Registries—A Dubious Panacea or the Best Thing Since Sliced Bread?

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Why Should Device Manufacturers Bother with Registries?

- ~~**Because FDA requires it**~~
- ~~**Because CMS requires it**~~

- **Because they are unique tools for data collection and communication of product safety, efficacy and customer satisfaction**

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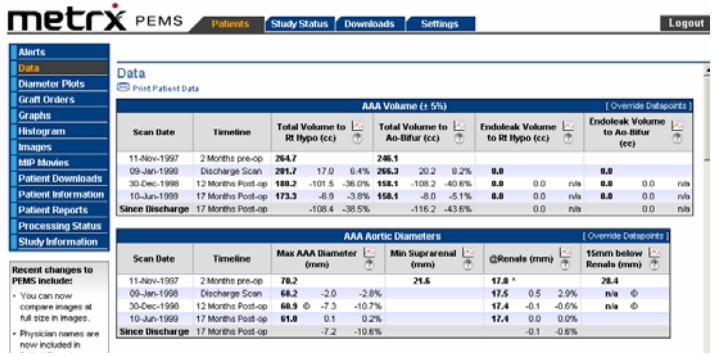
PEMS™

- 60,000+ AAA/TAA case registry
- 4 years in use
- Password protected, HIPAA-compliant secure website
- Catalogues patient-specific and scan-specific data, including images, graphs, measurements and other treatment analysis tools
- First and only commercially available Internet-based surveillance database that catalogues SVS endorsed anatomical metrics for aortic aneurysms
- Incorporates DAC transmission status page for confirmation or cancellation by institution



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What PEMS Does

- **PEMS is designed and implemented for the benefit of clinicians tracking their patients**
  - **Longitudinal tracking of standardized radiological measurements**
  - **Longitudinal tracking of Clinical outcomes**
  - **Integrated with pre-op/post-op planning tool**
  - **Integrated with device sizing, fitting and ordering**
  - **Allows formation of data pools as specified by clinicians for academic study**
  - **Offers world's largest standardized radiological database**
- **PEMS is used by hundreds of institutions, thousands of people, many thousands of times a month—it works!**

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What PEMS doesn't do

- **Regularly provide data to FDA, CMS or product manufacturers**
- **Provide data to SVS or other clinical organizations**
- **Why not?**
  - **Who owns the data**
  - **What can it be used for**
  - **What can't it be used for**
- **Why create the infrastructure for new registries when the existing data is under utilized?**

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Points of View

- **Clinical – Dr. Deaton, Vascular Groups, SVS**
- **Regulatory – FDA, CMS**
- **Device Manufacturers**

POV: Clinicians Registries Should Provide

- **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**

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POV: FDA and CMS Registries Should Provide

- **Regulators solicit data from manufacturers**
- **Regulators want dependable data—Part 11 compliant**
- **Internal validation via Imaging**
- **Controls—e.g. open AAA repair**

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POV: FDA and CMS

- **Practical Sample Sizes—universal participation is unnecessary**
- **Timeliness is essential—ascertain and fix problems as they happen**

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Why is This Hard?

- **3 customer groups with divergent requirements**
- **Manufacturer-specific IFU's**
- **Manufacturer-specific markers for device failure**
- **Loads of radiology data to be analyzed**
- **Surgeon or nurse coordinator time to fill in forms**

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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

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Outstanding Questions

- **“Each endovascular graft design has a unique risk/benefit profile. For endovascular grafts, the particular issues depend on device design.” [Dorothy Abel, FDA]**

- **For an individual patient with AAA disease, which is the optimal targeted device based on their morphology and measured outcomes?**

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POV: Device Companies Registries Should Provide

- **The company paying for the data should own its use and be assured that their data is private and separate from others.**
- **Data collected must be tailored to the individual product, but also meet regulatory requirements.**

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POV: Device Companies

- **Include Marketing, Sales and Clinical data.**
- **Be flexible to address changes in product, market, clinical or regulatory.**
- **Payment for data should produce data for every dollar spent—variable cost based.**

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Data. Knowledge.
Results.