

QIBA Dynamic Contrast-Enhanced (DCE) MRI Biomarker Committee (BC) Call

Monday, July 6, 2020 at 11 am (CT)

Call Summary

In attendance

Caroline Chung, MD (Co-Chair)

Wolter de Graaf, PhD

Nancy Obuchowski, PhD

RSNA staff

Joe Koudelik

Hendrik Laue, PhD (Co-Chair)

Hyunki (Harrison) Kim, PhD, MBA

Mark Shiroishi, MD

Susan Stanfa

Ryan Bosca, PhD

Review of the [DCE-MRI Profile](#) continued

- Remaining outstanding comments were reviewed and addressed

3.5: Periodic QA

- The availability of a phantom was noted, but additional details were moved to Appendix E
- The specification table was reviewed

3.6: Protocol and Reconstruction Design

- Dr. Bosca conducted an imaging comparison using compiled T1 mapping data (i.e., results of the Round 4 NIBIB funded parallel imaging study)
 - There were concerns re: setting limits on T1 mapping
 - A particular phantom has not been recommended; limits would need to be based on the phantom the Profile user utilizes
 - It was noted that the DCE body phantom and ISMRM phantom have different biases and variants
 - Specifying simple criteria for the DCE body phantom was challenging, due to the substantial range of bias for T1/R1
 - Another caveat is the Phantom Laboratory manufactures only the shell; slight differences in the internal vial solutions developed by manufacturers would be a source of bias across phantoms
 - It was recommended that the user validate vial solution concentration using a gold standard method such as variable T1 and use that as ground truth
 - A value cannot currently be set; recommendation to await suggestions received during public comment
 - Only high-level information to remain in this table
- The R1 phantom manuscript and link to the automated software on the QIDW is included
- Details re: phantom imaging for R1 can be found in Assessment Procedure 4.1
 - Phantoms with a range of 24 ms⁻¹ to 1330 ms⁻¹ shall be used
- Dr. Chung cleaned up the text in this section; details on signal linearity were moved to Appendix G: Acquisition Protocol

3.7: Subject Selection

- The QIBA DCE-MRI committee acknowledged that there are potential risks associated with the use of gadolinium-based contrast media
- Because the gadolinium-based contrast dosage is a clinical (site) decision, specifics are not included; it is also not required for meeting Profile Claims
- In efforts to avoid frequent Profile updates, links to more specific, or apt to change material are included
- Dr. Shiroishi agreed to reach out to Dr. Wu regarding this section; feedback expected from the public comment phase will also be useful

3.10: Image Data Reconstruction

- Parallels with the DWI Profile were sought in re: to the specification table
- It was noted that coil sensitivity has a significant impact on quantification; Dr. Laue added the text, “coil sensitivity profiles should be included into the reconstruction”

3.11: Image QA and 3.12: Image Distribution Sections were briefly reviewed

3.13: Image Analysis

- Updates were made to the specification table
- Requirements for the parameter: ROI determination were updated to specify that the ROI should be stored
- Requirements for the parameter: K^{trans} analysis were revised (Actor: Image analysis tool (no specific tools are provided))
 - Software performance should be evaluated using the QIBA DRO at baseline and after any major software upgrade to ensure consistent results (Appendix C)
 - The K^{trans} map or parameters for a ROI based curve must be calculated with the validated software and stored
 - The same software should be used across all time points for the same patient to evaluate change over time

3.14: Image Interpretation

- Determination of suitable tumor lesions subsection was reviewed and updated

Section 4.1 Assessment Procedure: R1/T1 Mapping accuracy and signal saturation

- Reference to the 3.11: Image QA section to be added to the T1/R1 phantom imaging subsection
- 4.1.3 Discussion on B1 mapping subsection
 - Although no solution is currently available to make B1-mapping correction feasible for all Profile users, B1-mapping was the main purpose of the Profile v2.0 and must be addressed
 - Explanatory text was added, noting that B1-mapping is highly recommended and improves results, but due to missing information, it could not be required in the Claims
 - Vendors may eventually make it possible for all to perform B1 correction
 - Dr. Chung to continue working on this subsection

4.2: Assessment Procedure: Image Analysis Software

- This section was significantly shortened and details were moved to Appendix G

Appendices

- Dr. Laue to continue working on Appendices and aims to complete review during the July 20 call

Next call: Monday, July 20, 2020 at 11 a.m. – 1 p.m. (CT) **[2-hour call]**

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