

QIBA Process Committee
Wednesday, October 5, 2016 at 3 PM CDT
Call Summary

Attendees:

Kevin O'Donnell, MASC (Chair)
Daniel Sullivan, MD (Co-Chair)
Cathy Elsinger, PhD

Brian Garra, MD
Edward Jackson, PhD
P. David Mozley, MD

Nancy Obuchowski, PhD
Eric Perlman, MD
Nicholas Petrick, PhD

RSNA Staff:

Joe Koudelik
Julie Lisiecki

Discriminatory Claim Discussion for SPECT BC Profile (Dr. Mozley)

- Goal of this discussion was to revisit the use of a discriminatory claim in a QIBA Profile with specific directive (but not uniquely) to the SPECT BC
- Since some bias characteristics (e.g. measurement precision and between subject variability) are unknown, concern was expressed about drawing conclusions related to clinical utility and therefore a discriminatory claim may be outside the scope of QIBA
- Dr. Mozley emphasized that two of the SPECT BC claims (one longitudinal and one cross-sectional) conform to QIBA standards and that substantial research data are available to support these claims
- Group is trying to determine how to bridge a technical conformance claim to a clinical discriminatory claim
 - For many QIBA groups, finding test-retest data to support cross-sectional claims is proving difficult, whereas there is abundant data to support the proposed discriminatory claim around a clinical-cut-point
- There was a perception that the proposed discriminatory claim is not a quantitative measurement of performance, but may be considered a correlation of an observation
 - Level of proof is needed, as there is an error gap between observations and conclusions
 - The inclusion of a discriminatory claim within a QIBA Profile must be reconsidered; might another product for delivery of this information, such as a white paper, be more appropriate?
 - Consider what does the QIBA Profile accomplish with a discriminatory claim

Outcome

- As this is a departure from the standard QIBA Process, this NM CC and the QIBA Steering Committee will be asked to vote on the Profile Open Questions:
 - Would the SPECT Profile be hindered if the discriminatory claim was removed?
 - What would the effect be of a "claim-confirmed" Profile?
 - Is there a reference procedure?
 - Could this document translate to a UPICT protocol?
 - The UPICT protocol does not contain a quantitative statement
- The Profile, as it stands now, will be presented to the QIBA Steering Committee on October 20th

Public Comment Formatting Options

1. The Profile could be released as is, including the discriminatory claim, requesting feedback
2. The discriminatory claim could be moved to the “Open Issues” Section of the Profile
 - Details from the discussion on this Process Committee call could be included in a brief introductory statement, requesting feedback

Next Steps

- Feedback via email will continue amongst those on this call through the upcoming weekend in order to move forward on Monday, 10/10
- Dr. Mozley would like a firm answer from Process Committee leaders by Monday, 10/10, so that he may move forward with plans for the Profile
- The Steering Cmte will be apprised of this discussion regarding proposed use of a discriminatory Claim
- The NM CC and SC will vote on whether to release the SPECT Profile for Public Comment
 - RSNA staff to prepare list of QIBA NM CC members with voting privileges for upcoming vote to consider release of the SPECT Profile for Public Comment

Next Calls: Wednesday, October 19, 2016 at 3 PM CDT – Process Committee

Thursday, October 20, 2016 at 10 am CT - SPECT Profile with QIBA Steering Committee