



**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

PEMSTM

- 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

The screenshot displays the metrx PEMS web application interface. The top navigation bar includes 'metrx PEMS', 'Patients', 'Study Status', 'Downloads', 'Settings', and 'Logout'. The left sidebar contains a menu with options: Alerts, Data, Diameter Plots, Graft Orders, Graphs, Histogram, Images, IVP Movies, Patient Downloads, Patient Information, Patient Reports, Processing Status, and Study Information. The main content area is titled 'Data' and contains two tables. The first table, 'AAA Volume (+ 5%)', shows patient data with columns for Scan Date, Timeline, Total Volume to Rt Iliac (cc), Total Volume to Ao-Bifur (cc), Endoleak Volume to Rt Iliac (cc), and Endoleak Volume to Ao-Bifur (cc). The second table, 'AAA Aortic Diameters', shows patient data with columns for Scan Date, Timeline, Max AAA Diameter (mm), Min Suprarenal (mm), @Renals (mm), and 15mm below Renals (mm). Below the tables, there is a 'Recent changes to PEMS include:' section with a list of updates.

Scan Date	Timeline	Total Volume to Rt Iliac (cc)	Total Volume to Ao-Bifur (cc)	Endoleak Volume to Rt Iliac (cc)	Endoleak Volume to Ao-Bifur (cc)
11-Nov-1997	2 Months pre-op	264.7	246.1		
09-Jan-1998	Discharge Scan	281.7	266.3	0.0	0.0
30-Dec-1998	12 Months Post-op	188.2	158.1	0.0	0.0
10-Jan-1999	17 Months Post-op	173.3	158.1	0.0	0.0
Since Discharge	17 Months Post-op	-108.4	-116.2	0.0	0.0

Scan Date	Timeline	Max AAA Diameter (mm)	Min Suprarenal (mm)	@Renals (mm)	15mm below Renals (mm)
11-Nov-1997	2 Months pre-op	78.2	21.6	17.8	28.4
09-Jan-1998	Discharge Scan	68.2	-2.0	17.5	n/a
30-Dec-1998	12 Months Post-op	68.9	-7.3	17.4	n/a
10-Jan-1999	17 Months Post-op	61.8	0.1	17.4	n/a
Since Discharge	17 Months Post-op	-7.2	-10.6%	-0.1	-0.6%

Recent changes to PEMS include:

- You can now compare images at full size in images.
- Physician names are now included in

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!**

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?

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**

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**

POV: FDA and CMS

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

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**

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

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?**

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.**

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.**



**Data. Knowledge.
Results.**