Lessons Learned: Creating a Dedicated Focused Ultrasound Center

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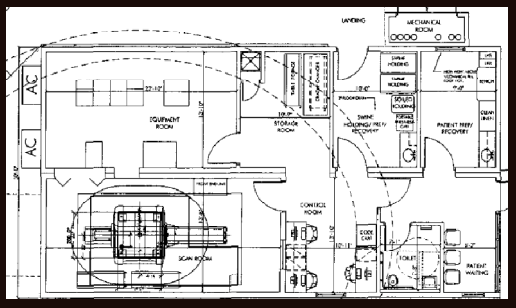
Still learning!

What have we learned?

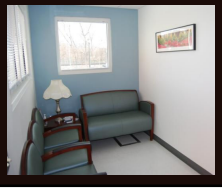
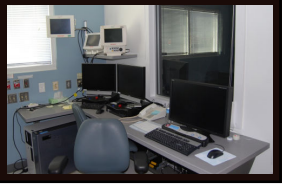
What were our goals for the center?

- Support both clinical operations and preclinical research
- Multidisciplinary
- Dedicated imaging and treatment equipment
- Within 10 minutes of an OR
- Able to reach financial self-sufficiency quickly
- "Lean and efficient"

Facility Design



An inside look

Separate clinical and research concerns

Patient entrance

Research entrance

What are we doing with it?

- Current Trials
  - Uterine Fibroids- Alan Matsumoto, MD, Department of Radiology
  - Pain from Bone Metastases – Paul Read, MD, Department of Radiation Oncology
  - Essential Tremor – Jeff Elias, MD, Department of Neurosurgery
- Future Trials for 2011
  - Brain Tumors – Jason Sheehan, MD, PhD, Department of Neurosurgery
  - Prostate Cancer
  - Facet Rhizotomy for Back Pain – Ben Messinger, MD, Department of Anesthesiology

What about when we aren't treating people?

- **Intracerebral Hemorrhage** - Jason Sheehan, MD, PhD, Department of Neurosurgery
- **Ischemic Stroke**– Max Wintermark, MD, Department of Radiology
- **Comparison of radiosurgery, radiofrequency and focused ultrasound in lesioning of the brain**– W. Jeff Elias, MD, Department of Neurosurgery
- **Trigeminal Neuralgia**- Jason Sheehan, MD, PhD, Department of Neurosurgery
- **Blood-Brain Barrier Opening for Therapeutic Nanoparticle Delivery to Invasive Brain Tumors** – Richard J. Price, Ph.D., Department of Biomedical Engineering
- **Blood-Brain Barrier Opening for Bevacizumab (Anti-VEGF Ab) Delivery to Invasive Brain Tumors** - Richard J. Price, Ph.D., Department of Biomedical Engineering
- **Tumor Growth Inhibition via Microvascular Ablation** - Richard J. Price, Ph.D., Department of Biomedical Engineering
- **Gene-Bearing Nanocarrier Delivery to Skeletal Muscle for Peripheral Arterial Disease** - Richard J. Price, Ph.D., Department of Biomedical Engineering
- **Adenocarcinoma Treatment via Non-Specific Immune Response Stimulation**– Alexander L. Klibanov, Ph.D., Department of Internal Medicine
- **Gene Delivery to Inflamed Bowel for Crohn's Disease** – Michael Lawrence, Ph.D., Department of Biomedical Engineering

How are we organized?

Department	Functions
Radiation Oncology	Director; center coordination; physics support; clinical trial support Bone
Neurosurgery	Co-director; clinical trial support Brain
Radiology	Co-director; clinical trial support Fibroids
Medical Center	Anesthesiology, nursing, MR tech support
Other participating departments	Clinical trial support, attending physician support

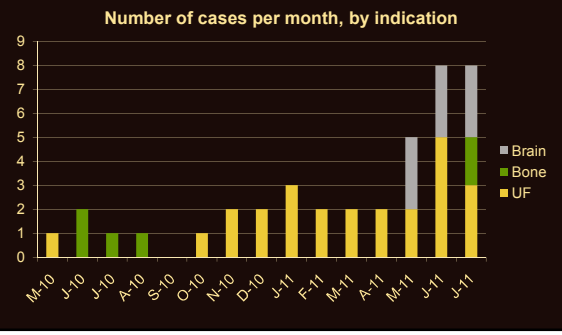
What does it cost to run?

Expense	Cost per hour (USD)	Cost per case (6 hour case)
MR Tech	$36	$216
Nurse	$40	$240
Sonication Kit		$300
Utilities		$300
Indirect Overhead		$500

Total per case ~ $1550
Total operating expenses since opening: ~$700K

But, many volunteers (physician, physicist, clinical trials coordinator, etc.)

How busy are we?



What have we learned?

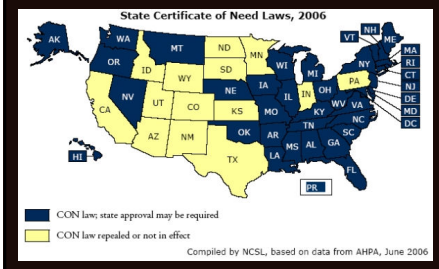
MRgFUS is a therapy system, not a diagnostic imaging system!

Backup power unit

Make sure the facility meets ALL requirements!

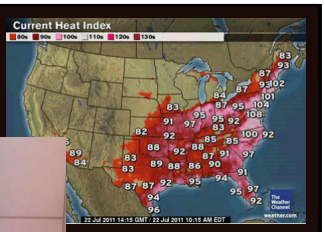
Medical Gas

Consider additional lines of revenue

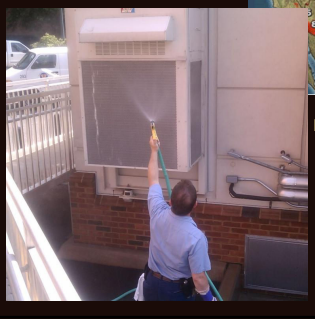


http://www.ncsl.org/default.aspx?tabid=14373

There are always surprises



East Coast heat wave, July 2011



What else did we learn?

Get all the right people in the room at the beginning.

Work quickly towards independence from vendors.

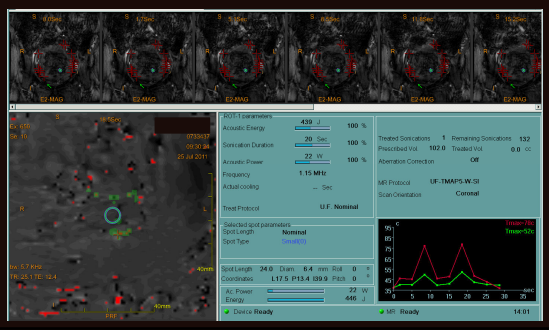
Do not underestimate the financial challenges given the current reimbursement situation.

Your results may vary!

So…you're a medical physicist. They want you to help get a FUS program going.

What should you do? Look for a new job?

Why even have Medical Physics involved?



So…be excited! Don't look for a new job!

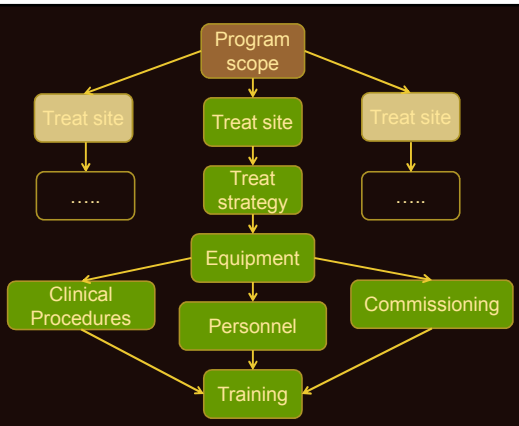
FUS Requires someone who has:

- Fairly in-depth knowledge of MR-physics, and some ultrasound physics
- Good knowledge of anatomy
- Expertise in managing patient immobilization and patient motion
- General technical expertise
- Familiarity with a scan/plan/verify/treat sort of workflow

Medical Physics is a natural fit!

Where to start?

AAPM Task Groups



AAPM TG-101: Stereotactic Body Radiation Therapy, Med Phys 37(8), Aug 2010

Where things get difficult

Who "owns" any given clinical indication?

Should personnel be borrowed from each department, or dedicated to center?

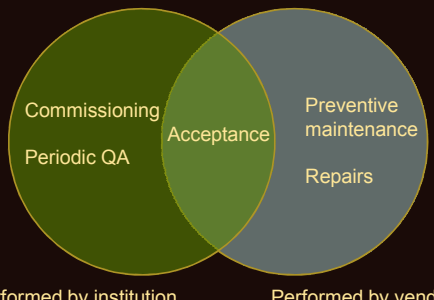
How best to estimate resources?

Who manages the schedule?

How are staff credentialed?

How are research and clinical operations prioritized?

How QM works in RadOnc



The New York Times

We are **not** perfect

THE RADIATION BOOM
By WALT BOGDANICH

Radiation Offers New Cures, and Ways to Do Harm
Published: January 23, 2010

As Technology Surges, Radiation Safeguards Lag
Published: January 26, 2010

What to QA for FUS?

- Little consensus on most important parameters
- Multiple biological effects
- Ablative vs. non-ablative techniques
- Quickly evolving technology

It's the **process** that fails, not just the technology

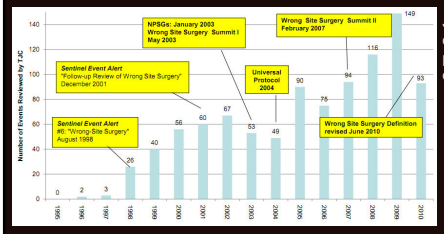
2004 through Fourth Quarter 2010 (N=137) *The majority of events have multiple root causes*	
Human Factors	98
Leadership	87
Physical Environment	85
Communication	84
Assessment	77
Information Management	20
Care Planning	18
Operative Care	6
Medication Use	5
Continuum of Care	4

Root Cause Information for Medical Equipment-related Events Reviewed by the Joint Commission

(resulting in death or permanent loss of function)

http://www.jointcommission.org/assets/1/18/SE_RootCausesEventType2004_4Q2010.pdf

It's the **process** that fails, not just the technology



Joint-commission documented wrong patient/site/procedure events, 1995-2010.

http://www.jointcommission.org/assets/1/18/Event_Type_by_Year_1995_4Q2010.pdf

Don't focus on QA..focus on the process!

BETTER

- **Eliminate – make mistake impossible**
- **Replace – make more reliable process**
- **Facilitate – make work easier**
- **Detect – make problems more obvious** (QA)
- **Mitigate – control damages**

Eric Ford, Tools to Improve Patient Safety in Radiation Oncology, MAC-AAPM Annual Meeting, 2010

How do I analyze a clinical process?

Failure Mode and Effects Analysis (FMEA) - start with process, identify and prioritize risks

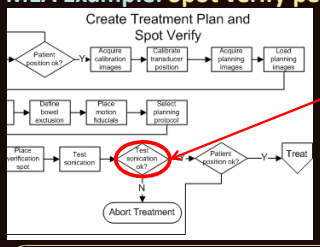
Fault Tree Analysis – Start with failure, identify causes and find opportunities to fix

Incident Reporting – Learn from your (almost) mistakes

Standards Bodies – Define standards of practice

Watch for the upcoming report on TG-100!

FMEA Example: Spot verify performed incorrectly



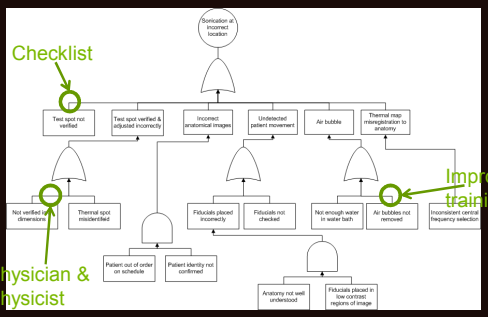
Possible effect: Treatment to wrong location!

RPN score: 160 (*RPN=SxOxD* = 8x5x4)

S: Severity (*No Harm 1 … 10 Severe Harm*)
O: Frequency of occurrence (*Low 1 ... 10 High*)
D: Detectability (*Easily Detected 1 … 10 Undetectable*)
Risk Priority Number, *RPN = S x O X D*

Stamatis, DH, Failure mode and effect analysis : FMEA from theory to execution, 2003

FTA Example: Treatment at incorrect location



Checklist

Improved training

Physician & Physicist presence

Clinical Standards

ASTRO — TARGETING CANCER CARE

ESTRO

American Association of Neurological Surgeons

The American Association of Physicists in Medicine

Technical Standards

NIST

IEEE

IEC

Task Group 193 – Image Guided FUS

Charges

- To review the literature and summarize the historical development of HIFU therapy, clinical findings to date, and current trends in research.
- To review relevant clinical products and describe the components in detail with an assessment of capabilities and current technology limitations.
- To recommend standards for quality assurance and quality management, including commissioning, periodic QA, patient-specific QA, and periodic QM.
- To determine criteria for designing and establishing an FUS facility including equipment, personnel resources, protocols, and credentialing.
- To recommend documentation standards for prescribing, reporting, and recording MRgFUS treatment data.

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