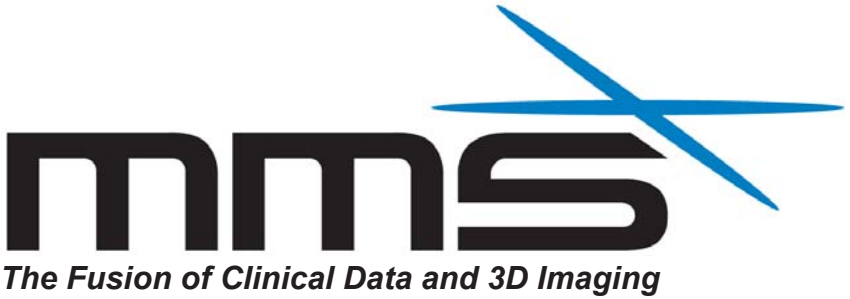


E is for Evidence

Wes Chapman
President & CEO

March 30, 2006

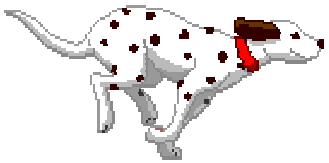
Medical Metrx Solutions, 12 Commerce Ave.,
West Lebanon, NH 03784, 603-298-5509 x 305, chapman@medicalmetrx.com

What happens if the dog catches the car?

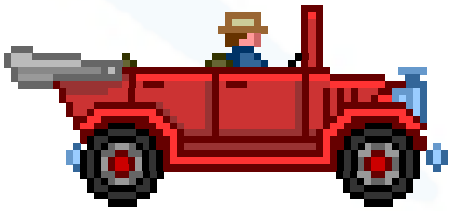
"Be careful what you wish for, you might get it."

- 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

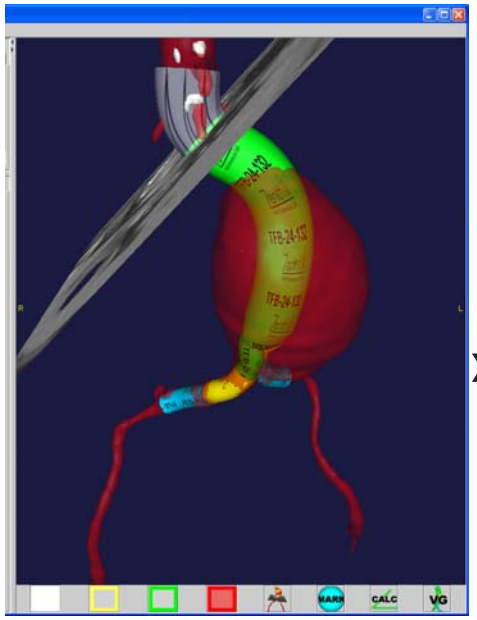
- Null hypothesis
  - Such a registry and data is neither possible, necessary nor desirable, ***or***
  - There is no framework for clinicians, regulators, or payors into which such evidence can be utilized.

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

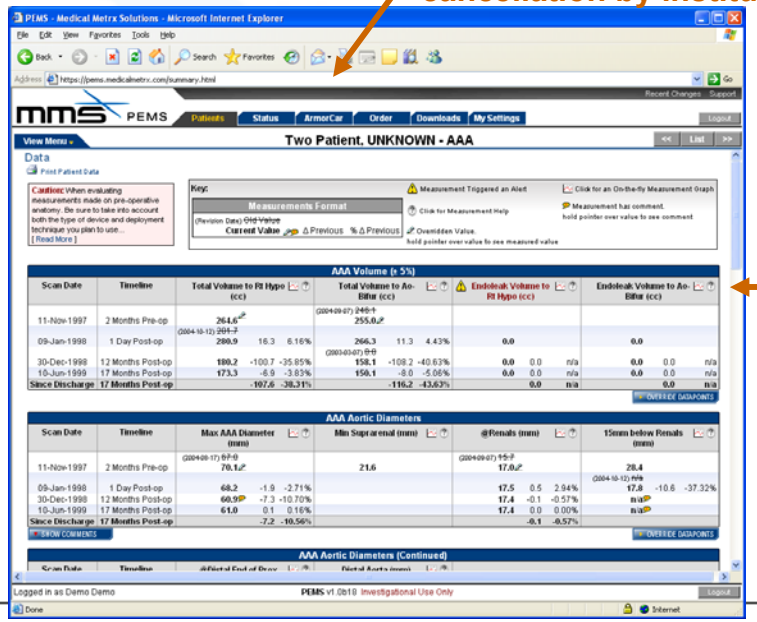
Fusion of

- 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

Device Manufacturers

✓ Comply with post-market surveillance

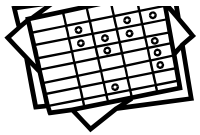
✓ Use data to improve product pipeline, IFU, and compliance

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" **

Registry



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

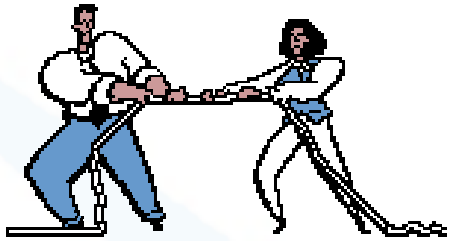
✓ Easy and quick data entry

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

* AHRQ "DEcIDE: Registries for Evaluating Patient Outcomes" http://effectivehealthcare.ahrq.gov/decide/registryOutline.cfm

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

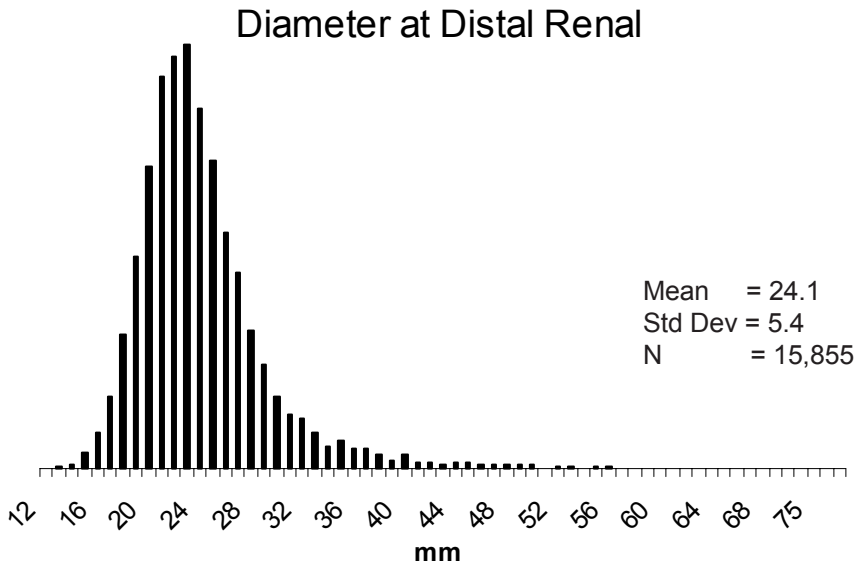
Value of Image-based Registry

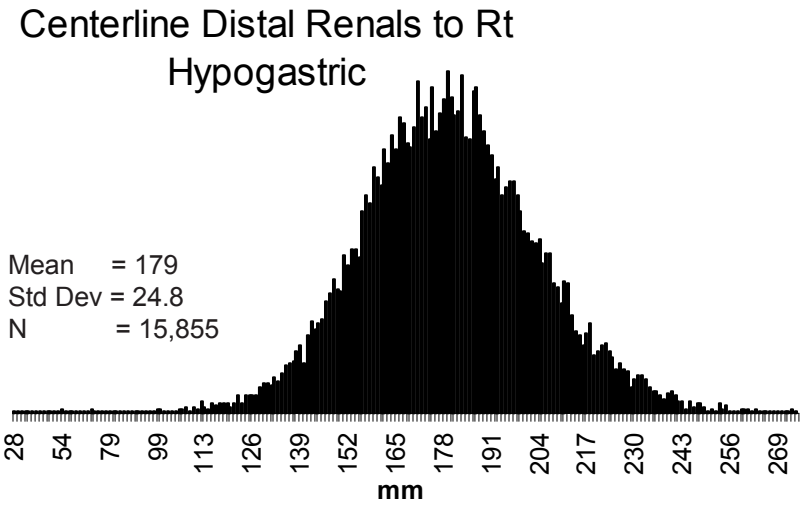
- Auditability
  - Level 1: was the patient actually seen?
  - Level 2: is the clinical report in line with the radiological evidence?
  - Level 3: is the protocol for follow-up adhered to?
- Quality of data collection
  - Reports and analysis can be done from a common baseline
  - More consistent and meaningful results
- Follow-on studies
  - Made possible by capturing primary data
- Accommodates new technology

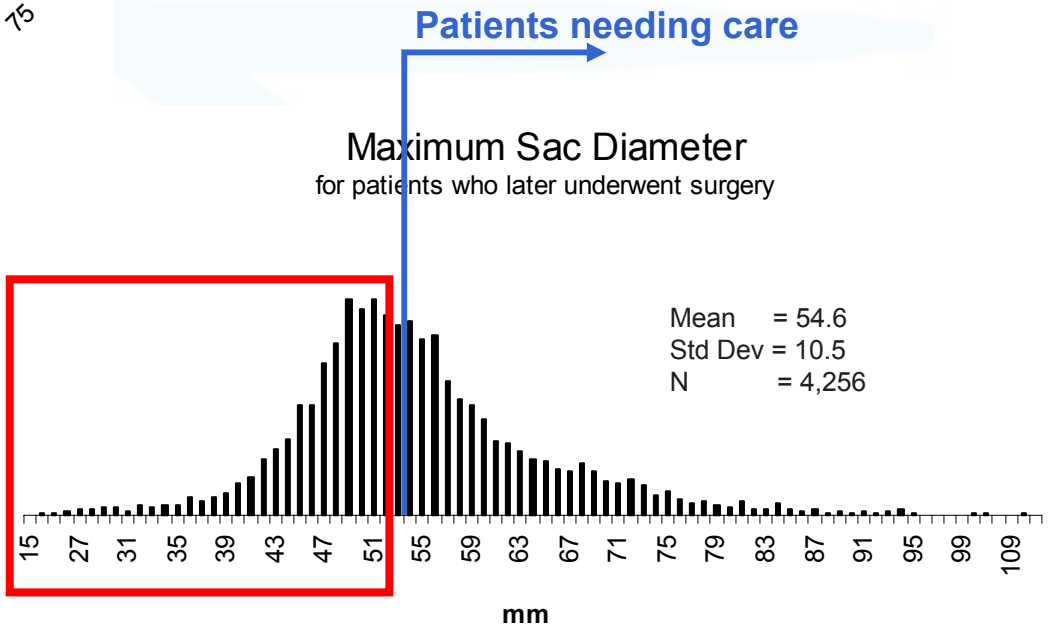
"Off-label use of medical devices is commonplace and demands a thoughtful assessment that acknowledges both the potential risks to the patient as well as the added benefits to medical treatments." *

* "Ensuring the Safety of Marketed Medical Devices CDRH's Medical Device Postmarket Safety Program" January 18, 2006

What Can PEMS Do? Preoperative Data

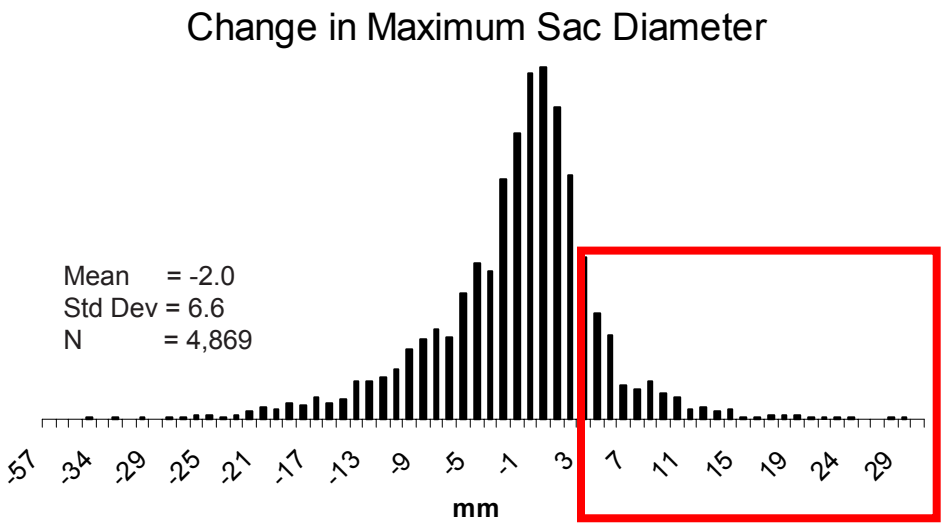


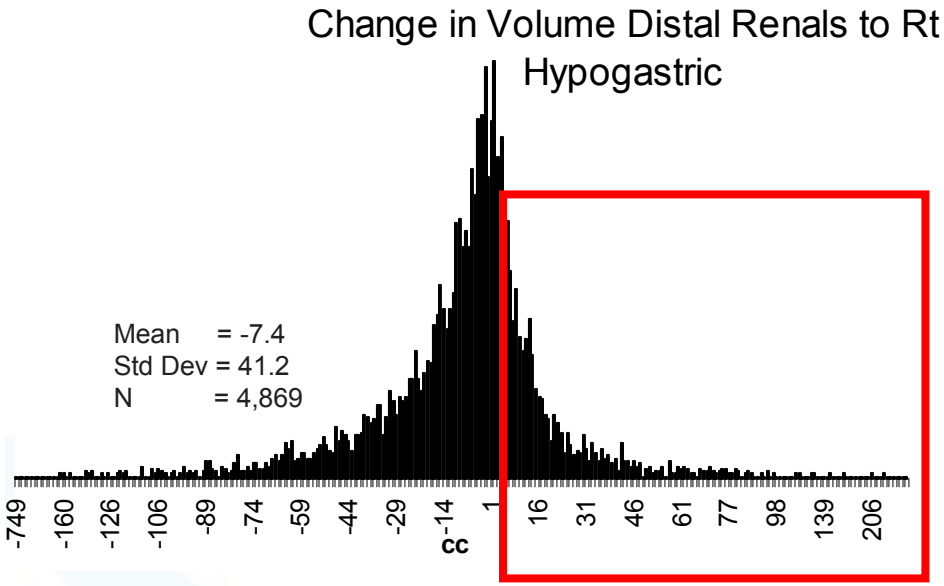


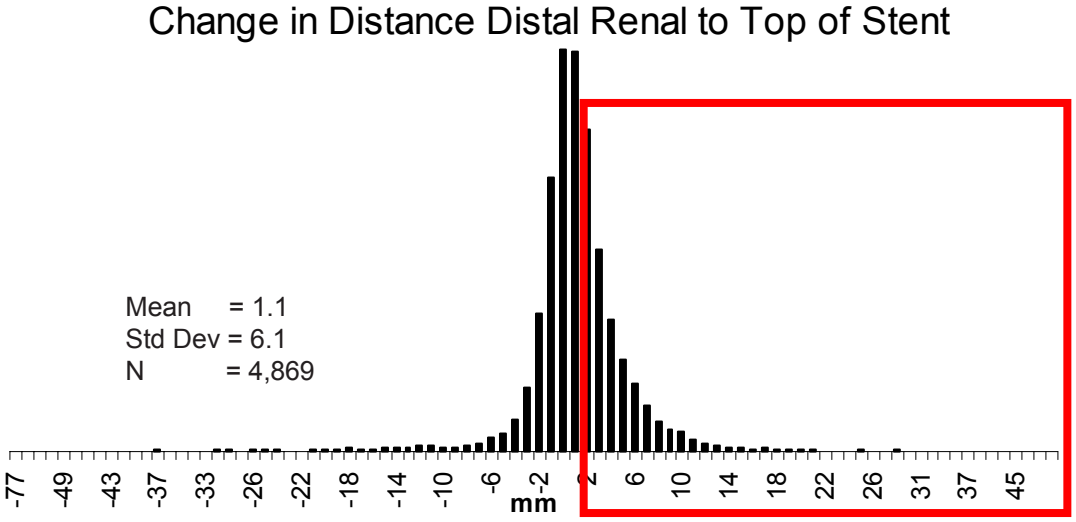


Whose are these?

What Can PEMS Do? Postoperative Data







Whose are these?

What Can PEMS Do?

Standardized.

Measurement Statistics

	Male Pre-op				Female Pre-op			
	Mean	Std Dev	Range	N	Mean	Std Dev	Range	N
Distal renal dia (mm)	24.6	5.6	[12.5-90.4	(14,243)	23.1	6.8	[5.7-109.6]	(4,412)
Max sac dia (mm)	52.2	12.8	[15.0-133.4]	(14,287)	48.0	12.8	[6.8-117.7	(4,425)
Vol to rt hypo (cc)	170.3	94.0	[17.3-1577.3]	(14,227)	133.8	76.5	[3.9-902.3]	(4,390)

Verify Measurements

	8553 11/11/1997	8554 1/9/1998	8555 12/30/1998	8556 6/10/1998	Fem/Preop Mean	Fem/Preop Std Dev
Distal renal dia (mm)	16.5	17.5	17.4	17.4	23.1	6.8
Dia 15 mm below renals (mm)	28.4	17.8	NA	NA	26.5	8.6
Dia top of neck (mm)	16.5	NA	NA	NA	23.0	6.5
Dia bottom of neck (mm)	17.2	NA	NA	NA	24.3	6.4
Min dia above bifurcation (mm)	28.3	NA	NA	NA	17.8	6.3
Proximal neck sealzone (mm)	22.6	NA	NA	NA	15.1	12.0
Max sac dia (mm)	70.2	68.2	60.9	61.0	48.0	12.8
Neck - aaa angle	122.9	127.5	124.8	122.4	138.9	18.3
Vol to bifurcation (cc)	246.0	266.3	158.1	150.1	122.4	75.7
Vol to rt hypo (cc)	264.7	280.9	180.2	173.3	133.8	76.5

Auditable.

Policy-Level Support – It's there and growing

- FDA
  - ➔ Evidence for Pre-Market Approvals
  - ➔ Post-Market Surveillance

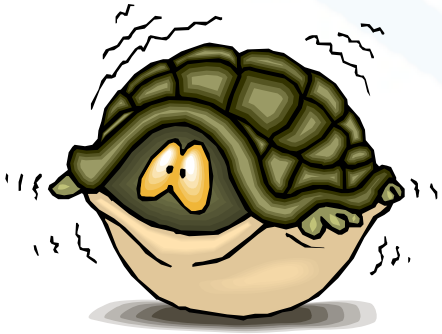
  *"Access comprehensive, accurate and timely statistical, epidemiological, and surveillance data that measures the safety and effectiveness of marketed medical devices and that alerts responsible parties to signals of potential risk"**
- CMS
  - ➔ Meaningful pay-for-performance initiatives
  - ➔ Covering all disease states
  - ➔ Coverage with evidence development
  - ➔ Access limitations based on evidence
- Clinicians
  - ➔ Improve patient care

* "Ensuring the Safety of Marketed Medical Devices CDRH's Medical Device Postmarket Safety Program" January 18, 2006

…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." *

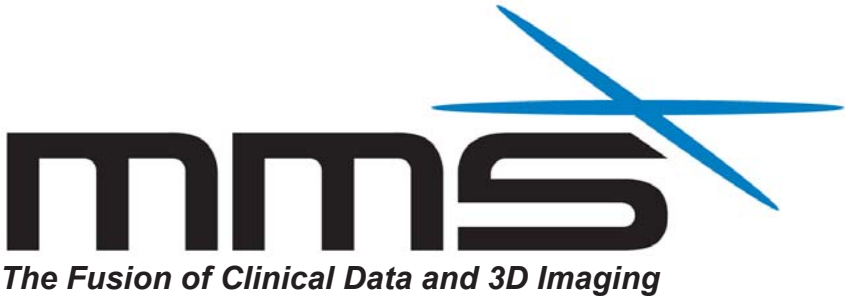
* AHRQ "DEcIDE: Registries for Evaluating Patient Outcomes" http://effectivehealthcare.ahrq.gov/decide/registryOutline.cfm

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

- 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

- 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.

Contact: Wes Chapman, President & CEO, Medical Metrx Solutions, 12 Commerce Ave., West Lebanon, NH 03784, 603-298-5509 x 305, chapman@medicalmetrx.com