Industry Perspective re: QIBA

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Speaking on behalf of the Medical Imaging & Technology Alliance (MITA)
For Gail Rodriguez, Executive Director

Disclosures

• Richard A. Frank, MD, PhD is employed by Siemens Healthcare USA as the Chief Medical Officer.

• The Medical Imaging & Technology Alliance (MITA) represents medical imaging, radiation therapy, and radiopharmaceutical manufacturers. Dr Frank chairs MITA’s Coverage and Research Committee.
Kudos to QI BA

- Profiling
  - Clinically relevant content
  - Validation of profile
  - Implementation via stakeholders
  - Accreditation of sites
  - Revision to catalyze enhanced product performance
- Education, Metrics
- Sustainability

What will drive use of the profiles? Is there a role for industry beyond innovation and design to performance?

Industry Roles - primary

- Innovation in technology for detection and characterization of pathology to inform patient management
  - Improve efficacy, enhance safety, and expand accessibility
- Innovation in therapeutic options and IT infrastructure eg EHRs
- Regulatory approval for innovative technology (safety and efficacy)
- Installation, validation, and training in use of technology
- Address quality issues which may be attributed to product design

Examples of innovations
- CAD
- Iterative Reconstruction
- Detector efficiency and configuration
- Minimally invasive surgery

Examples of incremental improvements
- Reporting tools
- EHRs, DICOM
- Quantitation

You asked for reduced radiation exposure with the same or better quality, and we delivered
2010: CT dose mentioned 2100 times in English language media
(Source: Google News)

Industry Roles - primary

Radiation Dose Mitigation Standards

- NEMA XR 25 (2010): *Computed Tomography Dose Check*
- NEMA XR 27 (2012): *X-ray Equipment for Interventional Procedures User Quality Control Mode*
- NEMA XR 28 (2013): *Supplemental Requirements for User Information and System Function Related to Dose in CT*
- NEMA XR 29 (2013): *Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management*
Dose Reduction Innovations

- Automatic Exposure Control
- Wider coverage detectors
- “Shutter” modes
- Advanced electronics
- First and second generation CT iterative reconstruction
- DICOM Radiation Dose Structured Report
- XR – 25 Dose Check Standard

Typical CTC Radiation Dose
(per exam)

Annual background from naturally occurring radiation


Industry Roles - primary

Typical Radiation Dose
(per exam)

*** Data on file at IELCAP

Industry roles - secondary

- Support the clinical community in gaining coverage for procedures
- Enable quality metrics in support of professional societies (eg, dose)

Examples of support for coverage and quality
- Establish quality standards for product design (a primary role for MITA)
- Standardize product design for quality metrics in professional use
- Standardize product design for reporting
- Advocate appropriate use and clinical practice guidelines
- Comment on research plans and HTAs by AHRQ/USPSTF, EBPs, Payers (public & private)
  Participate in design and build of research infrastructure
  Participate in development and implementation of pragmatic, relevant quality metrics
Industry roles - NOT

- Practice of medicine
- Clinical practice guidelines/Appropriate Use Criteria
- Promotion [off-label]
- Accrediting radiology sites
- Tracking performance of sites (quality of reads, doses administered)
- Conduct of CER

Industry Roles - secondary

Healthcare Technology Assessments

- New technology is MORE expensive and LESS effective than existing one
  - Rational decision to go against new technology
- New technology is MORE expensive and MORE effective than existing one
  - Decision makers must decide if the increased costs are worth the increase in effectiveness
- New technology is LESS expensive and LESS effective than existing one
  - Decision makers must decide if the reduced costs are worth the reduction in effectiveness
- New technology is LESS expensive and MORE effective than existing one
  - Rational decision to go in favor of new technology
Pursuing Coverage and Payment for New Applications

- Amyloid PET Imaging in Dementia
- CT Colonography for Colo-rectal Cancer
- Low Dose CT for Lung Cancer Screening
- FDA Approval Amyloid Agents

USPSTF “B”
CMS NCA
CMS CED
USPSTF Research Plan

MITA-QIBA Shared Objectives

How do we measure and report progress, and what’s next?

- Profiles for U/S, MR, CT
- Expanded and enhanced profiles for PET/CT, eg amyloid
- FDG PET/CT Profile

1st Profile
2nd-nth Profile
Site Accred’n
1st Profile up-spec’d

Validation Implementation
Site upgrades
Accreditation, Certification
Discussion
How best to work toward our common objective of raising the performance and value of quantitation?

Heard in the hallways;
"Help us validate profile X," and then,
"Release support for profile X in products."

Work backward from;
Who should aspire to the profiles and why?
What will be the value to them and what then is the commensurate resource they would allocate?
What must be done to raise awareness and enable the aspirations of these users?