Larger Centers Produce Better Outcomes in Pediatric Cardiac Surgery
Regionalization is a Superior Model

Charles D. Fraser, Jr., MD, FACS
Surgeon-in-Chief
Donovan Chair and Chief, Congenital Heart Surgery
Texas Children’s Hospital
Susan V. Clayton Chair in Surgery
Professor of Surgery and Pediatrics
Baylor College of Medicine
Do large volume centers produce superior outcomes?
### STS Definition of Center Size

<table>
<thead>
<tr>
<th>Volume (Index Cases)</th>
<th># of Centers Reporting*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt;100</td>
</tr>
<tr>
<td>Medium</td>
<td>101 – 249</td>
</tr>
<tr>
<td>High</td>
<td>&gt;250</td>
</tr>
</tbody>
</table>

*Does not represent all centers performing congenital heart surgery*
STS CHS Operative Mortality + 95% CI (Last 4 Years)

N=144 total participating centers

Dotted line is overall value for STS (3.51%)
Hospital Volume

Resource Availability

Hospital Size

Operating revenue (entire TCH system):
- 1995 $ 266.5M
- 2014 $ 2.6B

Square footage:
- 1995 1.7M ft^2
- 2014 8M ft^2

Admissions:
- 1989 11.7K
- 2014 32.4K

Early 1990's

2015
Texas Children’s Hospital Heart Center
Cardiovascular and Thoracic Surgery Case Volume

- 6 mortalities of 928 CH surgeries in 2014
- 2014 overall hospital mortality <1.0%
- 2014 STS national benchmark 3.2%

Represents data from 1/1/1995 through 12/31/2014
© 2015 Texas Children’s Hospital
<table>
<thead>
<tr>
<th>Author/Center</th>
<th>Study Design</th>
<th>Population</th>
<th>Findings</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chang UCLA 2002</td>
<td>- Effect of theoretically ↓ the # of CHS ctrs on mortality - CA discharge data 1995 – 1997</td>
<td>6,592 (20 hospitals)</td>
<td>- Overall mortality rate 5.34% - 83 deaths avoided when all pts referred from low/medium volume hospitals to high volume hospitals (mortality drops to 4.08%)</td>
<td>- Theoretical regionalization is associated with ↓ in surgical mortality - Regionalization may not be most feasible or cost effective way to reduce CHS mortality</td>
</tr>
<tr>
<td>Bazzani UC Davis 2007</td>
<td>- Re-evaluated volume-mortality association - CA discharge data 1998 – 2003</td>
<td>12,801 – 13,971</td>
<td>- ↑ hospital volume significantly associated with ↓ mortality (OR 0.86, CI 0.81 – 0.92)</td>
<td>- Weaker, less consistent volume-mortality relationship than previous reports</td>
</tr>
<tr>
<td>Welke Oregon 2008</td>
<td>- Hospital volume-surgical mortality - Nationwide Inpatient Sample 1988 – 2005</td>
<td>55,164 (307 hospitals)</td>
<td>- As discriminator of mortality, volume performed significantly worse than risk-adjusted model (ROC curve area 0.6 vs 0.8)</td>
<td>- Use of unadjusted mortality rates to evaluate institutional quality is misleading</td>
</tr>
<tr>
<td>Karamlou Michigan 2008</td>
<td>- Outcomes of GUCH pts operated by pedi heart surgeon (PHS) vs non-PHS - Nationwide Inpatient Sample 1988 – 2005</td>
<td>40,461 GUCH operations</td>
<td>- In hospital death rates for GUCH pts PHS 1.87% vs non-PHS 4.84%</td>
<td>- In hospital death rates are significantly ↓ when operation is performed by specialized PHS.</td>
</tr>
<tr>
<td>Welke Oregon 2009</td>
<td>- Volume-surgical mortality - STS CHS database 2002 - 2006</td>
<td>32,413 (48 hospitals)</td>
<td>- Surgical volume (categorical variable) ABC &gt; 3.0: Mortality ↓ from 14.8% small programs to 8.4% very large programs</td>
<td>- Inverse volume-mortality relationship became increasingly important as case complexity increased</td>
</tr>
<tr>
<td>Pasquali Duke 2012</td>
<td>- Center volume and mortality in pts with complications - STS CHS Database 2006 – 2009</td>
<td>35,776 (68 hospitals)</td>
<td>- ↓ center volume significantly associated with higher in hospital mortality (OR 1.60, CI 1.23 – 2.08)</td>
<td>- ↑ mortality observed at low-volume centers may be due to high mortality in those with complications - “Failure to rescue”</td>
</tr>
</tbody>
</table>
Chang - UCLA 2002

• Study Design:
  – Effect of theoretically ↓ the # of CHS ctrs on mortality
• Population:
  – 6,592 (20 hospitals)
• Findings:
  – Overall mortality rate 5.34%
  – 83 deaths avoided when all pts referred from low/medium volume hospitals to high volume hospitals (mortality drops to 4.08%)
• Conclusions
  – Theoretical regionalization is associated with ↓ in surgical mortality
  – Regionalization may not be most feasible or cost effective way to reduce CHS mortality
Welke - Oregon 2009

• Study Design:
  – Volume-surgical mortality
  – STS CHS database 2002 - 2006

• Population:
  – 32,413 (48 hospitals)

• Findings:
  – Surgical volume (categorical variable) ABC > 3.0: Mortality ↓ from 14.8% small programs to 8.4% very large programs

• Conclusions:
  – Inverse volume-mortality relationship became increasingly important as case complexity increased
Survival in Pediatric Lung Transplantation: The Effect of Center Volume and Expertise

Khan MS, Zhang W, Taylor RA, McKenzie ED, Mallory GB, Schecter MG, Morales DLS, Heinle JS, Adachi I

“Despite larger overall clinical volume, outcomes of pediatric lung transplant recipients in adult centers are not superior to those of pediatric centers. Not only center volume but pediatric-specific experience has an impact on outcomes of pediatric LTx.”
Overall Patient Survival (Pediatric)

Khan MS et al, J Heart Lung Transplant, 2015 (in press)

<table>
<thead>
<tr>
<th>Survival (%)</th>
<th>High Volume (n=517)</th>
<th>Low Volume (n=529)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>81%</td>
<td>75%</td>
</tr>
<tr>
<td>3 year</td>
<td>65%</td>
<td>49%</td>
</tr>
<tr>
<td>5 year</td>
<td>52%</td>
<td>36%</td>
</tr>
<tr>
<td>Half-Life</td>
<td>5.4 y</td>
<td>2.9 y</td>
</tr>
</tbody>
</table>

Hi Volume vs. Lo Volume – p<0.0001
Regionalization
Prenatal Diagnosis, Birth Location, Surgical Center, and Neonatal Mortality in Infants with Hypoplastic Left Heart Syndrome

Morris SA, Ethen MK, Penny DJ, Canfield MA, Minard CG, Fixler DE, Nembhard WN

- Examined effect of delivery near a cardiac surgical center (CSC) on neonatal HLHS mortality
- Relationship of CSC volume and surgical mortality
- Texas Birth Defects Registry 1999 – 2007

*Morris et al; Circulation 2014 Jan 21;129(3):285-92*
Neonatal mortality in infants born <10 minutes from CSC was 21% vs 39.6% >90 minutes

• Birth at further distance associated with increased mortality (OR 2.03; CI 1.19 – 3.45)
Prenatal Diagnosis, Birth Location, Surgical Center, and Neonatal Mortality in Infants with Hypoplastic Left Heart Syndrome

CSC HLHS volume inversely correlated with surgical mortality

- \( N = \frac{52}{369} \)
- \( OR = 0.88; CI 0.84 - 0.91 \)

*Morris SA, Ethen MK, Penny DJ, Canfield MA, Minard CG, Fixler DE, Nembhard WN*

*Circulation 2014 Jan 21;129(3):285-92*
Surgical Volume-to-Outcome Relationship and Monitoring of Technical Performance in Pediatric Cardiac Surgery

Kalfa D, Chai P, Bacha E

Relationship between institutional volume and outcomes in pediatric cardiac surgery
Study Design:
- Center volume and mortality in pts with complications
- STS CHS Database 2006 – 2009

Population:
- 35,776 (68 hospitals)

Findings:
- \( \downarrow \) center volume significantly associated with higher in hospital mortality (OR 1.60, CI 1.23 – 2.08)

Conclusions:
- \( \uparrow \) mortality observed at low-volume centers may be due to high mortality in those with complications
- “Failure to rescue”
Pt Perspective – “Ideal” Outcomes

- Low mortality risk
- Low morbidity
  - Vent times, CLABSI, residual lesions, bleeding, unplanned re-ops, etc.
- Neurological outcome optimized
- Hospital LOS minimized
- Cost/Value – affordable care
- Activity – “normal”
- Hospital experience
Pt Perspective – “Ideal” Program

• 24/7/365 (including holidays) – NEVER CLOSED

• Full time qualified staff
  – Surgeons, anesthesiologists, Intensivists perfusionists, ICU nurses, consultant subspecialists

• State-of-the-art facility/equipment (dedicated)
  – ECMO/VADs

• Data analysis – robust, up-to-date

• “Complete program” – can handle whatever comes in

• Transport – rapid, safe

• Fetal Program?
Optimal Resources for Children’s Surgical Care in the United States

From the Task Force for Children’s Surgical Care

The Task Force for Children’s Surgical Care, an ad hoc group of invited leaders in relevant disciplines, assembled in Rosemont, IL, initially from April 30 to May 1, 2012, and subsequently from May 30 to 31, 2013 to consider how to optimize the delivery of children’s surgical care in today’s competitive national health care environment. Specifically, a mismatch between individual patient needs and available clinical resources for some infants and children receiving surgical care is recognized as a problem in the United States and elsewhere. Although this phenomenon is apparent to most practitioners involved with children’s surgical care, comprehensive data are not available and relevant data are imperfect. The scope of this problem is unknown. However, it does periodically, and possibly systematically, result in suboptimal patient outcomes. The composition of the Task Force is detailed in Appendix 1 (2012) and Appendix 2 (2013) (available at http://www.journalsacs.org). Support was provided by the Children’s Hospital Association and the American College of Surgeons (ACS). The objective was to develop consensus recommendations that would be of use to relevant policy makers and to providers. The group represented key disciplines and perspectives. Published literature and data were used when available and expert opinion when not, as the basis for these recommendations. A research agenda was developed to inform the current situation and to direct providers with regard to improvement. This report details the consensus recommendations of this group. To be clear, the recommendations and opinions presented here reflect the personal views of the participants at present, not all of the various organizations delineated in the appendices. Currently, the Regents of the American College of Surgeons, the Board of Governors and the members of the American Pediatric Surgical Association, and the Board of the Society of Pediatric Anesthesia have endorsed these recommendations. A process to obtain comprehensive individual organizational endorsement has been initiated and this information will follow.

PUBLISHED LITERATURE

A summary of selected published data germane to the issue was provided and reviewed.1-99 Although definitive population-based data are not available, the weight of available evidence suggests differential outcomes in children undergoing surgery in specialized vs non-specialized environments for neonates,1,4,5,11-13,16,20,23,35,37,38 children requiring intensive care,5,7,10,25 seriously injured adolescents and children,20,21 those with congenital heart disease,19 and others.1,13,19,20,22,24,25 Generally, the benefit of a specialized environment was most apparent in higher-risk patients, such as neonates, infants, and inpatients undergoing more complex procedures, such as cardiac surgery.19,38,39 For example, assessment of the impact of theoretical regionalization in California for congenital heart disease patients is provided by Chang and Klitzner, who estimated that 83 lives could be saved annually in that state if congenital heart surgery patients from low-volume/higher-mortality centers were cared for in high-volume/lower-mortality institutions.19 In addition, these outcomes could be achieved in this exercise with only modest additional travel burden for families.

As part of the discussion of environments specialized in pediatric care, the specific topic of anesthesia was addressed in detail. Appropriate pediatric anesthesia expertise, including both relevant training and an adequate level of ongoing clinical pediatric practice, was judged to be critical based on both available data5,11,26-35 and consensus.

Even among neonates, a surgical cohort known to be at
## Overriding Principle: Tiered Care

<table>
<thead>
<tr>
<th></th>
<th>LEVEL I</th>
<th>LEVEL II</th>
<th>LEVEL III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>Any</td>
<td>Any</td>
<td>&gt; 6 months</td>
</tr>
<tr>
<td><strong>ASA</strong></td>
<td>1-5</td>
<td>1-3</td>
<td>1-2</td>
</tr>
<tr>
<td><strong>Co-morbidities</strong></td>
<td>All – complex</td>
<td>Typically single specialty management</td>
<td>None – healthy kids</td>
</tr>
<tr>
<td><strong>Operations</strong></td>
<td>All – complex diseases, multi-specialty care</td>
<td>Common anomalies, single specialty centric</td>
<td>Common “low-risk” procedures by single specialty</td>
</tr>
<tr>
<td><strong>Ambulatory</strong></td>
<td>ASA 1-3, guidelines for post anesthesia monitoring</td>
<td>ASA 1-3, guidelines for post anesthesia monitoring</td>
<td>Age &gt; 6 months Healthy</td>
</tr>
</tbody>
</table>
Gentlemen,
we will chase perfection,
and we will chase it relentlessly,
knowing all the while we can never
attain it. But along the way, we
shall catch excellence.

Vince Lombardi
Conclusion

- Center volume-mortality relationship seems well enough established in current literature.

- Emphasis should be on refinement of other variables in causality and contemporary “outcomes” beyond mortality.

- Regionalization is a lofty aspiration, but challenging? Tiered approach?