Lessons Learned: Creating a Dedicated Focused Ultrasound Center

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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

Research entrance

Patient 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 Wintzmark, 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 Savorusmab (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 — Michael Lawrence, Ph.D., Department of Biomedical Engineering
- Adenocarcinoma Treatment via Non-Specific Immune Response Stimulation – Alexander L. Khitrov, Ph.D. Department of Internal Medicine
- Gene Delivery to Inflamed Bowel for Crohn’s Disease — Michael Lawrence, Ph.D., Department of Biomedical Engineering

What does it cost to run?

<table>
<thead>
<tr>
<th>Department</th>
<th>Functions</th>
<th>Cost per hour (USD)</th>
<th>Cost per case (6 hour case)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncology</td>
<td>Director; center coordination; physics support; clinical trial support Bone</td>
<td>$38</td>
<td>$210</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>Co-director; clinical trial support Brain</td>
<td>$40</td>
<td>$240</td>
</tr>
<tr>
<td>Radiology</td>
<td>Co-director; clinical trial support Fibroids</td>
<td></td>
<td>$300</td>
</tr>
<tr>
<td>Medical Center</td>
<td>Anesthesiology, nursing, MR tech support</td>
<td></td>
<td>$300</td>
</tr>
<tr>
<td>Other participating departments</td>
<td>Clinical trial support, attending physician support</td>
<td></td>
<td>$500</td>
</tr>
</tbody>
</table>

Total per case ~ $1550
Total operating expenses since opening: ~$700K
But, many volunteers (physician, physicist, clinical trials coordinator, etc.)

How busy are we?

Number of cases per month, by indication

What have we learned?
MRgFUS is a therapy system, not a diagnostic imaging system!

Make sure the facility meets ALL requirements!

Consider additional lines of revenue

There are always surprises

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?

How QM works in RadOnc

How are research and clinical operations prioritized?

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

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 credentialled?
How are research and clinical operations prioritized?
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

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

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!

• Eliminate – make mistake impossible
• Replace – make more reliable process
• Facilitate – make work easier
• Detect – make problems more obvious
• Mitigate – control damages

Better

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

$RPN = S \times O \times D = 8 \times 5 \times 4$

S: Severity (No Harm 1 ... 10 Severe Harm)
O: Frequency of occurrence (Low 1 ... High 10)
D: Detectability (Easily Detected 1 ... Undetectable)

Risk Priority Number, $RPN = S \times O \times D$

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

FTA Example: Treatment at incorrect location

Checklist

Physician & Physicist presence

Improved training

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.

Clinical Standards

Technical Standards

Clinical Standards

Technical Standards

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