Ultrasound Activity in the RSNA Quantitative Imaging Biomarker Alliance

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What is the Quantitative Imaging Biomarker Alliance?

- Collaboration to identify needs, barriers and solutions to create consistent, reliable, valid and achievable quantitative imaging results across imaging platforms, clinical sites, and time
- Accelerate development and adoption of hardware and software standards to achieve accurate and reproducible quantitative results from imaging methods
- Originally formed in 2007; Ultrasound added in 1012

Who Forms QIBA?

- Over 850 individuals have joined the QIBA effort, representing all major stakeholders in the quantitative imaging initiative:
  - Radiologists
  - Imaging scientists
  - Pharmaceutical companies
  - Imaging device companies
  - Imaging informatics and other software companies
  - Government agencies
  - Professional societies
  - Clinical trialists and clinicians
  - Statisticians and metrologists
- 297 individuals from over 100 companies, 20 from the FDA, 46 from government (excluding FDA)
- Vast majority of stakeholder efforts are voluntary

RSNA QIBA Approach

- Profile
  - Describes a specific performance claim and how it can be achieved.
  - Claims: tell a user what can be accomplished by following the Profile.
  - Details: tell a vendor what must be implemented in their product; tell a user what procedures are necessary.
- Protocol
  - Describes how clinical trial subjects or patients should be imaged so as to achieve reproducible quantitative endpoints when those tests are performed utilizing systems that meet the specific performance claims stated in the QIBA Profiles.

Criteria for Identifying Biomarker Opportunities:

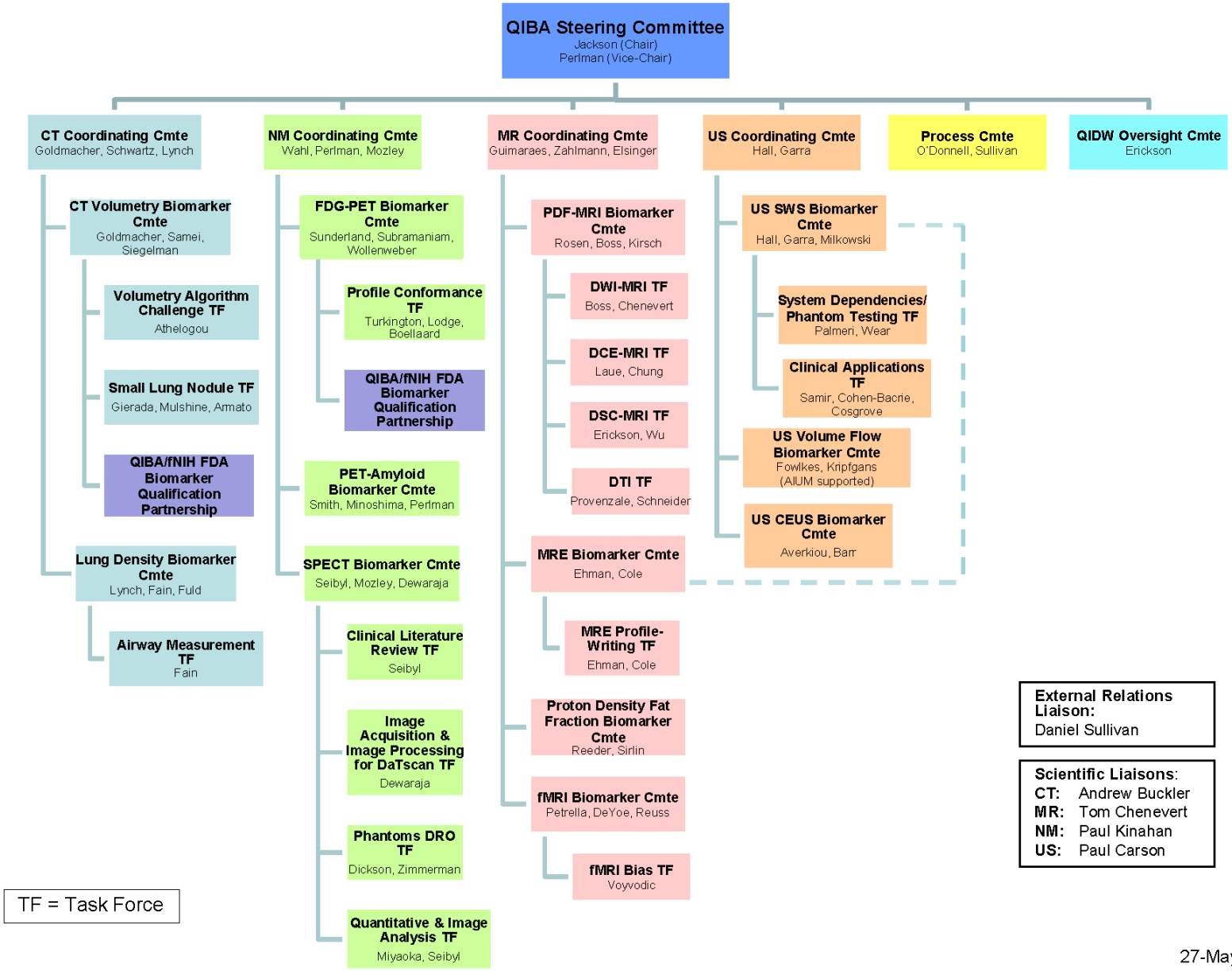
1. **Is it transformational?**
   - Does it address a significant medical biomarker need with a considerable impact on public health?
   - Does it address a critical gap in the biomarker qualification/validation process?
2. **Is it translational?**
   - Will the result improve the objectivity of metrics used in multicenter studies, or adoption into clinical care?
3. **Is it feasible?**
   - Can the result be achieved in 3-5 years with a likelihood of achieving the expected outcome?
4. **Is it practical?**
   - Does it leverage existing resources and/or warrant access to RSNA resources and support?
5. **Is it collaborative?**
   - Would it benefit from QIBA's multi-stakeholder approach and is it feasible under QIBA's policies?

Profile Stages

- Stage 1: Public Comment
  - Biomarker Committee experts have drafted the profile and believe it is practical and expect it to achieve the claimed performance.
- Stage 2: Consensus
  - The wider community has read the profile and believe it to be practical and expect it to achieve the claimed performance.
- Stage 3: Technically Confirmed
  - Sites (at least 2 and with at least 2 vendor platforms) have implemented the profile and found it to be practical and expect it to achieve the claimed performance.
- Stage 4: Claim Confirmed
  - Sites (at least 2 and with at least 2 vendor platforms) have implemented the profile and found it achieved the claimed performance.
- Stage 5: Clinically Confirmed
  - Many sites have implemented the profile and demonstrated the claimed performance is widely achievable.

http://qibawiki.rsna.org/index.php/QIBA_Profile_Stages

QIBA Organization Chart



TF = Task Force

External Relations Liaison:
Daniel Sullivan

Scientific Liaisons:
CT: Andrew Buckler
MR: Tom Chenevert
NM: Paul Kinahan
US: Paul Carson

27-May-2016

Current Profile Status

- Publicly Reviewed and Posted*:
  - *CT Tumor Volume Change* (v2.2) for tumor response
  - *FDG-PET/CT SUV as an Imaging Biomarker for Measuring Response to Cancer Therapy* (v1.05)
  - *DCE-MRI Quantification* (v1.0) for tumor response
  - *FDG-PET/CT Protocol* (with summary published in JNM in April 2015)

- In Final Stage of Development for Public Comment Phase:
  - CT Small Nodule Volumetry for lung cancer CT screening
  - CT Lung Densitometry for COPD
  - PET Amyloid for Alzheimer's Disease
  - DW-MRI for tumor response
  - fMRI for pre-surgical planning
  - Ultrasound Shear Wave Speed for liver fibrosis

*www.rsna.org/qiba

Current Profile Status

- In Development:
  - Revised CT Tumor Volume Change for liver lesions
  - Revised DCE-MRI to address 3T and parallel imaging
  - MR Diffusion Tensor Imaging (DTI) for traumatic brain injury
  - MR Elastography for liver fibrosis
  - Dynamic Susceptibility Contrast (DSC)-MRI for perfusion assessment in stroke
  - MR Proton Density Fat Fraction (PDFF) for liver disease
  - Ultrasound Volume Flow for perfusion studies
  - Contrast-Enhanced Ultrasound (CEUS) for perfusion studies
  - SPECT for brain diseases

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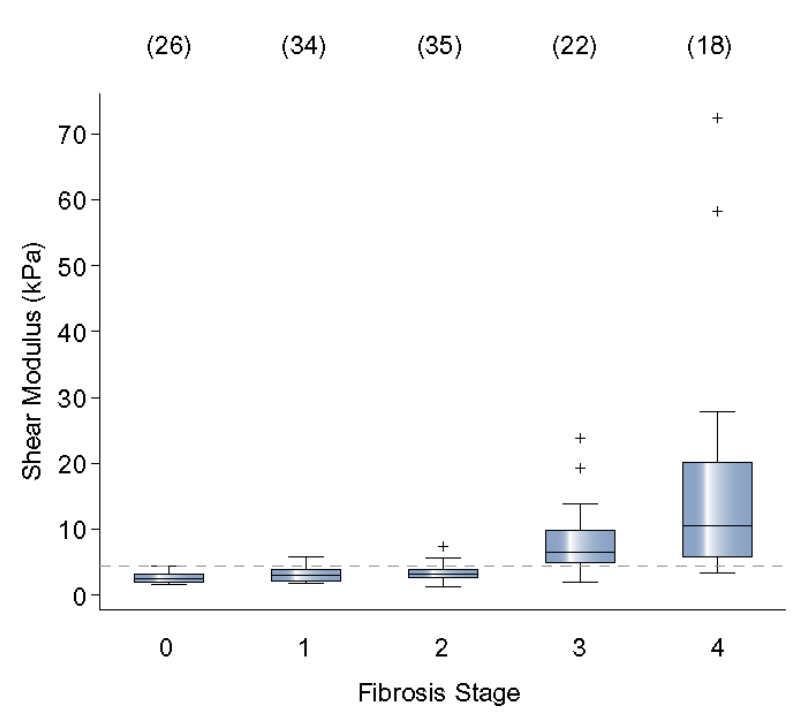
Shear Modulus vs. Fibrosis Stage



Journal of Hepatology **2011** vol. 55 | 666–672

Noninvasive evaluation of hepatic fibrosis using acoustic radiation force-based shear stiffness in patients with nonalcoholic fatty liver disease

Mark L. Palmeri[1,*], Michael H. Wang[1], Ned C. Rouze[1], Manal F. Abdelmalek[2], Cynthia D. Guy[3], Barry Moser[4], Anna Mae Diehl[2], Kathryn R. Nightingale[1]

[1]*Department of Biomedical Engineering, Duke University, Durham, NC, USA;* [2]*Division of Gastroenterology and Hepatology, Duke University Medical Center, Durham, NC, USA;* [3]*Department of Pathology, Duke University Medical Center, Durham, NC, USA;* [4]*Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC, USA*

SWS Threshold
4.24 kPa F0-2:F3-4

90% sensitivity
90% specificity
0.90 AUC

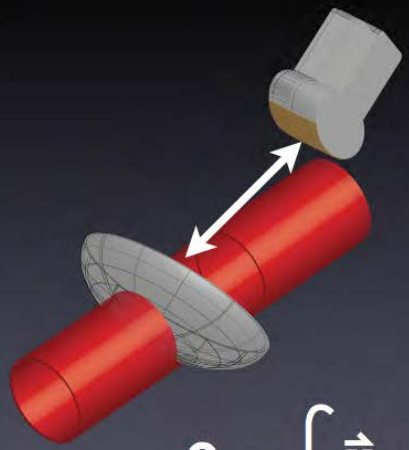
This threshold is system dependent

Volume Blood Flow BC

Flux

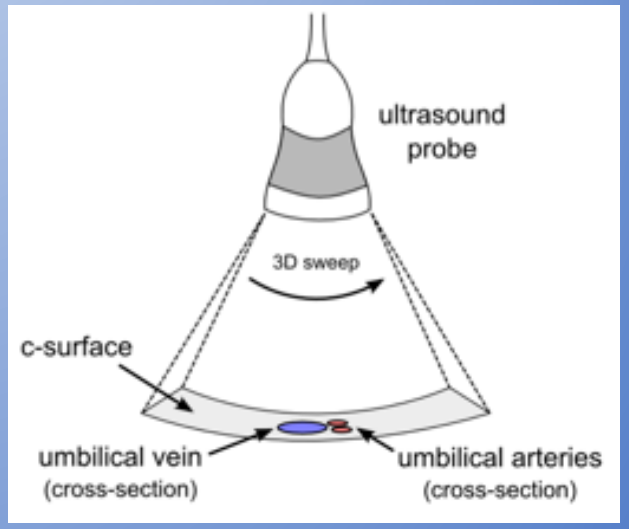
- Flow per unit area
- Flow is movement of blood per time
- Flux is a vector

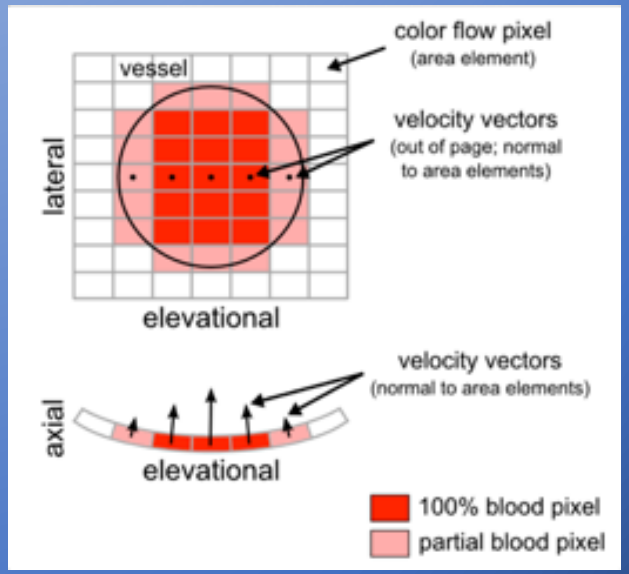
Carl Friedrich Gauss
(1777–1855)
(Gauss' Theorem)



$$Q = \int_S \vec{v} \cdot d\vec{A}$$

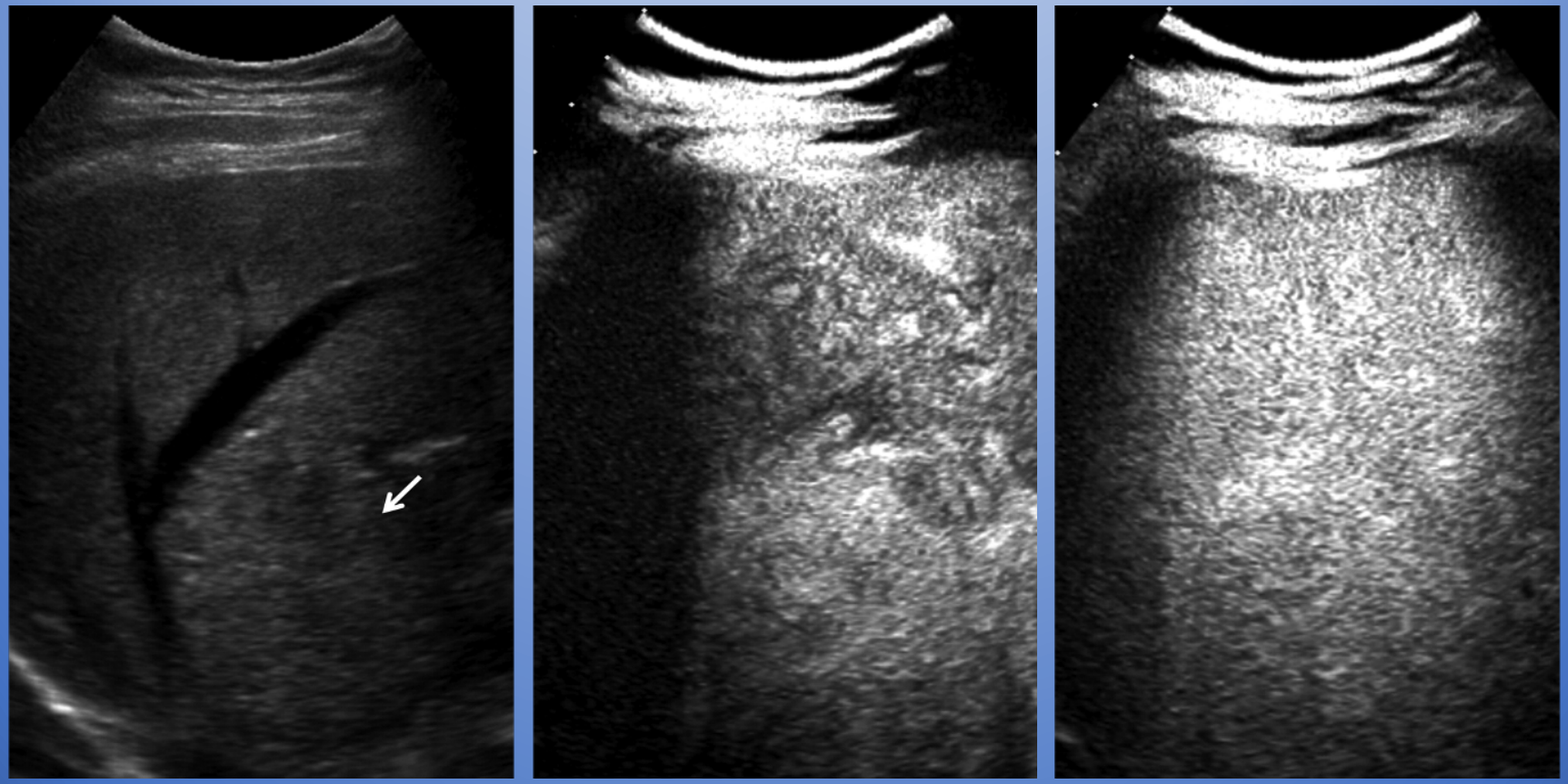
Gauss' Theorem





Contrast-Enhanced Ultrasound BC

Liver Metastaticy



B-Mode | Early Enhancement | Late Enhancement

Adoption of QIBA Products / Concepts

- Increasingly active imaging vendor representation on QIBA committees; senior NEMA/MITA, FDA, and NIST representation on QIBA Steering Committee
- Marketing of PET/CT scanners now emphasizes quantitative ability, and marketing of such ability by other modalities is expected
- QIBA Profiles adopted in whole or in part in clinical trials (Roche, Merck, ECOG-ACRIN)
- QIBA approach has been endorsed at several conferences (*e.g.*, IOM DTI workshop; NIST Workshop on Standards for Quantitative MR)
- Requests for QIBA presentations at national / international meetings of scientific and professional organizations (*e.g.*, AAPM 2015 Presidential Symposium, 2016 SPIE Plenary Symposium, 2016 ISMRM Plenary Symposium, 2016 75th Annual Meeting of the Japan Radiological Society, *etc.*)

Adoption of QIBA Products / Concepts

- Adoption and marketing of “QIBA compliance” by some imaging core labs
- Internationalization of QIBA:
  - Active participation from individuals in South America, Europe, and Asia
  - European Society of Radiology European Imaging Biomarker Alliance (EIBALL)
  - EORTC / IMI – QIBA collaboration (MR DWI)
  - Japan Radiological Society (“QIBA/Japan”)
  - São Paulo neuroradiology clinical trial adoption of QIBA profiles
  - Korean Society of Radiology participation

Thanks!

http://qibawiki.rsna.org