MR-guided focused ultrasound surgery (MRgFUS) is an emerging technology with the potential to disrupt traditional treatment techniques across a wide variety of surgical and medical disciplines. Proposed applications for MRgFUS are multiplying quickly and include indications as diverse as tumor ablation, thrombolysis, hemostasis, reversible blood-brain barrier disruption, targeted drug delivery, gene therapy, and neuromodulation. Interest in MRgFUS is quickly increasing, however the desire to find new potential treatment indications may be outpacing work on developing "best practices" for designing new centers, organizing clinical teams, and defining standards for treatment quality and reporting.

The University of Virginia recently started up one of the first programs in the world designed from the ground up specifically for the purpose of MR-guided focused ultrasound surgery. The lessons learned during this process, both positive and negative, may be valuable to the ongoing discussion of best practices. This lecture will provide an overview of the UVA experience, including center design, construction, and administrative organization, and funding /revenue, and program startup. A particular focus will be on the clinical startup experience, and how this might be improved with a more formal risk-based process analysis.

Learning objectives:

1. To understand the rationale for a stand-alone FUS center versus a center created out of existing resources in the medical center.
2. To understand the design features of the center, as well as the challenges that had to be overcome in the design and construction of the center.
3. To understand the multidisciplinary organization of the center and how inter-department conflicts are managed.
4. To understand the expectations vs. reality of the center regarding the distribution of treatment indications, the effort required to start clinical trials, and the ability to collect clinical revenue.
5. To understand the center's experience during clinical startup, and the successes and challenges faced by the center when trying to refine clinical processes and develop standards for quality assurance.

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