

QIBA MRE Biomarker Committee (BC) Call

Monday, March 15, 2021 at 2 p.m. CT

Call Summary

Participants

Patricia E. Cole, PhD, MD (Co-chair)

Richard Ehman, MD (Co-Chair)

David G. Bennett, PhD

Shelton Caruthers, PhD

Alexander Guimaraes, MD, PhD

M. Rehan Khan, MD

Paul McCracken, PhD

Michael Middleton, MD

Nancy Obuchowski, PhD

Kay Pepin, PhD

Suraj Serai, PhD

Bram Stolk, PhD, MBA

Gudrun Zahlmann, PhD

RSNA

Joe Koudelik

Susan Stanfa

Review of Previous Call Summary

- The January 23, 2020 call summary from the last MRE BC meeting was approved

Review Current Status of the MRE Profile

- The MRE Profile reached Consensus in May 2018 and a maintenance update was released in June 2019; another update is expected soon

Discussion of Updates to be Included in the MRE Profile Stage 2: Consensus 2021 Maintenance Version

- Minimum ROI area to be adjusted as discussed during past meetings
 - In the absence of formal research data, the MRE BC had originally deemed 2,000 pixels (500 pixels x 4 slices) acceptable, but it was suggested that a smaller number would work for clinical trials
 - With the Liver Imaging Group (UCSD Dept. of Radiology), Gilead Sciences Incorporated and Mayo Clinic (Rochester, MN), Dr. Middleton led a proof-of-concept study to evaluate liver MRE analyzability criteria using a simulation method based on successively and concentrically decreasing the size of selected ROIs
 - Cases containing large ROIs were examined and the pixel threshold was adjusted lower while maintaining image quality
 - There were no objections that the proposed limit of 500 pixels per exam (rather than 500 pixels per slice) be adopted into the Profile revision; clarification that this smaller ROI size was specific to homogeneous disease conditions to be added
- Where appropriate, ranges of values may replace exact numbers in the protocol parameter values, for applicability across platforms
- Per Kim DW, et al. [Comparison of technical failure of MR elastography for measuring liver stiffness between gradient-recalled echo and spin-echo echo-planar imaging: A systematic review and meta-analysis](#). *J. Magn. Reson. Imaging*. 2020; 51:1086-1102, with gradient-recalled echo (GRE) sequences, a magnetic field of 3T was associated with higher technical failure rates than was 1.5T
 - MRE conducted with SE-EPI sequences showed a lower technical failure rate than GRE sequences; the pooled proportion of technical failure under SE-EPI MRE was 2.0% and mostly due to human error
 - Skill is needed to obtain good scanning results; the Profile will be updated with a recommendation to use SE-EPI sequences at 3T
- Dr. Pepin will make updates to protocol for usability and clarity and the 2021 maintenance draft will be distributed to MRE BC members for feedback upon completion

Discussion on Plans for Moving toward Stage 3: Technical Confirmation (TC)

- Requirements for TC were reviewed with reference to the [TC Process page](#) of the QIBA Wiki
- The three phases include Planning, Soliciting Feedback, and Feedback after Publication
- Dr. Pepin to oversee the feasibility testing process as Field Test Leader; participating sites should include actors with MRE experience

- Volunteers included:
 - M. Rehan Khan, MD (Hunter Holmes McGuire VA Medical Center – Richmond, VA)
 - Alexander Guimaraes, MD, PhD (Oregon Health and Sciences University)
 - Suraj Serai, PhD (Children’s Hospital of Philadelphia)
 - Michael Middleton, MD, PhD (University of California, San Diego (UCSD))
- Dr. Zahlmann, QIBA Vice chair and QSIC Chair, emphasized the importance of the TC step in Profile development
 - The checklist should have been finalized, i.e., scientific debate concluded, during the consensus process
 - If a site were to follow the checklist requirement, then the Profile Claim should hold
 - Since regulations may differ by country, international users to be encouraged to provide input on Profile requirements
- Checklists will be distributed to sites, along with the request for feedback; the target completion is Summer 2021

Educational Outreach/Engagement with the Imaging and Clinical communities on Liver MRE QIBA profile

- Goals of the 2021 QIBA Campaign include encouraging educationally oriented presentations to non-radiology organizations and increasing visibility of QIBA
- Suggestions were requested and the following feedback was provided:
 - Topics to include instruction on how to properly perform exams, how to conduct analysis, draw ROIs, etc.
 - Instructional videos may be brief (1 – 3 minutes) and focused on only one aspect
 - Clips from past lectures could be incorporated into new content
 - There should be consideration that audience may include a variety of roles, e.g., radiologists, technologists working directly with patient, vendor outpatient trainers, etc.
 - Vendors may be invited to provide feedback on the educational content
 - Pharma representatives may be interested in learning about the availability of MRE, and how to decide when to use MRE
 - Site training for trialists would be helpful
 - The Pharma Imaging Network for Therapeutics and Diagnostics (PINTaD) suggested as a target audience
 - High quality educational material to be posted as a resource from which the general community (with a variety of perspectives) would benefit; this initiative is an opportunity to promote the QIBA brand
 - Educational videos would help sites to learn how to properly use the Profile, encouraging broader implementation
 - Hands-on educational media (e.g., additional types of learning resources) are needed to complement the existing breadth of print/text materials
- Dr. Pepin to ensure that methods and main messages are consistent; it is anticipated that users will appreciate shorter products
- It was agreed that publishing the MRE checklist via new media (e.g., online form, etc.) would be very helpful
- There was enthusiasm re: a QIBA partnership with Resoundant
- Suggestion to consider working with organizations that create entertaining, yet professional, educational content and adapt material for international audiences
- A request for volunteers to create educational content and a list of topics to be distributed to MRE BC members
- In discussion, it was confirmed that the MRE Profile being increasingly referenced as a guideline in clinical trials