STS/Intermacs Top 10 List: Missing Data Frequencies

How to manage missing data in a registry

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  • Nothing to disclose
Objectives

• Process of Managing Missing Data within a registry database system
  • Internal validity checks
  • External validity checks

• Impact of missing data on research/report results
Process for managing an ongoing data collection registry

*Integrity Checks and Feedback Loop of Data*

- **Site Enters Data**
- **WBDE**
- **DCCC Raw Data (Data Manager processes)**
- **DCCC Research Datasets (Data Manager generates)**
- **DCCC Integrity Checks (Data Manager generates)**

There may be times when the results from the integrity checks will require communication back to the site:

- Nurse/Auditor: Reviews all inconsistencies – *pt specific*
- DCCC: Reviews *database related issues* and any administrative inconsistencies
- Quality Assurance Site Reports, Data Quality Site Reports, Research
Examples of WBDE

**Internal Validity Checks**

i. Range Checks (e.g. Labs)
ii. Chronology Checks (are dates in appropriate order)
iii. Each Form submission requires ALL variables to be answered
**Internal Validity Checks**

**Range Checks**

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood urea nitrogen</td>
<td>20 mg/dL, 7 mmol/L</td>
</tr>
<tr>
<td>Creatinine</td>
<td>20000 mg/dL</td>
</tr>
<tr>
<td>SGPT/ALT (alanine</td>
<td>31 u/L</td>
</tr>
<tr>
<td>SGOT/AST (aspartate</td>
<td>27 u/L</td>
</tr>
<tr>
<td>LDH</td>
<td>1000 units/L, U/L, ukat/L</td>
</tr>
</tbody>
</table>

**Notes**

- RANGE Checks (WBDE internal)
- Lab value out of range
- Internal WBDE range check
Internal Validity Checks

Chronology Checks
Date out of range

DOB > Implant date
Internal Validity Checks

Each Form submission requires ALL variables to be answered ‘Complete’ status
Internal Validity Checks

Additional views in WBDE
checking completion of form submission

Subsections of Follow-up form

Pending and in-progress forms on Site Dashboard
Objectives

• Process of Managing Missing Data within a registry database system
  • Internal validity checks
    • External validity checks: Examples

• Impact of missing data on research/report results
Process for managing an ongoing data collection registry

**Integrity Checks and Feedback Loop of Data**

Site Enters Data → WBDE → DCCC Raw Data (Data Manager processes) → DCCC Research Datasets (Data Manager generates) → DCCC Integrity Checks (Data Manager generates)

There may be times when the results from the integrity checks will require communication back to the site:

- Nurse/Auditor: Reviews all inconsistencies – *pt specific*
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- Data Quality Reports, Quality Assurance Reports, Research

External Integrity Checks > 200
External Validity Checks
Missing vs Non-Missing values
External Validity Checks
Missing vs Non-Missing values
Examples from the External Checks (200+) run monthly

- Missing Device Brand (*informs pump flow type; axial, centrifugal etc*)
- Missing Device Strategy (*informs intent; destination vs BTT*)
- Missing Patient Profile Level (*informs how sick is the pt*)
- Primary COD is missing (*if patient is deceased*)
- Explant reason Transplant but missing Transplant date (*endpoint*)
External Validity Checks
Missing STS/Intermacs ENDPOINTS?

- When does STS/IM stop or censor a patient?

**STS/IM Endpoints**
- Death
- Transplant
- Explant for recovery

- And why is this important?
External Validity Checks

Missing deaths / transplants / recoveries (endpoints)
Site Data Quality Report example

Exhibit 6: Patients on a device greater than 6 years
The following table lists patients that have been followed at your hospital for more than 6 years with no terminal or censoring events (death, transplant, or device removal for recovery)

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Implant Date</th>
<th>Years Alive</th>
<th>Confirmed by Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td>01/01/2013</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>098765</td>
<td>06/01/2010</td>
<td>9.0</td>
<td></td>
</tr>
</tbody>
</table>

How does this impact results?
External Validity Checks

Missing deaths / transplants / recoveries (endpoints)

Comparing a Site to Overall STS/IM (EXAMPLE)

How missing data impacts research/report results?

Post Implant Survival: PRIMARY OVERALL
Primary Prospective Implants: June 23, 2006 to June 30, 2019

<table>
<thead>
<tr>
<th>Months After Device Implant</th>
<th>At Risk: 100</th>
<th>25538</th>
<th>13403</th>
<th>56</th>
<th>29</th>
<th>15</th>
<th>6</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>STS Intermacs (n = 25538, Deaths = 8852)</td>
<td>100</td>
<td>25538</td>
<td>13403</td>
<td>56</td>
<td>29</td>
<td>15</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>HOSPX-9999 (n = 100, Deaths = 31)</td>
<td>100</td>
<td>25538</td>
<td>13403</td>
<td>56</td>
<td>29</td>
<td>15</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

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) = 0.7087

Event: Death (censored at transplant or recovery)
External Validity Checks

Missing deaths / transplants / recoveries (endpoints)

Comparing a Site to Overall STS/IM (EXAMPLE)

How missing data impacts research/report results?

Post Implant Survival: PRIMARY OVERALL
Primary Prospective Implants: June 23, 2006 to June 30, 2019

Hospital Y
STS Internacs (n = 25538, Deaths = 8852)
HOSPX-9999 (n = 100, Deaths = 31)

Hospital X

Overall STS/IM

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) = 0.01
Event: Death (censored at transplant or recovery)
External Validity Checks

Missing vs Non-Missing
Follow-up and Adverse Events
External Validity Checks

Follow-up Form Completion Rates
(from STS/IM QA Report – Sample)

STS Intermacs Follow-up Compliance Percentages (2019-09)
All Patients and Devices: June 23, 2006 to August 31, 2019

Required Compliance for Good Standing

Number of STS Intermacs Hospitals

Percent Follow-up Form Completion
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
Follow-up Form Completion Rates: From 2007 to present

STS/IM Nurse Monitors came on-board in 2007
And implemented a plan to increase
follow-up compliance rates
### Missing vs Non-Missing Lab values at 3 months Follow-up

For those patients alive with device in place at 3 months – *Example of 10,000 pts*

(pt had opportunity for 3 month f/u)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Missing%</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Blood Cell Count (x10/uL)</td>
<td>9850</td>
<td>150</td>
<td>1.5%</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>9900</td>
<td>100</td>
<td>1.0%</td>
</tr>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>9900</td>
<td>100</td>
<td>1.0%</td>
</tr>
<tr>
<td>Albumin (g/dL)</td>
<td>8640</td>
<td>1360</td>
<td>13.6%</td>
</tr>
<tr>
<td>Total Bilirubin (mg/dL)</td>
<td>8900</td>
<td>1100</td>
<td>11.0%</td>
</tr>
<tr>
<td>Mean Right Atrial Pressure</td>
<td></td>
<td>&gt; 20%</td>
<td>missing</td>
</tr>
<tr>
<td>Six Minute Walk</td>
<td></td>
<td>&gt; 20%</td>
<td>missing</td>
</tr>
</tbody>
</table>
Evolution of STS/Intermacs Registry

- **June 2006**: Evolution of STS/Intermacs Registry
- **March 2007**: Hospital Transfer = patient endpoint
- **March 2009**: Hospital Transfer ≠ patient endpoint (unless transfer site is non-STS/IM)
- **June 2014**: Follow-up for Transfers
- **October 2016**: Waiver of Consent

Key Milestones:
- **June 2006**: Developed
- **March 2007**: Added Pediatric variables (e.g., PLE, Ross Class, etc.)
- **March 2009**: Bleeding Form Updated
- **May 2012**: Screening Log Updated
- **October 2016**: NIH Stroke Scale
- **February 2017**: Payer Information

Notable Updates:
- **June 2006**: ’retrospective’ patients excluded from analyses by v2.3
- **2014**: Device Strategy Issues mapped to Concerns & Contraindications
- **2016**: MRS added

**Historical Timeline**:
- **March 2006**: v1.0
- **March 2007**: v2.0
- **March 2009**: v2.2
- **May 2012**: v2.3
- **June 2014**: v3.0
- **October 2016**: v4.0
- **March 2009**: v5.0

**Legend**:
- Hospital Transfer= patient endpoint
- Hospital Transfer ≠ patient endpoint (unless transfer site is non-STS/IM)
Stroke scales (MRS/NIHSS) data capture at time of CVA
And at follow-up post CVA from June 2, 2014 (v4.0)

# Neurological Dysfunction Data Form

**Has the patient experienced a Neurological Event since time of implant?**

○ Yes  ○ No  ○ Unknown

*Note: This applies only to patients who have had a CVA, TIA or Anoxic Brain Injury.*

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke Scale.

### Modified Rankin Scale:
Please click here for further instruction on administering the Modified Rankin Scale in Appendix I.

- 0 – No symptoms at all
- 1 - No Significant disability, despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead

ST= ○ Not Documented ○ Not Done

### NIH Stroke Scale:
Please click here for further instruction on administering the NIHSS in Appendix I.

- 0: No Stroke
- 1-4: Minor Stroke
- 5-15: Moderate Stroke
- 16-20: Moderate to Severe Stroke
- 21-42: Severe Stroke

ST= ○ Not Documented ○ Not Done
KCCQ-12 - Scored
Follow-Up for Primary Prospective Implants: June 23, 2006 to June 30, 2019

Visit
Pre-Implant 3 Month 6 Month 1 Year 2 Year 3 Year 4 Year 5 Year
KCCQ-12 Score

GROUP
HOSPX-9999
STS Intermacs
6MW Pre-implant and Post implant*

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Completed 6MW</th>
<th>Too Sick to Complete 6MW</th>
<th>Missing 6MW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implant</td>
<td>20%</td>
<td>55%</td>
<td>25%</td>
</tr>
<tr>
<td>Follow-up</td>
<td>50%</td>
<td>30%</td>
<td>20%</td>
</tr>
</tbody>
</table>

*% reflect approximate overall rates
Possible Resolutions to Missing
There are many reasons and possible resolutions for missing data in STS/IM Registry WBDE

*Just to name a few:*

**Reasons**
- Evolution of WBDE System (versions)
- Patient too sick for test to be administered
- Data entry

**Possible Resolutions**
- External validity checking
- Mapping of elements or making agreed upon assignment of values (e.g. Pt ‘too sick’)
- Research: time windows for specific studies (MRS: 2014 forward)
- Implement processes to help with capture rate
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