

Executive Summary of Meeting Report: Quantitative Imaging Workshop XIII: Lung Cancer, COPD and Cardiovascular Disease- Exploring the Intersections

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On June 13 and 14, 2016, the Prevent Cancer Foundation convened the thirteenth annual Quantitative Imaging Workshop in Bethesda, MD. This interactive, cross disciplinary forum assembled oncologists, radiologists, federal researchers and administrators, biopharmaceutical and imaging industry leaders, members of relevant professional societies, computer and imaging scientists and representatives from leading advocacy organizations to explore the use of quantitative CT scanning as a tool for evaluating response to new therapies. The second area of focus was early detection by spiral CT, done in a more consistently precise fashion. In light of the recent Centers for Medicare and Medicaid Services' national coverage determination to support reimbursement for lung cancer screening, discussion was focused on the process of ensuring high quality and efficient lung cancer screening management. A key aspect in that regard involves the use of quantitative CT to accurately determine the volume of suspicious pulmonary nodules on screening CT images, since larger nodules are more likely to actually be malignant lung cancers. Algorithms for lung cancer screening management now routinely involve the determination of lung nodule size to decide whether or not to initiate an invasive diagnostic work-up.

In the keynote address of the Workshop, Dr. Kish Chakrabarti of the Food and Drug Administration reviewed how the process of quality control for breast cancer screening mandated by the FDA evolved and outlined how that process resulted in higher quality breast cancer screening. However, he pointed out that mammography has not involved the use of quantitative imaging; therefore he underscored the importance of the goal of the current Workshop in proactively developing new approaches that are specific for the complex challenges presented by the national implementation of lung cancer screening.

Workshop XIII also continued the tradition of recognizing outsized contributions to improving lung cancer outcomes by the awarding of the James L. Mulshine, M.D. Leadership Award. Former Secretary of Defense, Chuck Hagel, and the Dean of Global Health at New York University, Professor Cheryl Heaton, presented the 2016 award to Laurie Fenton Ambrose, CEO of the Lung Cancer Alliance, for her brilliant leadership in securing Centers for Medicare and Medicaid Services reimbursement for lung cancer screening in heavily tobacco-exposed individuals. , In a multi-year process, Ms. Fenton Ambrose organized a remarkably broad coalition of advocacy groups, professional societies and other institutions to advance the field of lung cancer.

Workshop XIII maintained the precedent of driving innovation and broad cross-disciplinary inclusion. Areas of concentration for 2016 included defining a national quality process of implementing lung cancer screening. Preliminary work on such quality standards has been performed in collaboration with the Quantitative Imaging Biomarker Alliance (QIBA) of the RSNA and in consultation with researchers from the Food and Drug Administration and the National Institute of Standards and Technology.

An innovative example of this focus was presented at the Workshop by Ricardo Avila, using crowd sourcing to evaluate variability in imaging devices used for lung cancer screening. This process involved using a simple reference object to evaluate the performance of CT scanners at screening sites, to ensure that the scanner detectors and the acquisition parameters are functioning at an appropriate level of performance to enable the desired quantitative evaluation of suspicious pulmonary nodules. This quick, inexpensive quality control measure for quantitative imaging ¹ (as described in the attached report by The ASCO Post) is unprecedented and discussions are ongoing with leaders from the imaging group at the FDA to consider rapid scaling of this

process improvement innovation which could be applied for both screening and for drug response assessment.

In subsequent presentations, Dr. Thomas Baer outlined the opportunity with quantitative imaging in lung cancer screening was a great example of applied photonics. Photonics is the science of the generation, transmission and control of light and the cornerstone of a vibrant area of innovative technology from computers, to lasers and across medical instrumentation. Dr. Baer reviewed the contribution of photonics technologies such as quantitative CT imaging to the War on Cancer and discussed how applied imaging could drive the next level of progress in improving cancer outcomes.

Previous Workshops have included a number of presentations on the ability of thoracic CT to also detect early tobacco-induced diseases, such as coronary artery disease and chronic obstructive pulmonary disease (COPD) in the course of lung cancer screening. A panel that included imaging and biopharmaceutical leaders considered how this opportunity to find the pre-symptomatic phase of the three most lethal diseases in our society could also be developed as a venue for integrated drug development. A key question was whether there were defined molecular targets that were relevant across the three diseases and then how the complex regulatory issues could be addressed to enable such research.

A number of presentations addressed technical issues with using imaging with large data analysis not only for quality control, but also for algorithm development, especially in regard to the other prevalent tobacco-related diseases. These issues were integrated into the discussions of the Breakout groups which proposed that developing a national infrastructure to house quantitative images would be an opportunity to ensure consistent quality with the imaging measurements. Expanding on the crowd sourcing experience presented at the Workshop, real-time monitoring of image acquisition quality can be performed using a national cloud-based infrastructure so that the subject does not leave the imaging suite until an image is acquired with sufficient quality to allow accurate nodule measurement. Other commercial quantitative imaging tests have already been proposed to the FDA with similar real-time monitoring approaches.

Such a real time acquisition monitoring approach would also facilitate broadening this more accurate approach to quantitative imaging to the pulmonary and cardiac imaging areas. The second breakout group focused on exploring how the issues with quantitative imaging with lung cancer screening are a use-case demonstrating the value of imaging and related photonic technologies in accelerating progress in the “War on Cancer”. An action item from that group was to engage with representatives from Vice President Biden’s “Moonshot Initiative” to advocate for inclusion of photonic innovations as a key part of catalyzing rapid progress in improving cancer outcomes.

Reference:

¹ McNeil, C. As Low-Dose CT Screening Moves Into the Clinic, Implementation Issues Move Up on the Agenda. ASCO Post, July 25th, 2016