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Why We Need an Amyloid PET QIBA Profile for Research and Clinical Care

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QIBA MISSION

Improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, sites, patients, and time.

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Timothy J. Hall, PhD

QIBA Chair

In My Opinion

Why We Need an Amyloid PET QIBA Profile for Research and Clinical Care

By NORMAN L. FOSTER, MD

Alzheimer's disease (AD) is a Grand Challenge facing our society in the 21st century. The lifetime risk of AD at age 45 is one in five for women and one in ten for men. AD is the *only one* of the top ten leading causes of death in the U.S. that is increasing in prevalence without a prevention or cure. Unless more effective treatments are found, the health care costs of AD in the U.S. will grow to \$1.1 trillion by 2050. Amyloid PET imaging is a spectacularly successful biomarker addressing this challenge. The three FDA-approved amyloid tracers quantitatively correlate 95-100% with postmortem neuropathology. This correspondence is so good that amyloid PET has become the gold standard for judging AD biomarkers. Amyloid PET results are incorporated into National Institute on Aging-Alzheimer's Association (NIA-AA) clinical diagnostic criteria and NIA-AD research framework.

The availability of such an accurate and specific quantitative imaging biomarker as amyloid PET is a significant unexpected achievement and should be thoughtfully utilized in clinical care and research. Amyloid PET proves that it is possible to diagnose AD *in vivo*. Misdiagnosis is especially common in neurodegenerative diseases that are by their nature complex and heterogeneous.

Without access to accurate diagnostic tests, patients and their families too often are forced to endure a prolonged diagnostic odyssey and yet fail to get a definitive evaluation. It is no wonder that outcomes are often less than ideal. Without a clear and confident diagnosis, treatment may be misguided and at worst, harmful. Lack of provider diagnostic confidence is common, delaying treatment and inhibiting education and support for patients and families. Lack of patient confidence in the diagnosis also is

common and contributes to poor follow-up and treatment adherence. The variability of clinical visual interpretation of imaging is easily documented and contributes to diagnostic uncertainty. While most imaging currently is not biomarker quality and intended only for visual interpretation, with modest additional effort, quantitative data can be extracted from an image allowing objective, pixel-by-pixel statistical comparison with a reference population. Clinicians need not fear quantitative image analysis; supplemental billing codes that insurers recognize are available for reimbursement of this additional effort. As clinical trials and diagnosis move earlier, objective methods can decrease the frequency with which assessments are ambiguous or indeterminate. High accuracy provided by quantitative imaging and QIBA Profile quality standards are not too much to ask when dealing with the diagnosis of a life-changing dementing disease.

Amyloid PET also has conclusively proven that AD pathology can be effectively treated. Once only theoretical, serial amyloid PET scans have shown that multiple anti-amyloid immunotherapies show quantitative reduction of amyloid plaque with PET. While convincing evidence still is needed to show the clinical efficacy of this reduction in AD pathology, quantitative amyloid PET has been essential to objectively detect slowed rates of amyloid accumulation and amyloid burden reductions within a short timeframe. This use of quantitative amyloid PET can only be expected to increase as many similar treatments using AD pathology as an outcome are in the pipeline and being tested. A clinical trial of Donanemab illustrates how these drugs might be used in clinical practice. The trial applied an innovative strategy using quantitative amyloid PET to decide whether quantitative amyloid PET has returned to normal, and treatment can be discontinued. This objective method of knowing when an expensive and burdensome therapy can be safely terminated likely is a preview of future clinical AD and dementia treatment paradigms. The development of Centiloids as a universal measure of brain amyloid burden means that comparable quantitation can be achieved with any amyloid PET ligand.

Clinicians share with imaging centers the responsibility for the accurate interpretation of biomarker results. Any biomarker by itself cannot make a diagnosis. Integrating clinical evidence obtained from a detailed history

and focused examination is a precondition for selecting patients receiving amyloid PET scans and interpreting biomarker results. Prior probability of a positive test result strongly influences the statistical characteristics of a test and are a strong caution against the indiscriminate use of amyloid PET. Appropriate use criteria for the clinical amyloid PET imaging have been published, as have the ethical guidelines for providing amyloid PET results to patients. Clinicians don't control imaging biomarker measurement; that is the responsibility of specialists at imaging centers. However, clinicians determine the information provided to imaging centers and must consider the clinical context and the relevant question that amyloid PET will answer.

Utilization of the QIBA amyloid PET Profile is not just a niche topic. With the increased emphasis on early diagnosis and advancement of new treatments that require highly confident and specific diagnosis, quantitative amyloid PET is needed. The accelerated approval of Aducanumab to treat AD has spurred discussion about the lack of diversity in clinical trials and the lack of equity in access to care. Addressing inequality in AD research and care will require community involvement, including the capability of performing quantitative amyloid PET imaging in more than just research centers. The lack of clinical reimbursement for amyloid PET has prevented clinicians from providing high quality dementia care and unnecessarily inhibited our understanding of the prevalence of AD and the effect of complications and co-morbidities. Substantial evidence showing the clinical value of amyloid PET has accumulated since the last CMS review for reimbursement. While we await CMS to reconsider its restrictive national coverage decision for clinical amyloid PET and continue to test new drug treatments, the nuclear medicine community would be well advised to adopt the QIBA amyloid PET Profile as part of its standard operating procedure. Only in this way can we best address medicine's generational challenge of better care for dementing neurodegenerative diseases.



Norman L. Foster, MD

Norman L. Foster, MD is a geriatric and cognitive neurologist who has specialized in brain imaging, clinical trials and the care of dementing neurodegenerative diseases for over 30 years. He was raised in Jacksonville, Illinois and received his BA degree in chemistry and biology summa cum laude from MacMurray College. After he received his MD degree from Washington University in St. Louis, he completed a medical internship at Jewish Hospital in St. Louis and a neurology residency at the University of Utah in Salt Lake City. Following a three-year fellowship at the National Institutes of Health, he joined the faculty of the University of Michigan where he rose to professor. In 2005, Dr. Foster's passion for improving Alzheimer's care brought him to the University of Utah, where he became the founding director of The Center for Alzheimer's Care, Imaging and Research (CACIR).



QIBA Promotional Videos

During the April 2022 in-person QIBA Steering Committee meeting at RSNA headquarters, several QIBA volunteers recorded QIBA promotional videos. These videos are now available on the [RSNA YouTube channel](#) via the QIBA Playlist: <https://tinyurl.com/QIBA-YouTube-Playlist>, and will be used in other social media applications such as LinkedIn for promotional purposes. QIBA Leadership invite members to “like” and share these videos through LinkedIn or Twitter. We hope to reach new volunteers through these videos, educate the imaging community regarding the benefits of quantitative imaging, and grow the QIBA community.

Additional videos will be posted soon. QIBA would like to express its gratitude to the volunteers who participated in the recordings and to the RSNA Public Information and Communications department staff, who were instrumental in overseeing the production of these videos.

#QIBA #RSNA #QI

QIBA Volunteer Page

QIBA is seeking volunteers to assist with a variety of ongoing and new committee projects. Details about specific opportunities will be posted as they arise. We will promote these volunteer opportunities on one or more QIBA platforms including [LinkedIn](#), [wiki](#), and the [QIBA Newsletter](#). Future signup sheets may look like this: [Google sign up form](#).

We hope this [new platform](#) will help biomarker committee leaders recruit additional help for new or ongoing committee tasks or projects.

To ensure that volunteers with the necessary experience are engaged, please provide a **brief description** to qiba@rsna.org and answer the

questions below for each volunteer opportunity you would like to be posted.

Please provide the following details:

1. Title and short description of the task or project.
2. Time commitment/duration: How many hours? Weeks? Months? For example: *one hour per week for __ amount of time.*
3. How many volunteers are needed?
4. Does your volunteer need to be an active QIBA member with previous QIBA experience?
5. What, if any, type of subject expertise is required?
6. What career stage would be helpful, for example, senior, mid-career, or junior?
7. Any other requirement(s)?

QIBA Acknowledgments Page

This page has been created for QIBA Leadership to acknowledge the biomarker committees and Profile authors and editors that have advanced Profiles. We realize that producing Profile takes dedication and hard work from many volunteers working together. We hope to be able to better recognize these efforts. Thank you.

QIBA Activities

QIBA Biomarker Committees are open to all interested persons. Meeting summaries, the [QIBA Newsletter](#) and other documents are available on the QIBA website RSNA.org/QIBA and wiki <http://qibawiki.rsna.org/>.

QIBA Resources:

- [About QIBA](#)
- [QIBA News](#)
- [QIBA Webpage](#)
- [QIBA Wiki](#)
- [QIBA Biomarker Committees](#)
- [QIBA Organization Chart](#)
- [QIBA LinkedIn page](#)

Please contact qiba@rsna.org for more information. We welcome your participation.

QIBA and QI/Imaging Biomarkers in the Literature

***Please note that the list of references has been migrated to EndNote.**

***To obtain access to the RSNA EndNote citations, please send an email request to: qiba@rsna.org.**

The list of references showcases articles that mention QIBA, quantitative imaging, or quantitative imaging biomarkers. In most cases, these are articles published by QIBA members or relate to a research project undertaken by QIBA members that may have received special recognition.

New submissions are welcome and may be directed to qiba@rsna.org.



For more information: <https://www.rsna.org/annual-meeting>