E is for Evidence

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March 30, 2006

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What happens if the dog catches the car?

“Be careful what you wish for, you might get it.”

- Ancient Chinese Proverb

Regulatory and Clinical Ambitions

Hard evidence
Be Careful What You Wish For…

■ Hypothesis
  • Clinicians, device manufacturers, and regulators want clean, unbiased data for the evaluation of cost/performance, efficacy, and safety in the post-market environment, and
  • A validated, auditable registry will provide the data necessary for evidence-based decision making, assuming:
    – Ubiquitous availability
    – In the clinical pathway
    – No/low startup costs and time
    – Safe, effective, patient-centered, efficient, equitable

■ Null hypothesis
  • Such a registry and data is neither possible, necessary nor desirable, or
  • There is no framework for clinicians, regulators, or payors into which such evidence can be utilized.
PEMS™: A Case Study for AAA/TAA

- 60,000+ AAA/TAA case registry
  - Abdominal Aortic Aneurysm (AAA) is the ballooning out of the wall of the abdominal aorta. Thoracic Aortic Aneurysm (TAA) affects the thoracic aorta.
- 4 years in use
- Password protected, HIPAA-compliant secure website

Fusion of
- Clinical Requirements
- Data Requirements – Endpoint Metrics
- Imaging Requirements

Catalogues patient-specific and scan-specific data, including images, graphs, measurements and other treatment analysis tools

DICOM ArmorCar (DAC) transmission status page for confirmation or cancellation by institution

SVS endorsed anatomical metrics for aortic aneurysms
Points of View: What Are Requirements for Registries

**Regulators (FDA / CMS / AHRQ)**
- Dependable data—Part 11 compliant
- Internal validation via Imaging
- Controls—e.g. open AAA repair
- Basis for keeping physicians and patients informed
- Provide data inputs to pay-for-performance initiatives
- Provide data for evidence-based health care

“Guiding principles such as limiting burden, maximizing relevance and value to all stakeholders, keeping it simple” *

**Device Manufacturers**
- Comply with post-market surveillance
- Use data to improve product pipeline, IFU, and compliance

**Clinicians**
- Data collection for long-term analysis of device safety and function
- Access to data for publication
- Follow the “natural progression” of a disease
- A resource to help establish clinical best practices
- Easy and quick data entry

You can’t manage what you don’t measure.

Why is This Hard?

- 3 stakeholders with divergent requirements

- Manufacturers **WANT** to avoid catastrophic outcomes, **DON’T WANT** to highlight product shortcomings

- Physicians **WANT** to improve patient care, **DON’T WANT** to be judged and paid accordingly

- Regulators **WANT** accurate and timely data, **DON’T WANT** to figure out and implement new regulatory system – particularly if it is disease-state specific
Practical Registry Requirements

- Image-based for validation
  - Image transfer & processing is essential
  - Clinician use is driven by ubiquitous imaging

- Standardization
  - Metrics
  - Clinical outcomes

- Customization
  - Requirements of individual manufacturers

- Timing
  - Registry must highlight real-time problems

- Security
  - Doctors, Manufacturers, Patients must all have confidence in the system.

- Financial Viability
  - Needs to be self-sufficient

- Utility
  - Day-to-day use validates the information gathered
Value of Image-based Registry

- **Auditability**
  - Level 1: was the patient actually seen?
  - Level 2: is the clinical report in line with the radiological evidence?
  - Level 3: is the protocol for follow-up adhered to?

- **Quality of data collection**
  - Reports and analysis can be done from a common baseline
  - More consistent and meaningful results

- **Follow-on studies**
  - Made possible by capturing primary data

- **Accommodates new technology**

“Off-label use of medical devices is commonplace and demands a thoughtful assessment that acknowledges both the potential risks to the patient as well as the added benefits to medical treatments.” *

*“Ensuring the Safety of Marketed Medical Devices CDRH’s Medical Device Postmarket Safety Program” January 18, 2006
What Can PEMS Do? Preoperative Data

Diameter at Distal Renal

Mean = 24.1
Std Dev = 5.4
N = 15,855

Centerline Distal Renals to Rt Hypogastric

Mean = 179
Std Dev = 24.8
N = 15,855

Maximum Sac Diameter for patients who later underwent surgery

Mean = 54.6
Std Dev = 10.5
N = 4,256

Whose are these?
What Can PEMS Do? Postoperative Data

Change in Volume Distal Renals to Rt Hypogastric

Change in Maximum Sac Diameter

Mean = -2.0
Std Dev = 6.6
N = 4,869

Change in Distance Distal Renal to Top of Stent

Mean = 1.1
Std Dev = 6.1
N = 4,869

Whose are these?
What Can PEMS Do?

**Measurement Statistics**

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<thead>
<tr>
<th></th>
<th>Male Pre-op</th>
<th></th>
<th>Female Pre-op</th>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Std Dev</td>
<td>Range</td>
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<td>Distal renal dia (mm)</td>
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<td>5.6</td>
<td>[12.5-90.4]</td>
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<td>[15.0-133.4]</td>
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<td>Vol to rt hypo (cc)</td>
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<td>94.0</td>
<td>[17.3-1577.3]</td>
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**Verify Measurements**

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<th>Fem/Preop Mean</th>
<th>Fem/Preop Std Dev</th>
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<td>Dia 15 mm below renals (mm)</td>
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<td>17.8</td>
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<td>NA</td>
<td>26.5</td>
<td>8.6</td>
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<tr>
<td>Dia top of neck (mm)</td>
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<td>NA</td>
<td>NA</td>
<td>23.0</td>
<td>6.5</td>
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<tr>
<td>Dia bottom of neck (mm)</td>
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<td>NA</td>
<td>NA</td>
<td>24.3</td>
<td>6.4</td>
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<td>Min dia above bifurcation (mm)</td>
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<td>Neck - aaa angle</td>
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<td>122.4</td>
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Policy-Level Support – It’s there and growing

- FDA
  - Evidence for Pre-Market Approvals
  - Post-Market Surveillance
    
    “Access comprehensive, accurate and timely statistical, epidemiological, and surveillance data that measures the safety and effectiveness of marketed medical devices and that alerts responsible parties to signals of potential risk”*

- CMS
  - Meaningful pay-for-performance initiatives
  - Covering all disease states
  - Coverage with evidence development
  - Access limitations based on evidence

- Clinicians
  - Improve patient care

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* "Ensuring the Safety of Marketed Medical Devices CDRH’s Medical Device Postmarket Safety Program" January 18, 2006
The Fusion of Clinical Data and 3D Imaging

…That Dies in Committee

- **FDA**
  - No policies governing post-market surveillance

- **CMS**
  - There is no overall solution

- **Clinicians**
  - “Transparent outcomes” – no risk adjustment

The Fear Factor
Let’s Consider the Registries Mandated To Date

- **Carotid**
  - Radiographic registry determined intervention at 70% stenosis
  - Contains no images

- **PET**
  - Registry to determine if PET changes the management for oncology patients
  - No standard measurements
  - No images

- **Fundamental problems with both registries**
  - Radiographic registries without images are an oxymoron
  - High cost setup & maintenance
  - Outside channel of care
  - No industry input into specifications
  - No bid process
  - No radiologically determined end points

*How can radiological registries not include images?*
Necessary Elements for Successful Registry Solution

Success will require:

- Specific and transparent guidelines for data ownership, generation, and use
- Specific and transparent technical requirements for registry applications
- Framework for development and implementation of future requirements
- A working relationship with government partners

“Design of protocols and data collection instruments including election of data elements, data definitions and data validation parameters.” *

...You might get it ... But not the way you are going

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  - Clinicians, device manufacturers, and regulators want clean, unbiased data for the evaluation of cost/performance, efficacy, and safety in the post-market environment, *and*
  - A validated, auditable registry will provide the data necessary for evidence-based decision making

- **Null hypothesis**
  - Such a registry and data is neither possible, necessary nor desirable, *or*
  - ✓ **There is no framework for clinicians, regulators, or payors into which such evidence can be utilized.**

We Accept the Null Hypothesis
Data. Knowledge. Results.

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