Society of Thoracic Surgeons

Intermacs/Pedimacs Quality Assurance Report Overview Quarterly Webinars

March 19, 2020

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Agenda

- Introduction
- Brief Review of Intermacs QA Reports and Resources
- 2020 Quality Assurance Report Edits
- Q&A

STS Intermacs Reporting Team

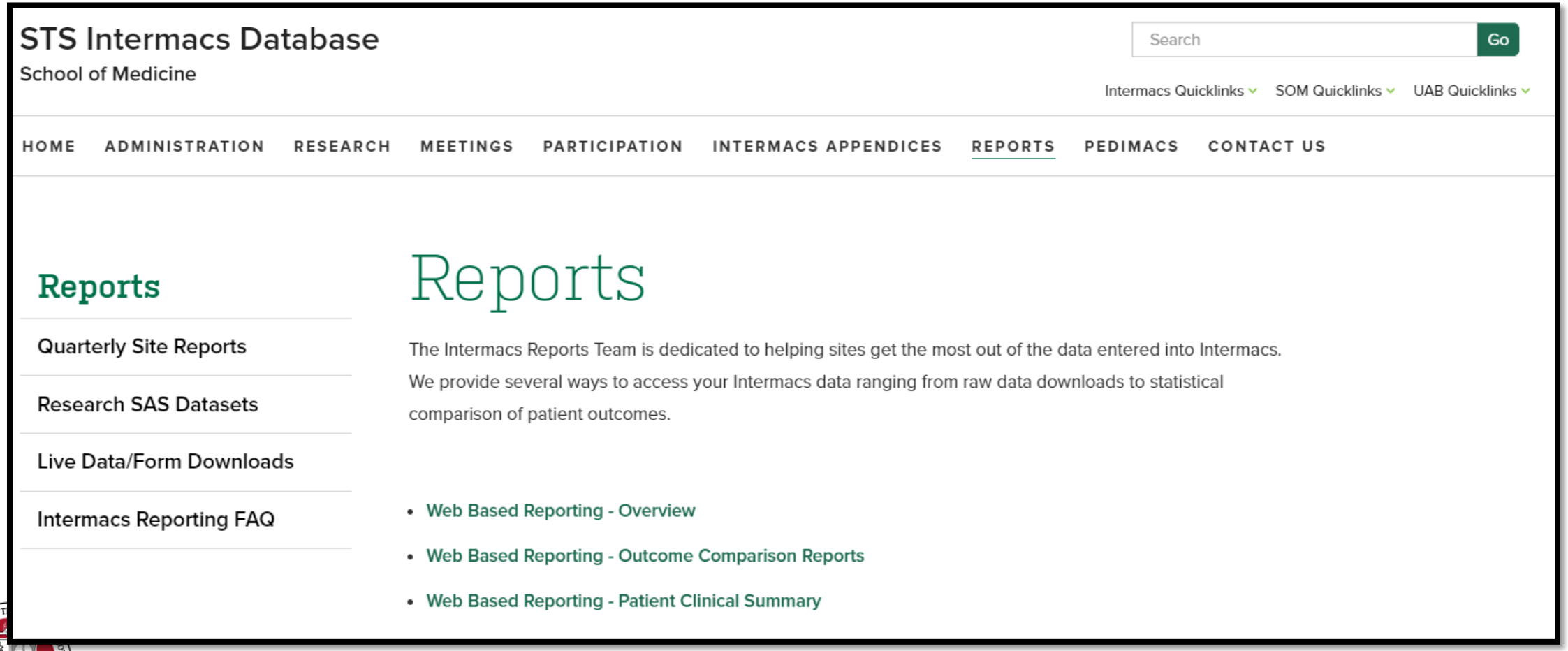
- **Nick Timkovich, MSHI**
  Director of Database Development, Management and Reporting
- **Maceo Cleggett**
  Analyst – Report Generation / Distribution, Site Questions
- **Ryan Cantor, PhD**
  Researcher / Statistician / Statistical Programming
- **Janella Miller, RN**
  Clinical Informatics / Internal Auditing
- **Devin Koehl**
  Data Download / Testing Support
- **Kathryn Hollifield, BSN, RN**
  STS National Database Manager - Intermacs

Intermacs Data / Reports

- Live Data Download
- Data Quality Report
- **Quality Assurance Report**
- Site Research Datasets (SAS)
- Customized Cohort Report (development)
- Outcome Analytics (development)
- Patient Management

INTERMACS Reports Website!

http://www.intermacs.org/reports



Report Distribution Schedule

Calendar Quarter	Coverage Stop Date	Distribution Date
Q1	March 31st	June 30th
Q2	June 30th	September 30th
Q3	September 30th	December 31st
Q4	December 31st	March 31st

Quality Assurance Report

- Contains information from your site compared to the overall Intermacs experience
- Primary prospective patients are analyzed for accurate comparison
- Facilitates the refinement of patient selection to maximize outcomes with current and new device options

Patient Inclusion/Exclusion in Main QA Report

I.F. Report Coverage - Patient Selection

The Quality Assurance Report contains information from your site compared to the overall STS Intermacs experience. To facilitate this comparison only primary prospective patients are analyzed.

Exclusion reasons from the QA report include:
a) Retrospective patients (implanted prior to site activation)
b) Patients whose first implant in STS INTERMACS is not their primary implant
c) Patients only receiving an RVAD
d) Pediatric patients entered into STS Intermacs prior to the launch of STS PediMACS
e) Patient with missing Implant Dates
f) If patients have had a previous cardiac operation (LVAD, RVAD, TAH)
g) If patient has had a Clinical Event and Intervention this hospitalization (Pre-implant) (LVAD, RVAD, TAH)
h) If patients have had a previous cardiac operation (LVAD, RVAD, TAH)
i) If patient has Interventions within 48 hours of implant (LVAD, RVAD, TAH)

Are included in report for patients with a history of a prior VAD report

Transfer patients and their subsequent experience are analyzed in the report for the site that implanted the primary implant.

The accompanying Data Quality Report lists all patients enrolled in STS Intermacs at your site.

INTERMACS Quarterly Report Packet

1. Data Quality Report

2. Quality Assurance Report - Cumulative
3. Quality Assurance Report - Cumulative - Patients with Prior VAD

4. Quality Assurance Report - Recent Year
5. Quality Assurance Report - Recent Year - Patients with Prior VAD

Overview of QA Exhibits

- Pre-Implant Patient Details
- Adverse Event Rates
- Functional Capacity and Quality of Life
- Post Implant Survival
  - Kaplan-Meier Survival Analysis
  - Competing Outcomes
- Follow-up Conditions
- Site Follow-up Compliance

HOSP-X Report

- Generated for report demonstrations and discussions
- 100 random selected patients
- Compared STS-INTERMACS cohort
- No PHI or site specific data
- https://www.uab.edu/medicine/intermacs/reports/quarterly-site-reports

2020 Quality Assurance Report Edits

2020 – Quality Assurance Report Updates
Most Recent Year Report Limited to a Rolling 4 Quarters

STS Quality Assurance Quarterly Report (2019 Q4) - Recent Year 10
COVERAGE: January 1, 2019 - December 31, 2019
SITE: Hospital X - (Random 100 Patients)

II.A. Pre-Implant Summaries - Demographics

Exhibit 2: Age Group

The following tables summarize age groups at your site and STS Intermacs over time.

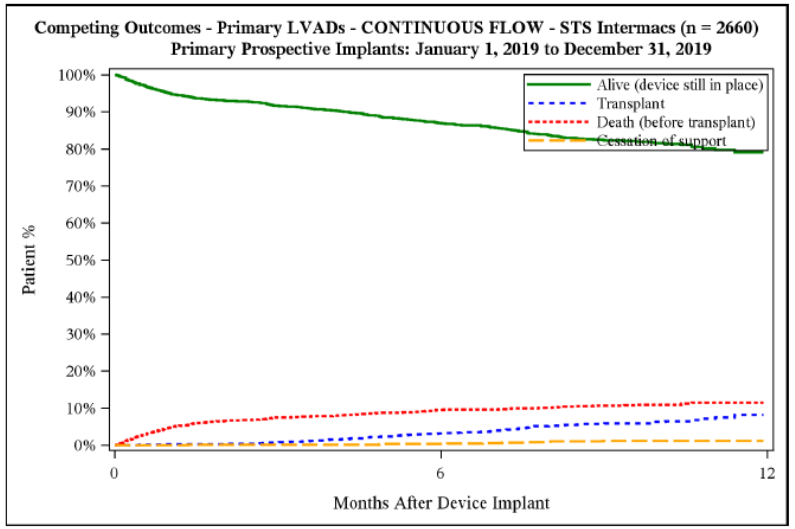
AGE GROUP (yr)	HOSPX-9999									
	2019 Q1		2019 Q2		2019 Q3		2019 Q4		TOTAL	
	n	%	n	%	n	%	n	%	n	%
19-39	5	19.2 %	5	22.7 %	1	3.4 %	3	13.0 %	14	14.0 %
40-59	14	53.8 %	8	36.3 %	11	37.9 %	5	21.7 %	38	38.0 %
60-79	7	26.9 %	9	40.9 %	16	55.1 %	15	65.2 %	47	47.0 %
80+	.	.	.	.	1	3.4 %	.	.	1	1.0 %
TOTAL	26	100.0 %	22	100.0 %	29	100.0 %	23	100.0 %	100	100.0 %

AGE GROUP (yr)	STS Intermacs									
	2019 Q1		2019 Q2		2019 Q3		2019 Q4		TOTAL	
	n	%	n	%	n	%	n	%	n	%
19-39	111	13.9 %	86	11.4 %	80	11.9 %	62	10.5 %	339	12.0 %
40-59	319	40.0 %	310	41.4 %	238	35.4 %	233	39.6 %	1100	39.2 %
60-79	362	45.4 %	347	46.3 %	350	52.0 %	290	49.4 %	1349	48.1 %
80+	5	0.6 %	5	0.6 %	4	0.5 %	2	0.3 %	16	0.5 %
TOTAL	797	100.0 %	748	100.0 %	672	100.0 %	587	100.0 %	2804	100.0 %

2020 – Quality Assurance Report Updates
Competing Outcomes - plotting and table

STS Quality Assurance Quarterly Report (2019 Q4) - Recent Year 118
COVERAGE: January 1, 2019 - December 31, 2019
SITE: Hospital X - (Random 100 Patients)

Exhibit 45a. Competing Outcomes - Primary LVADs - CONTINUOUS FLOW - STS Intermacs



Outcome	Months After Device Implant		
	0	6	9
Alive (device still in place)	100%	87.0%	82.4%
Transplant	0.0%	3.2%	5.8%
Death (before transplant)	0.0%	9.5%	10.7%
Cessation of support	0.0%	0.4%	1.2%
Total	100%	100%	100%

2020 – Quality Assurance Report Updates
Remove Total Rate Count Table

STS Quality Assurance Quarterly Report (2019 Q4) - Recent Year 68
COVERAGE: January 1, 2019 - December 31, 2019
SITE: Hospital X - (Random 100 Patients)

II.C. Post Implant Summary - Adverse Event Rates

Exhibit 23b. Adverse Event Counts

The following table includes overall counts and percentages for each type of adverse event reported at your site and STS Intermacs overall. These totals are based on adverse events reported for primary prospective patients.

Adverse Events	HOSPX-9999		STS Intermacs	
	Episodes	%	Episodes	%
Arterial Non-CNS Thromboembolism	.	.	11	0.1 %
Bleeding	26	14.8 %	680	10.9 %
Cardiac Arrhythmia	19	10.8 %	579	9.3 %
Device Malfunction and/or Pump Thrombosis	2	1.1 %	76	1.2 %
Hepatic Dysfunction	3	1.7 %	49	0.7 %
Infection	19	10.8 %	818	13.1 %
Myocardial Infarction	.	.	9	0.1 %
Neurological Dysfunction	5	2.8 %	285	4.5 %
Other Serious Adverse Event	26	14.8 %	756	12.1 %
Pericardial Drainage	2	1.1 %	59	0.9 %
Psychiatric Episode	3	1.7 %	93	1.4 %
Rehospitalization	48	27.4 %	2107	33.9 %
Renal Dysfunction	7	4.0 %	258	4.1 %
Respiratory Failure	11	6.2 %	369	5.9 %
Venous Thromboembolism	2	1.1 %	37	0.5 %
Wound Dehiscence	2	1.1 %	19	0.3 %
Total Events	175	100.0 %	6205	100.0 %

2020 – Quality Assurance Report Updates Remove Total Rate Count Table

STS Quality Assurance Quarterly Report (2019 Q4) - Recent Year 73
COVERAGE: January 1, 2019 - December 31, 2019
SITE: Hospital X - (Random 100 Patients)

II.C. Post Implant Summary - Adverse Event Rates

Exhibit 23e. Neurological Dysfunction by Category

The following table compares neurological dysfunction rates according to category at your site and STS Intermacs.

	HOSPX-9999				STS Intermacs			
	Early (During the First Three Months)		Late (After the First Three Months)		Early (During the First Three Months)		Late (After the First Three Months)	
	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)
CVA	2	0.82	1	0.35	126	1.77	47	0.53
Confusion	.	.	.	.	20	0.28	7	0.08
Encephalopathy	2	0.82	.	.	33	0.46	5	0.06
Seizure	.	.	.	.	17	0.24	3	0.03
TIA	.	.	.	.	21	0.29	6	0.07

2020 – Quality Assurance Report Updates
Calculating Overall GI Bleeding Rate

STS Quality Assurance Quarterly Report (2019 Q4) - Recent Year 71
COVERAGE: January 1, 2019 - December 31, 2019
SITE: Hospital X - (Random 100 Patients)

II.C. Post Implant Summary - Adverse Event Rates

Exhibit 23e. Bleeding Rates by Source

The following table compares bleeding rates according to source at your site and STS Intermacs. Every bleed source reported is counted in the table. NOTE: These rates are reported for patients receivng implant starting in March 2009

	HOSPX-9999				STS Intermacs			
	Early (During the First Three Months)		Late (After the First Three Months)		Early (During the First Three Months)		Late (After the First Three Months)	
	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)
Device anastamosis	.	.	.	.	2	0.03	1	0.01
ENT / Dental	3	1.22	.	.	42	0.59	10	0.11
GI OVERALL: upper, lower, unknown	12	4.90	3	1.05	250	3.51	114	1.29
GI: Lower gastrointestinal (colon, rectum, and anus)	3	1.22	.	.	63	0.88	20	0.23
GI: Upper gastrointestinal (esophagus, stomach, duod	7	2.86	2	0.70	122	1.71	58	0.66
GI: unknown, but guaiac positive stools	3	1.22	1	0.35	75	1.05	42	0.47
Intra-abdominal	2	0.82	.	.	11	0.15	.	.
Mediastinal: Unspecified	1	0.41	.	.	23	0.32	.	.
Mediastinal: aortic-venous cannulation site	.	.	.	.	1	0.01	.	.
Mediastinal: chest wall	2	0.82	.	.	28	0.39	2	0.02
Mediastinal: coagulopathy with no surgical site	1	0.41	.	.	9	0.13	.	.
Mediastinal: inflow conduit	.	.	.	.	2	0.03	.	.
Mediastinal: other surgical site	1	0.41	.	.	11	0.15	.	.
Mediastinal: outflow conduit	1	0.41	.	.	4	0.06	.	.
Mediastinal: outflow-aorta anastomosis	.	.	.	.	2	0.03	.	.
Other	3	1.22	.	.	139	1.95	28	0.32
Pleural space	2	0.82	.	.	24	0.34	.	.
Pulmonary	1	0.41	.	.	10	0.14	3	0.03
Retroperitoneal	.	.	.	.	5	0.07	2	0.02
Urinary tract	.	.	.	.	8	0.11	2	0.02

2020 Quality Assurance Reports Edits Under Construction

- Kaplan-Meier Exhibits - Update to latest plotting methods
- Add patient % to all rates exhibits

2020 Report Structural Edits – Coming the Fall

- We are currently identifying structural edits that will make the reports more useful to sites in improving care at their center and for tracking patient outcomes efficiently
- Streamline Reports
  - Make the report more device centered – if your center implants a device, the outcome will be included in at least some portion of 1 main report
    - Initial exhibit Tallying all device reported from your center
  - Combine primary patient report with prior VAD report
  - Highlight trends – continue to create a recent year version, but now on rolling 4 quarters
  - Identify exhibits that can be removed

Preliminary Draft of
Exhibit 1. Devices at your Site and Intermacs

HOSP-X		STS-Intermacs	
Device Sequence	**Devices**	**Device Sequence**	**Devices**
1 - No Prior VAD	100	1 - No Prior VAD	27217
1 - Prior VAD	7	1 - Prior VAD	2031
2	10	2	3637
3+	2	3+	689
TOTAL	119	TOTAL	33574

Basis for Cumulative Report
- inclusion based on this first device
- patient level outcomes

Basis for Cumulative Report – Prior VAD
- inclusion based on this first device
- patient level outcomes

Goal: A Single Report that if focused on the most important and usable comparisons, but with some information on every device implanted by your center

Planned edits for Pedimacs

- Expand Report Inclusion Criteria
  - Include every prospectively enrolled patients (currently only including patients receiving durable support)
- Device Class Change Censoring
  - Implement device class change censoring so that outcomes can be reported and compared for the various device classes
- Expand Exhibits
  - Incorporate applicable exhibits developed for the Intermacs Reports

Contact Information

Technical Issues, Obtaining Your Reports, Statistical Questions

- INTERMACS-Reports@uabmc.edu
- Maceo Cleggett
- Ryan S. Cantor, PhD

- **Report Exhibit Requests other Questions**
  - intermacsfaq@sts.org
  - Kathryn Hollifield, BSN RN

Questions & Answers

Please submit your questions using the Q&A function on the webinar

Pre-Implant Characteristics

Exhibit 7. Device Strategy

The following tables summarize pre-implant device strategy at your site and STS Intermacs over time.

PRE-IMPLANT DEVICE STRATEGY	HOSPX-9999							
	< 2012		2012 - 2015		2016 - 2019 (Jan-Jun)		TOTAL	
	n	%	n	%	n	%	n	%
BTT - Listed	6	31.5 %	5	15.6 %	10	20.4 %	21	21.0 %
BTT - Likely	3	15.7 %	7	21.8 %	5	10.2 %	15	15.0 %
BTT - Moderate	4	21.0 %	4	12.5 %	6	12.2 %	14	14.0 %
BTT - Unlikely	.	.	1	3.1 %	2	4.0 %	3	3.0 %
Destination Therapy	5	26.3 %	15	46.8 %	25	51.0 %	45	45.0 %
Bridge to Recovery	.	.	.	.	1	2.0 %	1	1.0 %
Rescue Therapy	1	5.2 %	.	.	.	.	1	1.0 %
Other	.	.	.	.	.	.	.	.
TOTAL	19	100.0 %	32	100.0 %	49	100.0 %	100	100.0 %

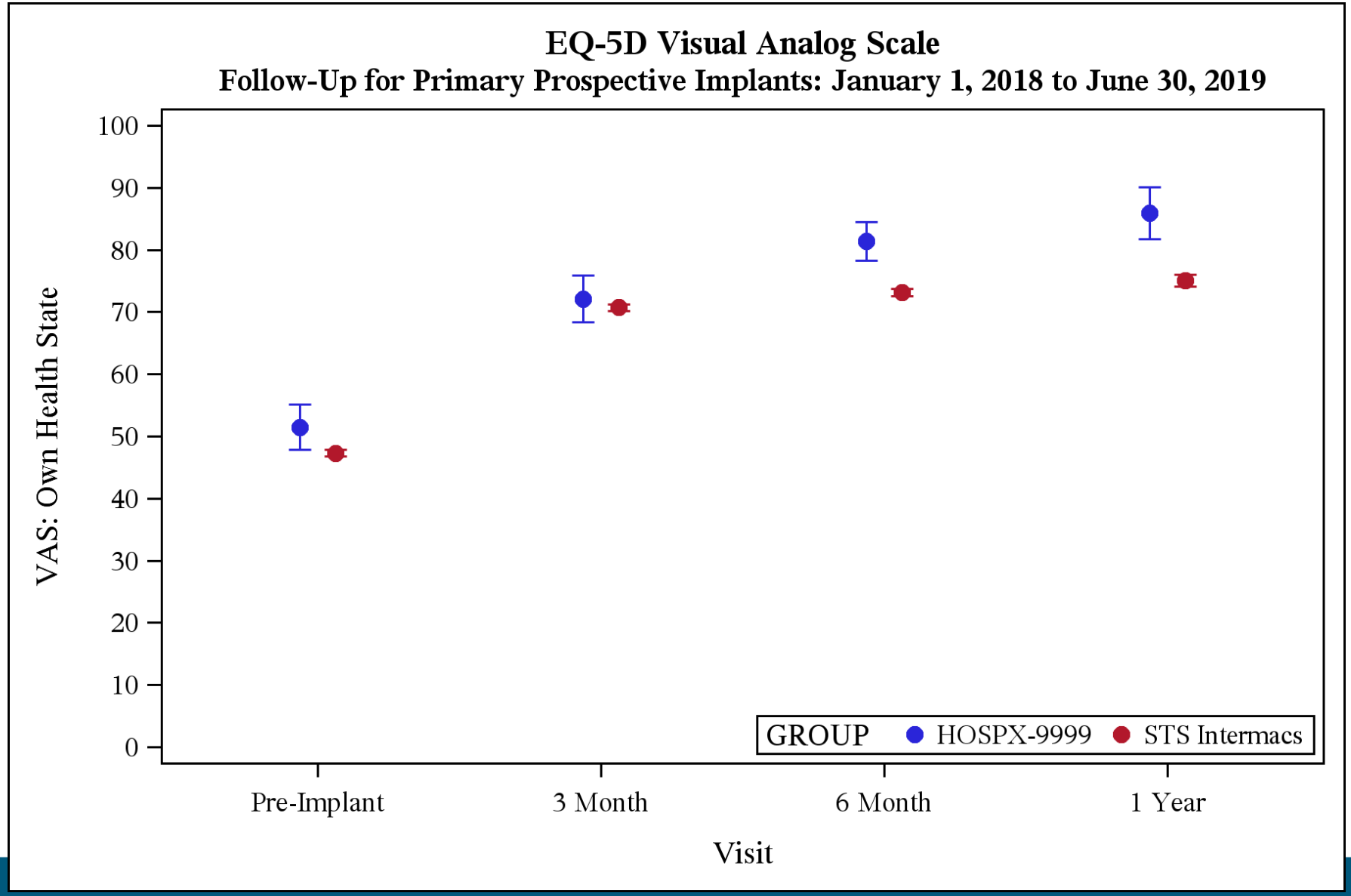
PRE-IMPLANT DEVICE STRATEGY	STS Intermacs							
	< 2012		2012 - 2015		2016 - 2019 (Jan-Jun)		TOTAL	
	n	%	n	%	n	%	n	%
BTT - Listed	1925	33.9 %	2751	25.8 %	1885	20.4 %	6561	25.6 %
BTT - Likely	1378	24.2 %	1841	17.2 %	1176	12.7 %	4395	17.2 %
BTT - Moderate	567	9.9 %	942	8.8 %	834	9.0 %	2343	9.1 %
BTT - Unlikely	211	3.7 %	276	2.5 %	235	2.5 %	722	2.8 %
Destination Therapy	1474	25.9 %	4759	44.6 %	4979	54.0 %	11212	43.9 %
Bridge to Recovery	75	1.3 %	36	0.3 %	80	0.8 %	191	0.7 %
Rescue Therapy	40	0.7 %	46	0.4 %	15	0.1 %	101	0.3 %
Other	2	0.0 %	.	.	11	0.1 %	13	0.0 %
TOTAL	5672	100.0 %	10651	100.0 %	9215	100.0 %	25538	100.0 %

Adverse Event Rates

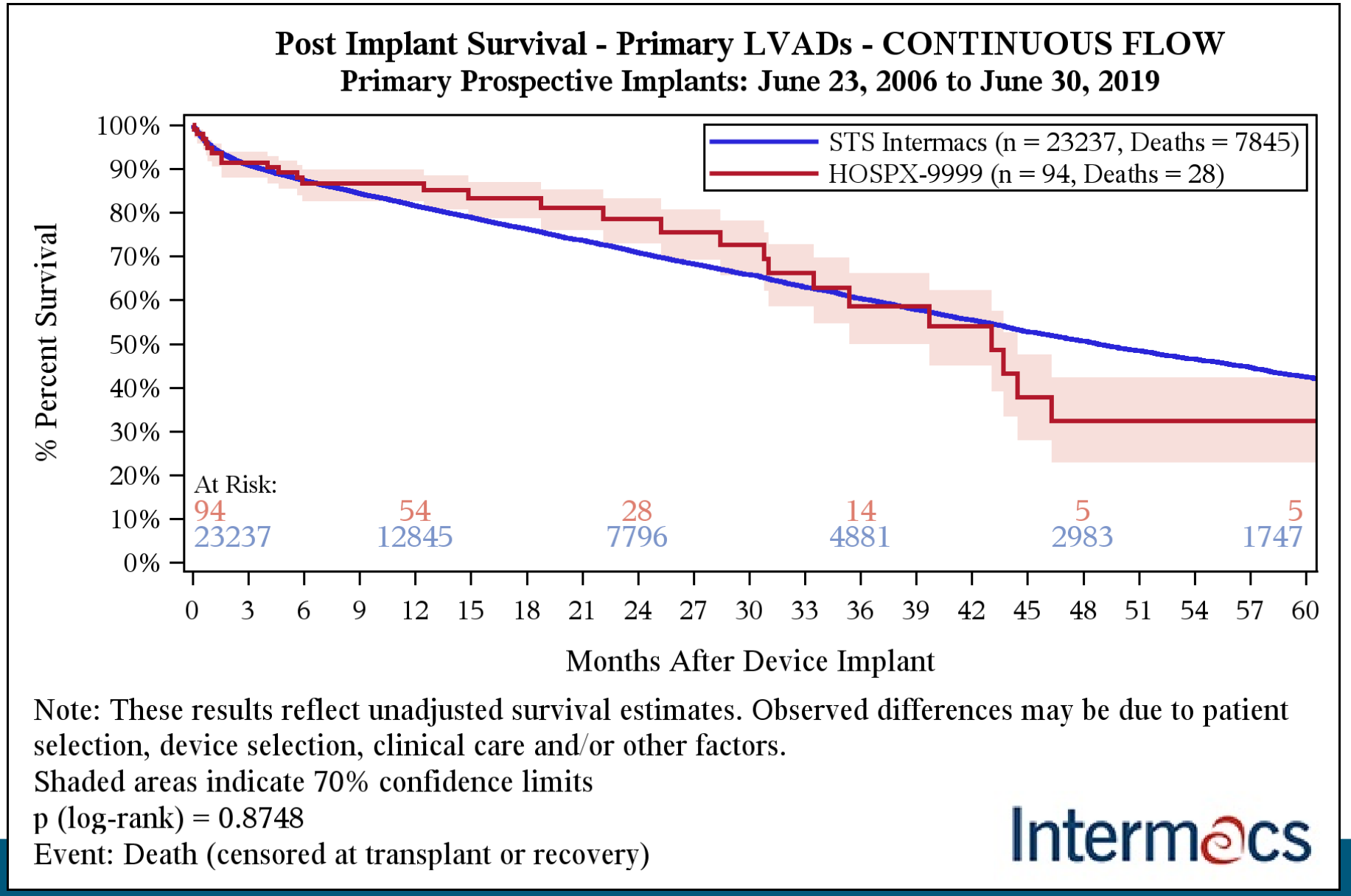
Exhibit 23c. Adverse Event Rates

	HOSPX-9999				STS Intermacs			
	Early (During the First Three Months)		Late (After the First Three Months)		Early (During the First Three Months)		Late (After the First Three Months)	
	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	.	.	1	0.22	16	0.15	7	0.04
Bleeding	20	7.91	14	3.03	994	9.47	496	2.62
Cardiac Arrhythmia	9	3.56	2	0.43	720	6.86	173	0.91
Device Malfunction and/or Pump Thrombosis	2	0.79	3	0.65	109	1.04	132	0.70
Hepatic Dysfunction	1	0.40	1	0.22	67	0.64	18	0.10
Infection	17	6.72	21	4.55	941	8.97	731	3.87
Myocardial Infarction	.	.	.	.	8	0.08	1	0.01
Neurological Dysfunction	9	3.56	2	0.43	398	3.79	224	1.18
Other Serious Adverse Event	17	6.72	3	0.65	867	8.26	283	1.50
Pericardial Drainage	.	.	.	.	105	1.00	3	0.02
Psychiatric Episode	1	0.40	.	.	90	0.86	27	0.14
Rehospitalization	38	15.02	51	11.05	1758	16.75	2805	14.83
Renal Dysfunction	8	3.16	2	0.43	367	3.50	69	0.36
Respiratory Failure	12	4.74	1	0.22	571	5.44	71	0.38
Venous Thromboembolism	.	.	.	.	56	0.53	9	0.05
Wound Dehiscence	.	.	.	.	30	0.29	5	0.03

Quality of Life



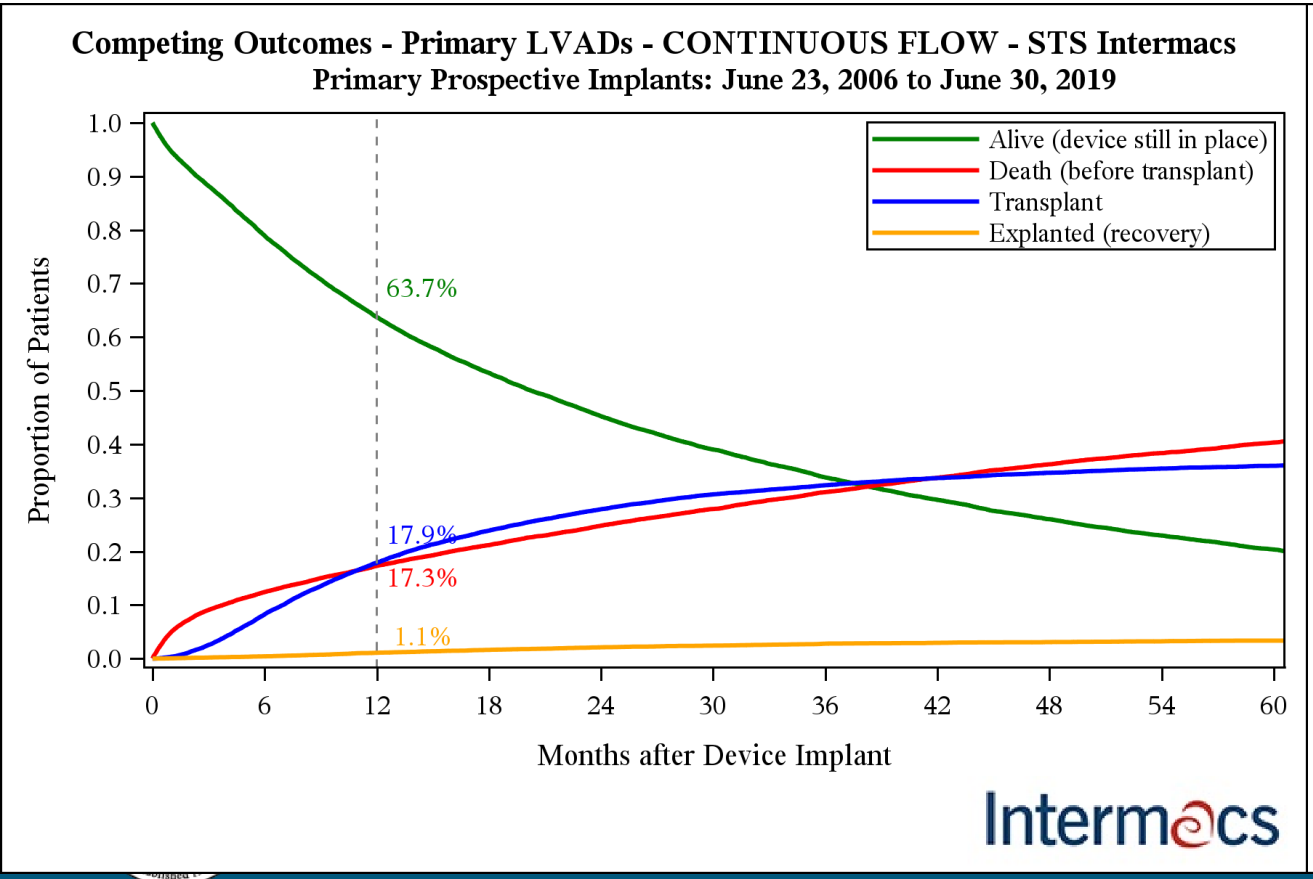
Post Implant Survival

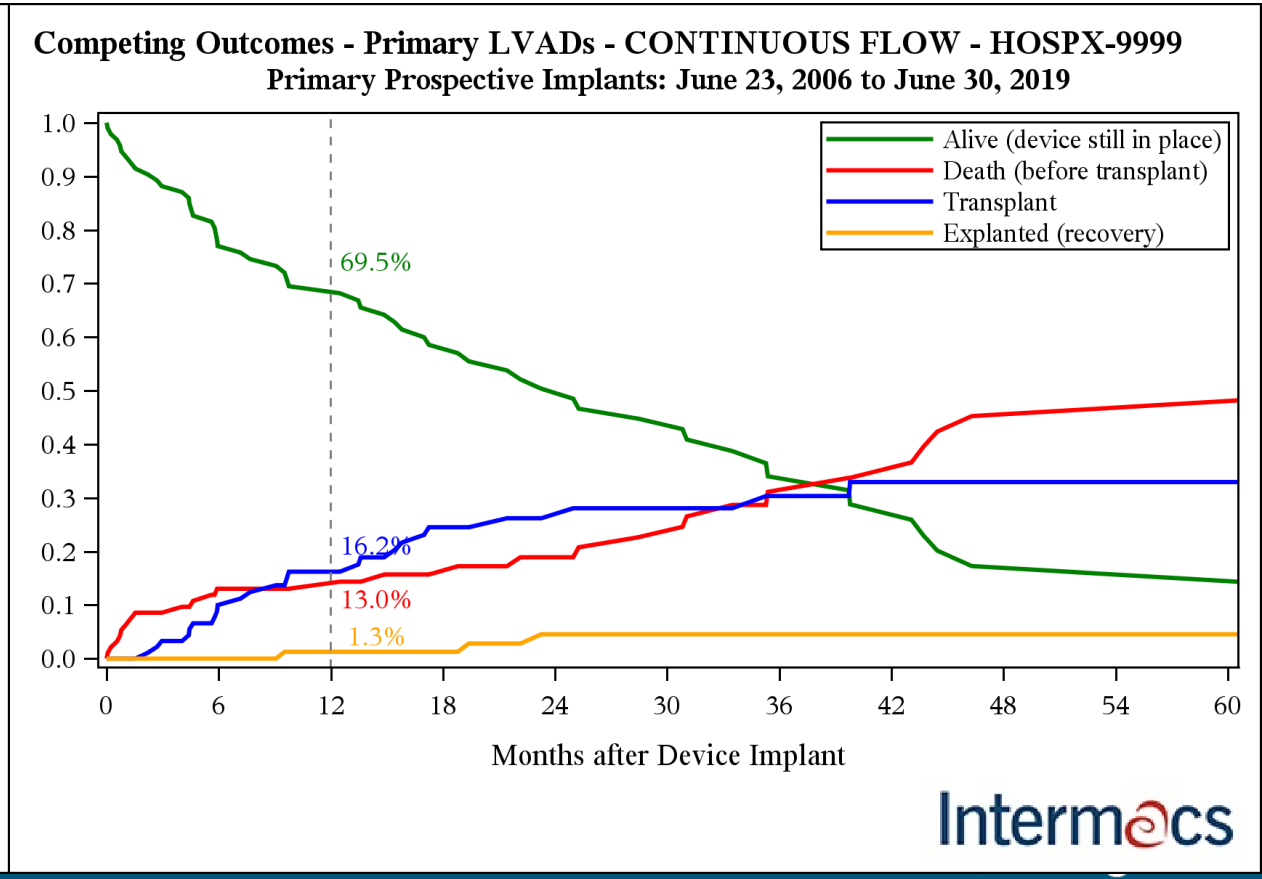


Note: These results reflect unadjusted survival estimates. Observed differences may be due to patient selection, device selection, clinical care and/or other factors.
Shaded areas indicate 70% confidence limits
p (log-rank) = 0.8748
Event: Death (censored at transplant or recovery)

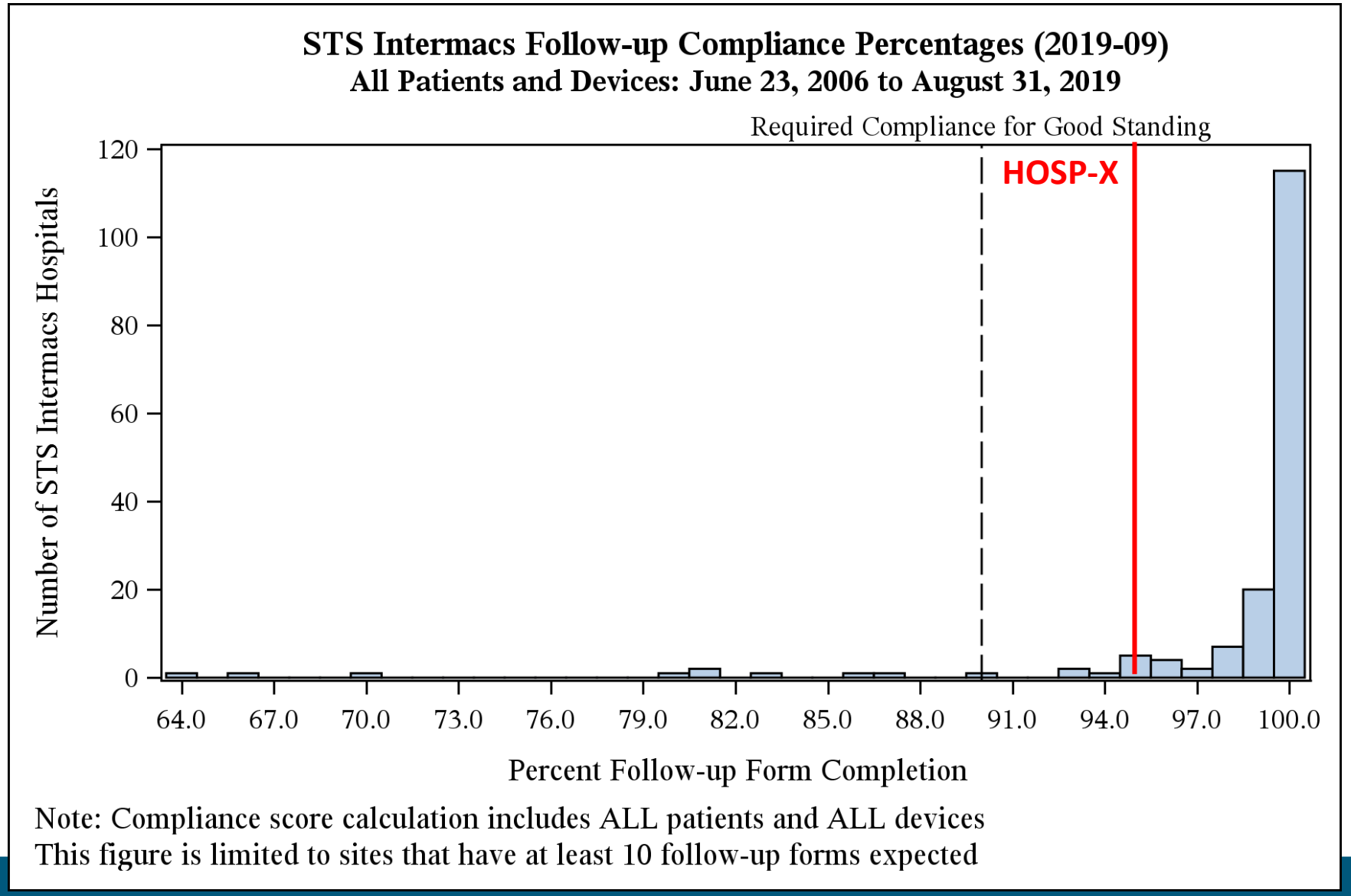
Intermacs

Competing Outcomes





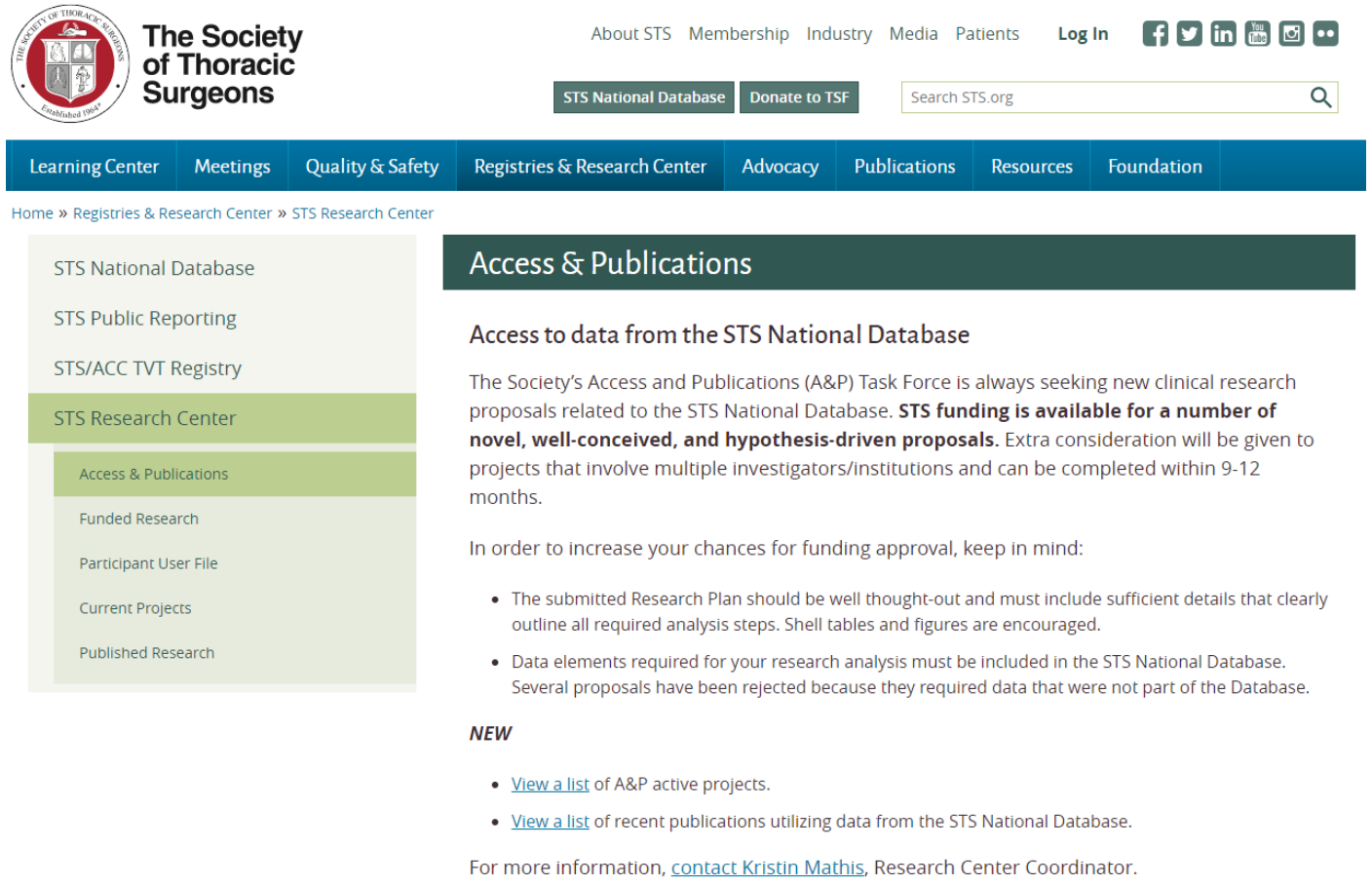
Site Compliance Score



Note: Compliance score calculation includes ALL patients and ALL devices
This figure is limited to sites that have at least 10 follow-up forms expected

Research Proposal Submissions

https://www.sts.org/registries-research-center/sts-research-center/access-publications



Submitted on Fri, 03/06/2020 - 09:50

Submitted by: Anonymous

Submitted values are:

Intermacs or Pedimacs Site Code:
TXCT

Name:
Kristi Campbell

Email:
kcampbell2@ascension.org

Role:
Study Coordinator, Site Administrator

Please specify the table or exhibit that you are referring to you in your question:
Outcomes

Question for the Quality Assurance report:
What is the metric definition for 30 day mortality? Meaning does the metric go from day of implant to 30 days or is it day of implant to 30 days post discharge?

1 month survival from KM? This would start at implant date to the 30 day post implant (regardless of discharge)

Suggested changes for the Intermacs/Pedimacs QA reports:
To have definitions that include inclusion criteria and exclusion criteria for each field on each Intermacs form. The question I get the majority of the time consists of 'what is the definition for that metric, what does it include and exclude' but without a manual that is a question I can not answer. Since my site not only participates in Intermacs but we participate in STS-GTS and STS-ACS. When my data and my co-worker for STS-ACS has different information, definitions, etc. it makes it harder for the physicians to trust what is being entered into the registry as well as the reports that come from them.

I think most of the INTERMACS AE definitions and report inclusion exclusion criteria are define. But maybe not in the most useful place. What exact is information needed? Would stand alone document of “metric definitions” be sufficient?

Submitted on Thu, 03/19/2020 - 08:24

Submitted by: Anonymous

Submitted values are:

Intermacs or Pedimacs Site Code:
MISHX

Name:
Kelli Britten

Email:
kelli.britten@spectrumhealth.org

Role:
Quality Improvement Specialist

Please specify the table or exhibit that you are referring to you in your question:
Adverse Events

Question for the Quality Assurance report:
In the FAQ's, it says that AE's are excluded for transfer patients. However, I was also told that AE's are attributed to the implaning center. I know our center continues to enter AE's for patients who have transfered to us. Which is it?

Patient level outcomes all linked back to the patient's first device (and the hospital that implanted it)

From the FAQ:

How are the transfer patients handled in the QA report?
Transfer patients and their subsequent experience are analyzed in the report for the site that implanted the primary implant.

~~**How are the Adverse Events (AEs) handled on transfer patients?**~~
~~AE's are calculated from the implanting site. Once patient has transferred, the AE rates are excluded.~~

This statement is incorrect. We will update accordingly.

Will need further discussion on a better way to handle transfer patients.

Suggested changes for the Intermacs/Pedimacs QA reports:

-Have an area of the report that combines both Quality Assurance Reports survival data to give overall program survival
-Make the "prior cardiac surgery" and "prior LVAD, RVAD, TAH" questions more specific to whether device was durable or non-durable VAD and use this info to look at outcomes (survival) & AE's respective to that.

Yes, we plan to have a few exhibit for overall program

And show outcomes of the patients with a history of support

Submitted on Thu, 03/05/2020 - 14:01

Submitted by: Anonymous

Submitted values are:

Intermacs or Pedimacs Site Code:
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Name:
Kristi Campbell

Email:
kcampbell2@ascension.org

Role:
Study Coordinator, Site Administrator

Please specify the table or exhibit that you are referring to you in your question:
Adverse Events

Question for the Quality Assurance report:
When a MCS patient is implanted at one center then their daily care is transferred to another center, does the adverse events reflect for the implanting center? Or the center that they are currently being followed at?

Currently all data for a patient is linked back to the implanting center

Suggested changes for the Intermacs/Pedimacs QA reports:
For my center, we follow adverse events such as Driveline infection, GI Bleed and Stroke. We would like to see the breakdown of the Infection, Bleeding, and Neurological Dysfunction sections on the Adverse Event Counts page. We would like to see the comparison between Intermacs and our site in showing the number of events with the corresponding percentage. Even the Adverse Event Rates section does not break down the types of Neurological Dysfunction.

Adding Neuro breakdown

Adding patient % to rates

Submitted on Thu, 03/05/2020 - 14:06

Submitted by: Anonymous

Submitted values are:

Intermacs or Pedimacs Site Code:
TXCT

Name:
Kristi Campbell

Email:
kcampbell2@ascension.org

Role:
Study Coordinator, Site Administrator

Please specify the table or exhibit that you are referring to you in your question:
Adverse Events

Question for the Quality Assurance report:
What is the reasoning behind excluding patients from the Quality Assurance reports? Especially for the criteria under number 2, 6, 7, and 8. And does these exclusions show in each page of the report or just certain sections?

To have a valid comparison group patients should have the same starting point. When they initiated VAD support. But we are planning to change some of the reporting to include all patients from each program.