
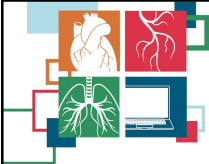


ADVANCES IN QUALITY & OUTCOMES:  
A Data Managers Meeting  
SEPTEMBER 26-29, 2023 ■ VIRTUAL



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ADVANCES IN QUALITY & OUTCOMES:  
A Data Managers Meeting  
SEPTEMBER 26-29, 2023 ■ VIRTUAL

# How to Use InterMACs Data for Performance Improvement and Quality Initiatives

Jennifer Cowger, MD, MS  
Section Head, Advanced Heart Failure  
Medical Director, MCS Program  
Henry Ford Health  
Detroit, Michigan



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## I, Dr. Cowger, have the following Disclosures

*Abbott, Inc:* Steering Committee for Tendyne, Advisory Board member and Steering Committee Member for HM3 clinical trials, speaker

*Medtronics, Inc:* National PI and Steering Committee for HVAD DT PAS study

*Procyron, Inc:* Advisor and Steering committee member for Aortix (stock options)

*Endotronix, Inc:* Steering committee member (unpaid) for Proactive HF trial

*Nuwellis, Inc:* Steering committee member (unpaid)

*Bioventrix, Inc:* Steering committee member for ALIVE trial (paid); speaker (paid)

*BiVACOR, Inc:* DSMB member

*CoreWave, Inc:* Advisory Board

*Berlin Heart Excor:* DSMB member

STS: unpaid member of Intermacs leadership panel

ACC and ISHLT: editorial board members (paid)



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## Learning Objectives

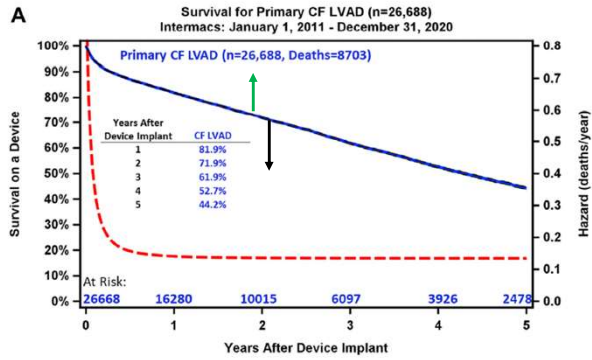
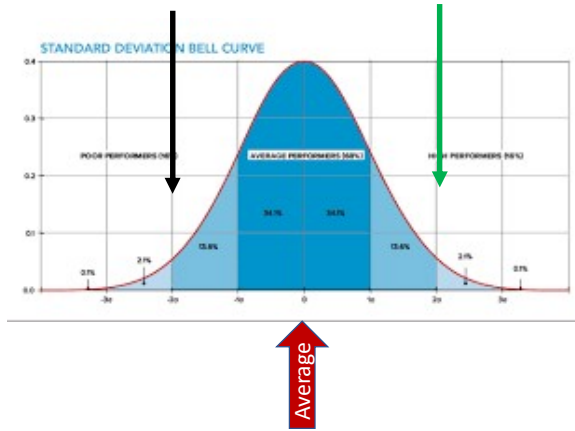
- 1) Integrate Intermacs data into programmatic quality assessment to reveal opportunities for programmatic performance improvement
- 2) Use Intermacs data to assess where improvements are needed for your center's short-term outcomes
- 3) Use Intermacs data to assess where improvements are needed for your center's long-term outcomes



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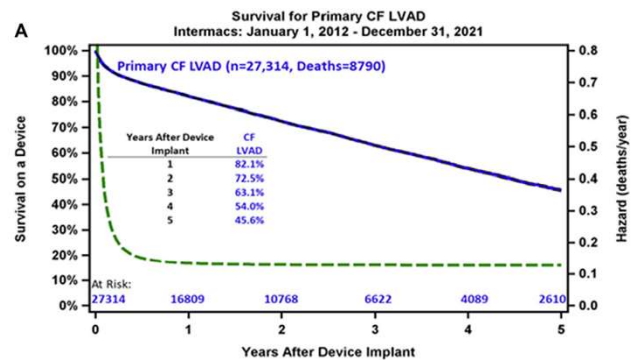
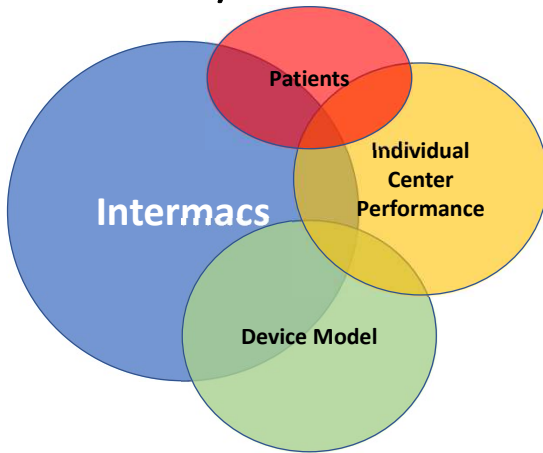
# Quality Assessment for Durable MCS



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# Quality Assessment for Durable MCS



Melana Yuzefpolskay, et al. Ann Thorac Surg 2023;115:311-28

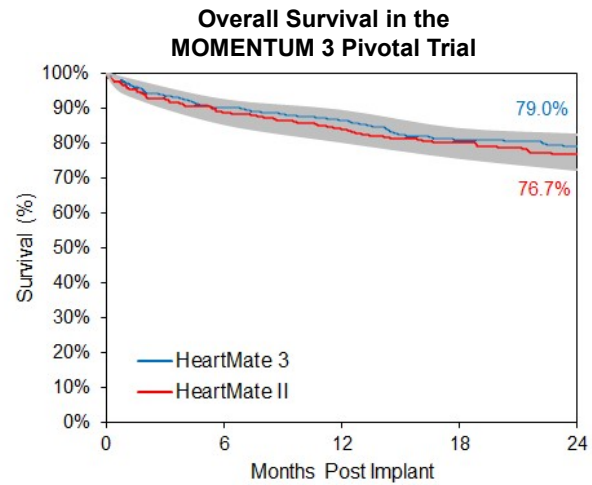


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## Looking Beyond the Average

- Randomized trial HM3 vs. HMII LVAD
- DT and BTT
- NYHA III-IV, EF  $\leq$ 25%
- Inotrope dependent  
or  
Cardiac index  $<$ 2.2 L/min/m<sup>2</sup>
- Survival at 2 years noninferior



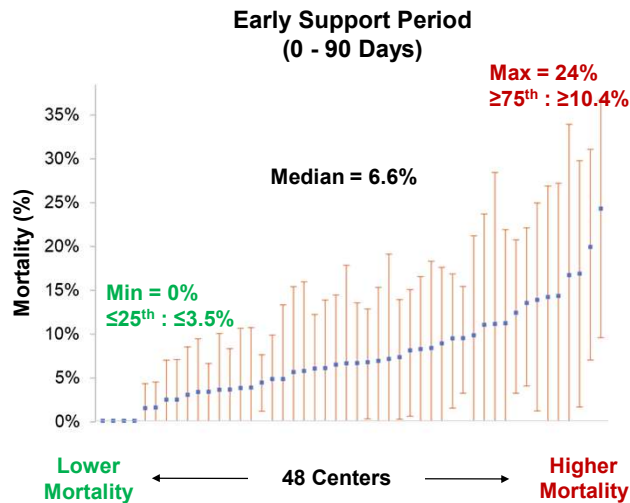
At risk:

HeartMate 3	515	447	383	322	289
HeartMate II	505	414	339	285	248

Kanwar, Cowger J Cardiac Fail 2022;28:1158-1168.  
Mehra, NEJM 2019;380:1618-27

7

## Variability of Mortality Across Centers



Error bars denote 95% confidence intervals

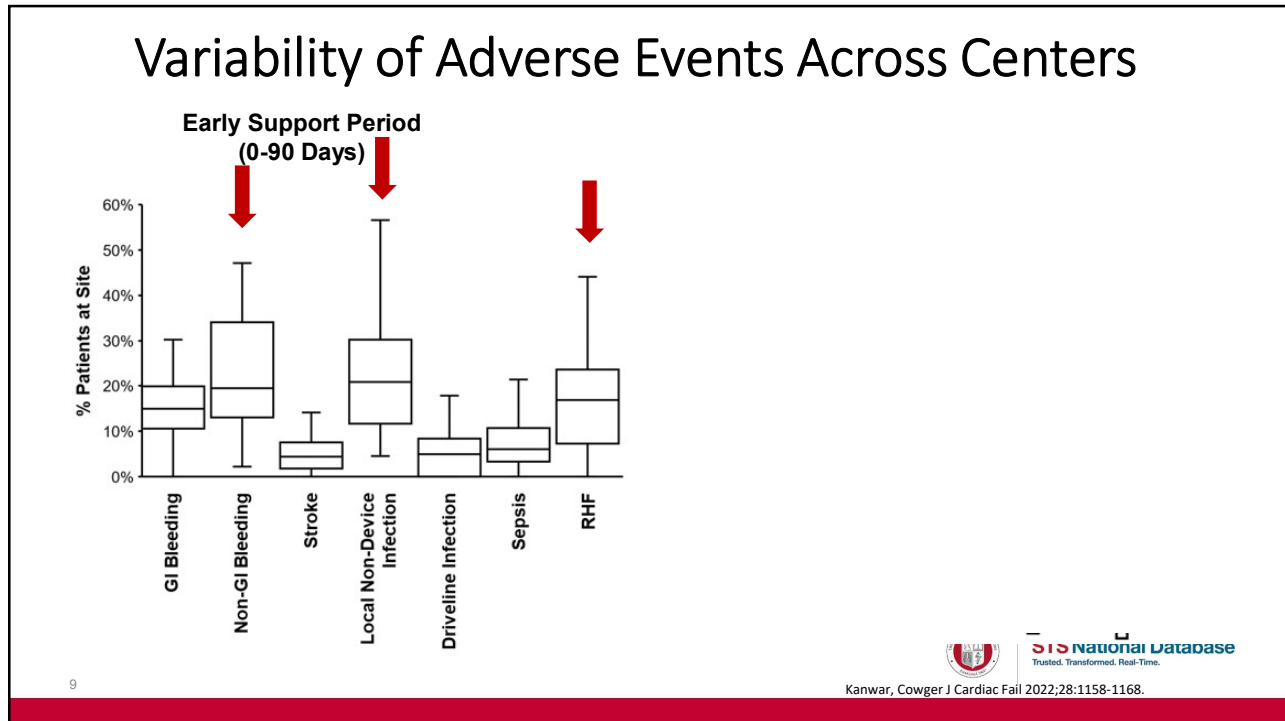


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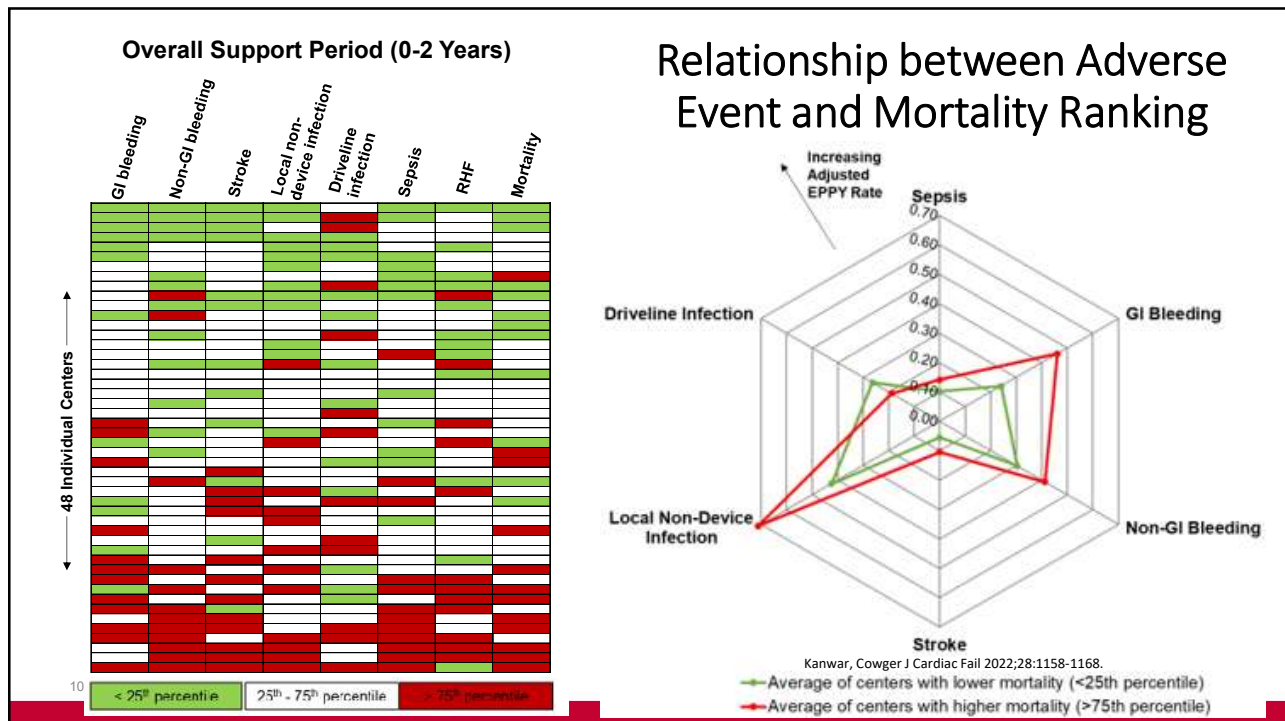
Kanwar, Cowger J Cardiac Fail 2022;28:1158-1168.

8

8



9



10

**“Science tells us what we can do; Guidelines what we should do; & Registries what we are actually doing”.**

--- Lucas Kappenberger (at Heart Rhythm Society Policy Conference, Washington, DC, 2005)



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## Quality Assessment within InterMACs

- InterMACs provides **national average benchmarks** for **"real world"** post LVAD
  - Survival
    - Causes of death
  - Key adverse events
- InterMACs provides **site-specific outcomes** to compare with above
- InterMACs provides a mechanism to assess impact of your programmatic change/intervention on outcomes
- InterMACs helps identify areas for programmatic quality improvement



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## Quality Assessment within InterMACs

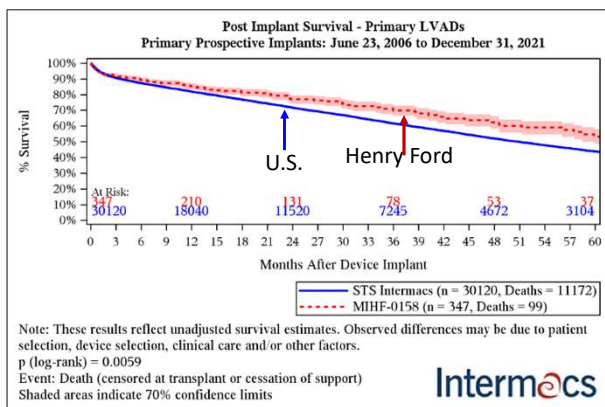
- **InterMACs provides the national average benchmark for**
  - Survival
  - Causes of death
  - Key adverse events
- **InterMACs provides site-specific outcomes to compare with above**
- InterMACs provides a mechanism to assess impact of programmatic change/intervention on outcomes
- InterMACs helps identify areas for programmatic quality improvement



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## Using the InterMACs Reports for QAPI



Months after Device Implant	STS InterMACs	MIHF-0158
1	94.8% (94.7%-95.0%)	94.5% (93.1%-95.6%)
3	90.6% (90.4%-90.8%)	92.2% (90.6%-93.5%)
6	87.2% (87.0%-87.4%)	89.3% (87.5%-90.9%)
9	84.5% (84.3%-84.7%)	87.3% (85.3%-89.0%)
12	81.9% (81.6%-82.1%)	85.3% (83.2%-87.2%)
24	71.7% (71.4%-72.0%)	76.9% (74.1%-79.4%)
36	61.6% (61.3%-62.0%)	70.9% (67.5%-73.9%)
48	52.1% (51.7%-52.5%)	62.5% (58.4%-66.3%)
60	43.8% (43.3%-44.2%)	53.3% (48.6%-57.9%)

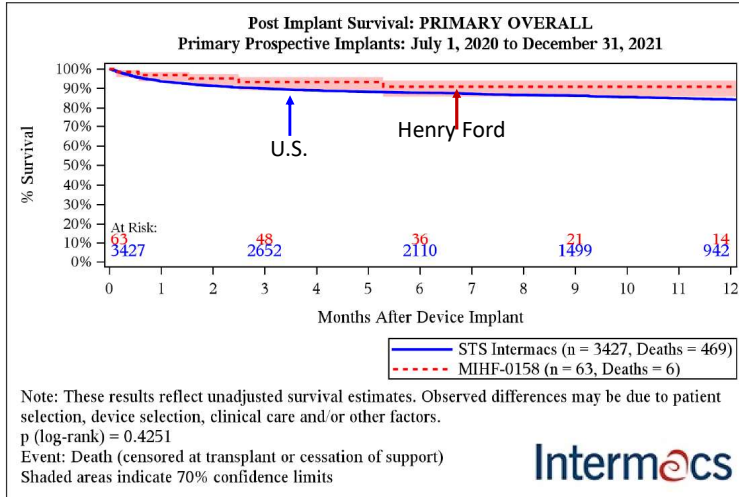


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# Contemporary Data

**Exhibit 34. Post Implant Survival - PRIMARY OVERALL**



Months after Device Implant	STS Intermacs	MIHF-0158
1	93.4% (93.0%-93.8%)	96.7% (93.5%-98.4%)
3	89.8% (89.2%-90.3%)	93.1% (88.9%-95.8%)
6	87.6% (87.0%-88.2%)	90.7% (85.7%-94.0%)
9	86.1% (85.5%-86.8%)	90.7% (85.7%-94.0%)
12	84.3% (83.5%-85.0%)	90.7% (85.7%-94.0%)



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## Assessing Your Center's Outcomes

How is your center's survival overall?

How is survival in the recent years?

- Is your survival inferior to national average?
- Is your survival too good?

How is short term survival vs. National?

How is long term survival vs National?

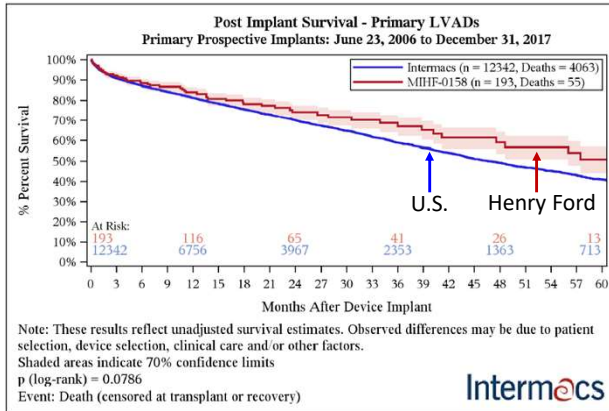


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# Example: Henry Ford Health VADs 2017



**N=35-40 VADs per year**

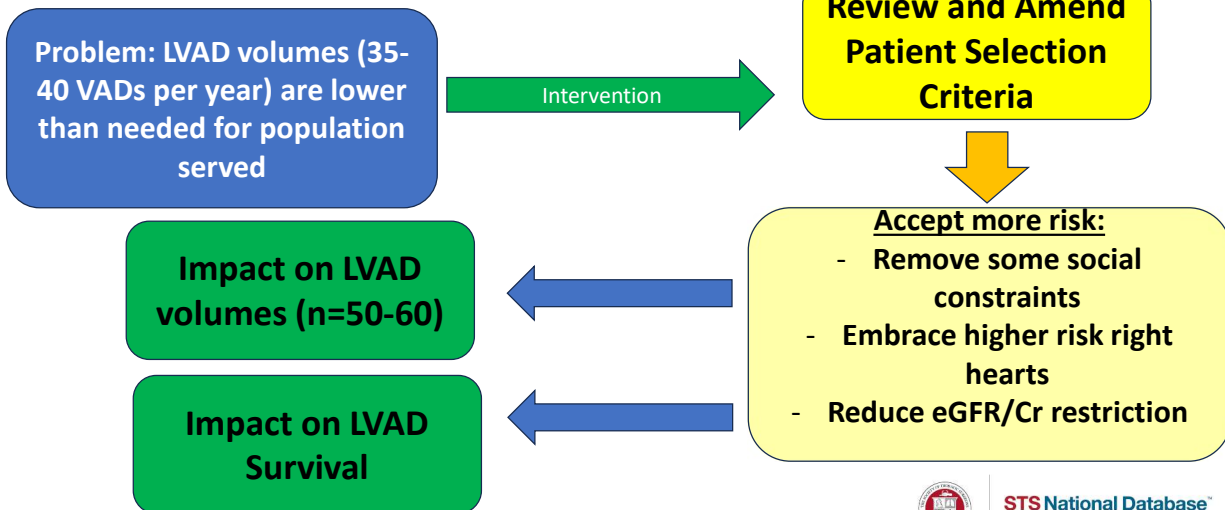
Months after Device Implant	Intermacs	MIHF-0158
1	95.2% (95.0%-95.4%)	95.3% (93.6%-96.6%)
3	90.9% (90.6%-91.1%)	92.2% (90.0%-93.9%)
6	87.1% (86.8%-87.4%)	88.4% (85.8%-90.5%)
12	81.2% (80.8%-81.6%)	83.8% (80.8%-86.4%)
24	70.1% (69.6%-70.6%)	74.0% (70.1%-77.6%)
36	59.0% (58.3%-59.6%)	68.7% (64.1%-72.8%)
48	49.1% (48.4%-49.8%)	59.1% (53.4%-64.4%)
60	40.9% (40.1%-41.8%)	50.7% (44.0%-57.0%)



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## Programmatic Introspection...



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## Quality Assessment within InterMACs

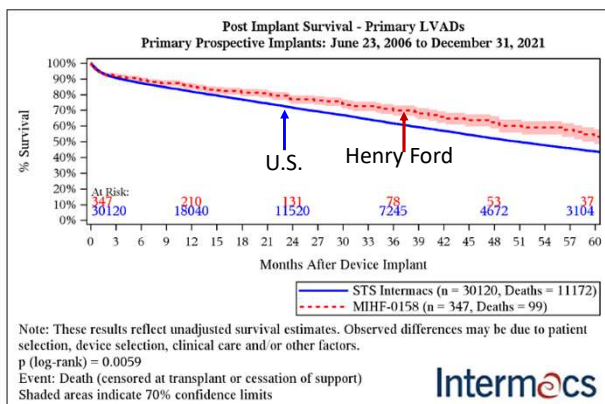
- InterMACs provides the national average benchmark for
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  - Causes of death
  - Key adverse events
- InterMACs provides site-specific outcomes to compare with above
- **InterMACs provides a mechanism to assess impact of programmatic change/intervention on outcomes**
- InterMACs helps identify areas for programmatic quality improvement



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## How is your Center's Long-Term Survival?



Months after Device Implant	STS InterMACs	MIHF-0158
1	94.8% (94.7%-95.0%)	94.5% (93.1%-95.6%)
3	90.6% (90.4%-90.8%)	92.2% (90.6%-93.5%)
6	87.2% (87.0%-87.4%)	89.3% (87.5%-90.9%)
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48	52.1% (51.7%-52.5%)	62.5% (58.4%-66.3%)
60	43.8% (43.3%-44.2%)	53.3% (48.6%-57.9%)

**Long term survival is acutely insensitive to programmatic change**

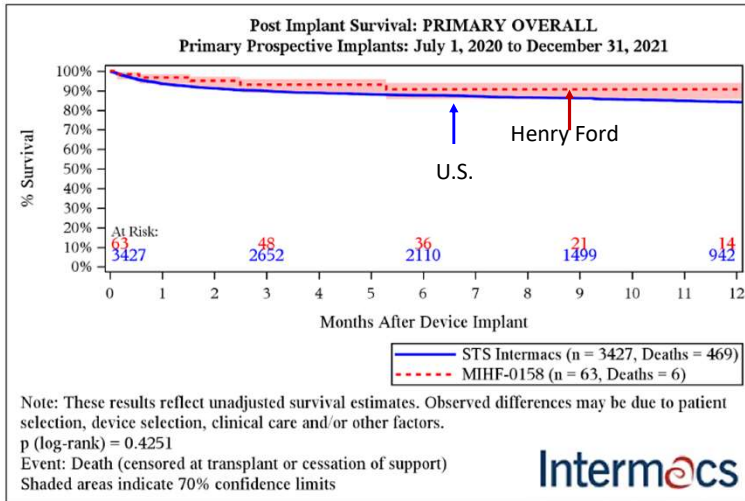


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# Keep close eye on your Center's Short-Term Survival

Exhibit 34. Post Implant Survival - PRIMARY OVERALL



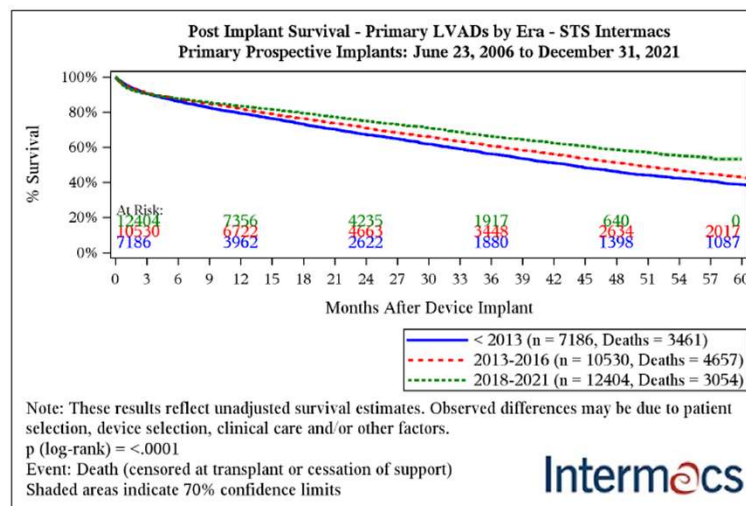
Months after Device Implant	STS Intermacs	MIHF-0158
1	93.4% (93.0%-93.8%)	96.7% (93.5%-98.4%)
3	89.8% (89.2%-90.3%)	93.1% (88.9%-95.8%)
6	87.6% (87.0%-88.2%)	90.7% (85.7%-94.0%)
9	86.1% (85.5%-86.8%)	90.7% (85.7%-94.0%)
12	84.3% (83.5%-85.0%)	90.7% (85.7%-94.0%)



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# After Intervention: How is Survival over chunks of Time?



Intermacs



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## Quality Assessment within InterMACs

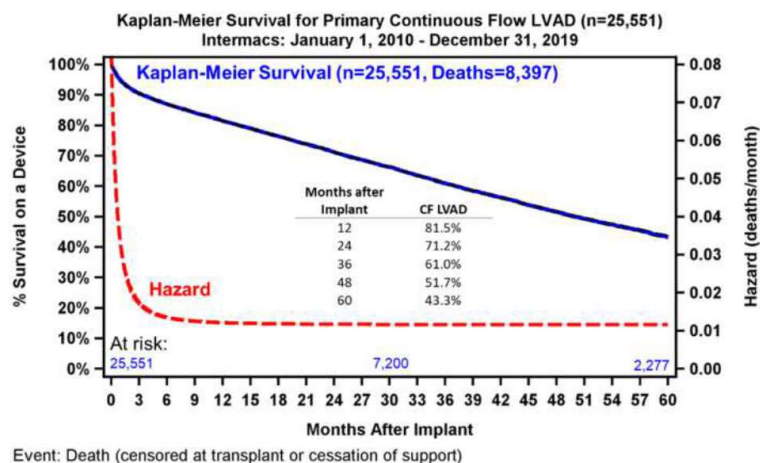
- InterMACs provides the national average benchmark for
  - Survival
  - Causes of death
  - Key adverse events
- InterMACs provides site-specific outcomes to compare with above
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- **InterMACs helps identify areas for programmatic quality improvement**



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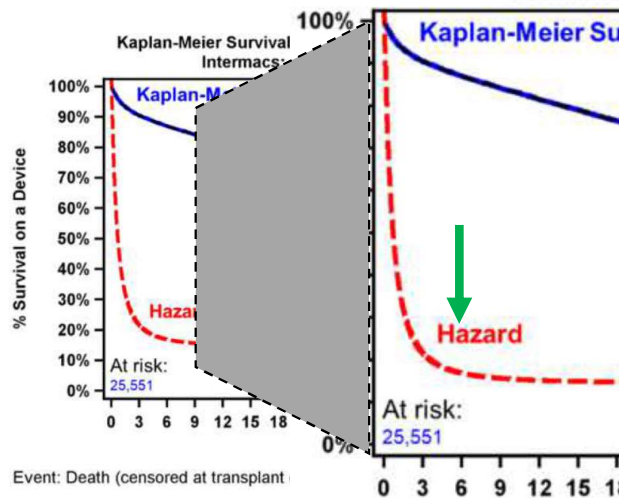
## Variability in Survival Hazard: Time Dependence from Implant



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# Variability in Survival Hazard: Short Term Hazard

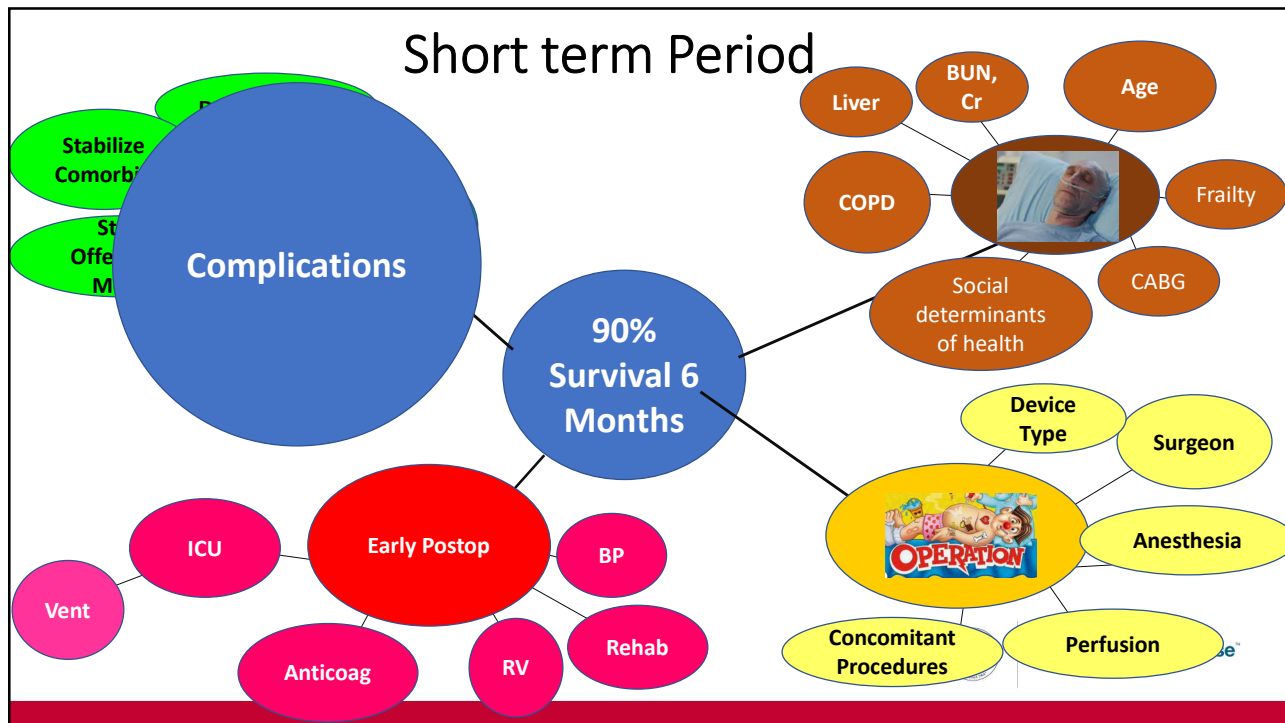


Average survival of 90% at 6 months for all Intermacs CF LVAD patients



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## Assessing Short Term Quality after LVAD Odds Ratios of 180-day Death on LVAD (N=20,044)

Composite Outcome Component	Crude (unadjusted) (N=20044)		Full model (multivariable) (N=20044)	
	OR (95%CI)	P-value	OR (95%CI)	P-value
Stroke	5.57 (5.01, 6.20)	<0.001	5.19 (4.63, 5.82)	<0.001
Respiratory Failure	6.66 (5.94, 7.46)	<0.001	3.66 (3.22, 4.17)	<0.001
Dialysis	5.81 (5.19, 6.49)	<0.001	3.52 (3.10, 4.01)	<0.001
Right Heart Failure	2.45 (2.21, 2.71)	<0.001	1.54 (1.37, 1.72)	<0.001
Reoperation	2.23 (2.02, 2.46)	<0.001	1.56(1.39, 1.76)	<0.001
Device Exchange	1.57 (1.30, 1.90)	<0.001	NA	-

Cowger et al. Presented at ISHLT 2022; under review.



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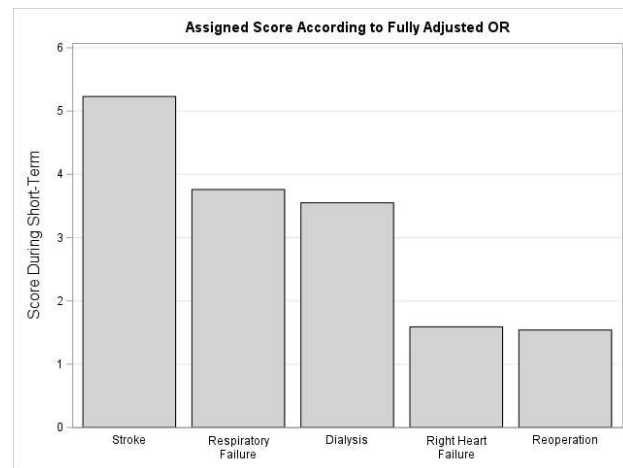
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## Scoring and Grouping

- Death = 20 points
- Non-recovery cessation of support = 20 points
- Urgent transplant =20 points
- Stroke = 5.2 points
- Respiratory Failure = 3.7 points
- Dialysis = 3.5 points
- Right Heart Failure = 1.5 points
- Reoperation = 1.6 points

### Score Grouping:

- 0
- 1-10
- 10 - 20
- 20 - 30
- 30 - 40



Cowger et al. Presented at ISHLT 2022; under review.



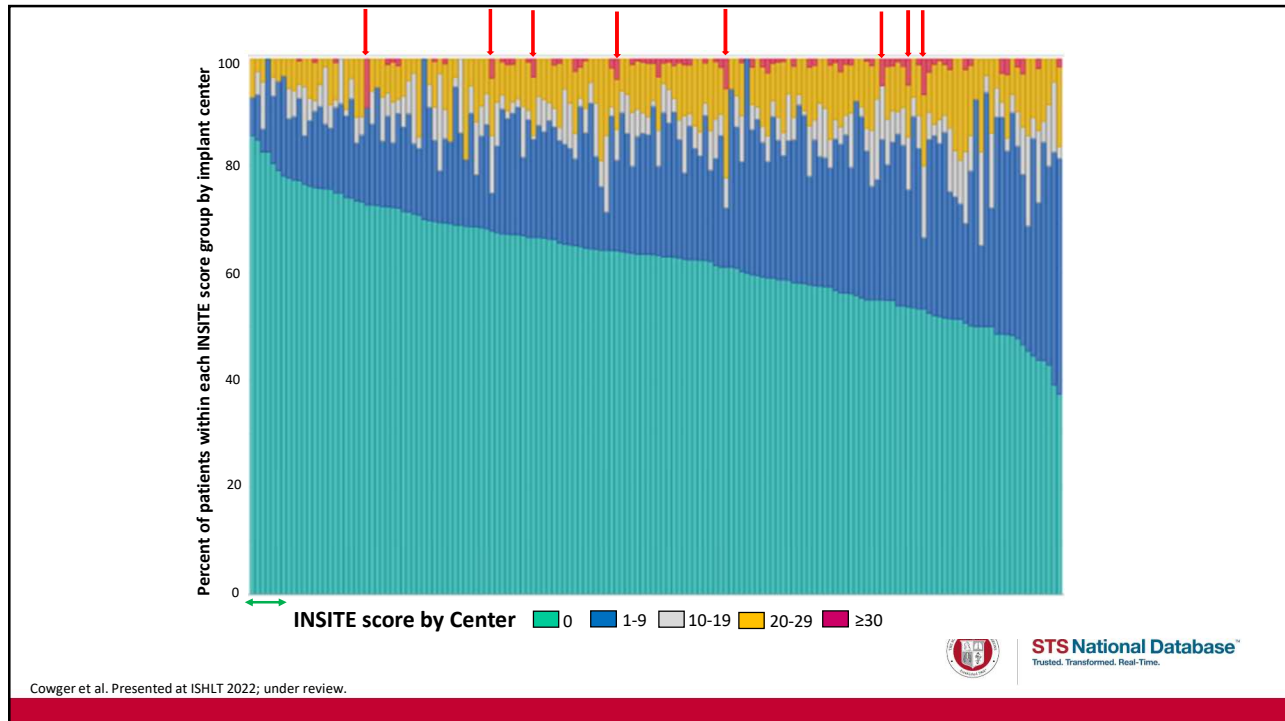
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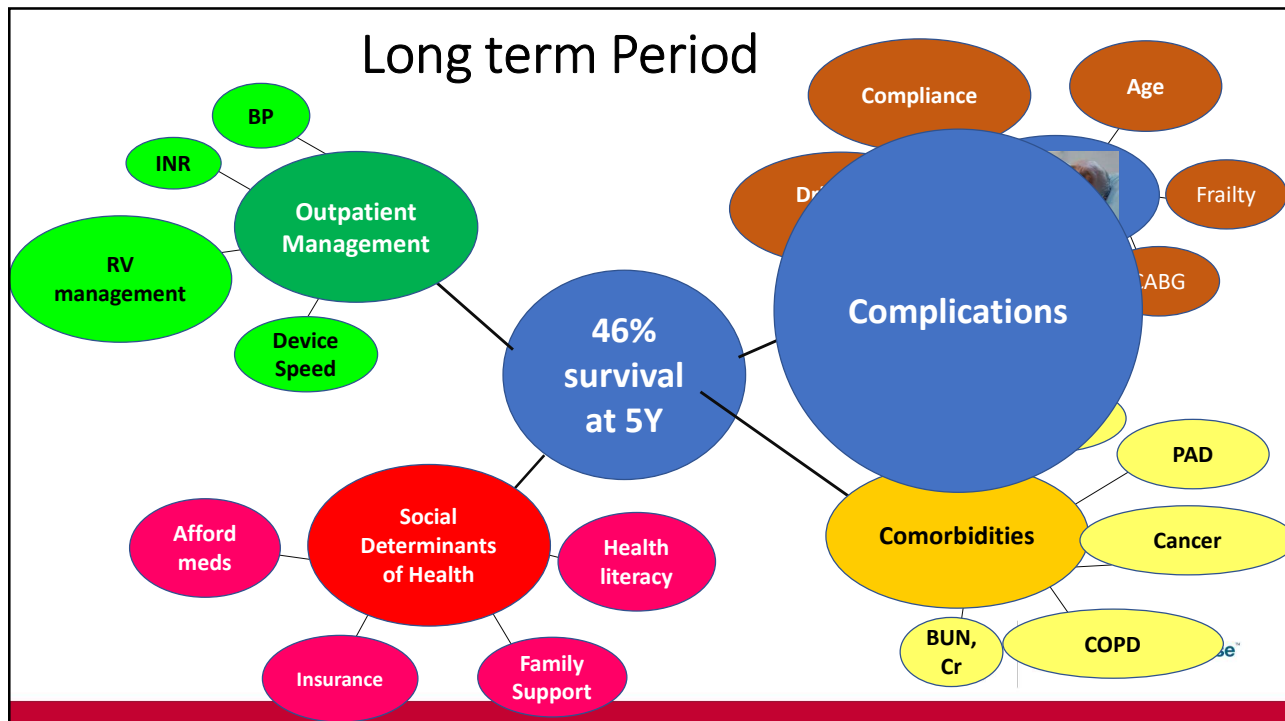


Intermacs

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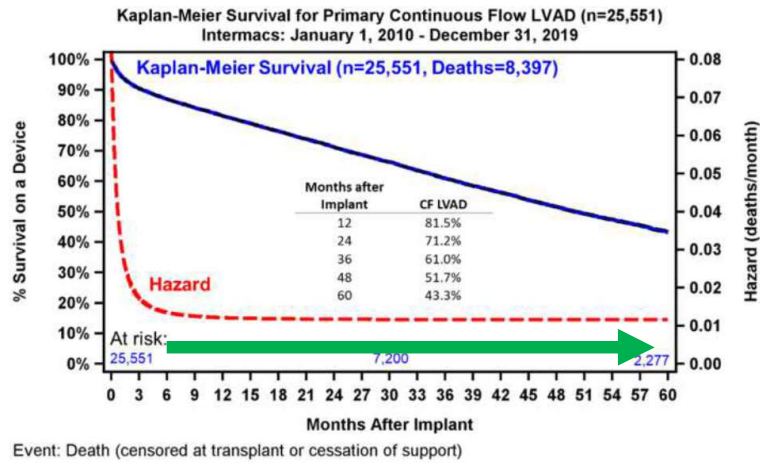


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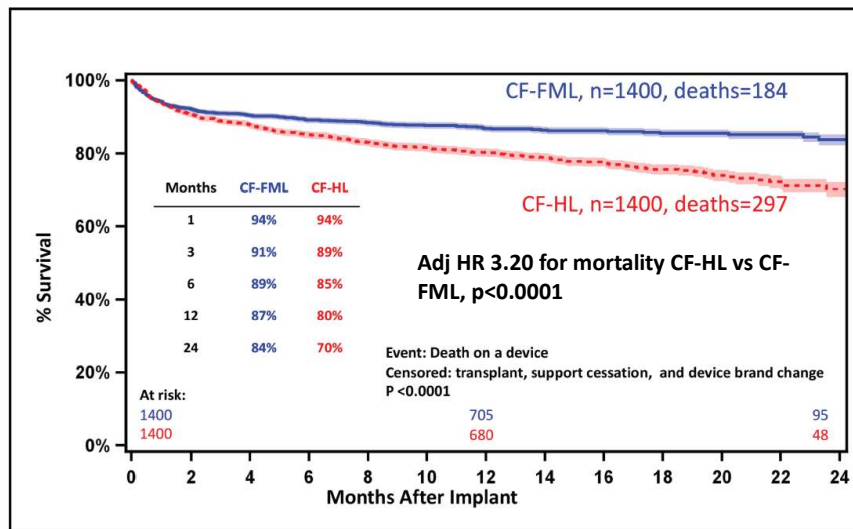
## Later Period after LVAD Implant



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## Influence of Device on CFLVAD Outcome



Pagani et al, Annals of Thoracic Surgery, in press <https://doi.org/10.1016/j.athoracsur.2021.05.017>

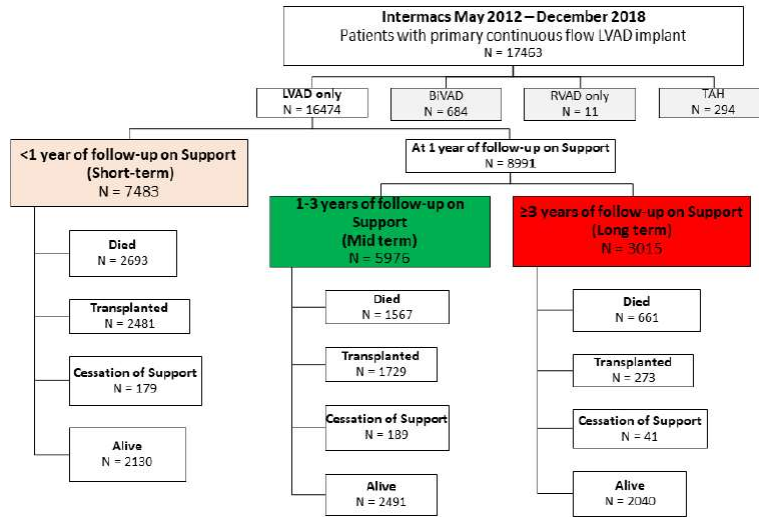


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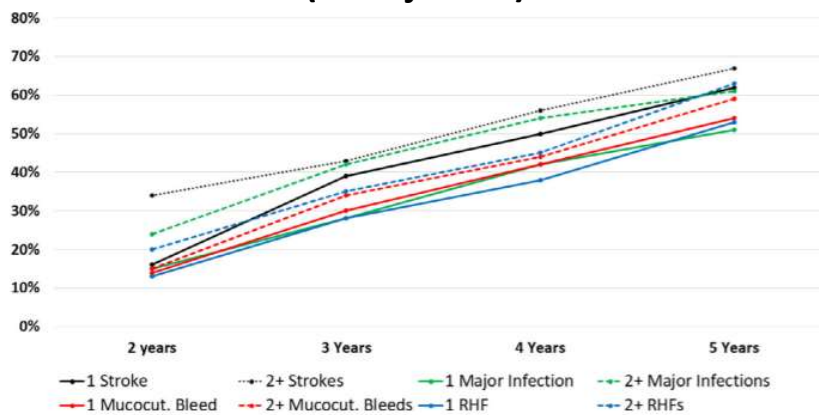
# Factors Impacting Long Term Survival Analysis



Hariri, Cowger, J Heart Lung Transplant 2022;41:161-170

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## Contribution of Aes (unadjusted) to death within 1 Y



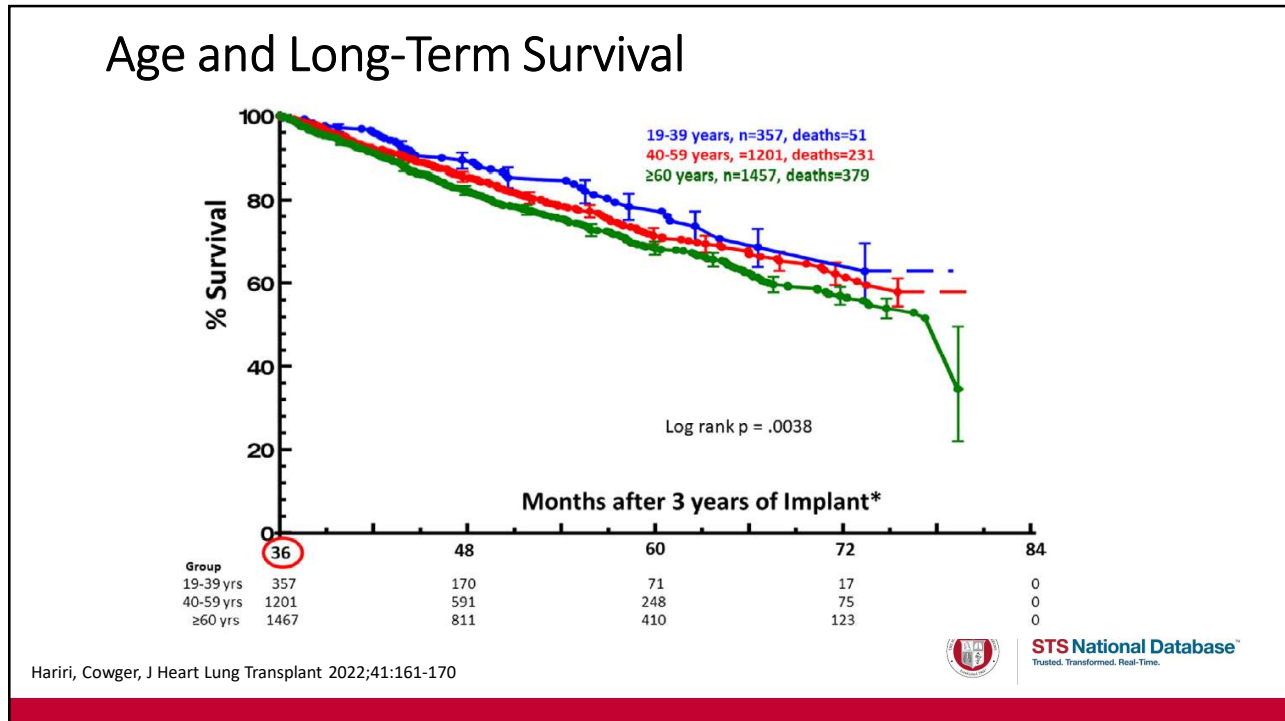
**Figure 3** Impact of Adverse Events on Survival in those Alive and on cLVAD Support at 1 Year. Adverse events occurring within 1 year of cLVAD implant were categorized according to frequency with corresponding survival after 1 year shown. RHF, right heart failure. cLVAD, continuous flow left ventricular assist device.

Hariri, Cowger, J Heart Lung Transplant 2022;41:161-170



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Risk Factors for Death	Mortality risk in those on support at 1 year		Mortality risk in those on support at 3 years	
	Constant Phase Hazard Ratio ( $n = 8,991$ at risk, $n = 2,228$ deaths)	$p$	Constant Phase Hazard Ratio ( $n = 3,015$ at risk, $n = 661$ deaths)	$p^b$
<b>Demographics</b>				
Age (per decade, with 50 to 60 years of age as reference)	1.15	<0.0001	1.08	0.02
BMI, per $\text{kg}/\text{m}^2$	1.01	0.0059		
Race: Caucasian	1.22	<0.0001	1.41	0.0002
Not married	1.16	0.0023		
<b>Clinical status</b>				
History of solid organ cancer	1.26	0.0051		
History of hepatitis	1.54	0.0017		
History of coronary artery bypass	1.24	<0.0001	1.29	0.0002
History of pulmonary disease	1.19	0.0075		
Current smoker of tobacco	1.44	<0.0001		
<b>Preimplant cardiopulmonary hemodynamics</b>				
Pulmonary artery systolic, per 10 mm Hg	0.96	0.0092		
Right atrial pressure, per 1 mm Hg	1.01	0.0001		
<b>Clinical events within 1 or 3 y of LVAD implantation</b>				
Stroke count (per event)	1.42	<0.0001	1.24	0.01
Infection count (per event)	1.13	<0.0001	1.10	<0.0001
Pump related infection count (per event)	1.19	<0.0001		
Device malfunction count (per event)	1.22	<0.0001	1.46	0.02
<b>Postoperative laboratory values obtained closest to 1 or 3-year follow up</b>				
Total bilirubin, per mg/dl	1.19	<0.0001		
BUN, per 10 mg/dl	1.07	<0.0001		
AST, per 100 unit	1.29	<0.0001	1.34	0.01
Creatinine, per mg/dl	1.09	0.0008	1.10	0.03
Albumin, per g/dl	0.66	<0.0001	0.63	<0.0001

Hariri, Cowger, J Heart Lung Transplant 2022;41:161-170

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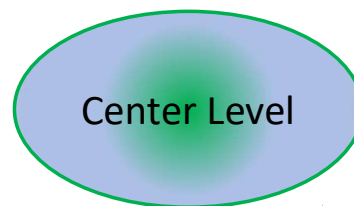
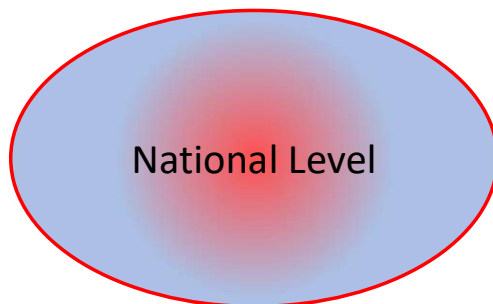
Risk Factors for Death	Mortality risk in those on support at 1 year		Mortality risk in those on support at 3 years			
	Constant Phase Hazard Ratio (n = 8,991 at risk, n = 2,228 deaths)	p	Constant Phase Hazard Ratio (n = 3,015 at risk, n = 661 deaths)	p <sup>b</sup>		
<b>Demographics</b>						
Age (per decade, with 50 to 60 years of age as reference)	1.15	<0.0001	1.08	0.02	} Patient selection	
BMI, per kg/m <sup>2</sup>	1.01	0.0059				
Race: Caucasian	1.22	<0.0001	1.41	0.0002		
Not married	1.16	0.0023				
<b>Clinical status</b>						
History of solid organ cancer	1.26	0.0051				
History of hepatitis	1.54	0.0017				
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Pulmonary artery systolic, per 10 mm Hg	0.96	0.0092			} Complications	
Right atrial pressure, per 1 mm Hg	1.01	0.0001				
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Albumin, per g/dl	0.66	<0.0001	0.63	<0.0001		

Hariri, Cowger, J Heart Lung Transplant 2022;41:161-170

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## Opportunities for Quality Improvement

- Key Opportunities for Improvement
  - Patient selection
  - Patient and Device Management
  - Device engineering- impact of AEs



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Use the Data Given...

### STS Intermacs

Quarterly Quality Assurance Report (2022 Q4) - Primary VAD Patients

Henry Ford Hospital

GROUP=MIHF-0158

GROUP=STS Intermacs

	MIHF-0158					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	1	1.7%	0.63	-	-	-
Bleeding	14	16.9%	8.76	3	5.1%	0.87
Cardiac Arrhythmia	10	16.9%	6.26	1	1.7%	0.29
Hemolysis	4	6.8%	2.50	-	-	-
Hepatic Dysfunction	1	1.7%	0.63	1	1.7%	0.29
Hypertension	1	1.7%	0.63	2	3.4%	0.58
Infection	25	25.4%	15.64	8	10.2%	2.33
Neurological Dysfunction	6	10.2%	3.75	-	-	-
Other Serious Adverse Event	9	13.6%	5.63	-	-	-
Pericardial Drainage	3	1.7%	1.88	-	-	-
Psychiatric Episode	6	10.2%	3.75	1	1.7%	0.29
Rehospitalization	15	22.0%	9.39	11	10.2%	3.21
Renal Dysfunction	7	11.9%	4.38	-	-	-
Respiratory Failure	12	11.9%	7.51	3	5.1%	0.87
Right Heart Failure	2	3.4%	1.25	-	-	-
Venous Thromboembolism	1	1.7%	0.63	1	1.7%	0.29
Wound Dehiscence	1	1.7%	0.63	-	-	-

	STS Intermacs					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	14	0.4%	0.17	-	-	-
Bleeding	702	16.9%	8.45	287	6.9%	1.67
Cardiac Arrhythmia	264	6.7%	3.18	13	0.3%	0.08
Device Malfunction and/or Pump Thrombosis	43	1.3%	0.52	26	0.8%	0.15
Hemolysis	459	11.6%	5.53	64	1.6%	0.37
Hepatic Dysfunction	29	0.9%	0.35	7	0.2%	0.04
Hypertension	39	1.1%	0.47	32	0.9%	0.19
Infection	912	21.3%	10.88	603	13.5%	3.50
Myocardial Infarction	3	0.1%	0.04	-	-	-
Neurological Dysfunction	330	9.6%	3.97	102	2.8%	0.59
Other Serious Adverse Event	290	6.8%	3.49	39	1.1%	0.23
Pericardial Drainage	26	0.8%	0.31	-	-	-
Psychiatric Episode	61	1.9%	0.73	14	0.4%	0.08
Rehospitalization	1089	25.3%	13.11	1940	29.7%	11.27
Renal Dysfunction	440	13.0%	5.30	96	2.5%	0.56
Respiratory Failure	279	8.1%	3.36	25	0.8%	0.15
Right Heart Failure	489	14.2%	5.89	69	1.5%	0.40
Venous Thromboembolism	46	1.4%	0.55	6	0.2%	0.03
Wound Dehiscence	22	0.7%	0.26	-	-	-

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## Quality Assessment/Performance Improvement QAPI

- How do your AE rates compare:
  - With other Intermacs Centers?
  - From year to year within your center?
- Is there an AE rate that stands out for QAPI? (example infection)
  - Time frame of AE: Infection rate at 6 months or 2 year?
  - What are the area of potential PI? Physical (Clinic, OR, ICU), personnel (RN, MD, ID consultations), protocol (dressing type, dressing frequency, education, Abx management, Extubation, central line days, bowel protocol)
  - What do the published data tell you is best practice for prevention and treatment?
  - What is your action plan and when will you reassess?



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# The Future of STS Quality Reports

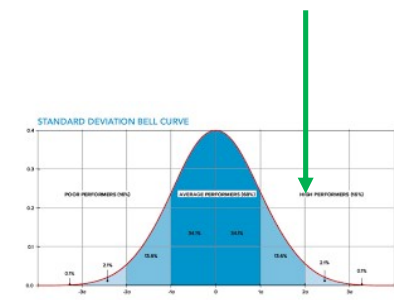


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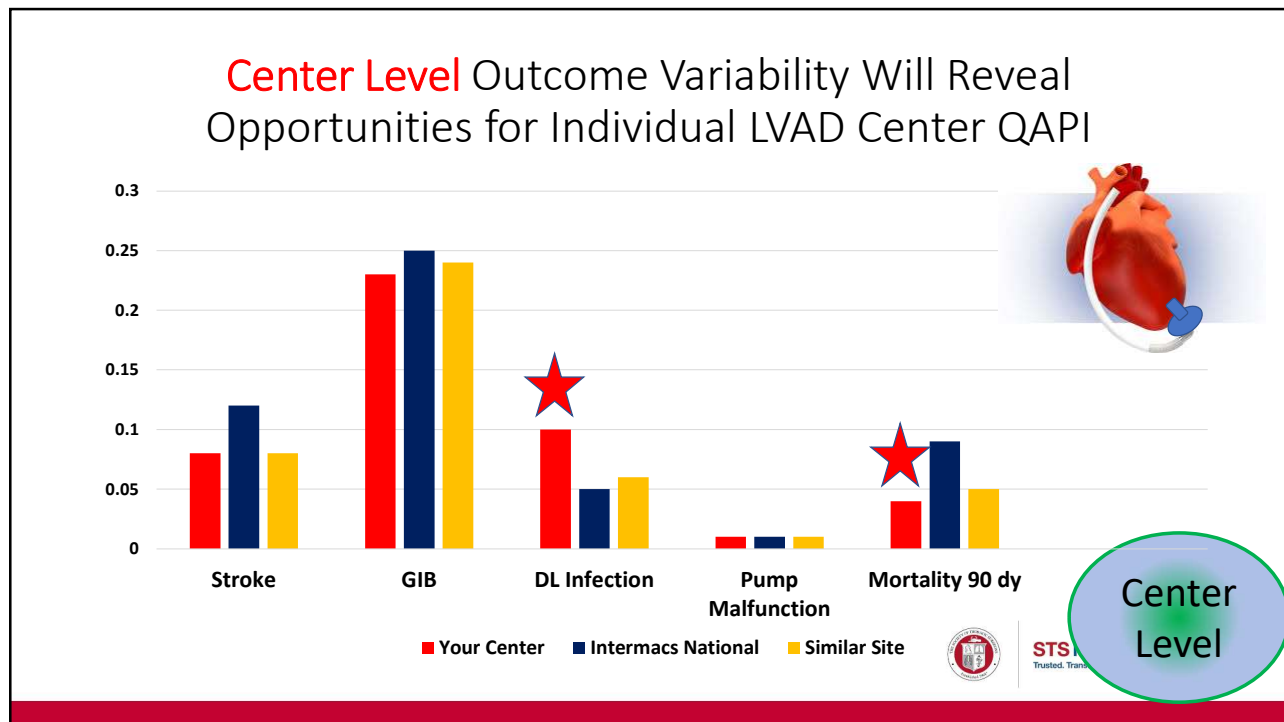
## Variability in **National Outcomes**: Opportunities for R&D at Clinician Scientist and Industry Levels

- Why do some centers have better than normal survival or AE rates?
  - Learn from peers
- The dispersion in outcomes around average may
  - Inform the MCS field about areas in need of further **clinical trial data**
  - Support need for **clearer guidelines** or best practices that standardize excellence in patient care



National  
Level



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## Short and Long-Term Metrics for Intermacs MCS patients

- Provide clear benchmarks for survival and key AEs for a program patient/center phenotype
  - Center volume
  - DT only
- Determine correlation between high performing centers and other AEs
- Provide confidential center report card

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## Summary.....

- Patient morbidity and mortality after durable LVAD implant are highly variable
  - averages provide only a limited snapshot of InterMACS sample outcomes.
  - Outcomes are greatly influenced by time from implant
  - What predicts short term mortality may not impact 2-5 Y mortality in operative survivors.
    - **Quality Assessment/Performance improvement must look at short- and long-term event rates**
- Information gleaned from dissecting the variability in outcome after LVAD can be:
  - A foundation for establishing adjusted national performance benchmarks
  - A mechanism for program-specific MCS quality assessment and improvement (QAPI)



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