The STS Intermacs National Database

Robert S.D Higgins, MD, MSHA
William Stewart Halsted Professor
Chair and Surgeon –in-Chief
Johns Hopkins Medicine
President – Society of Thoracic Surgeons
New Horizon for STS and INTERMACS
CONGESTIVE HEART FAILURE - THE PROBLEM

Epidemiology

- 5 million Americans, 10 million worldwide
- 500,000 to 1 million new cases diagnosed yearly
- 70% of men, 79% of women with CHF have history of hypertension
- Huge economic impact in diagnosis, treatment, including AICD, Bi-ventricular pacing, recurrent hospitalizations, transplant/LVADs

Requires extraordinary measures to address the problem!
Transplant Signature Program
Henry Ford Hospital (1993-1999)
TRANSPLANT AT A GLANCE: 2019

122,421
People needing a lifesaving organ transplant (total waiting list)

>30,000
Transplants performed this year (2016)

12,000
Donors – Organ donation and Transplantation can save lives

- Every 10 minutes, someone is added to the national transplant waiting list
- On average, 22 people die each day while waiting for a transplant
- One organ donor can save eight lives
The Problem

Demand > Supply

• Our challenge is to allocate a resource where demand greatly exceeds supply.
• This means we need to make trade-offs based on evidence, values and guiding principles.

Primary Goal: Reduce deaths on the waitlist.
ADVANCED HEART FAILURE OPTIONS

Cardiac Transplant

Permanent Assist Pump or Artificial Heart

15 years  ———  65 years (Age)
DIFFICULT DECISIONS OF END STAGE HEART FAILURE: MECHANICAL CIRCULATORY SUPPORT

The risks of multi-system organ failure from progressive heart failure (> 50% death in 1 year) vs. The risks of surgical intervention for MCSD and ongoing MCSD support.
In the meantime...
waiting for a heart transplant

Left to right:
Mr. J. Everett Logan, Mrs. Launa Logan, Dr. Robert Higgins
Adult Heart Transplants: % of Patients Bridged with Mechanical Circulatory Support*

Transplants: January 2005 – December 2015

* LVAD, RVAD, TAH, ECMO
THE GIFT OF LIFE
STS and Intermacs

STS National Database

INTERMACS Mechanical Circulatory Support

STS

INTERMACS

2018
Collaborative Patient Care, Quality Assessment and Research

- Intermacs was formed as a coalition of multiple diverse partners.

- “Interagency” partnership of the three Federal Agencies: NHLBI, FDA and CMS. In addition to the Federal Partners,

- Intermacs has strongly partnered with industry, hospitals, clinicians, basic scientists
STSW Intermacs Database How Did We get Here-Timeline

- Early 2014—Leadership of Intermacs Registry (Kirklin/Naftel/Pagani/Kormos/Young/ Warner Stevenson/Miller/Baldwin) written proposal to STS, seeking collaboration

- April 2014—Intermacs collaboration proposal discussed by STS Executive Committee in Toronto

- December 2014—Meeting between STS and Intermacs Registry leaders (including STS, UAB and NHLBI staff) held at NHLBI offices in Bethesda
STS Intermacs Timeline cont.

- April – May 2017 - MOU signed 4/27 by STS, 4/28 by UAB, 5/18 by NHLBI

- July 2017 - NHLBI funding of Intermacs Registry ends; no-cost extension through 12/31/17 issued

- November 10, 2017 - STS and UAB execute Data Warehouse and Analytics Center Agreement (3-year term)

- January 1, 2018 - Intermacs becomes fourth component of the STS National Database
STS and Intermacs

STS National Database

Intermacs Mechanical Circulatory Support

STS NATIONAL DATABASES

AS OF JANUARY 1, 2019

STS CONGENITAL

STS ADULT

STS THORACIC

STS INTERMACS
The STS Intermacs Database - joint effort among the National Heart, Lung, and Blood Institute, the Food and Drug Administration, the Centers for Medicare & Medicaid Services

Established in 2005 at the University of Alabama at Birmingham.

Intermacs is a North American registry for the clinical outcomes of patients who receive an FDA-approved mechanical circulatory support device to treat advanced heart failure.

- **Intermacs**
  - 174 Active Sites
  - 24,334 Patients Enrolled

- **Pedimacs**
  - 47 Active Sites
  - 589 Patients Enrolled
Initial Goals of Intermacs

- Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
- Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
- Develop consensus “best practices” to improve clinical management by reducing short and long term complications of MCSD therapy.
- Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.
- Guide clinical testing and approval of new devices.
Research and Reporting

A Platform for Progress after Innovation

> 60 Publications in the last 5 years

2010: INTERMACS Evolved into a QA Database

Numerous High Impact Publications Crystalizing Risk Factors and Outcomes

- Right Heart Failure
- Infection
- Device Exchange
- Destination Therapy
- QOL
- Ambulatory HF
- Concomitant Surgery for TR, MR
- Bridge to Candidacy
- Stroke
- Renal Failure
- Frailty

- Risk Factors for mortality
- Optimize Patient Selection
- Evaluate Strategies to Reduce Adverse Events

- Post Market Studies for Industry
- Detection of Pump Thrombosis Trends for FDA
- Joint Commission and DNV Benchmarks
- Hospital Reporting
- USA Collective Contributing to IMACS Registry
A New Pumping Device Brings Hope for Cheney

By LAWRENCE K. ALTMAN, M.D.
Published: July 19, 2010

Former Vice President Dick Cheney is recuperating from surgery to implant the kind of mechanical pump now being given to a small but growing number of people with heart failure so severe that they would most likely die within a few months without it.

The pumps are partial artificial hearts known as ventricular assist devices, and they come in various models. Mr. Cheney's kind is about the size of a D battery and
THORATEC HEARTMATE II

- Continuous, axial flow LVAD approved as BTT 2005 (CE Mark)
- FDA approval as BTT/DT 2008
- Clinical experience >700 implants worldwide
- 79% patients survive to transplant, recovery or ongoing support as DT
- mean support 169 days
- Requires aggressive anticoagulation
CAN LVADS OUTLIVE HEART TRANSPLANTS?

52 yo WF with breast cancer diagnosis
Complete cure after therapy
Chemotherapy (Adriamycin) induced cardiomyopathy
Advanced heart failure
Heartmate II 2005

*Uneventful postop course: Year 14*
INTERAGENCY REGISTRY FOR MECHANICALLY ASSISTED CIRCULATORY SUPPORT (INTERMACS)

ANALYSIS OF PUMP THROMBOSIS IN THE HEARTMATE II LVAD

James K. Kirklin, MD, David C. Naftel, PhD, Robert L. Kormos, MD, Francis D. Pagani, MD, Susan L. Myers, MPH, Lynne W. Stevenson, MD, Michael A. Acker, MD, Daniel L. Goldstein, MD,
Scott C. Silvestry, MD, Carmelo A. Milano, MD, J. Timothy Baldwin, MD, Sean Pinney, MD, J. Eduardo Rame, MD, Marissa A. Miller, DVM, MPH

The Journal of Heart and Lung Transplantation
Volume 33, Issue 1, Pages 12-22 (January 2014)
DOI: 10.1016/j.healun.2013.11.001

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PREVENT TRIAL CONCLUSIONS

24% of patients had sub-optimal pump position at baseline

Morbidly obese patients are more likely to have sub-optimal pump position

Patients with sub-optimal pump position have lower survival and experience significantly more pump thrombosis, hemolysis, and elevated LDH at 6 months¹

Maltais, Kilic, Nathan et al. JHLT 2017;36(1):1-12
NEXT GENERATION LVADS

- Smaller, easier implant
- Bridge to recovery possibility, destination, and application
- Still requires aggressive anticoagulation
- Pump (Blood) flow estimation based upon pump speed/power
- Pre-load dependent, after-load sensitive
- The HeartMate 3 LVAS a fully magnetically levitated centrifugal blood pump
EVOLVING LVAD TECHNOLOGY

**Continuous-flow Left Ventricular Assist Systems (LVAS) improve survival and quality of life in patients with advanced heart failure**

- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis


The HeartMate 3™ rotor and inlet have been designed to minimize shear and avoid stasis over the entire range of operation (2.5 to 10 L/min).
HEARTMATE III
MINIMALLY INVASIVE LVAD
The Society of Thoracic Surgeons Intermacs Database Annual Report: Evolving Indications, Outcomes, and Scientific Partnerships

Robert L. Kormos, MD, Jennifer Cowger, MD, MS, Francis D. Pagani, MD, PhD, Jeffrey J. Teuteberg, MD, Daniel J. Goldstein, MD, Jeffrey P. Jacobs, MD, Robert S. Higgins, MD, Lynne W. Stevenson, MD, Josef Stehlik, MD, Pavan Atluri, MD, Kathleen L. Grady, PhD, RN, James K. Kirklin, MD

The Annals of Thoracic Surgery
Volume 107, Issue 2, Pages 341-353 (February 2019)
DOI: 10.1016/j.athoracsur.2018.11.011
Implants: June 2006 – December 2017

All implants
n= 25145

RVAD/temporary device only
N=20

Hx of previous durable VAD
N=4656

All Primary implants for left ventricular support
n= 20469

TAH (Pulsatile Flow)
N=339

Pulsatile Flow LVAD (+/- RVAD)
N=923

Continuous Flow LVAD (+/- RVAD)
N=19206*

Analysis Cohort

Continuous Flow (LVAD only)
N=18539

Continuous Flow (LVAD + RVAD):
N=687

*1 CFLVAD removed from analyses (prior to 2008)
Fig 3

CF Isolated LVAD Implants: April 2008 – December 2017, n=18539

Note: n=339 primary Total Artificial Heart devices implanted during this time frame.
Overall Survival for patients with Continuous Flow isolated LVAD, n=18539

<table>
<thead>
<tr>
<th>Time post implant</th>
<th>% Survival</th>
</tr>
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<tbody>
<tr>
<td>1 month</td>
<td>96%</td>
</tr>
<tr>
<td>3 months</td>
<td>92%</td>
</tr>
<tr>
<td>6 months</td>
<td>90%</td>
</tr>
<tr>
<td>12 months</td>
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</tr>
<tr>
<td>48 months</td>
<td>63%</td>
</tr>
<tr>
<td>60 months</td>
<td>54%</td>
</tr>
<tr>
<td>72 months</td>
<td>46%</td>
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Event: Death (censored at transplant, death, recovery, device exchange)

n at risk: 18539, Deaths= 5241

Months post implant
“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
Are your innovative efforts in quality and safety improving patients’ lives?
Teamwork is the ability to work together toward a common vision. The ability to direct individual accomplishments toward organizational objectives. It is the fuel that allows common people to attain uncommon results.
Thank You!
Welcome (and Thank you for your support!)
How did we get here?
A Little history about cardiac surgery/advanced heart failure therapy
Intermacs Today
Looking to the Future-What’s on the Horizon?
Are your innovative efforts in quality and safety improving patients’ lives?
The 2019 John M. Eisenberg Patient Safety and Quality Awards trumpet the accomplishments of those individuals and organizations who have made significant and long-lasting contributions to improving patient safety and health care quality.

“The Eisenberg Awards are an annual reminder that we, as a nation, cannot take health care quality and safety for granted, and significant work remains to improve the care experienced by every person in communities across the country.”

—Dr. Shantanu Agrawal president and chief executive officer National Quality Forum
STS Database Staff Leadership
Evolution of Cardiac surgery

Developmental Phase

• 1953-54 Cardiopulmonary bypass
• 1958 Sones - Cardiac catheterization
• 1960 Valve prostheses
• 1967 Coronary bypass surgery
Open Heart Surgery (CPB Cases)
How it Developed World-Wide

TECHNOLOGY EVOLVES

Sustaining Mastery
Over a Technology:
- Building of firm foundations;
- Improving, augmenting, applying

LEARNING CURVE
- Diminishing Returns

Pioneering
Engineering & Science:
- Prospecting for new possibilities;
- Exploring, evaluating, inventing

MEASURE OF ADVANCEMENT

MEASURE OF APPLIED EFFORT

Gibbon's
ASD with
Gibbon oxy.
May 6, 1953

Lillehei's
VSD with
cross circ.
March 26, 1953
Coronary surgery relieves angina and prolongs life expectancy.

Impact of Coronary Revascularization
Not all CABG patents are the same-

**Historical Considerations**

**1970’s – 80’s:** advanced age, depressed EF associated with higher mortality in AMI and CABG

**1989:** indications for surgical treatment in acute MI
- evolving MI less than 6 hours from onset in patients where PCI or thrombolytic unsuccessful
- post infarction angina hours to days after transmural myocardial infarction unyielding to max medical therapy
- IABP dependent patients in cardiogenic shock without mechanical defects

Cohn, L, Cardiology 1989:76(2):167-72
National Surgical Quality Movement

**Background**

1986 – Veterans Healthcare Administration conducts National VA Surgical Risk Study in 44 VA Medical Centers with goal of developing and validating risk-adjustment models to predict surgical outcomes

1984 – National VA Surgical Quality Improvement Program (NSQIP) established in all 132 VAMC’s performing surgery

1998 - Khuri et al present first national, validated, out-come based, risk-adjusted report outlining structure, data collection, analysis and reporting

2000 – 2015

*Evidence supports that continuous quality assessment in NSQIP and process improvement enhances surgical outcomes*
U.S. RELEASING LISTS OF HOSPITALS WITH ABNORMAL MORTALITY RATES

By JOEL BRINKLEY, Special to the New York Times
Published: March 12, 1986

WASHINGTON, March 11—The Health and Human Services Department is preparing to release lists of the nation’s hospitals that have mortality rates significantly higher or lower than the national average, the first such lists ever compiled.

The lists, provided to The New York Times and scheduled for general release on Wednesday, indicate that more than twice as many patients died at certain hospitals than would have been expected under national norms.

The lists were derived using case records from 10.7 million patients treated in 1984 whose bills were paid by Medicare, the Government program that assists the elderly and the disabled in paying their hospital costs. Nearly all the nation’s hospitals treat Medicare patients, who make up almost half of all hospital patients. 'It Is Not a Report Card'

Several New York hospitals were identified as having higher-than-average mortality rates for elderly Medicare patients. [ Page A22. ] But Federal officials warned that the statistics
Performance metrics should be based on risk-adjusted clinical data.
It Is Time for a National Cardiothoracic Surgical Data Base

Richard E. Clark, MD
Surgery Branch, National Heart, Lung, and Blood Institute, Bethesda, Maryland

The Society of Thoracic Surgeons will soon sponsor an opportunity for its members to participate in a national clinical data base system for cardiac and thoracic operations and outcome. This effort by the STS to establish a national data base is more than 5 years old. An ad hoc committee initiated a pilot program that, unfortunately, did not evolve to national scope. The development of small portable computers that were fast and interactive and had large storage capabilities has made possible the formation of many local data bases for cardiac surgery. The time is now ripe for those with existing data bases and those who have none at present to participate in this national effort.

The reasons for the initiation of this program by the STS are many. The formation of a group to undertake the effort was prompted by the release by HCFA (Health Care Financing Administration), a component of the Department of Health and Human Services, of raw mortality data for Medicare patients undergoing coronary artery bypass grafting procedures without respect to any of the then-known risk factors associated with patients during coronary artery disease.

The Standards and Ethics Committee of the STS released its "Statement of Concern" with approval of Council late in 1986, which was well received by practitioners and hospitals. The Standards and Ethics Committee at the Toronto meeting of the STS in September of 1987 developed a proposal for the Council for the development of a national data base system sponsored by the STS.

The pressing need was clearly evident from a number of artery operations carried little or no risk was perpetuated. A third driving force was the action of the JCAHCO (Joint Commission on Accreditation of Health Care Organizations). Quality assurance programs for every segment of the health care system were required. Recredentialing on a yearly basis was to occur based on the previous year's clinical performance by the practitioner. Clearly, results of the surgeons were going to be readily evident in contrast to those of psychiatrists. Finally, Congress required of HCFA and a suborganization, the PPRC (Physicians Payment Review Commission), a complete study and review of physicians' billings and payments under the Medicare system with the requirement of reporting the results in late 1989 and early 1990. The purpose was to decrease the rate of increase in health care costs, which have been substantially exceeding the inflationary rate for more than a decade. The initial report by the investigator (Hsiao) to the HCFA recommended a rearrangement of payment schemes with greater weight given to so-called cognitive skills than to technical ones. Cardiothoracic surgeons were to receive a reduction in payments of 25% to 30%

The need, therefore, to determine accurately the amount of services provided in toto by the cardiothoracic community had become acute.

Edmunds and Kaiser, in their preface to the report of the Committee for the state of the art symposium on coronary arterial surgery, made a pertinent strong plea.

Proper solution to the risk-benefit equation requires knowledge of the natural history of the disease and of the incremental risk factors that affect operative mortality and long-
STS database established 1989, now \(\approx 90 - 95\%\) of adult CT programs in US

>6.8 million adult cardiac patient records
Membership organization to Enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy
Membership by Discipline*

*Among those who have reported their disciplines.
STS and Intermacs

STS National Database

Intermacs Mechanical Circulatory Support

STS NATIONAL DATABASES

AS OF JANUARY 1, 2019

STS CONGENITAL

STS ADULT

STS THORACIC

STS INTERMACS
Ultimate Goal is Improvement, Not Measurement

Use STS data to establish evidence-based best practices and document quality improvement
Linkage of Medicare Records to the Interagency Registry of Mechanically Assisted Circulatory Support
Qixing Liang, BS,* Sarah Ward, MD,* Francis D. Pagani, MD, PhD, Shashank S. Sinha, MD, MS, Min Zhang, PhD, Rob Kormos, MD, Keith D. Aaronson, MD, MS, Andrew D. Althouse, PhD, James K. Kirklin, MD, David Naftel, PhD, and Donald S. Likosky, PhD

• Using a merged data set of MCSDs implanted between 2008 and 2013, we report that the vast majority of CMS centers and Medicare beneficiaries receiving MCSDs are increasingly captured in INTERMACS.

• Accordingly, contemporary studies in INTERMACS are relevant and generalizable to the Medicare population.
Status Update on the STS/Northwestern University project to acquire longitudinal data in the STS National Database

• The objective of the project is to acquire longitudinal mortality, reoperation follow-up, and socioeconomic status (SES) data for the patient records captured in the STS National Database.

• The NDI search file for the patient records in the ACSD, CHSD, and GTSD will be optimized and submitted to the CDC by the end of November.

• STS anticipates paying CDC approximately $1 million in December 2019 (capitalized expense) to execute the NDI search.

• STS anticipates receiving results of the NDI search by mid-February 2020.

• March 2020 – STS will collaborate with Northwestern University on the work to adjudicate and merge the SES, Reoperation, Death (fact, time and cause of death) data into the supplemental datasets that correspond to the ACSD, CHSD, and GTSD.

• STS anticipates that by July 2020 the project will be completed and the supplemental data sets will be available for inquiry.
Portfolio of Composite Measures for the Most Common Cardiac Procedures

- Isolated CABG
- Isolated AVR
- AVR + CABG
- Cardiac Surgery Quality
- Isolated Mitral Repair
- Mitral Repair + CABG
- MVR
- MVR + CABG
STS Risk Calculator

Home / Quality, Research & Patient Safety / Quality / Short-Term Risk Calculator and Models

Short-Term Risk Calculator and Models

The STS Risk Calculator allows users to calculate a patient's risk of mortality and morbidity, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Click here to start using the STS Risk Calculator.
STS Database Opportunities

• Limited automated data extraction, requires skilled data managers completing data collection forms on paper or electronically (currently, 5 major EMR vendors in use).

• Site reports as PDF, compared to STS aggregate at regular intervals (6 months), are difficult to interpret

• Media scrutiny, congenital public reporting/star rating raised questions about risk stratification; led to secondary analysis of STS Risk Modeling by Harvard Research Group at significant cost and time (18 months)

• Database participation is resource-intensive and expensive

• **Star rating system provokes comparisons by programs primarily for marketing purposes; true quality assessment and improvement should be within programs ie. Better than, equal to or worse than expected outcomes compared to risk adjusted metrics**
STS Database Modernization Opportunities

• Sites want mobile based patient follow-up applications
• Real-time feedback reports/dashboard and patient-reported outcomes analysis
• Ideal Framework would include a web-based system that allows sites to manage data and reporting from one system
• Develop modular participation fee schedule/discount for high volume centers
• Growth opportunities to expand thoracic surgery participation in the future
Individual Surgeon Performance in Adult Cardiac Surgery

• The Society of Thoracic Surgeons (STS) is developing plans to operationalize its Individual Surgeon Composite Measure [1], which was published in 2015 and subsequently endorsed by the National Quality Forum.

• The goal of this initiative is to provide STS Adult Cardiac Surgery Database participating surgeons with feedback regarding their individual, nationally benchmarked performance scores. This is a natural next step in the continuing evolution of the STS quality program.

• What do you think?
What Does the Future Hold for Intermacs?

- **Streamlining** of data fields and refine key adverse event definitions.
- **Develop** quality outcomes metrics via NQF process
  - Short-term Index Hospital Metrics
  - Revitalize existing Longitudinal Metrics.
- **Establish** public reporting structure and practice
- **Define** International alliances
- **Strengthen** Industry and FDA partnerships and mission
### Understanding Confidence Intervals and Statistical Significance of STS Data

<table>
<thead>
<tr>
<th></th>
<th>Risk-adjusted Operative Mortality 2014-2017</th>
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<tbody>
<tr>
<td></td>
<td>Number of Patients</td>
<td>Patients who Died</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Actual Percent</td>
<td>Expected Percent</td>
<td>Risk-adjusted Rate (95% Confidence Interval)</td>
<td></td>
</tr>
<tr>
<td>Society of Thoracic Surgeons (STS)</td>
<td>5,000</td>
<td>7.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Hospital 1</td>
<td>130</td>
<td>7.7</td>
<td>7.6</td>
<td>7.6</td>
</tr>
<tr>
<td>Sample Hospital 2</td>
<td>140</td>
<td>2.9</td>
<td>7.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Sample Hospital 3</td>
<td>150</td>
<td>12.0</td>
<td>7.1</td>
<td>12.7</td>
</tr>
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</table>

- The hospital’s confidence interval includes the STS actual percent, so the hospital’s risk-adjusted operative mortality rate is not significantly different than expected.
- The hospital’s confidence interval is lower than the STS actual percent, so the hospital’s risk-adjusted operative mortality rate is significantly lower (better) than expected.
- The hospital’s confidence interval is higher than the STS actual percent, so the hospital’s risk-adjusted operative mortality rate is significantly higher (worse) than expected.
A House Divided.....

- House of Cardiac Surgery
- House of Cardiology and CV services
- Consequence?

Home for CV specialists
What does Washington want health care reform to accomplish?

- Integrate care across the continuum and break down silos
- Value/quality over volume
- Bend the cost curve
The Way Forward
Common Ground, Unity & Leverage

- Communication

- Be defined by our common interests vs. our differences

- Unite our efforts and better coordination

- Increase our leverage, power and influence

Source:
Another case in point

A 68-year-old male presents with acute onset of chest pain, shortness of breath and palpitations. Acute myocardial infarction diagnosed by ECG; chest x-ray shows pulmonary edema, cardiac echo shows left ventricular dysfunction (LVEF: 20%) with 3-4+ mitral regurgitation. SBP 90/60 mmHg/HR-120 bpm.
Stratum C Case – Preoperative MRI
Use STS data to establish evidence-based best practices and document quality improvement
Fig 1

Council on Quality, Research, and Patient Safety
David Shahian, MD

- WF on Research Development
  Felix Fernandez, MD
  - Access and Publications TF
    Jeffrey Jacobs, MD
  - Participant User File TF
    Kevin Lobdell, MD
  - TF on Funded Research
    Matt Williams, MD

- WF on Evidence Based Surgery
  Faisal Bakaeen, MD

- WF on National Databases
  Jeffrey Jacobs, MD
  - Adult Cardiac Surgery Database TF
    Richard D'Agostino, MD
  - Congenital Heart Surgery Database TF
    John Mayer, MD
  - Intermacs TF
    Robert Kormos, MD
  - Quality Initiatives
    Gaetano Paone, MD
  - Informatics TF
    David Wormuth

- WF on Patient Safety
  James Fann, MD
  - General Thoracic Surgery Database TF
    Benjamin Kozower, MD
  - Aortic TF
    Nimesh Desai, MD
  - Quality Measurement TF
    David Shahian, MD
  - Public Reporting TF
    Vinay Badhwar, MD
  - Patient Reported Outcomes TF
    Felix Fernandez, MD
Eighth Annual INTERMACS report: Special focus on framing the impact of adverse events

James K. Kirklin, MD, PhD, Francis D. Pagani, MD, PhD, Robert L. Kormos, MD, MPH, Lynne W. Stevenson, MD, Elizabeth D. Blixa, MD, Susan L. Myers, BBA, MPH, Marisa A. Miller, DVM, MHP, J. Timothy Baldwin, PhD, James B. Young, MD, and David C. Ruff, PhD

The INTERMACS Database is a registry for mechanically assisted circulatory support (MACS). All patients receiving a MACS device are enrolled in the database. All deaths and complications are captured. The purpose of this report is to highlight the impact of adverse events and to provide insight into the outcomes of patients receiving MACS devices.

BACKGROUND: The INTERMACS Database has captured data on over 20,000 patients treated with a variety of MACS devices. The impact of adverse events on patient outcomes is an important area of research.

CONCLUSION: This report highlights the importance of adverse events in determining patient outcomes and provides recommendations for improving patient care.

Implants: June 2006 – December 2016

<table>
<thead>
<tr>
<th>All implants</th>
<th>Hx of previous durable VAD</th>
<th>RVAD alone (no previous VAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=22866</td>
<td>N=3845</td>
<td>N=34</td>
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All Primary implants for Left Sided Support n=18937

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<thead>
<tr>
<th>TAH (Pulsatile Flow)</th>
<th>Pulsatil Flow LVAD ( +/- RVAD)</th>
<th>Continuous Flow LVAD ( +/- RVAD)</th>
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<td>N=396</td>
<td>N=957</td>
<td>N=17634</td>
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Patient and site enrollment

Between June 23, 2006, and December 31, 2015, 22,896 patients received a FDA-approved mechanical circulatory support (MCS) device was enrolled into the INTERMACS Database (Figure 3). Of the 157 participating hospitals, the rate of patient enrollment has continued at a pace exceeding 2,700 implants per year, with a decrease noted during 2016, likely related to increased enrollment of patients with longer implantation within clinical trials. INTERMACS captures only FDA-approved MCS devices. Thus far, 14,500 patients received an FDA-approved device (4,300 patients in 2016). These data are not captured in INTERMACS. Of the 15,397

All patients enrolled in INTERMACS are identified in a separate report.

Eighth Annual INTERMACS report: Special focus on framing the impact of adverse events

James K. Kirklin, MD, PhD, Francis D. Pagani, MD, PhD, Robert L. Kormos, MD, MPH, Lynne W. Stevenson, MD, Elizabeth D. Blixa, MD, Susan L. Myers, BBA, MPH, Marisa A. Miller, DVM, MHP, J. Timothy Baldwin, PhD, James B. Young, MD, and David C. Ruff, PhD

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</table>

All Primary implants for Left Sided Support n=18937

<table>
<thead>
<tr>
<th>TAH (Pulsatile Flow)</th>
<th>Pulsatil Flow LVAD ( +/- RVAD)</th>
<th>Continuous Flow LVAD ( +/- RVAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=396</td>
<td>N=957</td>
<td>N=17634</td>
</tr>
</tbody>
</table>

Patient and site enrollment

Between June 23, 2006, and December 31, 2015, 22,896 patients received a FDA-approved mechanical circulatory support (MCS) device was enrolled into the INTERMACS Database (Figure 3). Of the 157 participating hospitals, the rate of patient enrollment has continued at a pace exceeding 2,700 implants per year, with a decrease noted during 2016, likely related to increased enrollment of patients with longer implantation within clinical trials. INTERMACS captures only FDA-approved MCS devices. Thus far, 14,500 patients received an FDA-approved device (4,300 patients in 2016). These data are not captured in INTERMACS. Of the 15,397

All patients enrolled in INTERMACS are identified in a separate report.

Eighth Annual INTERMACS report: Special focus on framing the impact of adverse events

James K. Kirklin, MD, PhD, Francis D. Pagani, MD, PhD, Robert L. Kormos, MD, MPH, Lynne W. Stevenson, MD, Elizabeth D. Blixa, MD, Susan L. Myers, BBA, MPH, Marisa A. Miller, DVM, MHP, J. Timothy Baldwin, PhD, James B. Young, MD, and David C. Ruff, PhD

The INTERMACS Database is a registry for mechanically assisted circulatory support (INTERMACS). All patients receiving a MACS device are enrolled in the database. All deaths and complications are captured. The purpose of this report is to highlight the impact of adverse events and to provide insight into the outcomes of patients receiving MACS devices.

BACKGROUND: The INTERMACS Database has captured data on over 20,000 patients treated with a variety of MACS devices. The impact of adverse events on patient outcomes is an important area of research.

CONCLUSION: This report highlights the importance of adverse events in determining patient outcomes and provides recommendations for improving patient care.

Implants: June 2006 – December 2016

<table>
<thead>
<tr>
<th>All implants</th>
<th>Hx of previous durable VAD</th>
<th>RVAD alone (no previous VAD)</th>
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<tbody>
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## Required Data Elements

### (STS Adult Cardiac Surgery Database Version 2.81)

- **Procedure Type**
- **Patient Age**
- **Sex**
- **Height (cm)**
- **Weight (kg)**
- **Hemo Data – Ejection Fraction Done**
- **Heart Failure within 2 weeks**
- **Race Documented**
- **Hispanic or Latino or Spanish Ethnicity**
- **Risk Factors (RF)-Renal Failure-Dialysis**
- **RF- Last Creatinine Level**
- **Cardiac Presentation/Symptoms-At Time of This Admission**
- **Cardiac Symptoms-At Time of Surgery**
- **Prior MI**
- **Cardiac Arrhythmia**
- **RF-Chronic Lung Disease**
- **RF-Cerebrovascular Disease**
- **RF-Peripheral Arterial Disease**
- **RF-Diabetes**
- **RF-Hypertension**
- **RF-Immunocompromise Present**
- **RF- Endocarditis**
- **Coronary Anatomy/Disease Known**
- **Status**
- **Resuscitation**
- **Cardiogenic Shock**
- **IABP**
- **Meds-Inotropes**
- **Previous Cardiac Interventions**
- **Valve Disease (VD)-Mitral**
- **VD-Aortic**
- **VD- Insufficiency-Mitral**
- **VD- Insufficiency-Tricuspid**
- **VD- Insufficiency-Aortic**
- **Incidence**
STS public reporting

- Best data and analytical methodologies: NQF-endorsed, broad acceptance by providers and external stakeholders
- Promotes patient Autonomy
- Beneficence: one way to improve quality
- Potential impact on consumers and the market
- Pre-empt less responsible and credible reporting initiatives
### STS Composite Quality Rating

**Participant 99999**  
**STS Period Ending 06/30/2009**

<table>
<thead>
<tr>
<th>Quality Domain</th>
<th>Participant Score (95% CI)</th>
<th>STS Mean Participant Score</th>
<th>Participant Rating</th>
<th>Distribution of Participant Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 2008 - Jun 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>98.6% (95.7, 99.6)</td>
<td>95.3%</td>
<td>★★★</td>
<td></td>
</tr>
<tr>
<td>Jul 2008 - Jun 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoidance of Mortality</td>
<td>98.6% (98.7, 99.1)</td>
<td>96.0%</td>
<td>★★</td>
<td></td>
</tr>
<tr>
<td>Jul 2008 - Jun 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoidance of Morbidity</td>
<td>89.9% (85.9, 93.6)</td>
<td>84.4%</td>
<td>★★★</td>
<td></td>
</tr>
<tr>
<td>Jul 2008 - Jun 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of IMA²</td>
<td>98.6% (94.1, 98.5)</td>
<td>94.2%</td>
<td>★★</td>
<td></td>
</tr>
<tr>
<td>Jul 2008 - Jun 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications²</td>
<td>79.5% (74.0, 84.3)</td>
<td>73.9%</td>
<td>★★★</td>
<td></td>
</tr>
</tbody>
</table>
Isolated CABG and Isolated AVR

<table>
<thead>
<tr>
<th></th>
<th>10/1/13 - 9/30/16</th>
<th>Privileged &amp; Confidential</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Volume</td>
<td>ReOp Bleed</td>
</tr>
<tr>
<td>Isolated CAB</td>
<td>368</td>
<td>9</td>
</tr>
<tr>
<td>(In-reading calendar)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolated CAB STS</td>
<td></td>
<td>1.8%</td>
</tr>
<tr>
<td>Isolated AVR</td>
<td>363</td>
<td>8</td>
</tr>
</tbody>
</table>
Addressing Challenges
Congenital Database
Case in Point

The Society of Thoracic Surgeons

STS Volume Determination
4 year Period
July 1, 2012 - June 30, 2016

n=1462
CPB/CPB Cardiovascular/No CPB CV

n=287
Excluded: Other Procedures (VAD/ECMO/Thoracic)

n=1038
w/STAT Score

n=137
w/o STAT Score

n=985
Index Case

n=985
Index Case

n=53
Non-Index Case

n=921
 Eligible

n=64
Exclude PDA < 2.5 Kg

n=916
 Eligible

n=5
Exclude Pacemaker Age < 30 days

n=912
 Eligible

n=4
Exclude: In-patient at time of data harvest

n=909
 Eligible

n=3
Exclude: Weight for Age Z-Score Criteria

Non-Index Cases With STAT Category Excluded From Analysis: (n=53):
STAT 1 n=6 (Transcatheter AV Canal)
STAT 2 n=13 (VSD, Coarctation)
STAT 3 n=4 (MAPCA(s) occlusion, Pulmonary embolotomy)
STAT 4 n=26 (Arterial Switch, Heart Transplant, PA Banding)
STAT 5 n=4 (Damus-Kaye-Stansel, Norwood)

STS Volume Determination n = 1462
n = 538 Excluded from Analysis / Reporting
n = 909 Cases In STS Mortality/Benchmark Reports
LETTERS

New York Times, May 30


• Doctors, including Mehmet Oz, and a health researcher offer suggestions for improvement.
• June 4, 2019
• To the Editor:
• Re “Hope for Tiny Hearts, Then Trouble”
• (front page, May 30):
Parents’ Preferences Regarding Public Reporting of Outcomes in Congenital Heart Surgery

Mallory L. Irons, MD, MBE, J. William Gaynor, MD, Thomas L. Spray, MD, and Chris Feudtner, MD, PhD
Annals Thorac Surg 2017
Observed and expected mortality rates, O/E ratios, and prevalence of 6 major risk factors, by quarter, 2004–2014, in ACSD
STS Intermacs Timeline cont.

- April 2015 - STS and UAB execute a “Unilateral Confidential Disclosure Agreement”

- April 2015 - STS representatives meet with Jim Kirklin in Seattle during AATS Annual Meeting

- Mid-2015 thru - STS and UAB representatives engage in information exchange related to operations and finances

- May 2016 - Second meeting among STS and Intermacs Registry leaders at NHLBI office in Bethesda
Survival for patients with CFLVADs by Intention to Treat at time of implant, n=18422

P(overall) < .0001

<table>
<thead>
<tr>
<th>Time post implant</th>
<th>% Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BTT</td>
</tr>
<tr>
<td>1 month</td>
<td>97%</td>
</tr>
<tr>
<td>3 months</td>
<td>95%</td>
</tr>
<tr>
<td>6 months</td>
<td>92%</td>
</tr>
<tr>
<td>12 months</td>
<td>88%</td>
</tr>
<tr>
<td>24 months</td>
<td>80%</td>
</tr>
<tr>
<td>36 months</td>
<td>70%</td>
</tr>
<tr>
<td>48 months</td>
<td>61%</td>
</tr>
<tr>
<td>60 months</td>
<td>54%</td>
</tr>
<tr>
<td>72 months</td>
<td>46%</td>
</tr>
</tbody>
</table>

Event: Death (censored at transplant, death, recovery, device exchange)

Bridge to Transplant, Listed (BTT) n=4881, Deaths=851
Bridge to Decision (BTD) n=5508, Deaths=1378
Destination Therapy (DT) n=8033, Deaths=2983
Survival for patients with CFLVAD vs CFBiVAD pumps, n=19206

<table>
<thead>
<tr>
<th>Time post Implant</th>
<th>% Survival CFLVAD</th>
<th>% Survival CFBiVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>96%</td>
<td>80%</td>
</tr>
<tr>
<td>3 months</td>
<td>92%</td>
<td>70%</td>
</tr>
<tr>
<td>6 months</td>
<td>89%</td>
<td>64%</td>
</tr>
<tr>
<td>12 months</td>
<td>83%</td>
<td>58%</td>
</tr>
<tr>
<td>24 months</td>
<td>73%</td>
<td>51%</td>
</tr>
<tr>
<td>36 months</td>
<td>63%</td>
<td>43%</td>
</tr>
<tr>
<td>48 months</td>
<td>54%</td>
<td>38%</td>
</tr>
<tr>
<td>60 months</td>
<td>46%</td>
<td>31%</td>
</tr>
<tr>
<td>72 months</td>
<td>38%</td>
<td>28%</td>
</tr>
</tbody>
</table>

P < .0001

Event: Death (censored at transplant, death, recovery, device exchange)

n at risk for:

<table>
<thead>
<tr>
<th></th>
<th>CFLVAD</th>
<th>CFBiVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>14105</td>
<td>319</td>
</tr>
<tr>
<td>0</td>
<td>10379</td>
<td>217</td>
</tr>
<tr>
<td>1</td>
<td>5938</td>
<td>128</td>
</tr>
<tr>
<td>2</td>
<td>3351</td>
<td>68</td>
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<td>3</td>
<td>1805</td>
<td>43</td>
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<tr>
<td>4</td>
<td>987</td>
<td>16</td>
</tr>
<tr>
<td>5</td>
<td>471</td>
<td></td>
</tr>
</tbody>
</table>
Fig 8

Survival for patients with CFLVADs by INTERMACS Profile at time of implant, n=18539

<table>
<thead>
<tr>
<th>Time post implant</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Levels 4-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>92%</td>
<td>96%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>3 months</td>
<td>87%</td>
<td>92%</td>
<td>94%</td>
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<tr>
<td>6 months</td>
<td>84%</td>
<td>88%</td>
<td>91%</td>
<td>90%</td>
</tr>
<tr>
<td>12 months</td>
<td>79%</td>
<td>83%</td>
<td>86%</td>
<td>85%</td>
</tr>
<tr>
<td>24 months</td>
<td>71%</td>
<td>72%</td>
<td>76%</td>
<td>74%</td>
</tr>
<tr>
<td>36 months</td>
<td>62%</td>
<td>62%</td>
<td>65%</td>
<td>65%</td>
</tr>
<tr>
<td>48 months</td>
<td>54%</td>
<td>52%</td>
<td>56%</td>
<td>54%</td>
</tr>
<tr>
<td>60 months</td>
<td>48%</td>
<td>44%</td>
<td>48%</td>
<td>45%</td>
</tr>
<tr>
<td>72 months</td>
<td>43%</td>
<td>37%</td>
<td>39%</td>
<td>36%</td>
</tr>
</tbody>
</table>

P(overall) < .0001

Levels 4-7, n=3046, deaths=506

N=5 patients have unspecified patient profile
Survival for patients with CFLVADs by pump flow type
Implants from November 2012 – December 2017*, n=12368

* First approved centrifugal flow pump approved by FDA Nov 2012
This depiction includes all continuous flow FDA approved devices (HMII, HM3, HVAD)
Time to 1st Rehospitalization* by Pump Flow Type

<table>
<thead>
<tr>
<th>Time post implant (months)</th>
<th>Axial Flow Pump (% Freedom from Rehospitalization)</th>
<th>Centrifugal Flow Pump (% Freedom from Rehospitalization)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>71</td>
<td>70</td>
</tr>
<tr>
<td>3</td>
<td>52</td>
<td>49</td>
</tr>
<tr>
<td>6</td>
<td>38</td>
<td>34</td>
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<tr>
<td>12</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>24</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>36</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>48</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>60</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Event: Time to 1st Rehospitalization (time zero is index hospitalization discharge date)

*primary reason for Rehospitalization is transplantation is excluded in this depiction. Only patients with a valid index hospitalization discharge date is included in this depiction.