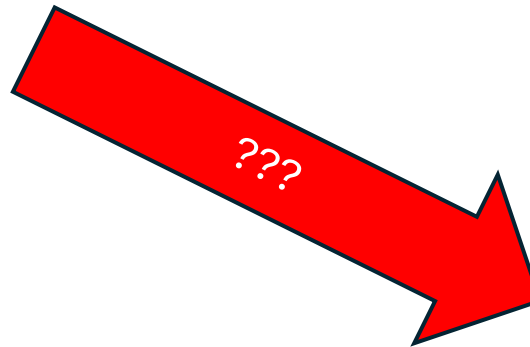
2001, 2006, 2013, 2015, 2016, 2019.....



I'm shocked – shocked! – to find
that gambling's going on in here.

Magnitude of Local Crises?

- Open Door
 - Publicized – whistleblower etc.
- Closed Door
 - Internal and External Review



A More Systematic Look in the Modern Era

Circulation



ORIGINAL RESEARCH ARTICLE

National Variation in Congenital Heart Surgery Outcomes

BACKGROUND: Optimal strategies to improve national congenital heart surgery outcomes and reduce variability across hospitals remain unclear. Many policy and quality improvement efforts have focused primarily on higher-risk patients and mortality alone. Improving our understanding of both morbidity and mortality and current variation across the spectrum of complexity would better inform future efforts.

METHODS: Hospitals participating in the Society of Thoracic Surgeons Congenital Heart Surgery Database (2014–2017) were included. Case mix-adjusted operative mortality, major complications, and postoperative length of stay were evaluated using Bayesian models. Hospital variation was quantified by the interdecile ratio (IDR, upper versus lower 10%) and 95% credible intervals (CrIs). Stratified analyses were performed by risk group (Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery [STAT] category) and simulations evaluated the potential impact of reductions in variation.

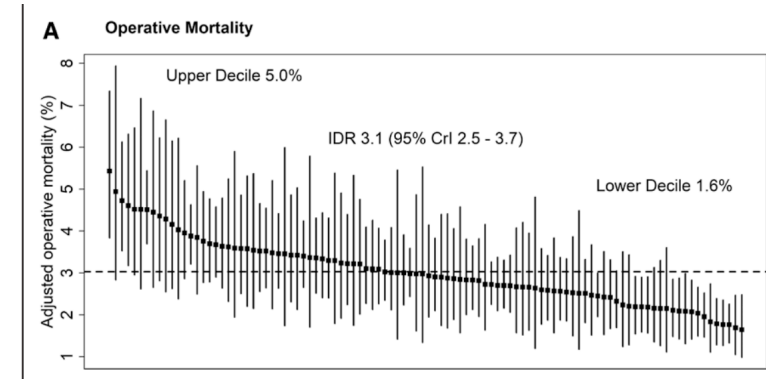
RESULTS: A total of 102 hospitals (n=84 407) were included, representing ≈85% of US congenital heart programs. STAT category 1 to 3 (lower risk) operations comprised 74% of cases. All outcomes varied significantly across hospitals: adjusted mortality by 3-fold (upper versus lower decile 5.0% versus 1.6%, IDR 3.1 [95% CrI 2.5–3.7]), mean length of stay by 1.8-fold (19.2 versus 10.5 days, IDR 1.8 [95% CrI 1.8–1.9]), and major complications by >3-fold (23.5% versus 7.0%, IDR 3.4 [95% CrI 3.0–3.8]). The degree of variation was similar or greater for low- versus high-risk cases across outcomes, eg, ≈3-fold mortality variation across hospitals for STAT 1 to 3 (IDR 3.0 [95% CrI 2.1–4.2]) and STAT 4 or 5 (IDR 3.1 [95% CrI 2.4–3.9]) cases. High-volume hospitals had less variability across outcomes and risk categories. Simulations suggested potential reductions in deaths (n=282), major complications (n=1539), and length of stay (101 183 days) over the 4-year study period if all hospitals were to perform at the current median or better, with 37% to 60% of the improvement related to the STAT 1 to 3 (lower risk) group across outcomes.

CONCLUSIONS: We demonstrate significant hospital variation in morbidity and mortality after congenital heart surgery. Contrary to traditional thinking, a substantial portion of potential improvements that could be realized on a national scale were related to variability among lower-risk cases. These findings suggest modifications to our current approaches to optimize care and outcomes in this population are needed.

Sara K. Pasquali¹, MD, MHS
 Dylan Thibault, MS
 Sean M. O'Brien, PhD
 Jeffrey P. Jacobs, MD
 J. William Gaynor, MD
 Jennifer C. Romano, MD, MS
 Michael Gales², MD, MPH
 Kevin D. Hill, MD, MS
 Marshall L. Jacobs, MD
 David M. Shahian, MD
 Carl L. Backer, MD
 John E. Mayer, MD

Key Words: congenital ■ outcome assessment, health care ■ quality of health care
 Sources of Funding, see page 1359
 © 2020 American Heart Association, Inc.
<https://www.ahajournals.org/journal/circ>

Outcome	Lower Quartile	Median	Upper Quartile	Inter-Quartile Ratio	Inter-Quartile Absolute Difference
Operative mortality (%)					
Overall	1.9 (1.7 - 2.1)	2.9 (2.7 - 3.1)	4.4 (4.0 - 4.9)	2.3 (2.0 - 2.6)	2.5 (2.0 - 3.0)
Non-neonates	1.1 (1.0 - 1.2)	1.7 (1.6 - 1.9)	2.7 (2.4 - 3.0)	2.4 (2.0 - 2.9)	1.5 (1.2 - 2.0)
Neonates	5.2 (4.6 - 5.9)	8.1 (7.4 - 8.9)	13.0 (11.5 - 14.9)	2.5 (2.0 - 3.1)	7.7 (5.9 - 9.9)
STAT 1-3	0.8 (0.7 - 0.9)	1.2 (1.1 - 1.3)	1.8 (1.6 - 2.1)	2.2 (1.7 - 2.9)	1.0 (0.7 - 1.3)
STAT 4-5	5.2 (4.6 - 5.7)	7.7 (7.1 - 8.3)	11.6 (10.5 - 13.1)	2.3 (1.9 - 2.7)	6.5 (5.0 - 8.2)



Simulations suggested potential ***reductions in deaths (n=282)***, major complications (n=1539), and length of stay (101 183 days) over the 4-year study period ***if all hospitals were to perform at the current median or better***, with 37% to 60% of the improvement related to the STAT 1 to 3 (lower risk) group across outcomes.

A More Systematic Look in the Modern Era

Circulation

ORIGINAL RESEARCH ARTICLE

National Variation in Congenital Heart Surgery Outcomes

BACKGROUND: Optimal strategies to improve national congenital heart surgery outcomes and reduce variability across hospitals remain unclear. Many policy and quality improvement efforts have focused primarily on higher-risk patients and mortality alone. Improving our understanding of both morbidity and mortality and current variation across the spectrum of complexity would better inform future efforts.

METHODS: Hospitals participating in the Society of Thoracic Surgeons Congenital Heart Surgery Database (2014–2017) were included. Case mix-adjusted operative mortality, major complications, and postoperative length of stay were evaluated using Bayesian models. Hospital variation was quantified by the interdecile ratio (IDR, upper versus lower 10%) and 95% credible intervals (CrIs). Stratified analyses were performed by risk group (Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery [STAT] category) and simulations evaluated the potential impact of reductions in variation.

RESULTS: A total of 102 hospitals (n=84 407) were included, representing ≈85% of US congenital heart programs. STAT category 1 to 3 (lower risk) operations comprised 74% of cases. All outcomes varied significantly across hospitals: adjusted mortality by 3-fold (upper versus lower decile 5.0% versus 1.6%, IDR 3.1 [95% CrI 2.5–3.7]), mean length of stay by 1.8-fold (19.2 versus 10.5 days, IDR 1.8 [95% CrI 1.8–1.9]), and major complications by >3-fold (23.5% versus 7.0%, IDR 3.4 [95% CrI 3.0–3.8]). The degree of variation was similar or greater for low- versus high-risk cases across outcomes, eg, ≈3-fold mortality variation across hospitals for STAT 1 to 3 (IDR 3.0 [95% CrI 2.1–4.2]) and STAT 4 or 5 (IDR 3.1 [95% CrI 2.4–3.9]) cases. High-volume hospitals had less variability across outcomes and risk categories. Simulations suggested potential reductions in deaths (n=282), major complications (n=1539), and length of stay (101 183 days) over the 4-year study period if all hospitals were to perform at the current median or better, with 37% to 60% of the improvement related to the STAT 1 to 3 (lower risk) group across outcomes.

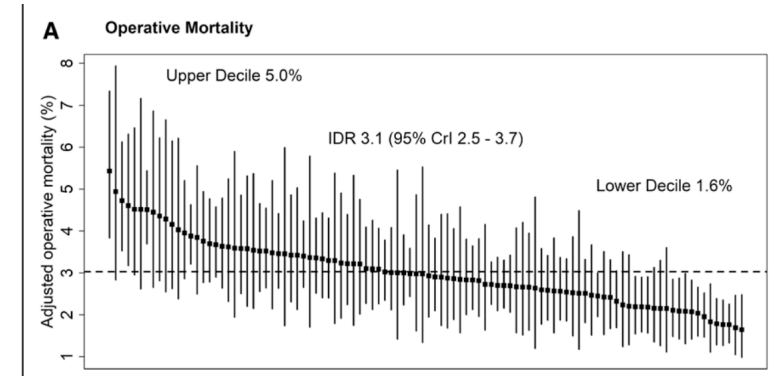
CONCLUSIONS: We demonstrate significant hospital variation in morbidity and mortality after congenital heart surgery. Contrary to traditional thinking, a substantial portion of potential improvements that could be realized on a national scale were related to variability among lower-risk cases. These findings suggest modifications to our current approaches to optimize care and outcomes in this population are needed.

Sara K. Pasquali¹, MD, MHS
 Dylan Thibault, MS
 Sean M. O'Brien, PhD
 Jeffrey P. Jacobs, MD
 J. William Gaynor, MD
 Jennifer C. Romano, MD, MS
 Michael Gales², MD, MPH
 Kevin D. Hill, MD, MS
 Marshall L. Jacobs, MD
 David M. Shahian, MD
 Carl L. Backer, MD
 John E. Mayer, MD

Key Words: congenital heart surgery, outcome assessment, health care quality, quality of health care
 Sources of Funding, see page 1359
 © 2020 American Heart Association, Inc.
<https://www.ahajournals.org/journal/circ>



Outcome	Lower Quartile	Median	Upper Quartile	Inter-Quartile Ratio	Inter-Quartile Absolute Difference
Operative mortality (%)					
Overall	1.9 (1.7 - 2.1)	2.9 (2.7 - 3.1)	4.4 (4.0 - 4.8)	2.3 (2.0 - 2.6)	2.5 (2.0 - 3.0)
Non-neonates	1.1 (1.0 - 1.2)	1.7 (1.6 - 1.9)	2.7 (2.4 - 3.0)	2.4 (2.0 - 2.9)	1.5 (.2 - 2.0)
Neonates	5.2 (4.6 - 5.9)	8.1 (7.4 - 8.9)	13.0 (11.5 - 14.5)	2.5 (2.0 - 3.1)	7.7 (5.9 - 9.9)
STAT 1-3	0.8 (0.7 - 0.9)	1.2 (1.1 - 1.3)	1.8 (1.6 - 2.0)	2.2 (1.7 - 2.9)	1.0 (0.7 - 1.3)
STAT 4-5	5.2 (4.6 - 5.7)	7.7 (7.1 - 8.3)	11.6 (10.5 - 13.1)	2.3 (1.9 - 2.7)	6.5 (5.0 - 8.2)



Simulations suggested potential **reductions in deaths (n=282)**, major complications (n=1539), and length of stay (101 183 days) over the 4-year study period **if all hospitals were to perform at the current median or better**, with 37% to 60% of the improvement related to the STAT 1 to 3 (lower risk) group across outcomes.

Risk Factors

TABLE 3 Results of Multivariable Logistic Regression Model With Inpatient Mortality as Outcome of Interest

Variable	Odds Ratio (95% CI)	P Value
Hospital volume		
High-volume	1	(Reference)
Mid-volume	1.13 (0.91-1.41)	.273
Low-volume	1.51 (1.19-1.90)	<.001
Age		
>1 y	1	(Reference)
Infant	1.16 (0.86-1.56)	.325
Neonate	2.21 (1.61-3.07)	<.001
Low birth weight (<2.5 kg)	2.19 (1.52-3.10)	<.001
Female sex	1.11 (0.92-1.34)	.258
White race	0.69 (0.57-0.83)	<.001
Genetic diagnosis	1.83 (1.28-2.53)	<.001
Heterotaxy	1.81 (0.72-3.88)	.161
Elective procedures	0.29 (0.22-0.39)	<.001
RACHS-2 category	1.37 (1.26 - 1.5)	<.001
Reoperation	1.46 (1.04-2.01)	.023
Preoperative length of stay, d	1.01 (1-1.01)	<.001

Modifiable Risk Factors

TABLE 3 Results of Multivariable Logistic Regression Model With Inpatient Mortality as Outcome of Interest		
Variable	Odds Ratio (95% CI)	P Value
Hospital volume		
High-volume	1	(Reference)
Mid-volume	1.13 (0.91-1.41)	.273
Low-volume	1.51 (1.19-1.90)	<.001



"Houston, we've had a problem.
... main B bus undervolt"

Project Leadership



Joseph A Dearani, MD

Carl L. Backer, MD

James S. Tweddell, MD

Sara K. Pasquali, MD



Committee members

Carl L. Backer MD

David M. Overman MD

Joseph A. Dearani MD

James S. Tweddell MD

Jennifer C. Romano MD, MS

S. Ram Kumar, MD, PhD

Bradley S. Marino MD, MPP, MSCE, MBA

Emile A. Bacha MD

Robert D.B. Jaquiss MD

Ali N. Zaidi MD

Michelle Gurvitz MD

John M. Costello MD, MPH

Trudy A. Pierick MSN, ARNP, CPNP-PC

William J. Ravekes MD

James A. Reagor MD

James D. St. Louis MD

James Spaeth MD

William T. Mahle MD

Andrew Y. Shin MD

Keila N. Lopez MD, MPH

Tara Karamlou MD, MSc

Karl F. Welke MD, MS

Roosevelt Bryant MD

S. Adil Husain MD

Jonathan M. Chen MD

Aditya Kaza MD, MBA

Winfield J. Wells MD

Andrew C. Glatz MD, MSCE

Mitchell I. Cohen MD

Doff B. McElhinney MD

David A. Parra MD

Sara K. Pasquali MD MHS

Working Groups

- Surgery
- Anesthesia
- Perfusion
- Critical Care
- Acute Care
- Imaging (echo/x-section)
- Catheterization
- Electrophysiology
- Heart Failure/Transplant/MCS
- Adult Congenital – Longitudinal Care
- Nursing and Advanced Practice
- Access; DEI

- First meeting March 2021
- Broad representation
 - 30 members
 - 13 societies
 - Diverse representation across program size & geography
 - Surgery, cardiology, anesthesia, nursing, perfusion, etc.
- 25 1-hour zoom meetings

Participating Professional Societies

Congenital Heart Surgeons' Society
Society of Thoracic Surgeons
American Association for Thoracic Surgery
American Heart Association
American College of Cardiology
American Academy of Pediatrics
Congenital Heart Public Health Consortium
Society of Pediatric Cardiovascular Nursing
Pediatric Cardiac Intensive Care Society
American Society of Extracorporeal Technology
Congenital Cardiac Anesthesia Society
Pediatric Heart Transplant Society
World Society for Pediatric and Congenital Heart Surgery



Carl Backer



Sara Kate Pasquali



jdearani



Christo Tchervenkov



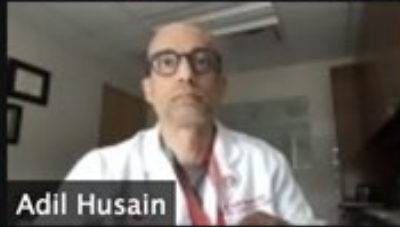
James St. Louis



AK Kaza



Jake Jaquiss



Adil Husain



Tara Karamlou



Andrew Shin



Andy Glatz



Jim Spaeth



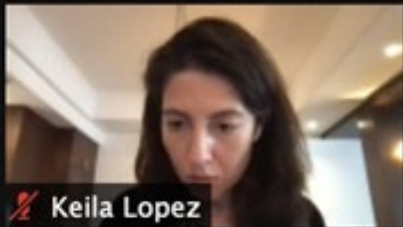
Jenna Romano



Trudy Pierick



John Costello



Keila Lopez



Roosevelt Bryant III



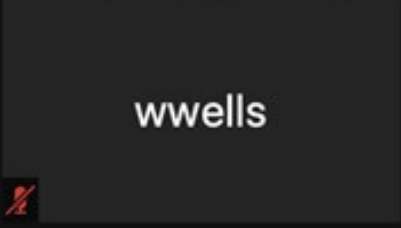
Emile Bacha



Tweddell



Jonathan Chen



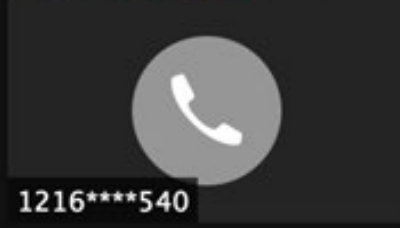
wwells



Maverick



Michelle Gurvitz



1216****540

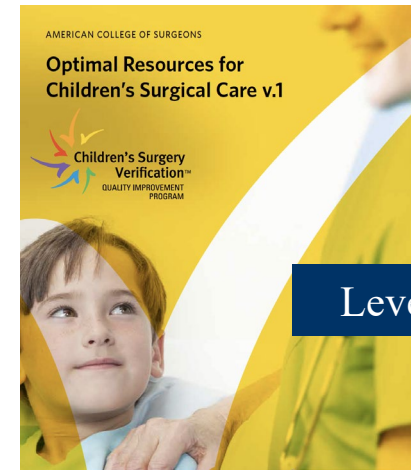


Congenital Heart Disease Standards & Specifications

CHD Surgery: UK (2018)

- minimum of 4 surgeons
- surgeons operate together - complex cases
- Each surgeon >125 procedures/yr

ACS 2015, 2022



Levels I, II, III

Pediatric Heart Center 2002



Guidelines for Pediatric Cardiovascular Centers
Section on Cardiology and Cardiac Surgery
Pediatrics 2002;109:544-549
DOI: 10.1542/peds.109.3.544

The online version of this article, along with updated information and services, is located on the World Wide Web at:
<http://www.pediatrics.org/cgi/content/full/109/3/544>

CHD Surgery: ECHSA/EACTS (2003)

- Optimal Structure of a Congenital Heart Surgery Department in Europe
 - Large units – Full spectrum
 - Smaller units – Standard care
- *Eur J Cardiothorac Surg* 2003;24:343-351

NICU (2012)



Levels of Neonatal Care
COMMITTEE ON FETUS AND NEWBORN
Pediatrics 2012;130:587
DOI: 10.1542/peds.2012-1999 originally published online August 27, 2012;

Levels I, II, III, IV (4 Levels)

Terms That Are Not Equivalent



Recommendations

I/We think you should...



Guidelines

I/We think you should...
because of this level of evidence



Standards

You must....

EXPERT CONSENSUS STATEMENT

Recommendations for Centers Performing Pediatric Heart Surgery in the United States



Carl L. Backer, MD,¹ David M. Overman, MD,² Joseph A. Dearani, MD,³
Jennifer C. Romano, MD, MS,⁴ James S. Tweddell, MD,¹ S. Ram Kumar, MD, PhD,⁵
Bradley S. Marino, MD, MPP, MSCE, MBA,⁶ Emile A. Bacha, MD,⁷ Robert D. B. Jaquiss, MD,⁸
Ali N. Zaidi, MD,⁹ Michelle Gurvitz, MD,¹⁰ John M. Costello, MD, MPH,¹¹
Trudy A. Pierick, MSN, ARNP, CPNP-PC,¹² William J. Ravekes, MD,¹³
James A. Reagor, MPS, CCP, FPP,¹⁴ James D. St. Louis, MD,¹⁵ James Spaeth, MD,¹⁶
William T. Mahle, MD,¹⁷ Andrew Y. Shin, MD,¹⁸ Keila N. Lopez, MD, MPH,¹⁹
Tara Karamlou, MD, MSc,²⁰ Karl F. Welke, MD, MS,²¹ Roosevelt Bryant, MD,²²
S. Adil Husain, MD,²³ Jonathan M. Chen, MD,²⁴ Aditya Kaza, MD, MBA,²⁵
Winfield J. Wells, MD,⁵ Andrew C. Glatz, MD, MSCE,²⁶ Mitchell I. Cohen, MD,²⁷
Doff B. McElhinney, MD,¹⁸ David A. Parra, MD,²⁸ and Sara K. Pasquali, MD, MHS²⁹

Care and outcomes for the more than 40,000 patients undergoing pediatric and congenital heart surgery in the United States annually are known to vary widely. While consensus recommendations have been published across numerous fields as one mechanism to promote a high level of care delivery across centers, it has been more than two decades since the last pediatric heart surgery recommendations were published in the United States. More recent guidance is lacking, and collaborative efforts involving the many disciplines engaged in caring for these children have not been undertaken to date. The present initiative brings together professional societies spanning numerous care domains and congenital cardiac surgeons, pediatric cardiologists, nursing, and other healthcare professionals from diverse programs around the country to develop consensus recommendations for United States centers. The focus of this initial work is on pediatric heart surgery, and it is recommended that future efforts focus in detail on the adult congenital population. We describe the background, rationale, and methodology related to this collaborative effort, and recommendations put forth for Essential Care Centers (essential services necessary for any program), and Comprehensive Care Centers (services to optimize comprehensive and high-complexity care), encompassing structure, process, and outcome metrics across 14 domains.

(Ann Thorac Surg 2023;116:871-907)

© 2023 The Society of Thoracic Surgeons, The American Association For Thoracic Surgery, and World Society for Pediatric and Congenital Heart Surgery. Published by SAGE Publications Inc. on behalf of World Society for Pediatric and Congenital Heart Surgery and Elsevier Inc on behalf of The Society of Thoracic Surgeons and The American Association For Thoracic Surgery. All rights reserved.

Endorsed By:

Congenital Heart Surgeons' Society
Society of Thoracic Surgeons
American Association for Thoracic Surgery
American Heart Association
American College of Cardiology
American Academy of Pediatrics
Congenital Heart Public Health Consortium
Society of Pediatric Cardiovascular Nursing
Pediatric Cardiac Intensive Care Society
American Society of Extracorporeal Technology
Congenital Cardiac Anesthesia Society
Pediatric Heart Transplant Society
World Society for Pediatric and Congenital Heart Surgery

EXPERT CONSENSUS STATEMENT

Recommendations for Centers Performing Pediatric Heart Surgery in the United States



Carl L. Backer, MD,¹ David M. Overman, MD,² Joseph A. Dearani, MD,³ Jennifer C. Romano, MD, MS,⁴ James S. Tweddell, MD,¹ S. Ram Kumar, MD, PhD,⁵ Bradley S. Marino, MD, MPP, MSCE, MBA,⁶ Emile A. Bacha, MD,⁷ Robert D. B. Jaquiss, MD,⁸ Ali N. Zaidi, MD,⁹ Michelle Gurvitz, MD,¹⁰ John M. Costello, MD, MPH,¹¹ Trudy A. Pierick, MSN, ARNP, CPNP-PC,¹² William J. Ravekes, MD,¹³ James A. Reagor, MPS, CCP, FPP,¹⁴ James D. St. Louis, MD,¹⁵ James Spaeth, MD,¹⁶ William T. Mahle, MD,¹⁷ Andrew Y. Shin, MD,¹⁸ Keila N. Lopez, MD, MPH,¹⁹ Tara Karamlou, MD, MSc,²⁰ Karl F. Welke, MD, MS,²¹ Roosevelt Bryant, MD,²² S. Adil Husain, MD,²³ Jonathan M. Chen, MD,²⁴ Aditya Kaza, MD, MBA,²⁵ Winfield J. Wells, MD,⁵ Andrew C. Glatz, MD, MSCE,²⁶ Mitchell I. Cohen, MD,²⁷ Doff B. McElhinney, MD,¹⁸ David A. Parra, MD,²⁸ and Sara K. Pasquali, MD, MHS²⁹

Care and outcomes for the more than 40,000 patients undergoing pediatric and congenital heart surgery in the United States annually are known to vary widely. While consensus recommendations have been published across numerous fields as one mechanism to promote a high level of care delivery across centers, it has been more than two decades since the last pediatric heart surgery recommendations were published in the United States. More recent guidance is lacking, and collaborative efforts involving the many disciplines engaged in caring for these children have not been undertaken to date. The present initiative brings together professional societies spanning numerous care domains and congenital cardiac surgeons, pediatric cardiologists, nursing, and other healthcare professionals from diverse programs around the country to develop consensus recommendations for United States centers. The focus of this initial work is on pediatric heart surgery, and it is recommended that future efforts focus in detail on the adult congenital population. We describe the background, rationale, and methodology related to this collaborative effort, and recommendations put forth for Essential Care Centers (essential services necessary for any program), and Comprehensive Care Centers (services to optimize comprehensive and high-complexity care), encompassing structure, process, and outcome metrics across 14 domains.

(Ann Thorac Surg 2023;116:871-907)

© 2023 The Society of Thoracic Surgeons, The American Association For Thoracic Surgery, and World Society for Pediatric and Congenital Heart Surgery. Published by SAGE Publications Inc. on behalf of World Society for Pediatric and Congenital Heart Surgery and Elsevier Inc on behalf of The Society of Thoracic Surgeons and The American Association For Thoracic Surgery. All rights reserved.

Endorsed By:

Congenital Heart Surgeons' Society
Society of Thoracic Surgeons
American Association for Thoracic Surgery
American Heart Association
American College of Cardiology
American Academy of Pediatrics
Congenital Heart Public Health Consortium
Society of Pediatric Cardiovascular Nursing
Pediatric Cardiac Intensive Care Society
American Society of Extracorporeal Technology
Congenital Cardiac Anesthesia Society
Pediatric Heart Transplant Society
World Society for Pediatric and Congenital Heart Surgery

Number of times "regionalization" is used - 0
Number of times "standardization" is used - 4
-handoffs, training, care protocols

Format of Recommendations

- Structure; Process; Outcomes
- Two Tiers
 - Volume & Complexity of Surgery
 - Scope of Service
 - Relationship-Affiliation
- Focus on Process-Variability Reduction
 - Failure to Rescue
 - Case Planning & Review
 - Organization/Structure Matter
 - Dependence on Systems *not* Individuals

Selected Recommendations

	Comprehensive	Essential
Minimum Index Case Volume	200	75
Complex Cases	Yes	In collaboration with CCC
Transplant / VAD	Yes	In collaboration with CCC
Number of Surgeons	>/= 3	2*
Coverage	24/7/365	24/7/365
Cardiac ORs	>/=2	1
Prespecified Transfer/Collaboration	NA	Yes
Transparent Internal and External Outcome Reporting – STS Participation	Yes	Yes
Dedicated CICU	Yes	No
PC4 and PAC3	Yes/Yes	Yes/Encouraged
Minimum Catheterization Volume	150	?

- Take a drink of water....interlude

Numbers and Measurements.... Lies, Damned Lies, and Statistics

THE SHIRKY PRINCIPLE

INSTITUTIONS WILL TRY TO PRESERVE THE PROBLEM TO WHICH THEY ARE THE SOLUTION

GOOD NEWS! I FIXED ALL THE CARS SO WELL THEY WON'T NEED TO COME IN AGAIN.

GREAT! WAIT... WHAT??



Clay Shirky

Lawyers, statisticians, medical researchers....."more study is needed"

OPINION

Why Can't Everyone Get A's?

Excellence is not a zero sum game.

June 15, 2019



Alvaro Dominguez

[Share full article](#) [↻](#) [🔖](#) [💬 1K](#)

By Alfie Kohn

Mr. Kohn is the author of books on human behavior and education.

Statistician-supported and industrially-sponsored cognitive bias

OPINION

Why Can't Everyone Get A's?

Excellence is not a zero sum game.

June 15, 2019



Alvaro Dominguez

[Share full article](#) [↻](#) [🔖](#) [💬 1K](#)

By **Alfie Kohn**

Mr. Kohn is the author of books on human behavior and education.



We can't all be here.....

Who Is Served By Rankings?

Home / Best Hospitals / Pediatric Rankings / Pediatric Cardiology & Heart ...

Best Children's Hospitals for Cardiology & Heart Surgery

Fifty centers were ranked in pediatric cardiology care. Survival after complex heart surgery, such as heart transplants and corrective surgery for congenital heart defects, specialized staff, services and technologies, commitment to best practices and ability to prevent infections accounted for most of each hospital's score.

[How We Rank And Rate Hospitals »](#)



80 matches


[Clear Filters](#)

[Children's Hospitals](#) X

[Pediatric Cardiology & Heart Surgery](#) X

SORT BY: Ranking ▾

Hospital/Center employed
“Departments of US News and World
Report”

	[REDACTED] PhD, LSSBB <i>Vice President National Excellence</i> <i>National Excellence Strategy</i> C: [REDACTED]
	E: [REDACTED] @childrens.com
1935 Medical District Drive Dallas, TX 75235	
Follow Children's Health SM childrens.com      	

Who Is Served By Rankings? – Not patients


Home / Best Hospitals / Pediatric Rankings / Pediatric Cardiology & Heart ...

Best Children's Hospitals for Cardiology & Heart Surgery

How centers were ranked in pediatric cardiology care: survival after complex heart surgery, such as heart transplants and corrective surgery for congenital heart defects, specialized staff, services and technologies, commitment to best practices and ability to prevent infections accounted for most of each hospital's score.

[How We Rank And Rate Hospitals >](#)

80 matches [Clear Filters](#) [Children's Hospitals](#) [Pediatric Cardiology & Heart Surgery](#) SORT BY: Ranking



OPINION

Why Can't Everyone Get A's?

Excellence is not a zero sum game.

June 15, 2019



Alvaro Dominguez

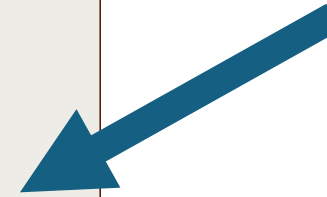
Share full article

By Alfie Kohn

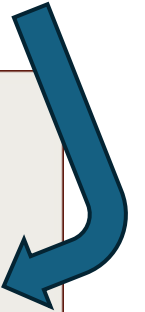
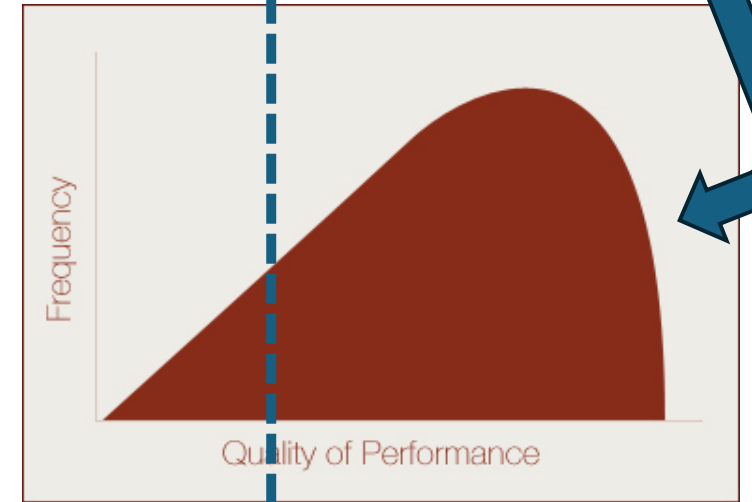
Mr. Kohn is the author of books on human behavior and education.



We can't all be here.....

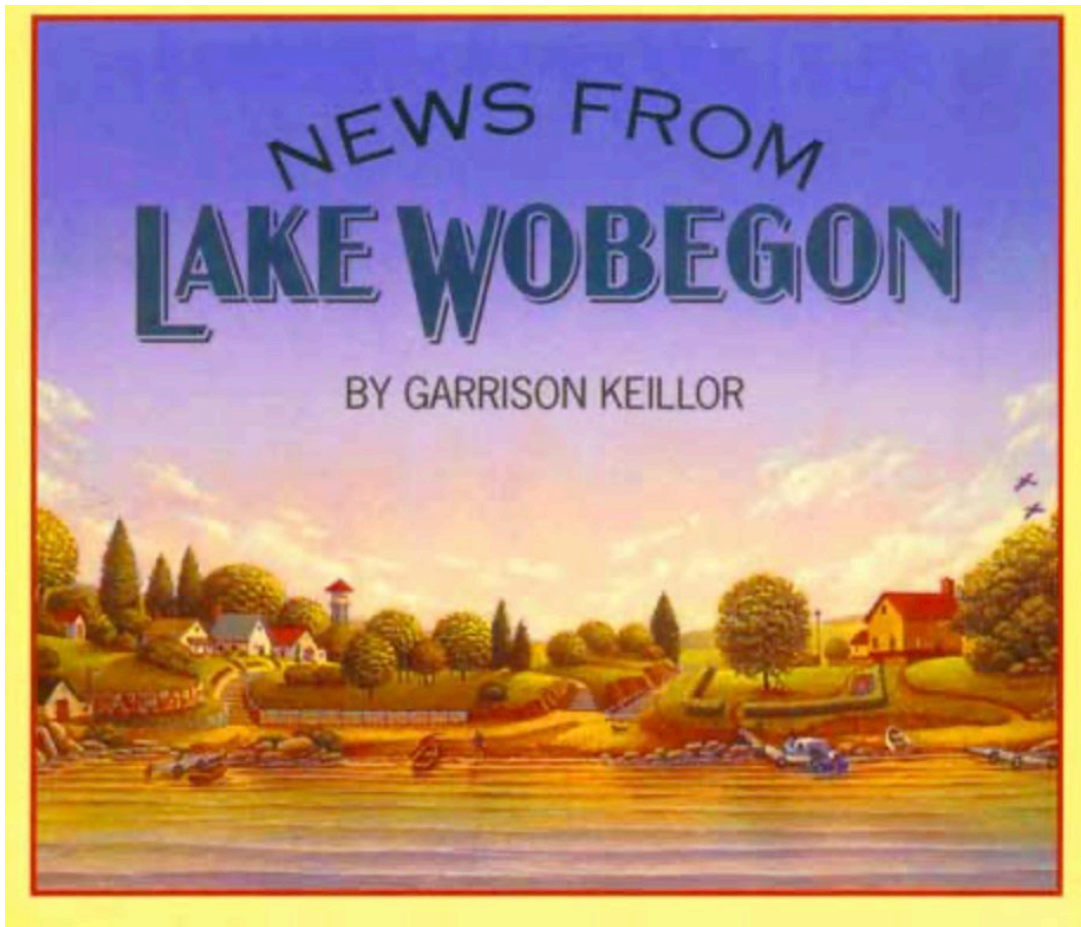


Can most of us be here?



Not Acceptable

Acceptable



"Where the women are strong, the men are good- looking and all the children are above average."



“Patients and families made it clear that they did not want to travel to the best hospital. Rather they expected that we would provide excellent care, everywhere.”

Professor Martin Elliott



“It would be better if everyone worked together as a system, with the aim for everybody to win.”

Dr. W. Edwards Deming

Choosing a Center?

STS Public Reporting



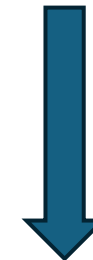
Adult Cardiac **General Thoracic** Resources Patient Information

Congenital Heart Surgery Public Reporting

Public reporting for the STS Congenital Heart Surgery Database (CHSD) presents hospital-specific results over a 4-year period.

Operative and Adjusted Operative Mortality (July 2019-June 2023)

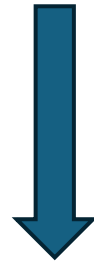
Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	30 / 1390	2.16%	2.63%	0.82 (0.54, 1.09)	2.18 (1.45, 2.9)
STAT Mortality Category 1	5 / 701	0.71%	0.61%	1.17 (0.38, 2.73)	0.76 (0.25, 1.76)
STAT Mortality Category 2	2 / 289	0.69%	1.94%	0.36 (0.04, 1.28)	0.69 (0.08, 2.48)
STAT Mortality Category 3	4 / 180	2.22%	2.86%	0.78 (0.21, 1.95)	2.6 (0.71, 6.53)
STAT Mortality Category 4	7 / 149	4.7%	7.56%	0.62 (0.25, 1.25)	4.86 (1.98, 9.77)
STAT Mortality Category 5	12 / 71	16.9%	14.54%	1.16 (0.62, 1.9)	17.4 (9.31, 28.47)



Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
2.16%	2.63%	0.82 (0.54, 1.09)	2.18 (1.45, 2.9)

- 40% of deaths in STAT 5; 5% of cases
- 24% of death in entire STS; 4% of cases

Measuring “Performance” in the STS Database

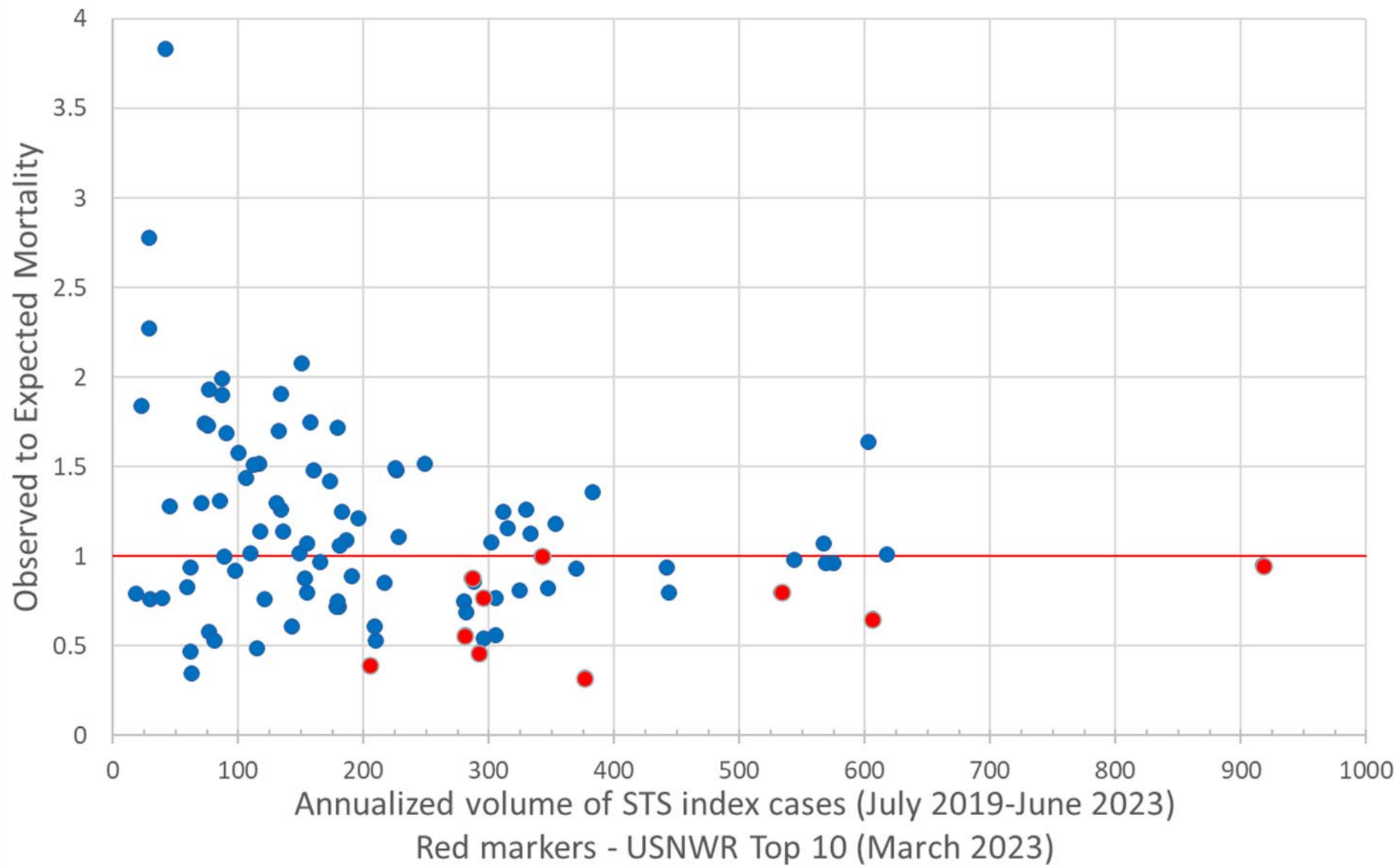


Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
2.16%	2.63%	0.82 (0.54, 1.09)	2.18 (1.45, 2.9)

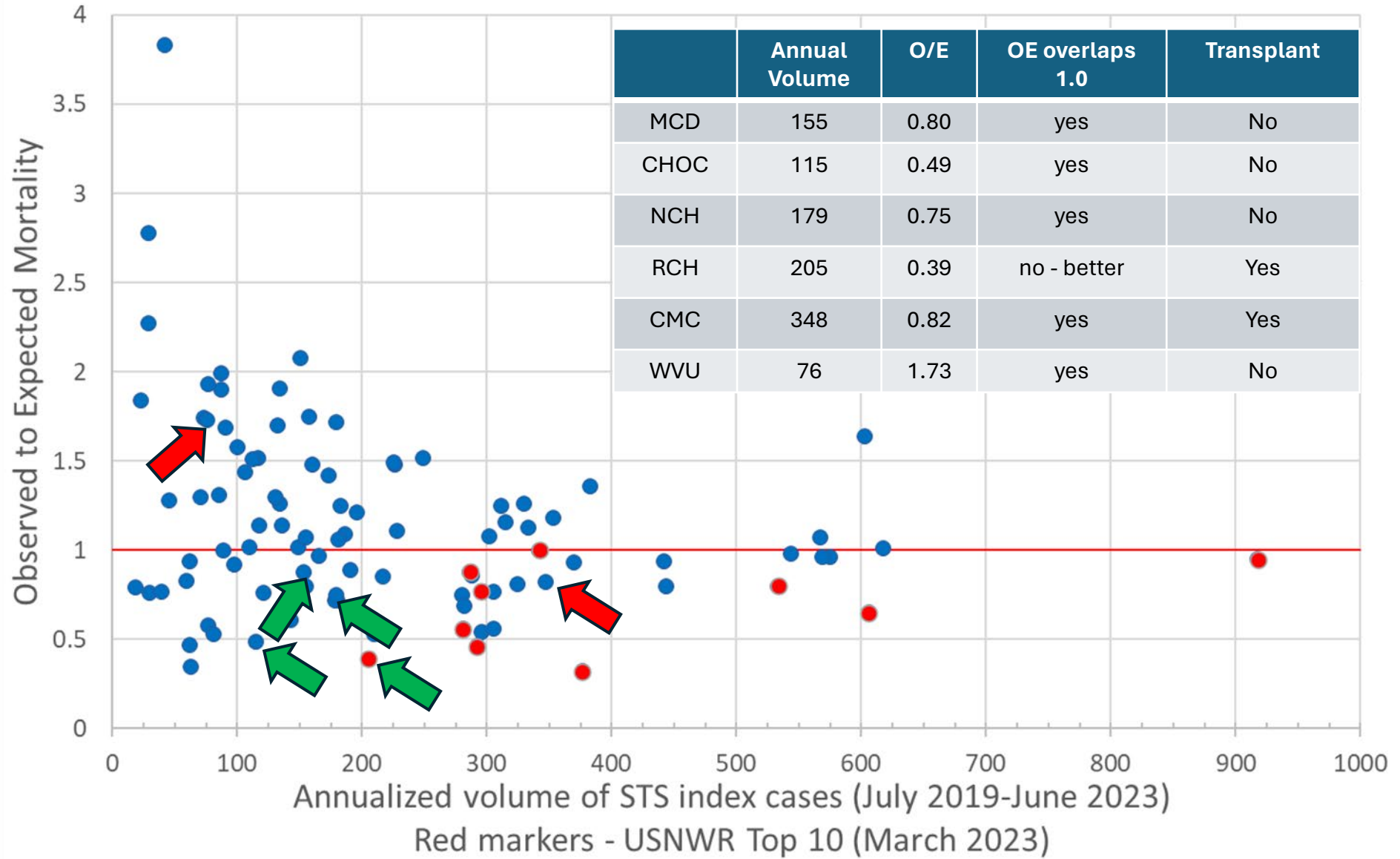
The Confidence Interval – an Ally and an Enemy

- How sure are we that our point estimate is a true reflection?
- For small n measurements, the confidence interval is very wide
 - This gives cover (a place to hide)

O/E ratio vs Annualized volume of STS index cases



O/E ratio vs Annualized volume of STS index cases



Observed to Expected Mortality by Size Category

All Cases

	< 75 Cases	75-200 Cases	200-400 Cases	>400 Cases
O:E Ratio > 1	8	29	10	2
O:E Ratio =/<1	7	14	18	9

Observed to Expected Mortality by Size Category

STAT 5 Cases

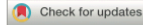
	< 75 Cases	75-200 Cases	200-400 Cases	>400 Cases
O:E Ratio > 1	5	25	10	4
O:E Ratio =/<1	0	17	17	7



CONGENITAL HEART SURGERY:

The *Annals of Thoracic Surgery* CME Program is located online at <http://www.annalsthoracicsurgery.org/cme/home>. To take the CME activity related to this article, you must have either an STS member or an individual non-member subscription to the journal.

Contemporary Relationship Between Hospital Volume and Outcomes in Congenital Heart Surgery



Karl F. Welke, MD, MS,¹ Tara Karamlou, MD, MSc,² Sean M. O'Brien, PhD,³ Joseph A. Dearani, MD,⁴ James S. Tweddell, MD,⁵ S. Ram Kumar, MD, PhD,^{6,7} Jennifer C. Romano, MD, MS,^{8,9} Carl L. Backer, MD,^{10,11} and Sara K. Pasquali, MD, MHS¹²

ABSTRACT

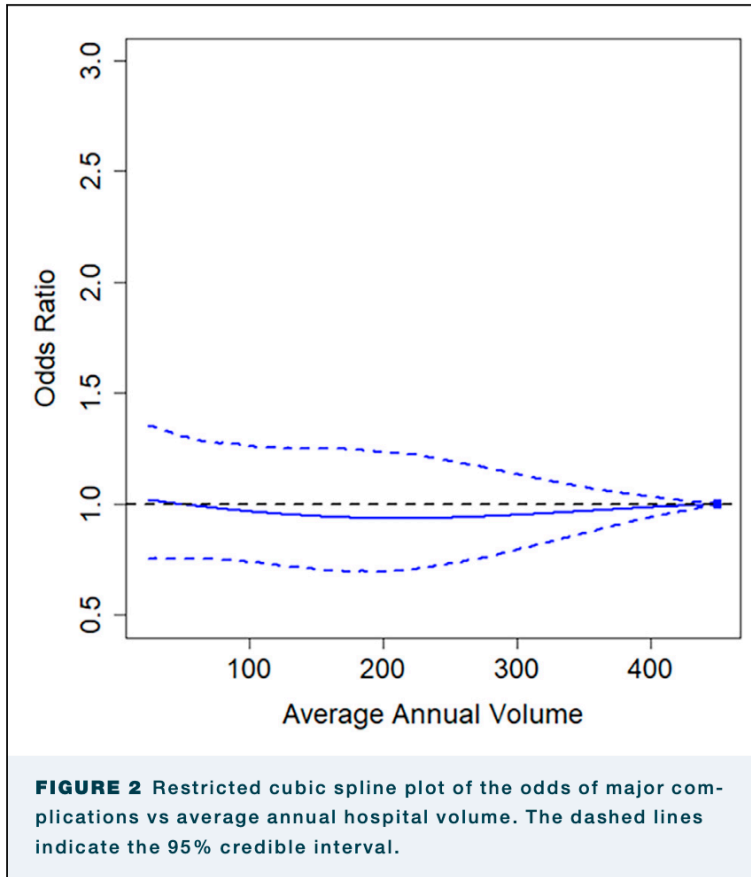
BACKGROUND Studies examining the volume-outcome relationship in congenital heart surgery (CHS) are more than a decade old. Since then, mortality has declined, and case-mix adjustment has evolved. We determined the current relationship between hospital CHS volume and outcomes.

METHODS Patients aged ≤18 years undergoing index operations in The Society of Thoracic Surgeons-Congenital Heart Surgery Database (2017-2020) were included. Associations between annual hospital volume and case-mix-adjusted operative mortality, major complications, failure to rescue (FTR), and postoperative length of stay (PLOS) were assessed using Bayesian hierarchical models, overall, by The Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STAT) category, and for the Norwood procedure.

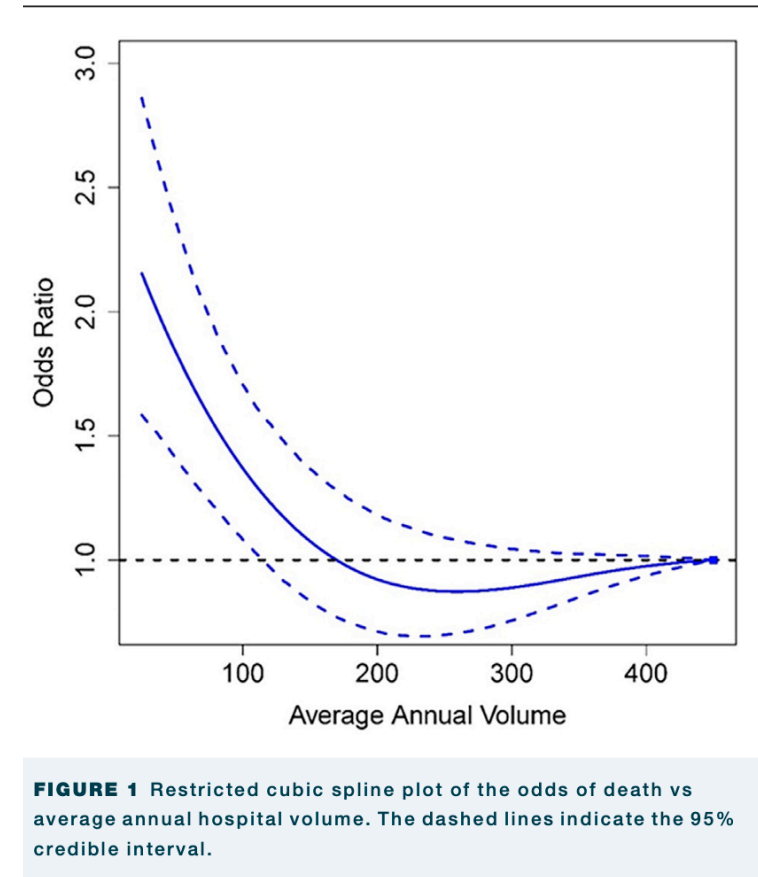
RESULTS Across 101 centers (76,714 index operations), median annual volume was 144 operations/y. Operative mortality was 2.7%. Lower-volume hospitals had higher mortality, with an apparent transition zone at ~190 operations/y (95% credible interval [CrI], 115-450 operations/y), below which a sustained uptick in the estimated odds of death occurred. Odds of death compared with a 450 operations/y reference were 50 operations/y (odds ratio [OR], 1.84; 95% CrI, 1.41-2.37), 100 operations/y (OR, 1.37; 95% CrI, 1.08-1.71), 200 operations/y (OR, 0.92; 95% CrI, 0.1-1.18), 300 operations/y (OR, 0.89; 95% CrI, 0.76-1.04). The volume-outcome effect was more apparent for STAT 4 to 5 than STAT 1 to 3 operations. In the overall cohort, PLOS and complications were similar across hospital volumes, whereas FTR rates were higher at lower-volume hospitals. Lower-volume hospitals had worse outcomes after the Norwood procedure, most notably mortality and FTR.

CONCLUSIONS Hospital volume is associated with mortality and FTR after CHS. The relationship is strongest for high-risk operations. These data can inform ongoing initiatives to improve CHS care.

(Ann Thorac Surg 2023;116:1233-40)



Complications



Mortality

A Protest Appears...

Specious Reasoning

- **Opinions Without Evidence**
- **Straw Man**
- **Selective Argument**
- **Flawed Premise**
- **Circular Logic**
- **Virtue Signalling**

A Straw Man Meets Selective Argument

Congenital & Pediatric: Research

JAMES S. TWEDDELL MEMORIAL PAPER FOR CONGENITAL CARDIAC SURGERY

Volume Alone Does Not Predict Quality Outcomes in Hospitals Performing Pediatric Cardiac Surgery

Dhaval Chauhan, MD,¹ J. Hunter Mehaffey, MD, MS,¹ J. W. Awori Hayanga, MD, MPH,¹ Jai P. Udassi, MD,² Vinay Badhwar, MD,¹ and Christopher E. Mascio, MD¹

ABSTRACT

BACKGROUND Lower institutional volume has been associated with inferior pediatric cardiac surgery outcomes. This study explored the variation in mortality rates among low-, mid-, and high-volume hospitals performing pediatric cardiac surgery in the United States.

METHODS The Kids' Inpatient Database was explored for the years 2016 and 2019. Hospitals performing only off-bypass coarctation and ventricular septal defect repair were omitted. The hospitals were divided into 3 groups by their annual case volume. Multivariable logistic regression models were fit to obtain risk-adjusted in-hospital mortality rates.

RESULTS A total of 25,749 operations performed by 235 hospitals were included in the study. The risk-adjusted mortality rate for the entire sample was 1.9%. There were 140 hospitals in the low-volume group, 64 hospitals in the mid-volume group, and 31 in the high-volume group. All groups had low-mortality (mortality <1.9%) and high-mortality (mortality >1.9%) hospitals. Among low-volume hospitals, 53% were low-mortality (n = 74) and 47% were high-mortality (n = 66) hospitals. Among mid-volume hospitals, 58% were low-mortality (n = 37) and 42% were high-mortality (n = 27) hospitals. Among high-volume hospitals, 68% were low-mortality (n = 21) and 32% were high-mortality (n = 10) hospitals. There was no statistically significant difference in risk-adjusted in-hospital mortality when comparing low-, mid-, and high-volume centers for 7 Society of Thoracic Surgeons benchmark procedures.

CONCLUSIONS This national, real-world, risk-adjusted volume outcome analysis highlights that volume alone may not be the sole arbiter to predict quality of pediatric cardiac surgery outcomes. Using case volume alone as a surrogate for quality may unfairly asperse high-performing, low-volume programs.

(Ann Thorac Surg 2024; ■:■-■)

© 2024 by The Society of Thoracic Surgeons. Published by Elsevier Inc.

“Volume Alone Does Not Predict Quality Outcomes...in ...Pediatric Cardiac Surgery”

JAMES S. TWEDDELL MEMORIAL PAPER FOR CONGENITAL CARDIAC SURGERY

Volume Alone Does Not Predict Quality Outcomes in Hospitals Performing Pediatric Cardiac Surgery

Dhaval Chauhan, MD,¹ J. Hunter Mehaffey, MD, MS,¹ J. W. Awori Hayanga, MD, MPH,¹ Jai P. Udassi, MD,² Vinay Badhwar, MD,¹ and Christopher E. Mascio, MD¹

ABSTRACT

BACKGROUND Lower institutional volume has been associated with inferior pediatric cardiac surgery outcomes. This study explored the variation in mortality rates among low-, mid-, and high-volume hospitals performing pediatric cardiac surgery in the United States.

METHODS The Kids' Inpatient Database was explored for the years 2016 and 2019. Hospitals performing only off-bypass coarctation and ventricular septal defect repair were omitted. The hospitals were divided into 3 groups by their annual case volume. Multivariable logistic regression models were fit to obtain risk-adjusted in-hospital mortality rates.

RESULTS A total of 25,749 operations performed by 235 hospitals were included in the study. The risk-adjusted mortality rate for the entire sample was 1.9%. There were 140 hospitals in the low-volume group, 64 hospitals in the mid-volume group, and 31 in the high-volume group. All groups had low-mortality (mortality <1.9%) and high-mortality (mortality >1.9%) hospitals. Among low-volume hospitals, 53% were low-mortality (n = 74) and 47% were high-mortality (n = 66) hospitals. Among mid-volume hospitals, 58% were low-mortality (n = 37) and 42% were high-mortality (n = 27) hospitals. Among high-volume hospitals, 68% were low-mortality (n = 21) and 32% were high-mortality (n = 10) hospitals. There was no statistically significant difference in risk-adjusted in-hospital mortality when comparing low-, mid-, and high-volume centers for 7 Society of Thoracic Surgeons benchmark procedures.

CONCLUSIONS This national, real-world, risk-adjusted volume outcome analysis highlights that volume alone may not be the sole arbiter to predict quality of pediatric cardiac surgery outcomes. Using case volume alone as a surrogate for quality may unfairly asperse high-performing, low-volume programs.

(Ann Thorac Surg 2024; ■:■-■)

© 2024 by The Society of Thoracic Surgeons. Published by Elsevier Inc.

We recommend the community to **steer away from using specific numbers as a sole metric** and give merit to a program on the basis of the presence of a comprehensive system of care.

JAMES S. TWEDDELL MEMORIAL PAPER FOR CONGENITAL CARDIAC SURGERY

Volume Alone Does Not Predict Quality Outcomes in Hospitals Performing Pediatric Cardiac Surgery

Dhaval Chauhan, MD,¹ J. Hunter Mehaffey, MD, MS,¹ J. W. Awori Hayanga, MD, MPH,¹ Jai P. Udassi, MD,² Vinay Badhwar, MD,¹ and Christopher E. Mascio, MD¹

ABSTRACT

BACKGROUND Lower institutional volume has been associated with inferior pediatric cardiac surgery outcomes. This study explored the variation in mortality rates among low-, mid-, and high-volume hospitals performing pediatric cardiac surgery in the United States.

METHODS The Kids' Inpatient Database was explored for the years 2016 and 2019. Hospitals performing only off-bypass coarctation and ventricular septal defect repair were omitted. The hospitals were divided into 3 groups by their annual case volume. Multivariable logistic regression models were fit to obtain risk-adjusted in-hospital mortality rates.

RESULTS A total of 25,749 operations performed by 235 hospitals were included in the study. The risk-adjusted mortality rate for the entire sample was 1.9%. There were 140 hospitals in the low-volume group, 64 hospitals in the mid-volume group, and 31 in the high-volume group. All groups had low-mortality (mortality <1.9%) and high-mortality (mortality >1.9%) hospitals. Among low-volume hospitals, 53% were low-mortality (n = 74) and 47% were high-mortality (n = 66) hospitals. Among mid-volume hospitals, 58% were low-mortality (n = 37) and 42% were high-mortality (n = 27) hospitals. Among high-volume hospitals, 68% were low-mortality (n = 21) and 32% were high-mortality (n = 10) hospitals. There was no statistically significant difference in risk-adjusted in-hospital mortality when comparing low-, mid-, and high-volume centers for 7 Society of Thoracic Surgeons benchmark procedures.

CONCLUSIONS This national, real-world, risk-adjusted volume outcome analysis highlights that volume alone may not be the sole arbiter to predict quality of pediatric cardiac surgery outcomes. Using case volume alone as a surrogate for quality may unfairly asperse high-performing, low-volume programs.

(Ann Thorac Surg 2024; ■:■-■)

© 2024 by The Society of Thoracic Surgeons. Published by Elsevier Inc.

We recommend the community to *steer away from using specific numbers as a sole metric* and give merit to a program on the basis of the presence of a comprehensive system of care.

TABLE 3 Results of Multivariable Logistic Regression Model With Inpatient Mortality as Outcome of Interest

Variable	Odds Ratio (95% CI)	P Value
Hospital volume		
High-volume	1	(Reference)
Mid-volume	1.13 (0.91-1.41)	.273
Low-volume	1.51 (1.19-1.90)	<.001

JAMES S. TWEDDELL MEMORIAL PAPER FOR CONGENITAL CARDIAC SURGERY

Volume Alone Does Not Predict Quality Outcomes in Hospitals Performing Pediatric Cardiac Surgery

Dhaval Chauhan, MD,¹ J. Hunter Mehaffey, MD, MS,¹ J. W. Awori Hayanga, MD, MPH,¹ Jai P. Udassi, MD,² Vinay Badhwar, MD,¹ and Christopher E. Mascio, MD¹

ABSTRACT

BACKGROUND Lower institutional volume has been associated with inferior pediatric cardiac surgery outcomes. This study explored the variation in mortality rates among low-, mid-, and high-volume hospitals performing pediatric cardiac surgery in the United States.

METHODS The Kids' Inpatient Database was explored for the years 2016 and 2019. Hospitals performing only off-bypass coarctation and ventricular septal defect repair were omitted. The hospitals were divided into 3 groups by their annual case volume. Multivariable logistic regression models were fit to obtain risk-adjusted in-hospital mortality rates.

RESULTS A total of 25,749 operations performed by 235 hospitals were included in the study. The risk-adjusted mortality rate for the entire sample was 1.9%. There were 140 hospitals in the low-volume group, 64 hospitals in the mid-volume group, and 31 in the high-volume group. All groups had low-mortality (mortality <1.9%) and high-mortality (mortality >1.9%) hospitals. Among low-volume hospitals, 53% were low-mortality (n = 74) and 47% were high-mortality (n = 66) hospitals. Among mid-volume hospitals, 58% were low-mortality (n = 37) and 42% were high-mortality (n = 27) hospitals. Among high-volume hospitals, 68% were low-mortality (n = 21) and 32% were high-mortality (n = 10) hospitals. There was no statistically significant difference in risk-adjusted in-hospital mortality when comparing low-, mid-, and high-volume centers for 7 Society of Thoracic Surgeons benchmark procedures.

CONCLUSIONS This national, real-world, risk-adjusted volume outcome analysis highlights that volume alone may not be the sole arbiter to predict quality of pediatric cardiac surgery outcomes. Using case volume alone as a surrogate for quality may unfairly asperse high-performing, low-volume programs.

(Ann Thorac Surg 2024; ■:■-■)

© 2024 by The Society of Thoracic Surgeons. Published by Elsevier Inc.

We recommend the community to *steer away from using specific numbers as a sole metric* and give merit to a program on the basis of the presence of a comprehensive system of care.

TABLE 3 Results of Multivariable Logistic Regression Model With Inpatient Mortality as Outcome of Interest

Variable	Odds Ratio (95% CI)	P Value
Hospital volume		
High-volume	1	(Reference)
Mid-volume	1.13 (0.91-1.41)	.273
Low-volume	1.51 (1.19-1.90)	<.001



”

”

**BEWARE OF EXCEPTIONAL
EXAMPLES USED TO
MAKE A POINT ABOUT
A WHOLE GROUP.**

– HANS ROSLING



Hans Rosling, MD
1948-2017

- Volume isn't everything (and no one said it was)
- Volume isn't nothing

EXPERT CONSENSUS STATEMENT

Recommendations for Centers Performing Pediatric Heart Surgery in the United States



Carl L. Backer, MD,¹ David M. Overman, MD,² Joseph A. Dearani, MD,³
Jennifer C. Romano, MD, MS,⁴ James S. Tweddell, MD,¹ S. Ram Kumar, MD, PhD,⁵
Bradley S. Marino, MD, MPP, MSCE, MBA,⁶ Emile A. Bacha, MD,⁷ Robert D. B. Jaquiss, MD,⁸
Ali N. Zaidi, MD,⁹ Michelle Gurvitz, MD,¹⁰ John M. Costello, MD, MPH,¹¹
Trudy A. Pierick, MSN, ARNP, CPNP-PC,¹² William J. Ravekes, MD,¹³
James A. Reagor, MPS, CCP, FPP,¹⁴ James D. St. Louis, MD,¹⁵ James Spaeth, MD,¹⁶
William T. Mahle, MD,¹⁷ Andrew Y. Shin, MD,¹⁸ Keila N. Lopez, MD, MPH,¹⁹
Tara Karamlou, MD, MSc,²⁰ Karl F. Welke, MD, MS,²¹ Roosevelt Bryant, MD,²²
S. Adil Husain, MD,²³ Jonathan M. Chen, MD,²⁴ Aditya Kaza, MD, MBA,²⁵
Winfield J. Wells, MD,⁵ Andrew C. Glatz, MD, MSCE,²⁶ Mitchell I. Cohen, MD,²⁷
Doff B. McElhinney, MD,¹⁸ David A. Parra, MD,²⁸ and Sara K. Pasquali, MD, MHS²⁹

Care and outcomes for the more than 40,000 patients undergoing pediatric and congenital heart surgery in the United States annually are known to vary widely. While consensus recommendations have been published across numerous fields as one mechanism to promote a high level of care delivery across centers, it has been more than two decades since the last pediatric heart surgery recommendations were published in the United States. More recent guidance is lacking, and collaborative efforts involving the many disciplines engaged in caring for these children have not been undertaken to date. The present initiative brings together professional societies spanning numerous care domains and congenital cardiac surgeons, pediatric cardiologists, nursing, and other healthcare professionals from diverse programs around the country to develop consensus recommendations for United States centers. The focus of this initial work is on pediatric heart surgery, and it is recommended that future efforts focus in detail on the adult congenital population. We describe the background, rationale, and methodology related to this collaborative effort, and recommendations put forth for Essential Care Centers (essential services necessary for any program), and Comprehensive Care Centers (services to optimize comprehensive and high-complexity care), encompassing structure, process, and outcome metrics across 14 domains.

(Ann Thorac Surg 2023;116:871-907)

© 2023 The Society of Thoracic Surgeons, The American Association For Thoracic Surgery, and World Society for Pediatric and Congenital Heart Surgery. Published by SAGE Publications Inc. on behalf of World Society for Pediatric and Congenital Heart Surgery and Elsevier Inc on behalf of The Society of Thoracic Surgeons and The American Association For Thoracic Surgery. All rights reserved.

Endorsed By:

Congenital Heart Surgeons' Society
Society of Thoracic Surgeons
American Association for Thoracic Surgery
American Heart Association
American College of Cardiology
American Academy of Pediatrics
Congenital Heart Public Health Consortium
Society of Pediatric Cardiovascular Nursing
Pediatric Cardiac Intensive Care Society
American Society of Extracorporeal Technology
Congenital Cardiac Anesthesia Society
Pediatric Heart Transplant Society
World Society for Pediatric and Congenital Heart Surgery

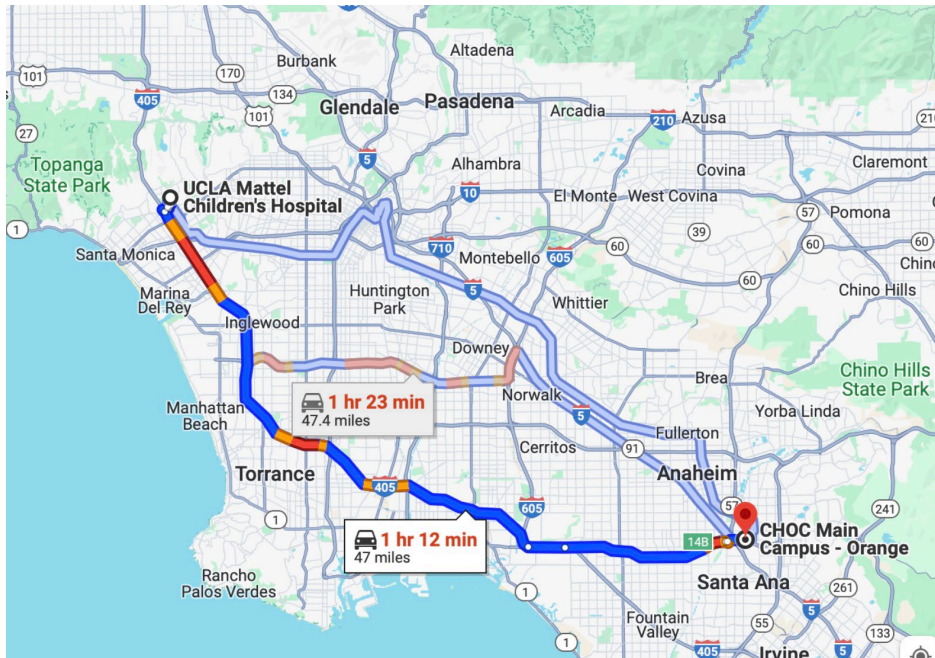
Format of Recommendations

- Structure; Process; Outcomes
- Two Tiers
 - Volume & Complexity of Surgery
 - Scope of Service
 - Relationship-Affiliation
- Focus on Process-Variability Reduction
 - Failure to Rescue
 - Case Planning & Review
 - Organization/Structure Matter
 - Dependence on Systems *not* Individuals

Some Things That Might Work...

- Affiliation
- (A Little) Regionalization
- Collaborative Learning (Cardiac Networks United etc.)
- Actual and Virtual Site Visits/Verification

Affiliation



Operative and Adjusted Operative Mortality (July 2019-June 2023)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	3 / 460	0.65%	1.33%	0.49 (0, 1)	1.3 (0, 2.66)
STAT Mortality Category 1	0 / 271	0%	0.47%	0 (0, 2.88)	0 (0, 1.86)
STAT Mortality Category 2	2 / 102	1.96%	1.3%	1.5 (0.18, 5.3)	2.92 (0.36, 10.29)
STAT Mortality Category 3	0 / 34	0%	1.94%	0 (0, 5.3)	0 (0, 17.74)
STAT Mortality Category 4	1 / 51	1.96%	5.27%	0.37 (0.01, 1.98)	2.91 (0.07, 15.5)
STAT Mortality Category 5	0 / 2	0%	8.69%	0 (0, 9.69)	0 (0, 100)

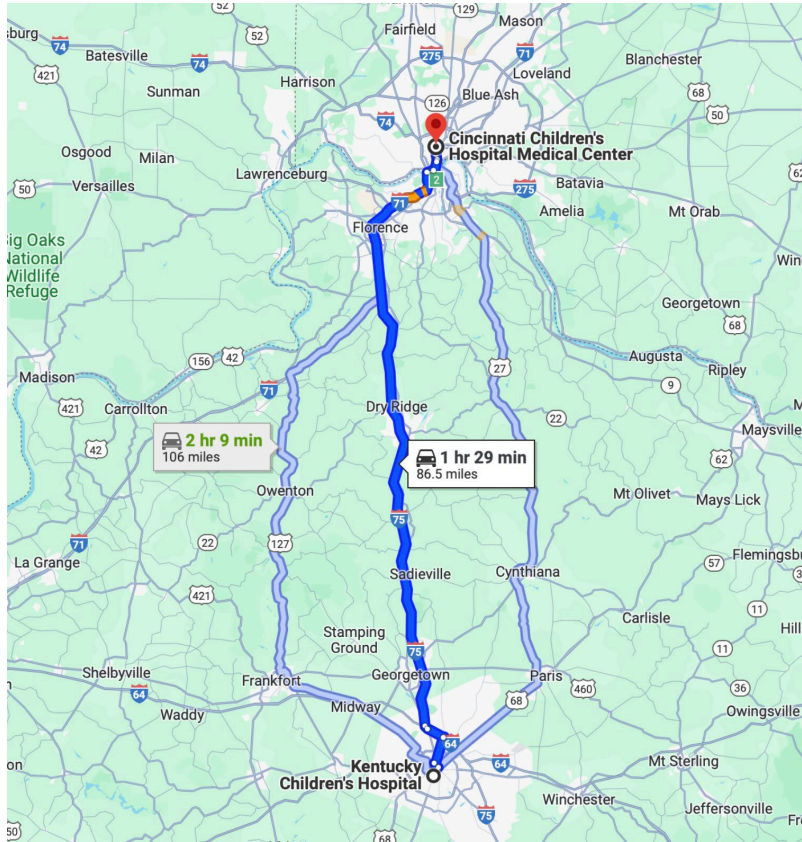
CHOC STAT 4 51/460 = 11% STAT 5 2/460 = 0.4%

Operative and Adjusted Operative Mortality (July 2019-June 2023)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	26 / 1222	2.13%	2.77%	0.77 (0.52, 1.05)	2.04 (1.37, 2.79)
STAT Mortality Category 1	5 / 536	0.93%	0.7%	1.33 (0.43, 3.08)	0.86 (0.28, 1.99)
STAT Mortality Category 2	4 / 346	1.16%	1.7%	0.68 (0.19, 1.72)	1.32 (0.36, 3.35)
STAT Mortality Category 3	4 / 119	3.36%	3.16%	1.06 (0.29, 2.65)	3.56 (0.98, 8.87)
STAT Mortality Category 4	9 / 164	5.49%	7.54%	0.73 (0.34, 1.35)	5.69 (2.64, 10.54)
STAT Mortality Category 5	4 / 57	7.02%	14.16%	0.5 (0.14, 1.2)	7.42 (2.06, 17.98)

UCLA. STAT 4 164/1222 = 13% STAT 5 57/1222 = 4.6%

Affiliation



Operative and Adjusted Operative Mortality (July 2019-June 2023)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	1 / 250	0.4%	1.16%	0.35 (0, 1.27)	0.92 (0, 3.39)
STAT Mortality Category 1	0 / 174	0%	0.56%	0 (0, 3.76)	0 (0, 2.43)
STAT Mortality Category 2	0 / 43	0%	1.51%	0 (0, 5.45)	0 (0, 10.58)
STAT Mortality Category 3	1 / 17	5.88%	2.97%	1.98 (0.05, 9.66)	6.63 (0.17, 32.31)
STAT Mortality Category 4	0 / 16	0%	4.83%	0 (0, 4.26)	0 (0, 33.34)
STAT Mortality Category 5	0 / 0	0%	0%	0 (0, 0)	0 (0, 0)

UKCH STAT 4 16/250 = 6% STAT 5 0/250 = 0%

Operative and Adjusted Operative Mortality (July 2019-June 2023)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	41 / 1368	3%	3%	1 (0.73, 1.28)	2.65 (1.94, 3.41)
STAT Mortality Category 1	2 / 582	0.34%	0.75%	0.46 (0.06, 1.65)	0.3 (0.04, 1.07)
STAT Mortality Category 2	8 / 343	2.33%	1.87%	1.24 (0.54, 2.42)	2.42 (1.05, 4.71)
STAT Mortality Category 3	4 / 189	2.12%	3.34%	0.63 (0.17, 1.6)	2.12 (0.58, 5.33)
STAT Mortality Category 4	17 / 174	9.77%	8.12%	1.2 (0.71, 1.87)	9.41 (5.58, 14.63)
STAT Mortality Category 5	10 / 80	12.5%	12.3%	1.02 (0.5, 1.77)	15.21 (7.5, 26.51)

CCHMC STAT 4 174/1368 = 13% STAT 5 80/1368 = 6%

Regionalization

Regionalization Exists Already, Albeit Imperfectly

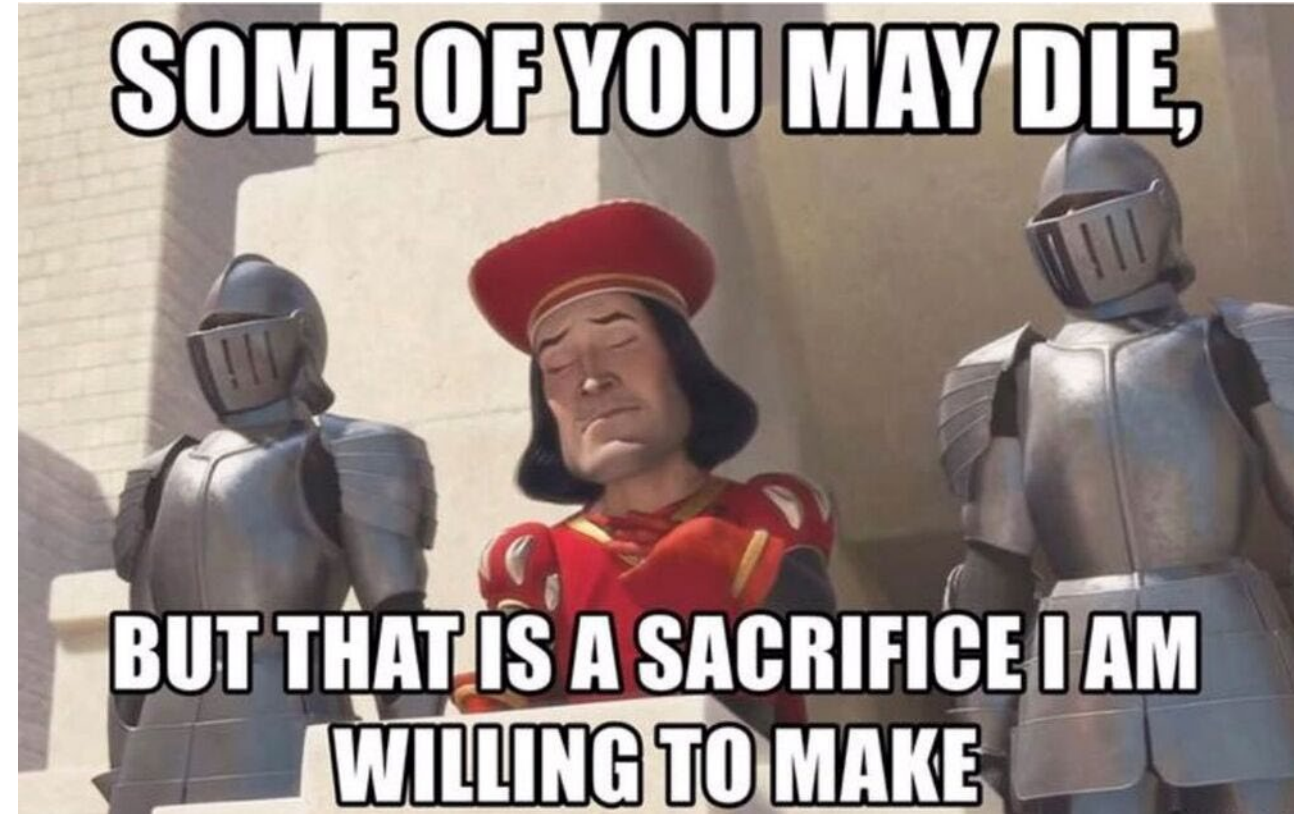
- Patients are referred for transplant to regional centers, sometimes
- Patients are referred for certain rare diagnoses and procedures
 - TOF/MAPCA
 - Ebstein anomaly
 - Fetal intervention
- Cooperative arrangements
 - Cincinnati/UK; Columbia/Cornell; UCLA/CHOC; UCSF/Oakland; Duke/ECU; Mayo/Children's Minnesota
 - Not always successful – UTSW/Dell; others; 2 pediatric transplant programs in Houston; etc.
 - Too early to tell – Duke/UNC

Reasons to Oppose Regionalization - Legitimate

- Potential for "reduced access" (expense, time, insurance coverage, family support, coherent/continuous follow-up)?
- Logistical complexity (sharing of images/records/consultation)
- Capacity constraints at existing facilities
- Feasibility – financial, logistical, political, bureaucratic obstacles

Reasons to Oppose Regionalization - Other

- Cardiac care is profitable – Tens/hundreds of millions of \$/yr
- Cardiac care is important for education – UGME/GME
- Cardiac care provides halo effect – infrastructure
- Cardiac care is prestigious – medical school dean, CEO



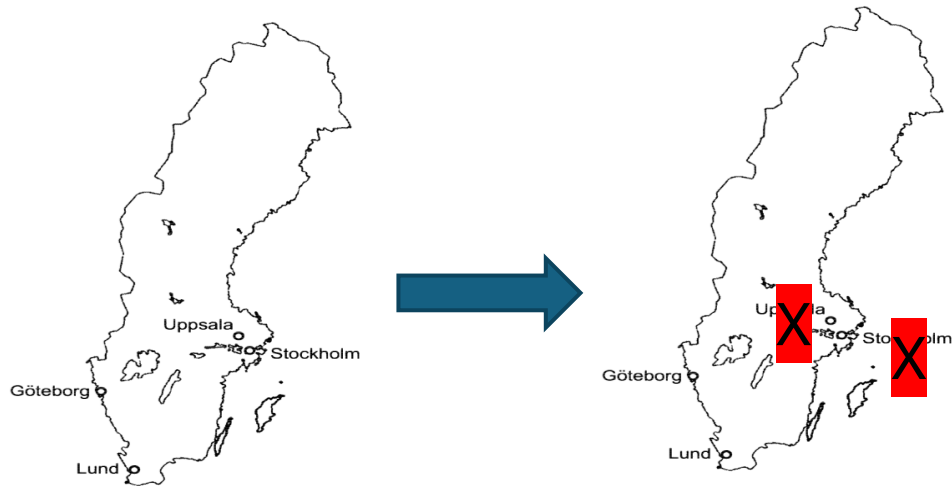
Reasons to Support Regionalization

- Improved outcomes = lives saved
- Faster improvement of care/better clinical research with larger n
- Economic efficiency
- Better education for specialists

Is Regionalization Effective and Feasible?

- Sweden – unequivocal yes
- Canada – unequivocal yes
- UK/Britain – maybe/likely

Sweden – “Voluntary” Regionalization



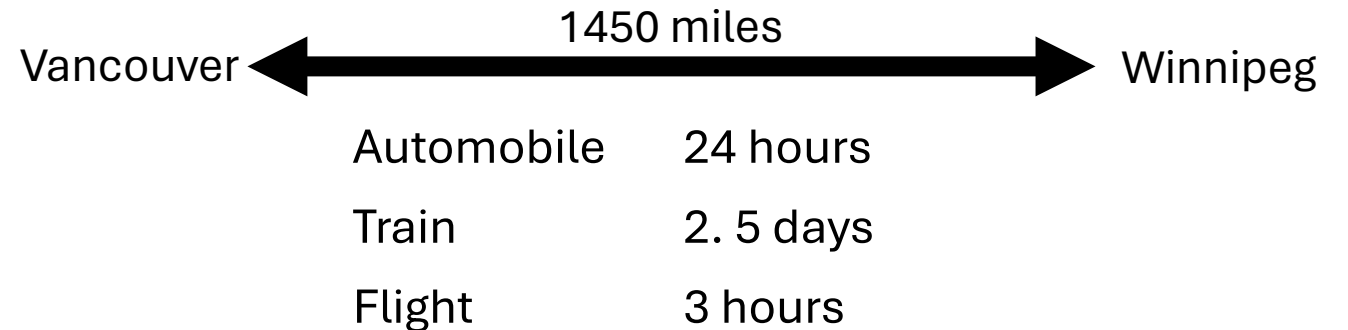
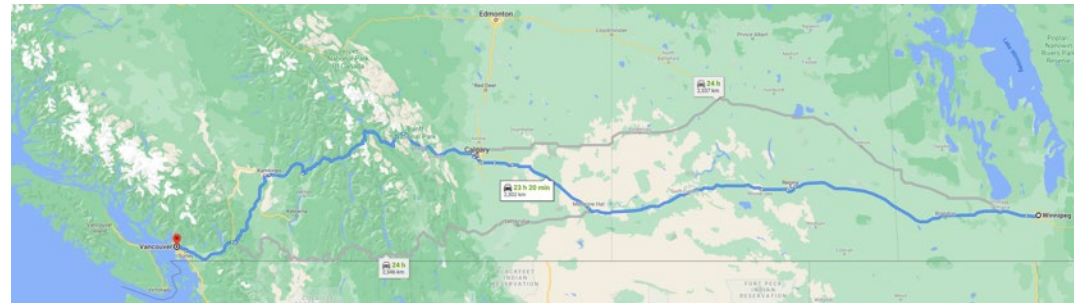
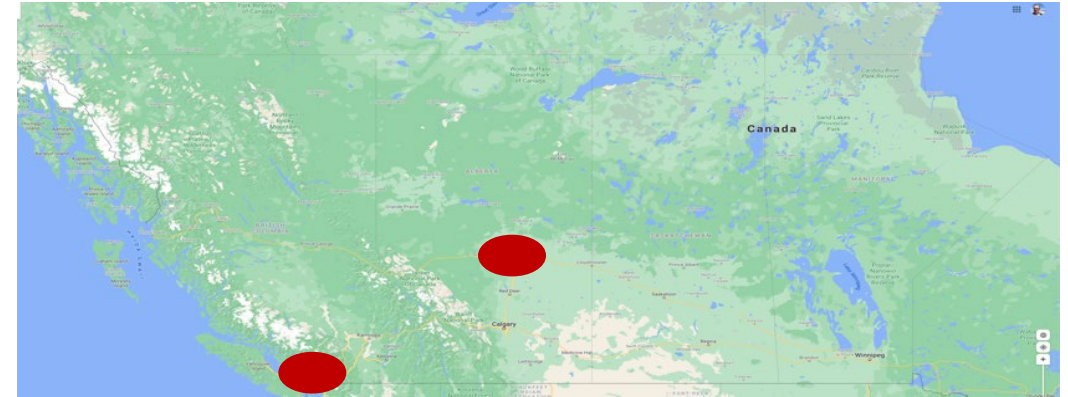
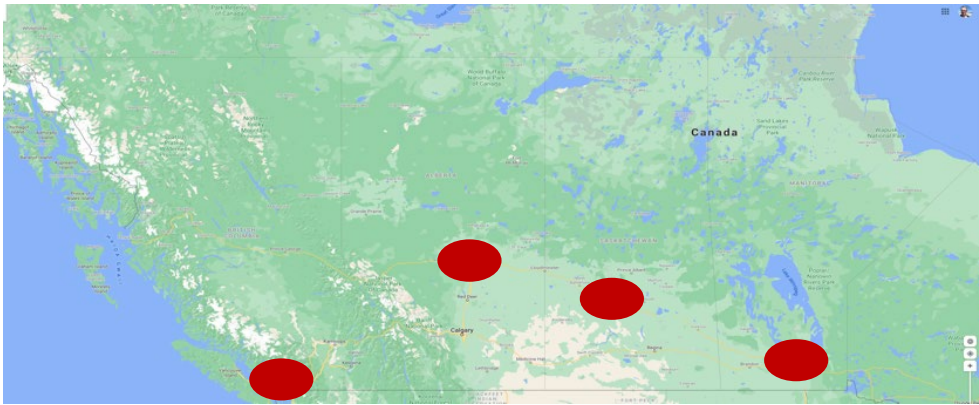
Jens Johansson Ramgren, MD

"My conviction is that centralization has been decisive for the good results we have been able to show."

	1988-1991	1995-1997	2010-2019
Op Mortality	9.5%	1.9%	0.6%

Regionalization in Western Canada – Access

Is “Access” A Virtue-Signalling Argument?



	Population 2020	Land area (km ²)	Population density (per km ²)
British Columbia	5,120,184	922,503.01	5.0
Alberta	4,428,247	640,330.46	6.4
Manitoba	1,379,121	552,370.99	2.3
Saskatchewan	1,181,987	588,243.54	1.9

LITTLE HEARTS BIG CALLING



BIENNIAL REPORT
2020-21 & 2021-22

Western Canadian Children's Heart Network	
Total Population	11,900,000
Congenital Heart Surgical Centers	2
Congenital Heart Centers	5
Total Cases/yr	620
Cases/yr/center	310
Operative Mortality	1.7%

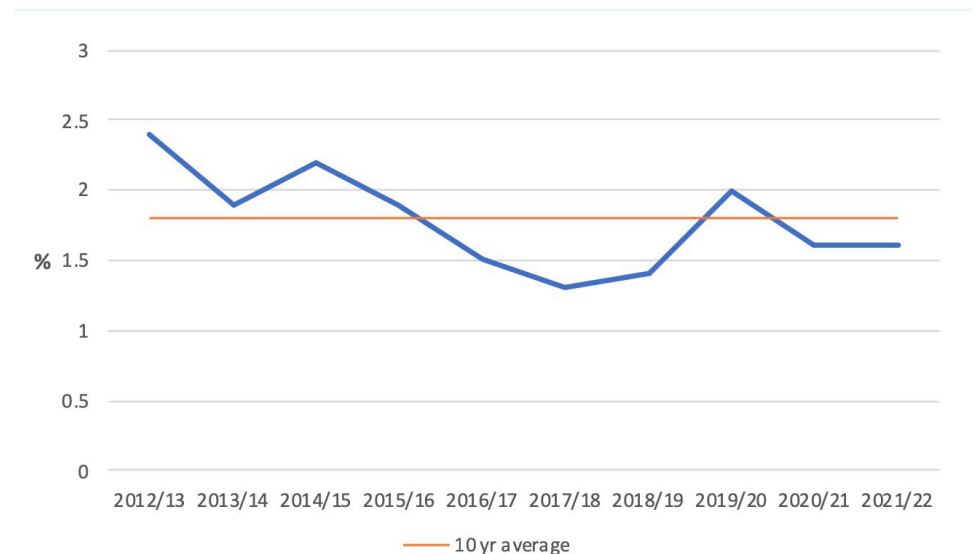
UK- NHS Standards for Surgical Centres



Congenital Heart Disease: Draft Standards and Service Specifications for consultation

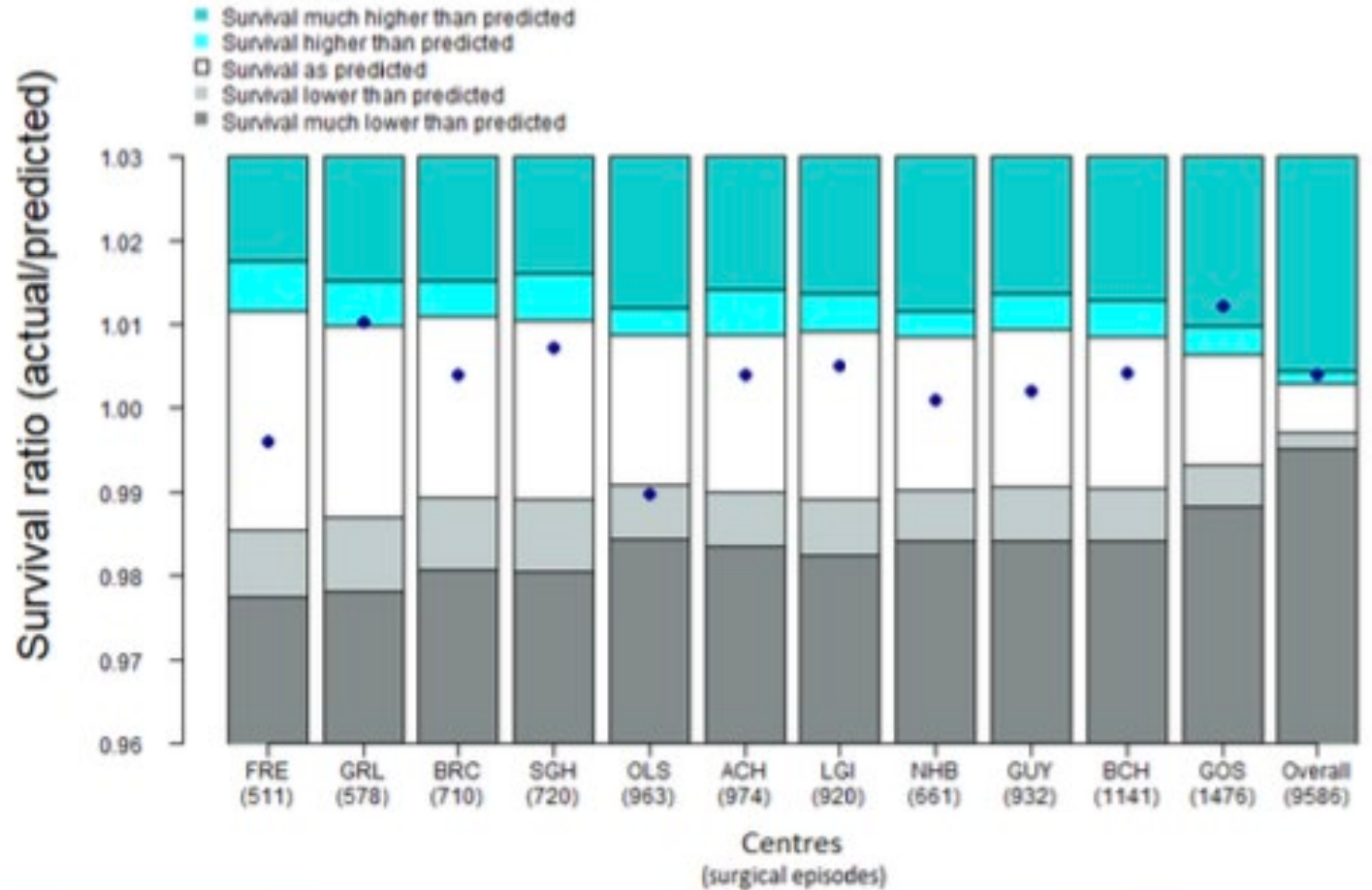
- Must have minimum of 4 WTE surgeons
- Must provide 24/7 surgical care
- Surgeons operate together on complex cases.
- Each surgeon must perform > 125 operations/year

Reduction from 11 to 7 centres - **blocked by lawsuits**



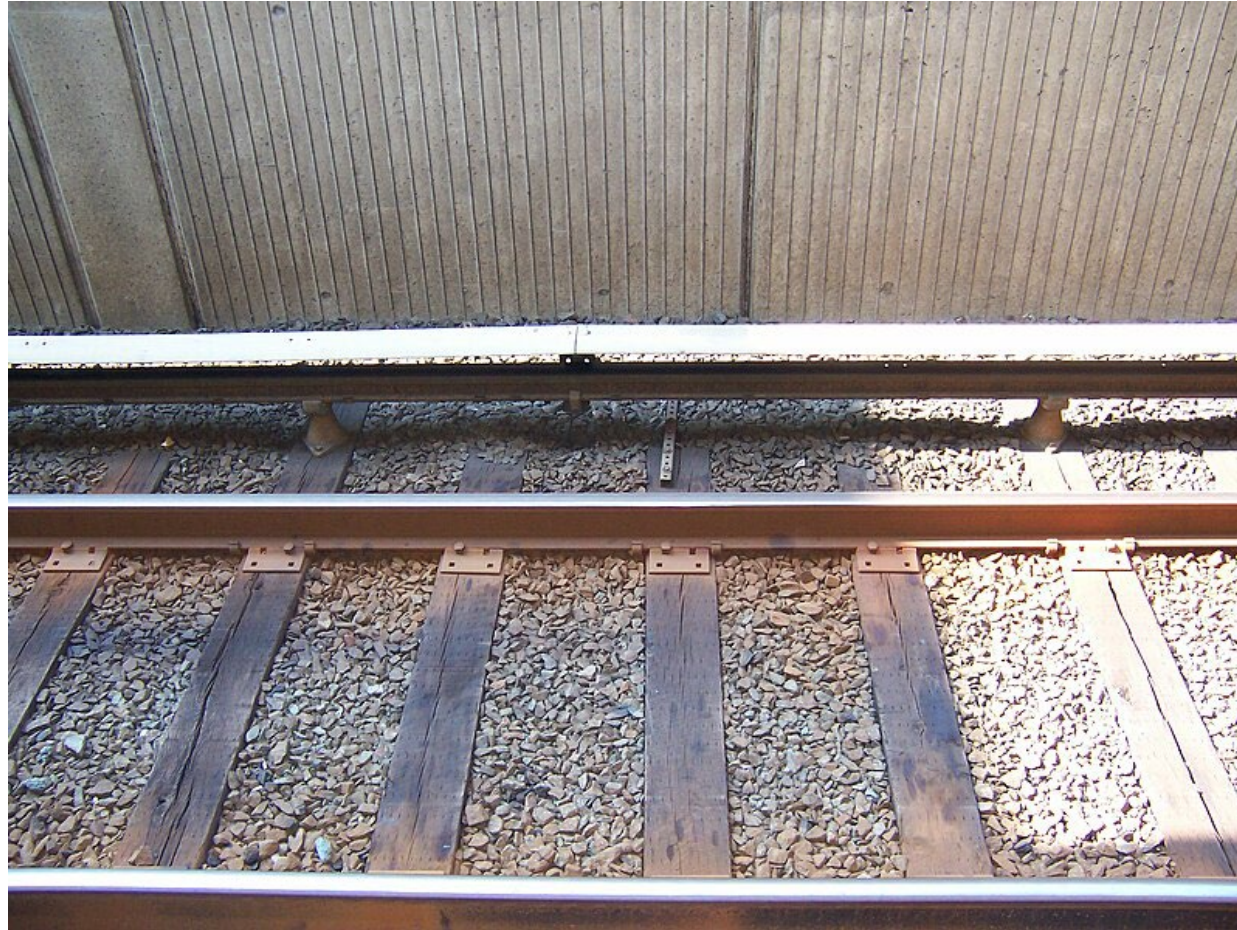
National Congenital Heart Disease Audit (NCHDA)

2023 Summary Report
(2019/20 – 2021/22)

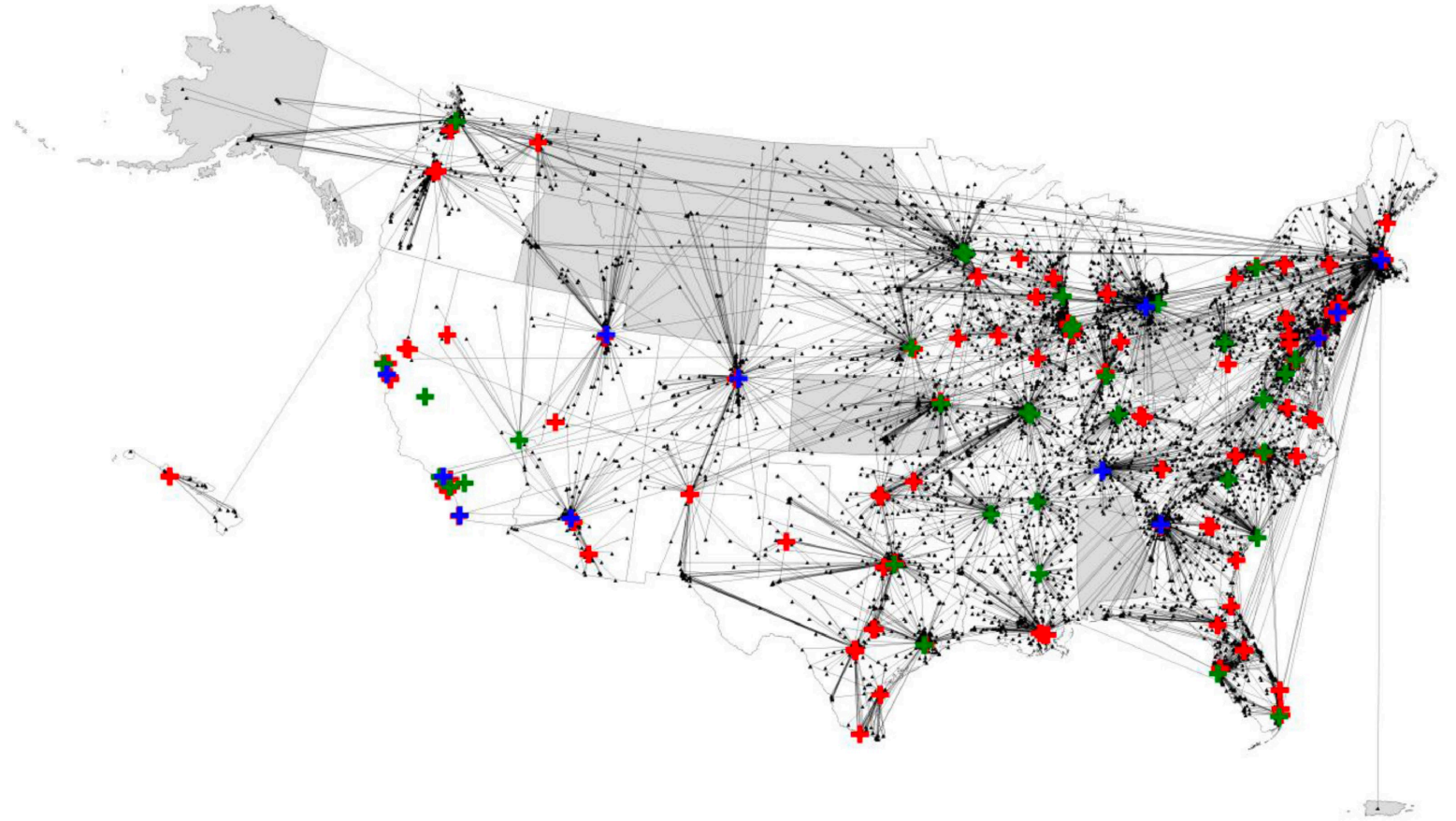


- "Vastly superior to STS reports and transparent/publicly available" – speaker's opinion
- ***Note the number of programs which are "underperforming".....***

Regionalization in the US?



The Geography of US Congenital Heart Surgery



Hospital Volume

+ < 150 Operations **+** 150-310 Operations **+** > 310 Operations

■ States without Hospital Data

▲ Zip Location of Patients

An Ideal World -

Theoretical Model for Delivery of Congenital Heart Surgery in the United States

Check for updates

Karl F. Welke, MD, MS, Sara K. Pasquali, MD, MHS, Paul Lin, MS, Carl L. Backer, MD, David M. Overman, MD, Jennifer C. Romano, MD, MS, and Tara Karamlou, MD, MSc
Division of Congenital Cardiothoracic Surgery, Levine Children's Hospital/Atrium Health, Charlotte, North Carolina; Division of Pediatric Cardiology, Department of Pediatrics, University of Michigan C. S. Mott Children's Hospital, Ann Arbor, Michigan; Institute for Healthcare Policy and Innovation, University of Michigan Medical School, Ann Arbor, Michigan; Division of Cardiovascular-Thoracic Surgery, Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, Illinois; Division of Cardiovascular Surgery, The Children's Heart Clinic, Children's Hospitals and Clinics of Minnesota, Minneapolis, Minnesota; Department of Cardiac Surgery, University of Michigan C. S. Mott Children's Hospital, Ann Arbor, Michigan; and Division of Pediatric Cardiac Surgery and the Heart and Vascular Institute, The Cleveland Clinic, Cleveland, Ohio

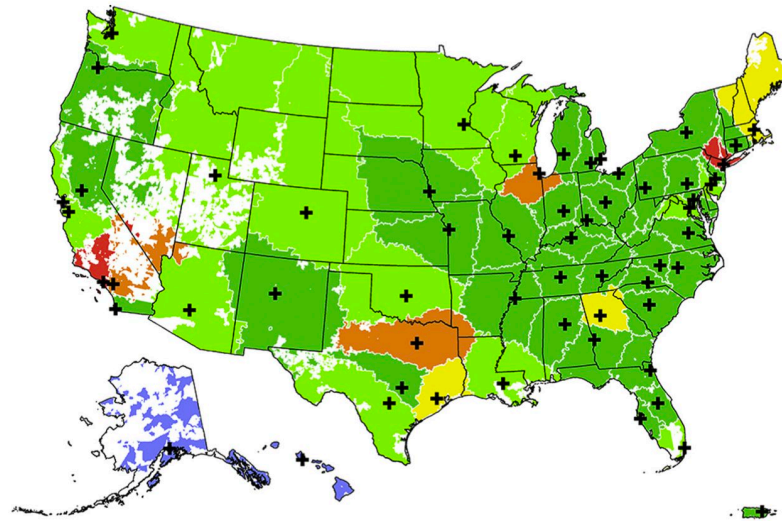
Background. Over 150 hospitals perform congenital heart surgery (CHS) in the United States. Many hospitals are close together, with a median patient travel distance of 38.5 miles. We began with a theoretical blank slate and used objective methodology guided by population density and volume thresholds to estimate the optimal number and locations of hospitals to provide CHS in the United States.

Methods. Guided by published data, we estimated the number of CHS operations in the United States in to be 32,500 per year. We distributed patients geographically based on population density. Metropolitan Statistical Areas (population centers and surrounding areas with close economic/social ties) were used as potential hospital locations. Patients were assigned to the closest hospital location such that all hospitals had a CHS volume of 2300 operations.

Results. We estimated 57 hospitals could serve the contiguous United States. Median theoretical hospital volume after regionalization was 451 operations (interquartile range, 366-688). Median patient travel distance was 35.1 miles. Some patients (6396/31,895, 20%) traveled more than 100 miles.

Conclusions. Our model suggests the United States could be served by approximately 100 fewer CHS hospitals than currently exist. With hospitals optimally placed, patient travel burden would decrease. This model serves as a platform to improve care delivery by regionalization of CHS.

(Ann Thorac Surg 2021;111:1628-33)
© 2021 by The Society of Thoracic Surgeons

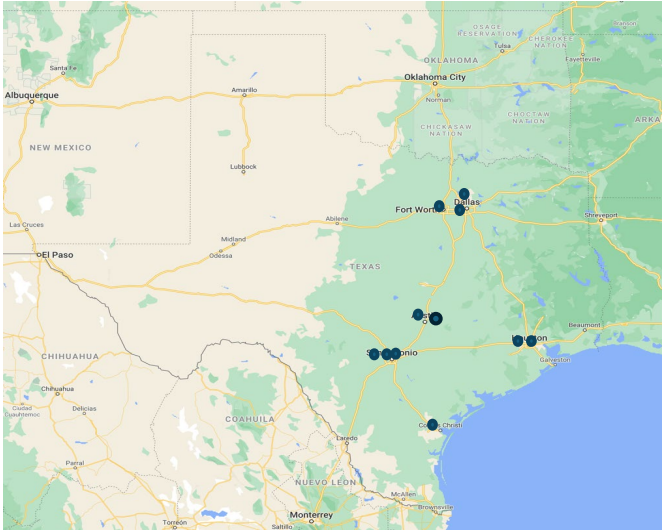


Legend
+ Theoretical Hospital Site
Operations: < 200 200-300 300-499
500-749 750-999 1000-1249 1250+

Simulation -all centers >300 cases/yr

- 116 lives saved
- **17% reduction in mortality**
- Increase mean travel distance of 31 miles
- **WOULD CLOSE 80-100 CENTERS**

Republic of Texas



Texas Population 2024 – 30,964,000
Congenital Cardiac Surgery (n=10 **11**; ~~8~~ **9** public report):
Dallas-Ft. Worth - 3
Austin – 1 **+ 1**
Houston – 2
San Antonio – 3
Corpus Christi -1
Pediatric Transplant Programs – 2 **4**





PEDIATRIC CARDIAC TECHNICAL ADVISORY PANEL



“In 2016, the Florida Legislature enacted a new requirement to establish a pediatric cardiac technical advisory panel (PCTAP)...”

Pediatric Cardiac Technical Advisory Panel Annual Report Calendar Year 2023

SUBMITTED BY THE AGENCY FOR HEALTH CARE ADMINISTRATION

December 2023



Better Health Care for All Floridians

“Dr. McCormack asked about an update on site visits for panel members. Dr. Scholl stated he didn’t believe AHCA would allow site visits Dr. Blanchard noted that site visits are in statue and were added to proactively help improve programs. Dr. Scholl stated he would like AHCA’s legal counsel to keep this under consideration as they investigate how to conduct site visits while staying within the Sunshine Law.”



A Congenital Heart Care “System”



A Congenital Heart
Care “System”
Designed (?) by “Florida Man”



Center	2015 -18	2019 - 22	Transplant
A	120	111	
B	119	84	
C	82	46	Yes
D	155	156	Yes
E	129	70	Yes
F		77	
G	251	183	
H	160	161	
I	215	218	Yes
J	131	120	

Population – 22,975,931



Center	2015 -18	2019 - 22	Transplant	Classification
A	120	111		Essential
B	119	84		Essential
C	82	46	Yes	? + T
D	155	156	Yes	Essential +T
E	129	70	Yes	Essential? + T
F		77		?
G	251	183		Comprehensive-T?
H	160	161		Essential
I	215	218	Yes	Comprehensive
J	131	120		Essential



Center	2015 -18	2019 - 22	Transplant	Classification
A	120	111		Essential
B	119	84		Essential
C	82	46	Yes	? + T
D	155	156	Yes	Essential +T
E	129	70	Yes	Essential? + T
F		77		?
G	251	183		Comprehensive-T?
H	160	161		Essential
I	215	218	Yes	Comprehensive
J	131	120		Essential

Comments

- During 2 eras, 30% of programs were near /below minimum vol.
 - **All continued to do complex (STAT 5 cases)**
 - 3 “non-comprehensive” programs did transplants
- All essential or sub-threshold programs except 1 were **within 25 miles** of another program; the other was 73 miles away
- Two programs “affiliated” with out of state partners



Affiliation/Alignment/Cooperative Model

Center	2015 -18	2019 - 22	Transplant	Classification
A	120	111		Essential
B	119	84		Essential
F		77		?
Group	239	272		Comprehensive
C	82	46	Yes	? + T
D	155	156	Yes	Essential +T
G	251	183		Comprehensive-T?
Group	488	385	Yes*	Comprehensive
E	129	70	Yes	Essential? + T
H	160	161		Essential
Group	289	231	Yes	Comprehensive
I	215	218	Yes	Comprehensive
J	131	120		Essential
Group	346	338	Yes	Comprehensive

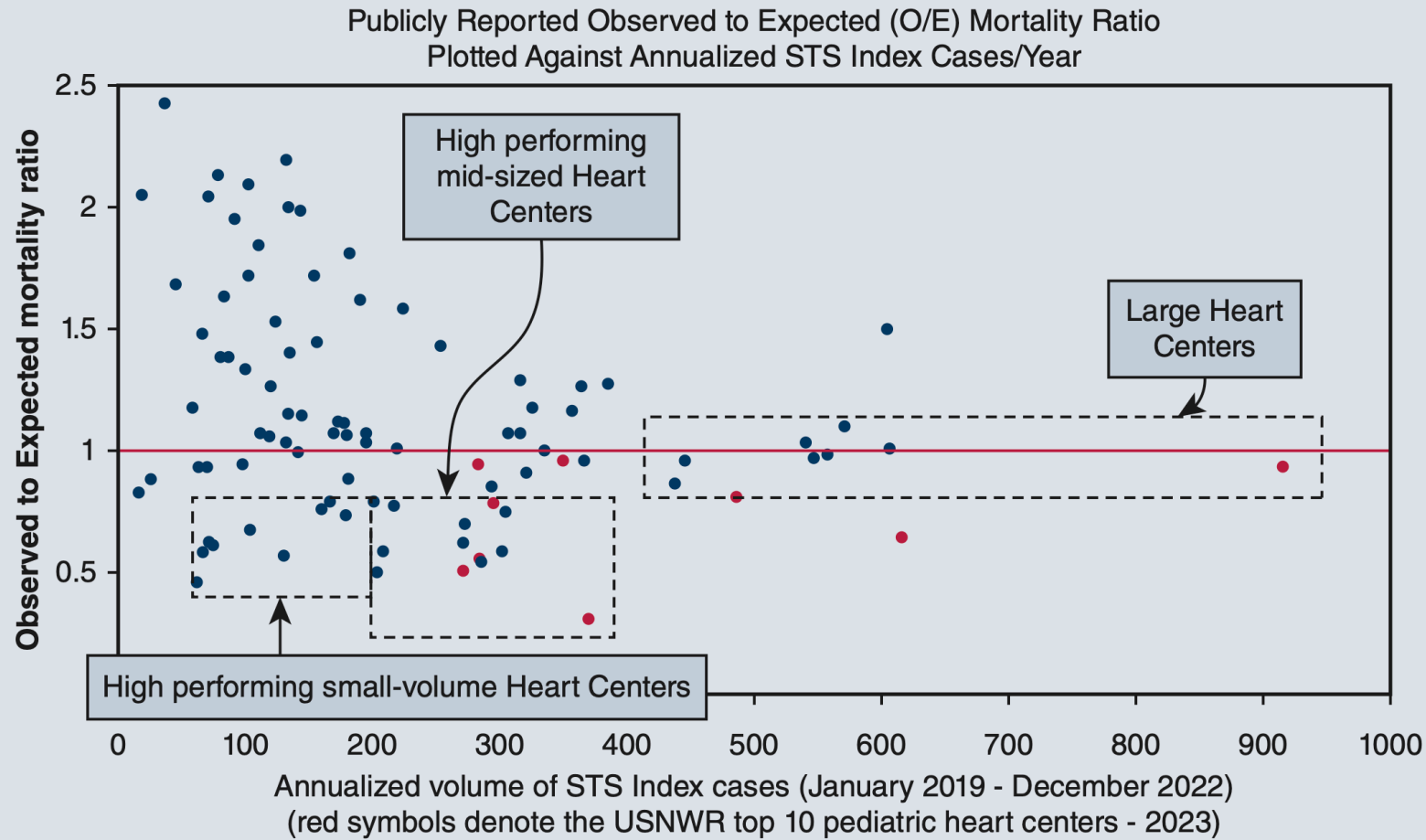


Center	2015 -18	2019 - 22	Transplant	Classification
A	?	?		?
B	?	?		?
F		?		?
Group	239	272		Comprehensive
C	?	?		?
D	?	?		?
G	?	?		?
Group	488	385	Yes*	Comprehensive
E	?	?		?
H	?	?		?
Group	289	231	Yes	Comprehensive
I	?	?		?
J	?	?		?
Group	346	338	Yes	Comprehensive

Next Steps

1. Convert Recommendations to Standards – to be verified by CHSS/PCICS/Cardiac Networks United/Etc.
 - Voluntary participation – Initial and Q3(?) years
 - Consultancy/Site Visit early if needed and requested by site
 - Issue Verification/”Seal of Approval”
2. For Essential Centers, Regionalization **WITHOUT** Closure
 - Urge transfer of most complex cases (STAT5, some STAT 4, transplants, VADs, etc.)
 - ` -less than 10% of case volume
3. For “Too Small Centers”, no verification offered or possible – alignment/closure urged
4. Vastly enhanced Real-Time public reporting – VLAD, granular/practical/simplified
5. Consign USNWR to the scrap heap of history.
6. CHSS Study – Seek success factors in high performing small centers...underway

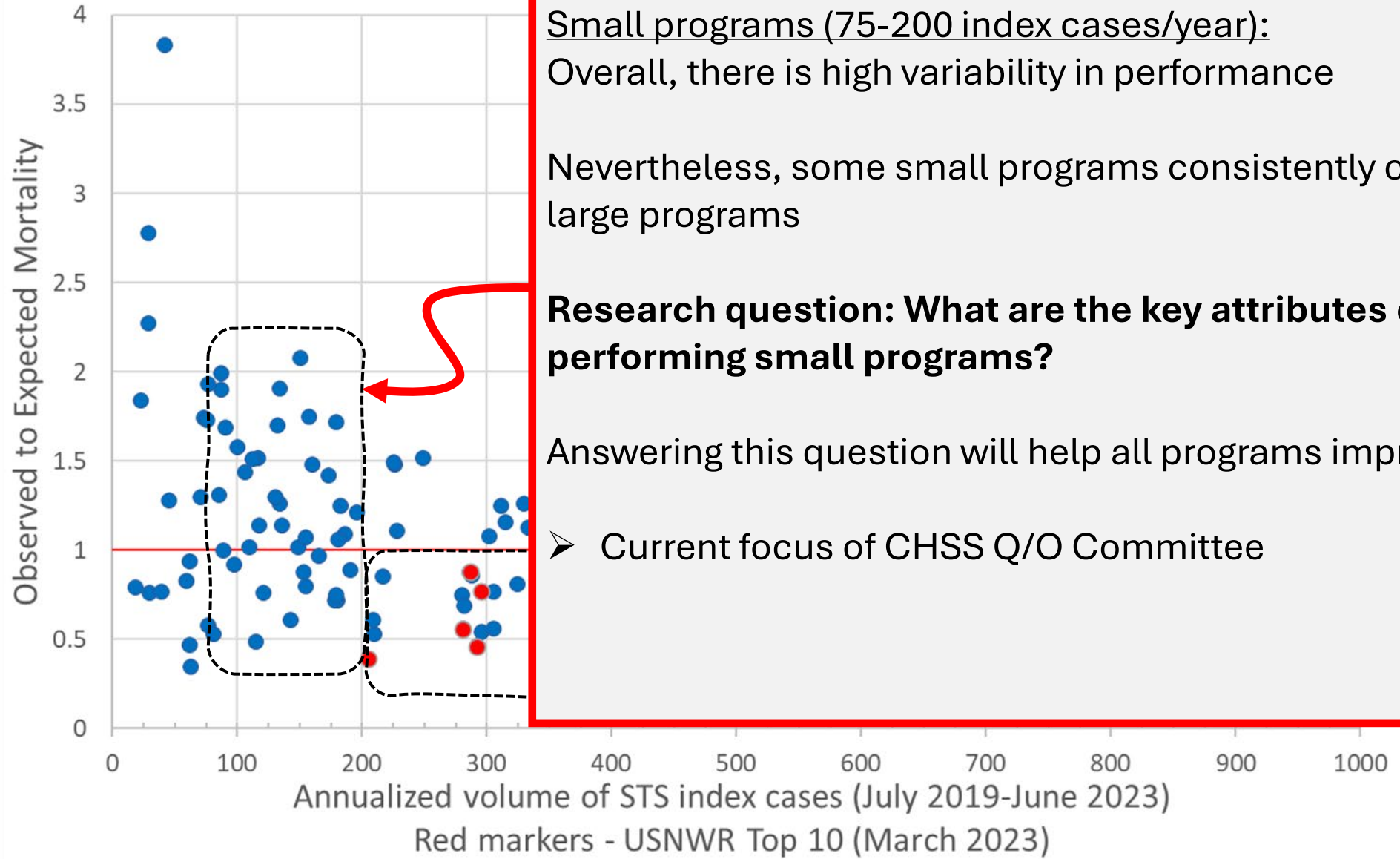
Building High Levels of Performance into Congenital Heart Centers



Greater volume is not the sole contributor to high performance.
Mission, Structure, Process and Culture should be optimized.



O/E ratio vs Annualized volume of STS index cases



Small programs (75-200 index cases/year):
Overall, there is high variability in performance

Nevertheless, some small programs consistently outperform large programs

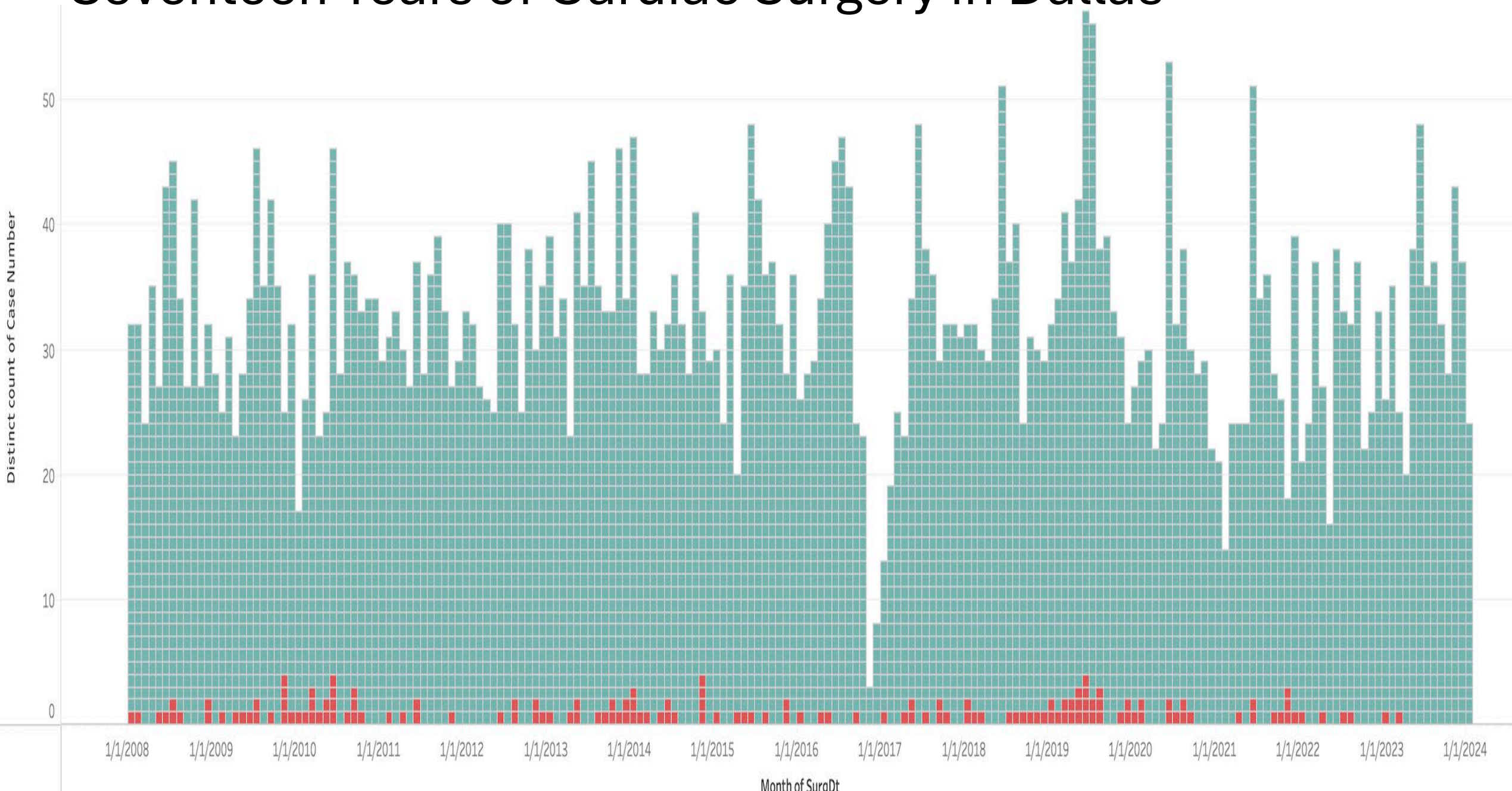
Research question: What are the key attributes of the top performing small programs?

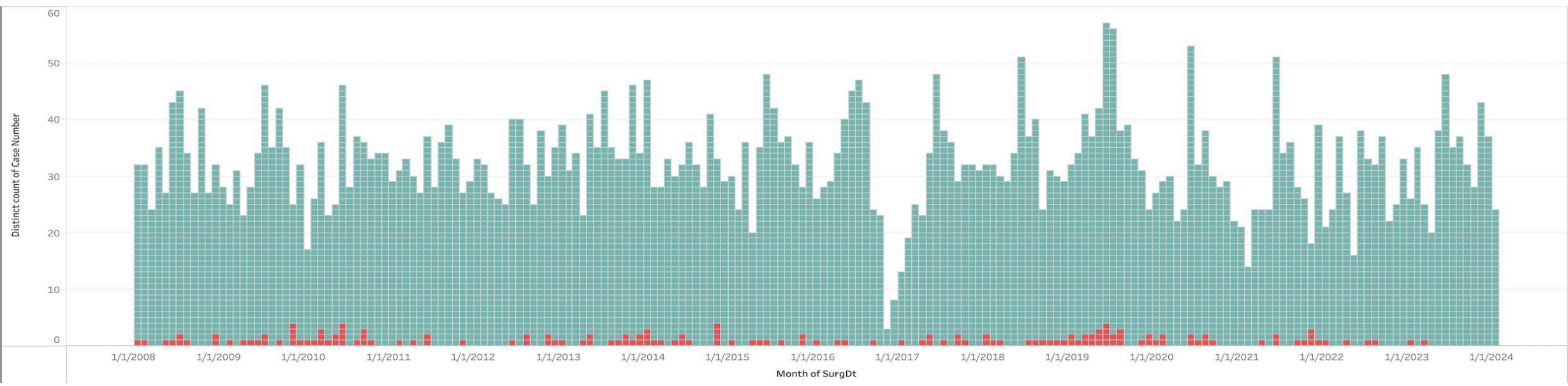
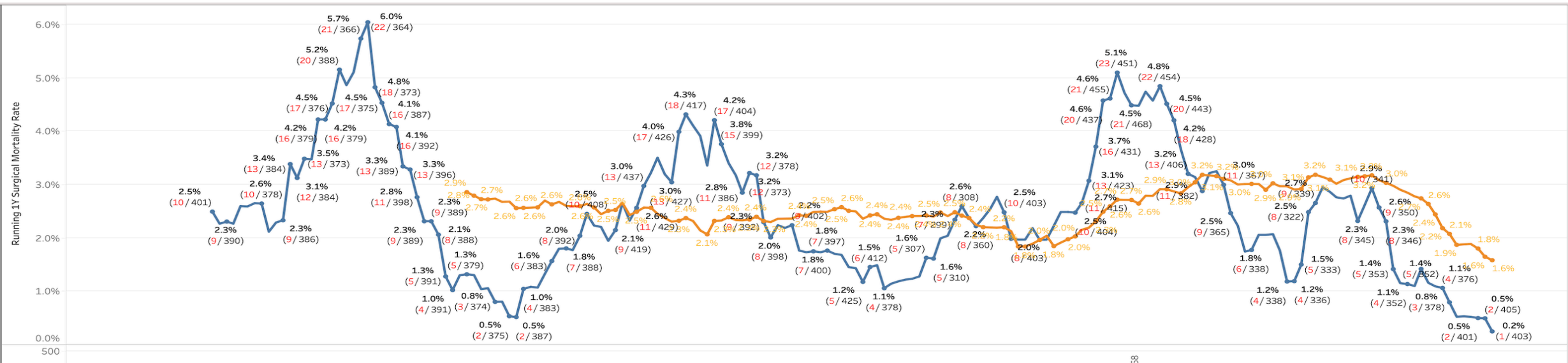
Answering this question will help all programs improve

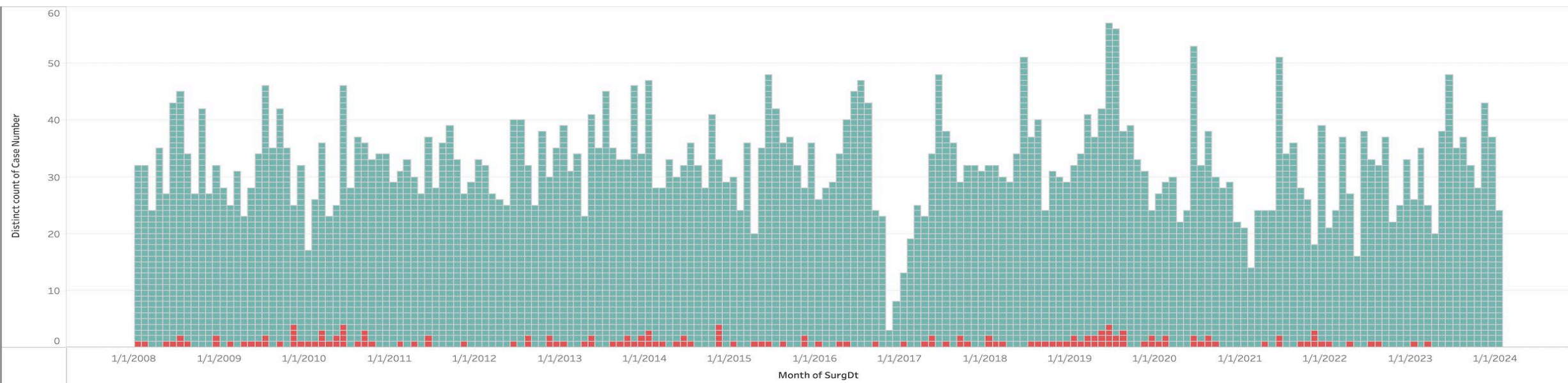
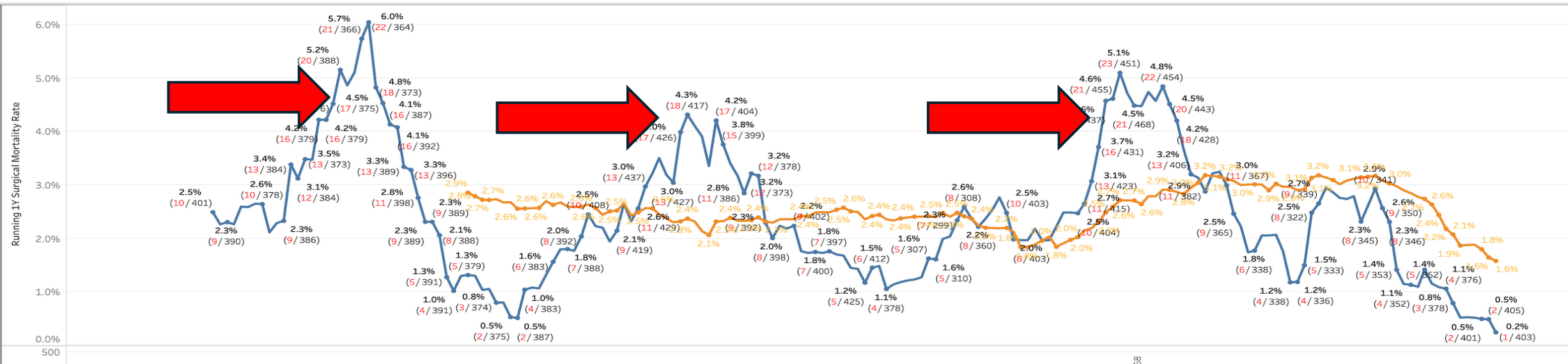
➤ Current focus of CHSS Q/O Committee

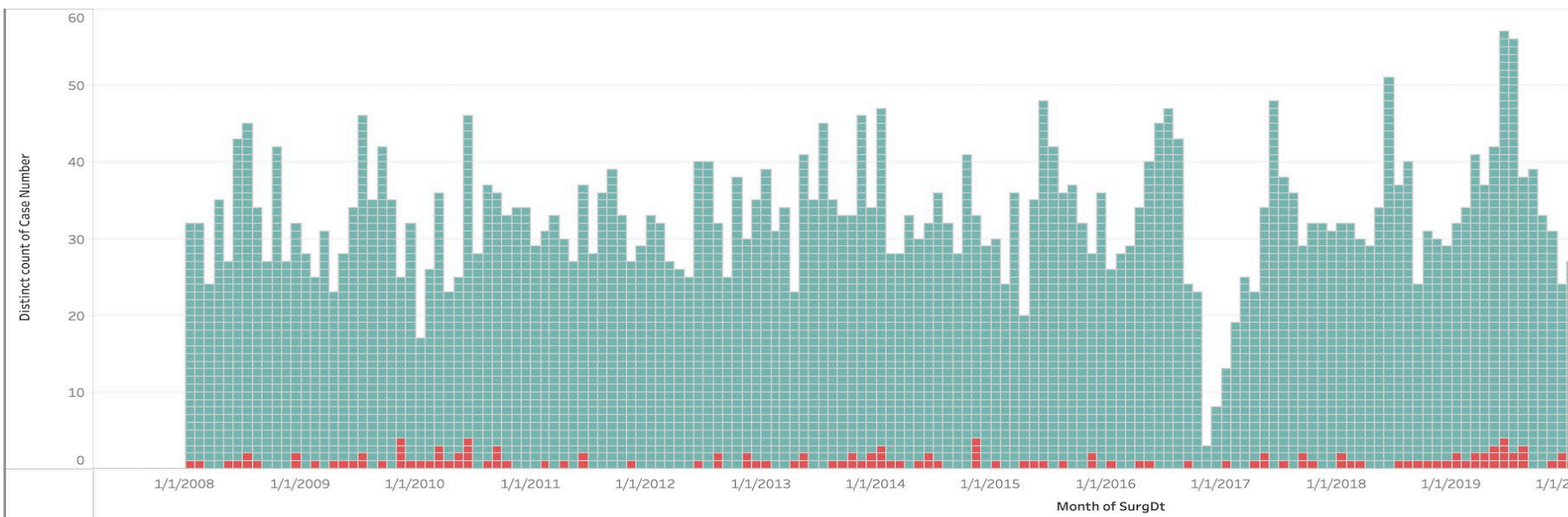
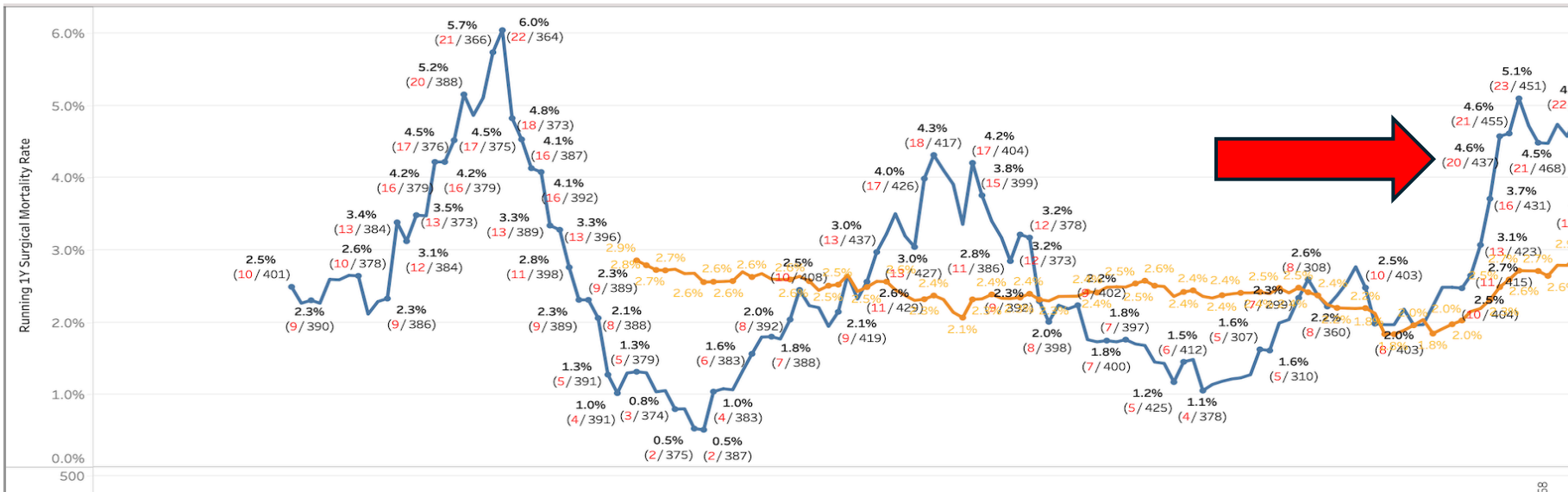
Other Solutions Are Crucial

Seventeen Years of Cardiac Surgery in Dallas









Same Surgeons, Same ICU, Same Volume

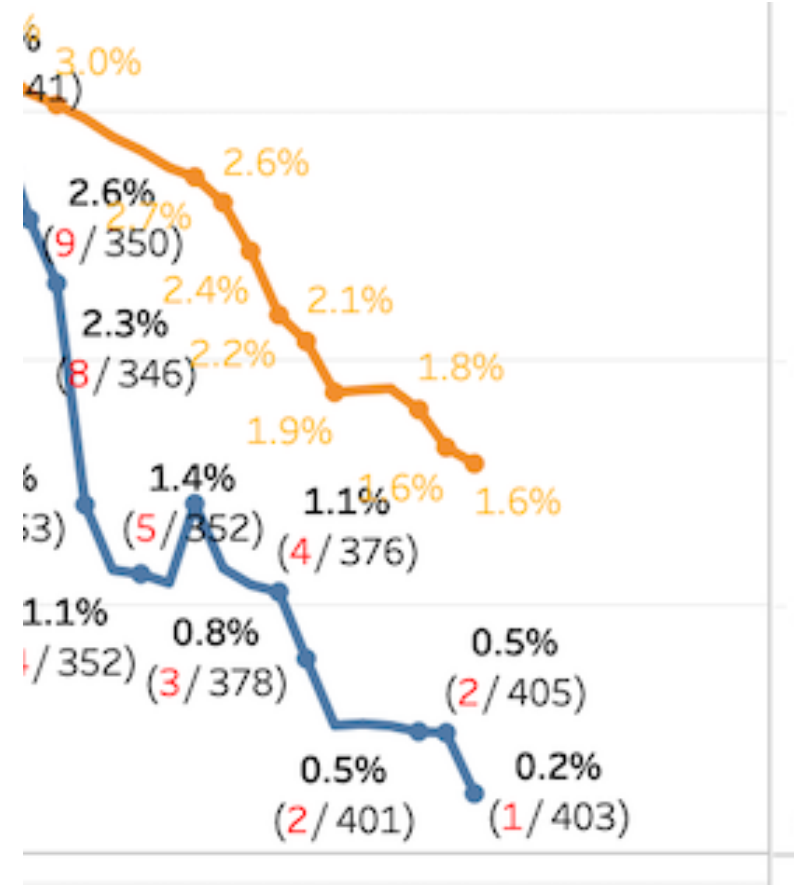
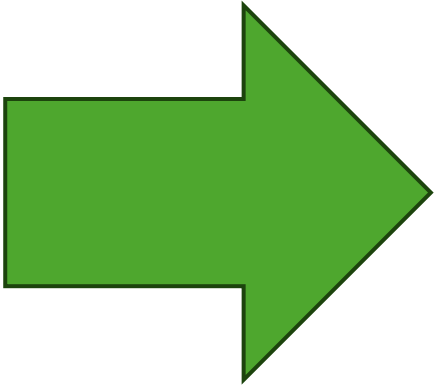
Patient Information: (name, MRN, wt)	Age	Surgeon:	Anesthesia:	CICU:	ACC	Cardiologist	STAT	TBC
Admission diagnosis		INTERVENTION						
1. Left atrioventricular valve regurgitation and stenosis 2. S/p repair of complete atrioventricular septal defect 3. Trisomy 21		Date: [redacted] Surgical history: Mitral valve replacement (Melody valve within a 16mm PECA ex-graft) Reoperative sternotomy						

ECHO [redacted]

- Original diagnosis: Trisomy 21, Complete atrioventricular canal defect
- S/p two patch CAVC repair with partial cleft closure and left AV valve repair, secundum ASD closure, PDA ligation
- S/p s/p bioprosthetic 18mm Melody valve in the mitral position
- No mitral valve post-surgical residual abnormality
- Mitral valve mean gradient = 3.0 mmHg
- Mild tricuspid valve insufficiency
- TR peak velocity 2.80 m/s yields TR peak gradient 29.4 mmHg
- Low normal left ventricular systolic function
- No left ventricular outflow tract obstruction
- Normal right ventricular cavity size and systolic function
- No pericardial effusion

Procedure
Intubation
Extubation
ACC
Discharge

LOS: 13



Ad Hoc 4/19 at 7:30 (after surgical rounds)

Friday, April 19, 2024 from 7:30 AM to 8:00 AM
30 minutes

You accepted [Edit RSVP](#)

[Join](#)

None

[Meeting Details](#)

Hello,

There will be an ad hoc discussion at ~7:30 for this patient following surgical CICU rounds. Please join via the surgical rounds zoom link:

Join Zoom Meeting
<https://chilidrens.zoom.us/j/94464001875?pwd=WXpPMUhnZTFBbXV2V1lHa0lZMmtlQT09>

Meeting ID: 944 6400 1875

Passcode: 555398

“You can always count on the Americans to do the right thing,



“You can always count on the Americans to do the right thing, after they have exhausted all the other possibilities.”





There is much more to do.....

References

- Backer J Thorac Cardiovasc Surg 2023;166:1782-820
- Pasquali Circulation. 2020;142:1351–1360
- Welke Ann Thorac Surg 2023;116:1233-40
- Welke Ann Thorac Surg 2021;111:1628-35
- Allen Pediatrics 2003;112(1): 24-28
- Caldarone J Thorac Cardiovasc Surg 2024; 167(4):1435-1443
- Chauhun Ann Thorac Surg 2024 <https://doi.org/10.1016/j.athoracsur.2024.01.006>
- Barnhart Semin Pediatr Surg. 2023 Apr;32(2):151276.
- <https://www.nicor.org.uk/national-cardiac-audit-programme/congenital-audit-nchda>. – accessed 5 1 2024

Impact of Diffusion of Programs on Education

- Young surgeons leaving training are, in general, very poorly prepared to function independently
- Established surgeons, in general, do a lousy job of mentoring junior partners – too little experience early on; partners become fodder; exceptions exist but are rare
- EON call is terrible, and only exceeded by EN call