QUANTITATIVE IMAGING WORKSHOP XVIII:

Optimizing Thoracic Imaging to Detect and Manage Early Lung Cancer/COPD

November 4-5, 2021 | Virtual

INTRODUCTION:

This document is a summary of the 2021 Quantitative Imaging Workshop, which was a multi-disciplinary Zoom-delivered workshop to address current issues with the integration of quantitative imaging analyses into the screening detection and management of early lung cancer. This is the 18th year that the Prevent Cancer Foundation® has hosted this forum, and for the last two years the American Lung Association has joined as co-host.

The intent of these workshops has been to accelerate the use of quantitative assessment to optimize the lung cancer screening process. However, over the last decade it has become evident that the screening CT scans performed in this older, tobacco-exposed cohort also frequently show X-ray findings of other tobacco-related diseases, especially emphysema. Therefore, the main focus of this Workshop is how to continue to advance the use of lung cancer screening while more systematically leveraging the information about emphysema occurrence in a responsible and productive way to enhance the health benefit of thoracic CT screening.

Newly expanded Medicare eligibility for lung cancer screening may result in rapid growth in the uptake of this screening service, at a time when innovations with advanced imaging analysis tools for thoracic CT also are emerging. In an ideal world, this could result in extracting more comprehensive information about the medical consequences of tobacco exposure for individuals undergoing screening. In the 2021 Workshop, we analyzed the prospects for this dynamic from policy, clinical and technical imaging perspectives across panels of experts for each topic.

As outlined below, we had five sessions, moving from an introduction of the Workshop, to dedicated sessions on each relevant Workshop topic. For each session, you can explore a short, written summary of the content and then a YouTube video link to the Zoom recording of the session. In general, each session starts with an overview and then moves to a discussion across our participating expert panel, followed by a joint discussion. In addition, slides to all of the available Zoom presentations are available on the Prevent Cancer Foundation website.

In closing, we would like to thank all of the faculty and participants of this Workshop for allowing us to assemble this timely and relevant material, as well as the sponsors and administrators who have enabled this information to be available for broader sharing. In these efforts, we all share a deep desire to improve health outcomes as rapidly as possible for these lethal thoracic diseases.

The video link to each specific session is provided at the end of the corresponding section below:

SESSION ONE: WELCOME, KEYNOTE ADDRESS, & NATIONAL LEADERSHIP AWARD

WELCOME & OVERVIEW

Carolyn R. ("Bo") Aldigé, Prevent Cancer Foundation

Carolyn R. ("Bo") Aldigé, President and CEO of the Prevent Cancer Foundation, welcomed the speakers, co-chairs, panelists and participants to the 18th Annual Quantitative Imaging Workshop.

The relationship between the topic of this year's workshop, "Optimizing Thoracic Imaging to Detect and Manage Early Lung Cancer/COPD," and COVID-19 was acknowledged. Appreciation was expressed for the contributions from scientists, researchers and health care workers toward COVID-19 with regards to vaccination, treatment and frontline care.

The steering committee, sponsors, staff, supporters and friends were thanked for their tireless efforts throughout the year to bring about this comprehensive workshop.

The steering committee is comprised of people with unique perspectives and expertise from a range of disciplines, institutions and geographical areas. James L. Mulshine, who led the group, is the Scientific Director of Prevent Cancer Foundation and has an unwavering passion and years of experience in lung cancer screening. Other members of the steering committee are Ricardo Avila, Raúl San José Estépar, Anita McGlothlin, Bruce S. Pyenson, Albert Rizzo and David Yankelevitz.

The conference sponsors were acknowledged. The gold sponsor was the American Lung Association and silver sponsors were Johnson and Johnson, Median Technologies and the International Association for the Study of Lung Cancer.

The Prevent Cancer Foundation staff, who were involved in the full range of administrative support, were Jody Hoyos, Karen Peterson, Lisa Berry Edwards, Adrienne Harkness, Liz Hall, Sarah Mahoney and Becca Ginns.

The Prevent Cancer Foundation runs its activities throughout the year and can be found on Facebook, Twitter, Instagram, LinkedIn, Discord and TikTok.

James L. Mulshine, M.D., Rush University Medical Center

Dr. James Mulshine, a professor at Rush University, where he has served as associate provost and vice president for research, as well as acting dean of the Graduate College, provided the conference overview. Prior to joining Rush University, he was at the National Cancer Institute for 25 years, where he was on the research faculty. He is an international expert on lung cancer and currently is serving as the Scientific Director of the Prevent Cancer Foundation.

Dr. Mulshine provided insight into the 18 years of convening the Quantitative Imaging Workshop, the goals of the Workshop, the current state of lung cancer and COPD screening and the proposed potential action items which may result from this workshop.

Goals of the Workshop:

- Review the status of detecting and managing early tobacco related disease with thoracic CT
- Explore how social determinants of disease can help morph cancer screening from early cancer detection into a more personal-centric "health check," with physical activity as an example of a health intervention
- Define strategies for sustained screening uptake in the current national transition to a population health model of health care reimbursement

- Develop reliable, accessible imaging acquisition quality processes to support the development of quantitative tools for early thoracic disease detection and management, using well characterized CT images and clinical follow-up data.
- Define process for analysis and reporting tools embedded in routine clinical work flows to guide the management of CT-detected early thoracic disease, especially regarding the intersection of lung cancer and COPD.

Current State of Lung Cancer and COPD Screening:

Lung cancer screening is gaining acceptance; however, the uptake of this tool is just over 6% nationally. There are many potential barriers preventing an increase in uptake including: acceptance of favorable screening benefits to harms ratio, cost effectiveness, structural social barriers, access to quantitative tools to extract medically relevant information from thoracic CT, and more recently, the safety concerns due to the ongoing COVID-19 pandemic. Due to these barriers, the rate of uptake of this beneficial screening service is being slowed. The use of quantitative image analysis in the lung cancer screening process provided important benefits, such as lowering the false positivity rate while preserving high diagnostic sensitivity, assessment of diagnostic aggressiveness using growth rate, quantitative measurement of other imaging biomarker features and improved characterization of additional thoracic diseases from radiomic analysis of the thoracic CT. This additional diagnostic information provided by more comprehensive analysis of the acquired LDCT screening is emerging as a key tool to advance the earlier diagnosis of pre-symptomatic COPD, which is currently the 4th leading cause of premature death in the U.S.

Since the diagnostic imaging features for lung cancer and COPD are quite different due to the unique features for these two diseases, there is an urgent priority to optimize image acquisition and analysis for both lung cancer and COPD without inadvertently compromising image analysis performance for either disease. To this end, it is beneficial to consider the previous work by members of two Quantitative Imaging Biomarker Alliance (QIBA) profile groups (COPD and Small Nodule Profile) to optimize the quality of CT imaging of COVID-19. This effort laid the foundation for an optimal quantitative assessment of COPD from images acquired for lung cancer screening.

The new U.S. Preventive Services Task Force recommendations for lung cancer screening increased the pool of eligible individuals by 50%. Now the pool of individuals eligible for lung cancer screening has increased from nine to 14 million. Given the workforce implication of this larger pool, improving screening efficiency by moving to standardized processes and integrating computational tools to catalyze relevant information extraction from the thoracic CT scans within the constraints of clinical workflows emerge as critical priorities.

Accordingly, an important topic explored during the Workshop was the opportunity to integrate preventive interventions to pre-empt the progression of early COPD, as well as subsequent lung cancers. Such preventive measures include smoking cessation, increasing physical activity and improving diet, as well as adapting existing COPD management strategies. Other relevant research opportunities in this setting include evaluating for targeted-drug therapy research (i.e., anti-inflammatory or other precision medicine strategies) for early thoracic disease pre-emption or prevention.

To further improve the delivery of screening management as well as health outcomes with the screening process, in the Workshop we further considered possible future options leveraging the quantitative information

that can be extracted on an annual basis from longitudinal screening of this high risk for thoracic disease cohort. Given high quality imaging data along with routinely followed clinical parameters, this setting is ideal to develop informative signatures for early thoracic disease detection, leveraging artificial intelligence and other advanced computational tools.

Therefore, there are several possible action items that would be important to consider, including:

- Reconsider the benefits/harms relationship for LDCT screening if the early detection of asymptomatic COPD is considered a routine outcome of the thoracic imaging during the lung cancer screening encounter
- Advocate for the inclusion of early COPD detection with LDCT screening to allow enhanced intervention efforts for smoking cessation and for increased physical activity to mitigate progression of COPD and lung cancer
- Write a radiology editorial on the pragmatic benefit of separating the CT image data required for radiologists' visual review from the larger, non-processed CT imaging data needed for optimal computer quantitative analysis review
- Propose a technical CT imaging approach for image quality processes, as well as a harmonized standardized report structure for the integrated thoracic CT screening for lung CA and COPD
- Report on the possibility for significant progress in developing advanced computational tools, such as with artificial intelligence, that could improve the reliability, accuracy, efficiency and economy of thoracic CT screening and the requirement to engage relevant stakeholders to support such efforts

Link to session recording: https://www.youtube.com/watch?v=1Me07mBr6R4

KEYNOTE ADDRESS: EXERCISE FOR PRIMARY PREVENTION AMONG PATIENTS RECEIVING LUNG CANCER SCREENING

Kathryn H. Schmitz, Ph.D., MPH, FACSM, FTOS, FNAK, Penn State College of Medicine

Speaker Introduction: Dr. Kathryn H. Schmitz is a distinguished professor of public health at Penn State University Medical College and Penn State Cancer Institute. She has been working in the areas of physical activity for her entire career an exercise physiologist.

Summary: Dr. Schmitz presented multiple publications demonstrating the importance of exercise for cardiovascular health, including to reduce risk of lung disease. Both increased cardiovascular health and muscle strength correlate strongly to lung health.

Dr. Schmitz proposes the referral of patients in the lung cancer screening population to exercise programs. The concept that exercise can be part of standard of care and prescribed as a medication is emerging. The data is vast and long-standing, with precise data to show dosage of exercise as it relates to outcomes. A FITT prescription precisely indicates frequency, intensity, time and type of exercise that a patient should perform.

While data strongly show that exercise reduces risks, additional research would help to show how exercise can improve outcomes for lung cancer and COPD after diagnosis by thoracic CT. Changes in policy, stakeholder awareness, program development, workforce development and research can accelerate the degree to which exercise can be more fully integrated into health care systems.

Link to session recording: https://www.youtube.com/watch?v=sJz7Sub4K_0

2021 JAMES L. MULSHINE, M.D. NATIONAL LEADERSHIP AWARD

Introductory Remarks: Claudia I. Henschke, Ph.D., M.D., Icahn School of Medicine at Mount Sinai

Award Recipient: Mary Pasquinelli, DNP, APRN, FNP-BC, CTTS, University of Illinois Hospital and Health Science System

Dr. Mary Pasquinelli was awarded the 2021 James L. Mulshine, M.D. National Leadership award for her work to advance lung cancer screening through screening participant engagement, research and publications.

Dr. Pasquinelli has been a practicing nurse since 1985 and received a doctorate in nursing practice from the University of Illinois at the Chicago College of Nursing in 2018. Through her work providing care for HIV patients receiving bone marrow transplants she realized the importance of providing outstanding health care in diverse and often disadvantaged community settings. In 2015, she became the principal investigator of an IRB approved study on health disparities assessment in the lung cancer screening program which she established at the University of Illinois Medical Center. This activity reflected her long-standing interest in improving health outcomes in challenging settings. Currently, she serves as the director of the lung cancer screening program and as a nurse practitioner for the pulmonary and medical oncology lung cancer service line at the University of Illinois Hospital. The University of Illinois screening center is housed in a federally qualified health center and serves an underserved community in the Chicago urban environment of principally older African Americans. She also has developed a dedicated lung nodule clinic which primarily evaluates pulmonary patients who are at high risk of lung cancer but also provides clinical care to medical oncology patients diagnosed with lung cancer.

Dr. Pasquinelli approaches her work with a global perspective and is involved in collaborations with groups around the world, including Cambodia, Guatemala, Tanzania and India. Based on her experience in launching the University of Illinois screening program, she provides substantive input to various local, national and international health care organizations, especially as it relates to the issues of women and minorities in the process of lung cancer screening. She has also published several important papers on screening optimization and given many talks about the screening experience, with special emphasis on health equity for this new cancer screening test. Her work and leadership also highlight the efforts of screening champions throughout the U.S. and the world. Medical professionals like her are succeeding against all odds and bringing the service forward.

Dr. Pasquinelli pointed out the importance of the contributions of Dr. Claudia Henschke, who is a previous National Leadership awardee and the presenter introducing Dr. Pasquinelli to the workshop participants. Dr. Pasquinelli noted that Dr. Henschke started the International- Early Lung Cancer Action Project (I-ELCAP) and that this multidisciplinary collaborative research team made numerous seminal contributions such as advancing knowledge regarding optimization of the lung cancer screening process, defining nodule characteristics associated with cancer, to defining a process for measuring nodule volume doubling-time, defining algorithms to decrease false-positive diagnostic rates, optimizing of screening intervals, and defining measures to improve mortality outcomes. These innovations are vital to the evolution of screening practices. In addition, the multidisciplinary framework of this workshop mirrors the broad scope of I-ELCAP activities and shapes its broad focus from public policy, advocacy, population health, equity, clinical, imaging and informatic to financial analysis, unifying all the communities required to drive

progress with the future evolution of lung screening as a transformational public health service.

Dr. Pasquinelli kindly acknowledged the work of Prevent Cancer Foundation through workshops, grants, research and education and thanked her multidisciplinary team at the University of Illinois, Chicago, for their support and guidance. Lastly, she thanked her co-authors for their guidance and mentorship; patients who put their trust in us every day; and the Prevent Cancer Foundation for recognizing and supporting her work.

Link to session recording: https://www.youtube.com/watch?v=tXEIEe_pEuo

SESSION TWO: WHAT IS NEEDED FOR THORACIC HEALTH TO FIT INTO POPULATION HEALTH?

HOW MEASUREMENT DRIVES POPULATION HEALTH MODELS

Moderator: Bruce S. Pyenson, FSA, MAAA, Milliman, Inc.

Panel Overview: This panel was about population health and discussed how thoracic health does and does not yet fit into population health efforts. The conversations focused on measurement and quantification on a grand scale and how the health of populations is affected and changed. Today's population health efforts are increasingly focused on public health outcomes, and these conversations followed that trend.

A Thoracic Health Straw Dog was created to center these conversations:

- Implementing widespread lung cancer screening will have large health benefits for at-risk populations—including identifying lung cancer at early, curable stages and diagnosing COPD and cardiac conditions earlier.
- Will provider organizations or communities be willing to take a risk for successful lung cancer screening in their populations?

The federal Medicare program has taken the lead in population health, and it has ~60 million beneficiaries in 2021. Medicare has two forms: 24 million beneficiaries are in Medicare Advantage (private insurance) and 36 million in fee for service (original Medicare). Among the fee for service beneficiaries, 12 million are in accountable care. When putting together those in Medicare Advantage and accountable care, the majority of beneficiaries are in some form of population health programs. [A Medicare Accountable Care Organization (ACO) is a group of providers who voluntarily work together to provide high quality managed care to Medicare fee-for-service (FFS) beneficiaries.]

The Center for Medicare and Medicaid Innovation (CMMI) has been key in sponsoring pilot programs. CMMI implements these programs based on financial and quality of care outcomes, therefore it is important to ask: "Does it make sense for advocates to attempt a thoracic health pilot through CMMI?"

Link to recording: https://www.youtube.com/watch?v=AMC-INHKza8

Mary Barton, M.D., MPP, Performance Measurement, National Committee for Quality Assurance

Overview: Mary Barton, M.D., MPP presented on how to hold health plans accountable using health care effectiveness data and information set (HEDIS) measurements.

Summary: HEDIS measures are used by over 90% of U.S. health plans, including both commercial and Medicare plans. 200 million people are enrolled in health care plans which report HEDIS data. HEDIS measures include 96 measures across six domains. Measures must be relevant to patients and providers, and must be scientifically sound, feasible to implement in the same way and auditable.

The data landscape has changed significantly in the 30 years since HEDIS measures were implemented. In the past five years, a new kind of measure has been created to look at electronic data systems, including electronic health records, registries, case management systems and claims.

The process NCQA goes through for creating a new HEDIS measure has several steps, including selection, development, public comment and review during the first year—without public reporting. There is then a vote to allow the measure to be publicly reported the next year. After it is released for public reporting, there is ongoing evaluation with the hope that measures will top out and be retired.

A HEDIS measure for colorectal cancer (CRC) screening was presented as an example of a cancer screening measure. The measure includes adults who are 50-75 years old, excluding those who are frail, or have advanced illness, colorectal cancer or total colectomy. The measure includes screening for CRC using various defined methods, including colonoscopy, occult blood test and more. The performance on this measure from 2010-2018 shows that Medicare plans are increasing performance at a much faster rate than commercial plans. In 2018, only ten commercial health care plans surpassed the measure goal, which is 80% of target population screened, whereas 105 Medicare plans surpassed the goal. The key to the measure leading to success and increased screening was an incentive program.

Link to recording: https://www.youtube.com/watch?v=56s4utsgdL8

Cory Gusland, FSA, MAAA, Milliman, Inc.

Overview: Cory Gusland, FSA, MAAA presented on Accountable Care Organization (ACO) perspectives and incentives and explains how ACOs think about their risk options when taking on a pilot program centered on population health interventions or health care screening.

Summary: It is important to understand a few key aspects about ACOs to understand how they take on risk:

- There is significant variation in ACO structure and characteristics which change the incentives and economics of the ACO.
- The population that an ACO is accountable for is typically broad and often includes cancer patients.
- ACOs are accountable for Part A and B services, but not Part D services.

The Centers for Medicare and Medicaid Services (CMS) define value in Medicare ACO programs by measurement of an ACO's performance against its benchmark. Financial benchmarks are defined by historical baseline expenditures and regional performance. The key thing to realize is that multiple years of experience are required to set a target, meaning that ACOs are competing against themselves in addition to other ACOs in their region. Another key consideration is that the baseline or benchmark period can move over time.

The risk and incentive options provided by CMMI or CMS to ACOs were reviewed and how they are tied to risk was explained. ACOs will usually select the options with the greatest opportunity for success without exposure to high risk.

Regarding implementation of thoracic screening, there are many competing opportunities for ACOs to reduce spending, and this screening procedure is not a focus. The incentives may be clear, but there are easier targets for reduced spending e.g., post acute care management.

Link to recording: https://www.youtube.com/watch?v=59KM.D.KfIXNA

Spencer Carrucciu, MPA, Oxeon Venture Studio, Oxeon Partners

Overview: Spencer Carrucciu, MPA presented on the framework for how the Center for Medicare and Medicaid Innovation (CMMI) brings value-based payments to different populations using payment and service delivery models.

Summary: CMMI is focused on three major goals: improve patient care, lower costs and better align payable systems to promote patent-centered practices. The center recently released a framework for how to achieve these goals. This framework uses the following tools/strategies: Driving accountable care, advancing health equity, supporting innovation, addressing affordability and partnering to achieve system transformation. These strategies are used to develop payment and service delivery models.

After 10 years, there are multiple lessons learned regarding transition to value using models. Models must have health equity embedded and must be streamlined to reduce complexity and overlap. Models should encourage long-lasting care delivery transformation and broad provider participation, where the ultimate end goal is for models to build upon each other to create the future health care system that all desire.

When moving to implement a model there are three major considerations: Is it scalable? Is it generalizable? Does it improve quality and lower cost? Additionally, there are considerations to ensure a model will achieve the set forth goals; these include funding, capitation, risk and flexibilities. These considerations help to determine whether a given intervention should be a model or a feature of an existing model. Building a new model requires implementing all model design elements. Building on existing models enables testing of smaller components on an existing chassis.

Link to recording: https://www.youtube.com/watch?v=K5oKpB1pvQY

Discussion: The discussion was first focused on whether lung cancer screening would be best implemented as a new program/model or as an addition to an existing program/model. Mary Barton commented that it would most likely be easier to add on to an existing program/model for sake of timeliness. Spencer Carrucciu agreed this is the best starting place and suggested the measure start as optional. This way it can be selected for the right patients and by the right providers because they see the value. Then, once operationalized, the measure can be scaled into a mandatory construct. Cory Gusland stated there is a case for either a new or existing model add-on and that current trends are moving toward consolidation and reduction of overlap for models. Therefore, an add-on would follow current trends.

Bruce S. Pyenson directed the discussion to the CRC screening example given by Mary Barton, pointing out that reimbursement is much higher from commercial plans than from Medicare Advantage plans. But, Medicare Advantage plans, which are subject to CRC HEDIS metrics and financial incentives, has been much more successful than commercial plans. The amounts paid to the providers did not directly impact the success of the measure. Mary Barton agreed and pointed out this is a key point of the example. She emphasized that it is important for HCPs to consider the variables they can control. In the CRC screening example, the HCPs had different CRC screening methods to use. CRC screening includes not only colonoscopy, but also FIT cards mailed to the home. Another way for plans to increase screening rates could be to increase their gastroenterologist network. Therefore, success of the measure did not directly tie into amounts paid to providers.

An audience question was posed to the group. The question was whether autonomous reading of new images can be used as a model for new lung cancer screening. Mary Barton pointed out that while this is an innovation, the current challenge of lung cancer screening is not so much related to reading of the scan but rather performing the scan. The group agreed and had no further comments.

Conclusion: Increasing the rate for lung cancer screening will require consideration of alternative payment models and development of measures to define outcome goals. The best approach for adoption will be to add lung cancer screening to an existing program/model rather than as a standalone program.

HOW ORGANIZATIONS OPERATIONALIZE POPULATION HEALTH

Moderator: Bruce S. Pyenson, FSA, MAAA, Milliman, Inc.

Panel Overview: Population health models can help to pinpoint how lung cancer screening can reduce cost, and this panel considered how lung cancer screening can fit into population health models.

Implementing widespread lung cancer screening will have large health benefits for at-risk populations—including identifying lung cancers at early, curable stages, and diagnosing COPD and cardiac conditions early. Will provider organizations or communities be willing to take risks for successful lung cancer screening in their populations?

The appeal of thoracic health and cancer downstaging are discussed as possible targets. However, there is concern that these may not be a priority for health care payers, who may be focused on other ways to reduce costs.

Link to recording: https://www.youtube.com/watch?v=p8Be5fAChtc

Jonathan B. Jaffery, M.D., MS, MMM, University of Wisconsin-Madison and UW Health ACO

Overview: Jonathan B. Jaffery, M.D., MS, MMM discussed a population health approach to screening.

Summary: Dr. Jaffery is the chief population officer at UW Health, where his work is focused on leading the transformation of the health care system away from the fee-for-services model of health care reimbursement to one focused on value-based care.

Dr. Jaffery's presentation focused upon an example from his work in 2013-2014. This example included poor performance scores for screening procedures, including fall risk, depression and potential conflicts in medications through reconciliation. Immediate changes were necessary to correct these poor performance scores before the end of 2013 to avoid financial impact in 2014. His organization was able to implement new screening workflows and see performance scores increase within a month, then reach target levels in 2014, which continue to be sustained. The example demonstrates that the right incentives and payment models are important for implementing change and can quickly lead to sustained performance.

Link to recording: https://www.youtube.com/watch?v=0JR-YyZHbbo

Paul Limburg, M.D., MPH, Exact Sciences and Mayo Clinic

Overview: Paul Limburg, M.D., MPH presented about leveraging new innovative technology to advance cancer screening. He currently serves as chief medical officer for screening at Exact Sciences, where he is working to develop CancerSEEK, a multi-cancer early detection assay.

Summary: There is strong evidence supporting the need to increase lung cancer screening rates. A possible approach to increasing screening rates is to change the screening

paradigm from single organ to multi-organ detection i.e., multi cancer early detection via liquid biopsy.

Exact Sciences conducted the DETECT-A study, which enrolled over 10,000 women between the ages of 65-75 with no prior history of cancer. The goals of the study were to detect cancers not found by standard of care, pilot their blood test and workflow in a large clinical population, and manage patient care by delivering test results.

The study results showed that CancerSEEK doubled the number of cancer cases first detected by screening methods (24 by standard of care and 26 additional based upon the assay) and demonstrated feasibility of the methods. Furthermore, specific to lung cancer, CancerSEEK detected lung cancer in nine women—tripling the number detected by existing screening methods. Importantly, among these nine women, seven were not eligible for lung cancer screening and the two who were eligible were not adherent to standard methods.

With projected availability of the CancerSEEK and other cancer detection assays, the expected benefits include increasing the target population, increasing screening participation rates, identifying additional target organ cancers, shifting to early-stage cancer diagnoses, reducing cancer treatment costs and improving clinical outcomes. The next steps will include initiation of an FDA registration trial.

Link to recording: https://www.youtube.com/watch?v=dUTg4qSsJ38

Discussion: The first topic for discussion was about what it may take to include lung cancer screening and/or multi-cancer screening as a quality health metric included in population health management. The panelists concluded that the metrics ACOs follow are more about the quality reporting because screening cannot reduce costs within a single year.

Furthermore, from a physician point of view, we need to identify cancers earlier to reduce mortality.

The next topic of discussion was regarding questions specific to the sensitivity of the CancerSEEK liquid biopsy. It was clarified that sensitivity is not the current goal of the test. The current goal is specificity and to compliment standard of care. As the technology is improved, sensitivity will continue to be improved.

A discussion then pursued regarding how there was a precedented need for randomized controlled trials to approve low-dose CT as a screening method for lung cancer, however this is not anticipated for other cancer screening assays.

The third point of discussion was regarding downstream costs of a positive liquid tumor when the cancer cannot be detected by imaging, leading to many additional follow-up procedures. For the DETECT-A study, few patients experienced a positive CancerSEEK test with negative PET-CT. These patients had additional follow-up procedures that were not part of the trial. From a broader population health perspective, we must consider that methods which drive better patient outcomes do not always lower cost. Cost savings are often seen, but much later than the increase in quality.

A final question was raised over the workflow used for the DETECT-A study. The question was regarding possible use of both PET/CT and CT to confirm positive tests. This is because PET/CT has a low resolution for smaller, more curable lesions and is an expensive follow-up test. Dr. Limburg confirmed this is being considered by Exact Sciences.

Conclusion: Quality metrics, incentives and payment models are important when considering how to successfully incorporate screening tests into population health models.

For lung cancer screening, quality metrics will be most important because they will be evidenced before cost savings. New innovative methods for screening exist and evidence to suggest additional benefits to the existing approved CT imaging approaches will be available from ongoing studies. Further information about CT-based optimization may arise by gathering more data from population health pilots measuring quality and cost impacts.

SESSION THREE: TRANSFORMING THORACIC HEALTH FOR EVERYONE—WHAT DOES THE FIELD NEED AND WHAT DO PEOPLE NEED?

BIG DATA AND VULNERABLE POPULATIONS – ADDRESSING THE GAP

Moderator: David Yankelevitz, M.D., Icahn School of Medicine at Mount Sinai

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Overview: David Yankelevitz, M.D. discussed a pathway to development of a useful database while focusing on low-dose CT in the context of lung cancer screening.

Summary: Current challenges with big data include legacy databases, which are small and were built with different standards, challenges with combining data from databases (e.g., combining imaging, molecular and genetic data), establishing normal value for diverse populations, obtaining data and releasing data from a database.

Larger databases are needed and a purpose must be defined to create them.

Image quality considerations were discussed, and the point was made that image quality standards and larger databases must be developed for a meaningful database. Many small databases are currently used and standards are not well defined.

The Medical Imaging and Data Resource Center (MIDRC) was discussed. This is an organization built to accelerate the development of AI and address the challenges of gathering big data.

Link to session recording: https://www.youtube.com/watch?v=sUqYWXKdk3Q

Discussion: Questions were posed to each panelist.

Anthony P. Reeves, Ph.D., School of Electrical and Computer Engineering, Cornell University

Challenges with CT for the development of AI tools and quantitative imaging and the difference between these two missions were discussed. In addition, the discussion addressed the importance of image calibration and standardization across vendors and scanners, as well as data sets size needs for the development of new CT-based technology, especially in the setting of artificial intelligence tools which may require vast image archival resources.

Melinda Aldrich, Ph.D., MPH, Department of Medicine, Vanderbilt University Medical Center

Dr. Aldrich was asked to discuss her experience in lung cancer research using different databases and the challenges faced. The importance of combining datasets was discussed, as were the challenges with individual institutional databases, which use different data structures and terminology.

Emanuela Taioli, M.D., Ph.D., Institute for Translational Epidemiology, Icahn School of Medicine at Mount Sinai

Dr. Taioli described how we can develop databases which are inclusive and the challenges with lack of diversity. Census data, cell phone demographics and driver's licence demographics were discussed as data sources which can be used to understand population demographics where the goal is for health care databases to represent

the general population in terms of diversity. The importance of dynamically determining normal values was also discussed.

Heather Pierce, J.D., MPH, Center for Health Justice, Association of American Medical Colleges

Heather Pierce, J.D., MPH discussed data sharing. The Association of American Medical Colleges (AAMC) perspective about data sharing is to increase sharing to improve science. Use of data for secondary purposes and related ethical concerns was discussed, along with concerns related to whom should have access to data and how credit should be given to organizations who work to collect and provide curated data.

Erik Lium, Ph.D., Mount Sinai Innovation Partners and Mount Sinai Health System

Dr. Lium spoke to the considerations that individual institutions face when releasing data, including costs of the data, collecting the data and protecting investigators' access to the data before it is released. The building of public databases and limiting access to academic entities was discussed, where the point was made that value must be fed back into the database system if it will be used for commercial purposes.

Conclusion: A lung cancer screening program will generate big data. There is an enormous amount of screening data potentially available and a publicly available database that includes high-quality annotated data has the potential to dramatically improve development of new software tools. This would include tools for lung cancer screening as well as tools for other major tobacco-related illnesses, including COPD and heart disease. With continuing advances, the information available within a chest CT scan, and especially with repeat scans obtained annually, could provide an overall health check. Data from the I-ELCAP consortium represents one major potential source of such data and is especially attractive since it continues to accrue new data from screening sites. Potentially expanding its existing infrastructure would further enhance its ability to accrue useful data. Database planning is necessary, including considerations about data standards, data collection, data sharing and data access. Involvement of key organizations needs to be considered.

MODELS OF OPEN DATABASE RESEARCH: THE ETHICS OF USING BIG DATA FOR TOOL DEVELOPMENT – HOW DO WE GET THERE FOR CLINICALLY ACTIONABLE AI?

Moderator: Christopher Lathan, M.D., MS, MPH, Thoracic Medical Oncology at Dana-Farber Cancer Institute

Panel Overview: To use data to empower patients we must change the focus from clinicians, institutions and policymakers and bring it back to participants, patients and community, with special emphasis on our historically marginalized communities.

Christopher Lathan, M.D., MS, MPH, Thoracic Medical Oncology at Dana-Farber Cancer Institute

Overview: Dr. Lathan discussed the ethics of using big data in medicine and progress vs. protection. He discussed big data inequity and how we can protect our communities.

Summary: AI and big data have many practical applications in health care, and we must be mindful of unintended future consequences of this new tool. Bias occurs not only due to data collection methods, but also with development of AI algorithms. The issue with algorithms is hard to correct because many algorithms are proprietary, thus there is no access to the methods or a way to correct them. When developing a database or algorithm, there may be good intent yet an impact which puts people at risk.

Transdisciplinary research, including prospective community engagement and transdisciplinary teams, was discussed as a solution to reducing inequity in big data.

Link to session recording: https://www.youtube.com/watch?v=x_2Kv_qUlNM

Shonta Chambers, MSW, Health Equity and Community Engagement, Patient Advocate Foundation

Overview: Shonta Chambers, MSW shared remarks in the context of big data and AI related to putting patients first.

Summary: There are many historic examples of big data being used in a discriminatory fashion. Unbiased algorithms were presented as a solution, however even with the removal of race and gender from algorithms, the bias remains. One reason is that race tends to correlate to many additional variables. It is important to acknowledge the historical and current challenges with big data in finance, criminal justice systems and education systems when looking to expand its use in health care.

For big data to be successfully integrated in health care we must consider what is expected from the algorithms in terms of patient outcomes and the patient experience, who will participate in the algorithm design, what the algorithms can do in addition to their intended use and what they won't allow us to do. These considerations must be made while acknowledging that the patient is the primary benefactor.

Patients must be on board and aware of how AI systems are advising their care. Without this understanding, AI systems can be a challenge and threat to the patient-provider relationship by decreasing trust.

There is a clear and growing role for big data and AI in patient care due to the enormous benefits. There are also challenges that must be considered. To reach its full potential, AI must be developed with patients and not for them.

Link to recording: https://www.youtube.com/watch?v=DWu7yxU_EC8

Samuel Cykert, M.D., Health and Clinical Informatics Program, University of North Carolina School of Medicine

Overview: Dr. Cykert discussed a multifaceted informatics intervention designed to achieve equity in the cancer system by attenuating Black/white treatment disparities.

Summary: Racial disparities in lung cancer have been well described for 20+ years. Dr. Cykert participated in a study on this topic in 2010 which showed that treatment completion, and specifically surgery, was less likely for Black than white patients.

To address this finding, the Greensboro Health Disparities Collaborative was established. The collaborative determined that this was not a provider problem but a system problem. Providers needed real time information regarding Black/white treatment disparities and patients needed enhanced communication involving engagement and reengagement. A follow-up study was conducted by implementing the proposed interventions at five cancer centers and the results were published in 2019. A navigation protocol was developed by the community and supported by human navigators who engaged and communicated with patients.

The intervention group not only showed an equal rate of completion of care among white patients and Black patients, but also showed that both groups had an increased rate of treatment completion.

The key to the success of the intervention was working with affected communities to determine outcome measures, measuring the outcomes according to race (or other disadvantaged populations), and applying the interventions in real time to include transparency and accountability. The success demonstrates how technology can be used to build trust and engage patients when used appropriately and with human interaction.

Link to recording: https://www.youtube.com/watch?v=OXsKRzQ22Lw

Discussion: The panelists first discussed how to get researchers and other entities to acknowledge diversity across disciplines.

The next topic of discussion was about bidirectional conversations, how this relates to the topic of religiosity and fatalism, and how this may be a factor for some of the disparities seen in patient populations.

The final topic of discussion was regarding the need to adjust screening guidelines to address a diverse population and in consideration of the social determinants of health.

Conclusion: Ethics are an important consideration for using big data in developing tools for health care. For big data and resulting tools to be successful they must use unbiased data collection methods and algorithms. Furthermore, bidirectional community discussions will be needed to ensure engagement and trust.

SESSION FOUR: ELUCIDATING THE EVOLUTION OF THORACIC DISEASE AS THE BASIS FOR RATIONAL CLINICAL MANAGEMENT

Session Overview: The theme of this session was pre-symptomatic screening for thoracic disease using low-dose CT thoracic imaging techniques. The main topics centered around leveraging the emerging annual thoracic CT screening encounter for lung cancer as a potential opportunity to perform a more comprehensive CT analysis to look for imaging biomarkers of other tobacco-related diseases. The issue of integrating relevant preventive interventions for major CT findings were also extensively discussed to bring specific benefits to screening subjects. In parallel, there was an in-depth technical discussion on how to develop a guidance document outlining quality and robustness measures to ensure that signatures of pre-symptomatic pulmonary disease identified by thoracic screening were objectively documented.

Background: A crucial component to improving lung cancer intervention is the acceleration and adoption of lung cancer screening, which requires improvements in standardizing low-dose computed tomography (LDCT) imaging methodology, as well as reporting processes along with referral of individuals found to have a screen-detected lung cancer to an appropriate clinical specialist. An additional emerging opportunity is the routine identification of many types of other tobacco-related diseases from thoracic CT, especially including COPD, emphysema and bronchiectasis. In particular, there is a concern regarding how to validate early, standardized clinical interventions that could pre-empt the progression of the CT-detected pulmonary lung diseases.

Discussion: Lung health is currently defined as a lack of lung disease and current therapies were developed under the assumption that early disease is the first manifestation of abnormal physiological findings, such as reduced spirometry measures, which could be too late. Similar to the landmark Framingham heart studies, the ALA Lung Health Cohort (LHC) study is collecting clinical data and LDCT imaging to determine longitudinal effects of environmental exposure, behaviors and aging on lung health. This will connect the dots between early abnormalities on lung imaging to recognize clinically aggressive

cases of lung disease, manifesting debilitating clinical symptoms later in life. Redefining lung health based on the earlier CT detection of aggressive lung injury earlier in the natural history of this disease allows for tailored interventions against the development of advanced symptomatic lung disease and will be critical to enhancing the value of standardizing, annual thoracic CT screening in otherwise healthy people.

The practical challenge to clinical interventions for pre-symptomatic disease is a lack of standard procedures across health care systems, insurance and billing requirements, cultures in various communities and health care practitioners across the U.S. First establishing a consensus of sub-clinical imaging findings from studies like the ALA-LHC will help standardize procedures, and then implementing a central database and referral structure would reduce time-to-action and improve clinical decision making. Advances in machine learning and artificial intelligence could help to manage the radiology and clinician workload and fatigue in screening nearly 15 million individuals annually, but must be done with careful implementation to minimize measurement and other biases, as well as cost to ensure optimal management quality.

The first step in addressing these challenges is for the American Lung Association, in conjunction with professional societies (ATS, CHEST, ACR) to develop a guidance document which outlines the context, clinical data, technical challenges and potential pitfalls in developing clinical interventions for pre-symptomatic pulmonary disease. Providing guidance for better physician-patient communication, such as walking through quantitative CT images, can improve behavioral interventions, such as smoking cessation and habitual exercise. This white paper will urge medical associations to advocate for thoracic screening and improvements in health care infrastructure to ensure early interventions before lung diseases progress too far.

Conclusion: The approach to improving outcomes for early lung cancer and other lung disease screening arises with reliable, economical and efficient disease detection using thoracic CT to define individual progressing to early lung disease in apparently healthy individuals using cohort studies. Standardized procedures for diagnosis and reporting of these early changes, using a centralized database and referral structure, will be essential to delivery of early interventions to relevant screening subjects. Advances in lung disease screening will facilitate development of successful interception of early thoracic disease, and thus improve patient outcomes and ultimately reduce mortality.

Although more work is needed, there appears to be findings such as emphysema that can now be reported on a structured basis by interpreting radiologists, leading to implementation of interventions including smoking cessation emphasis, increasing physical activity and updating relevant vaccinations for respiratory pathogens as well as measurement of lung function by spirometry. The benefit of this approach is to diagnose otherwise asymptomatic, but at-risk, individuals who have tobacco-related disease. These efforts would mirror emerging management of coronary-calcium findings on thoracic CT that are now incorporated in standard care of early CT-detected evidence of coronary calcifications including in the lung cancer screening setting.

Link to session recording: https://www.youtube.com/watch?v=qh7m8PV46UA

SESSION FIVE: LUNG CANCER & COPD IMAGING – TECHNICAL IMAGING GUIDANCE

IMPROVING CT LUNG CANCER SCREENING THROUGH IMAGE QUALITY OPTIMIZATION

Moderator: Ricardo Avila, MS, Accumetra LLC

Panel Overview: The goal of this session was to discuss the importance of image quality and consistency for lung cancer screening. The topics discussed included use of phantoms, need for reconstruction and reading models, and increasing demand for quantitative measurements on CT scans.

Ricardo Avila, MS, Accumetra LLC

Overview: Ricardo Avila, MS presented on improving CT lung cancer screening through calibration phantom and software innovations.

Summary: Early detection of lung cancer is critical for improving overall survival. Detection of lung cancer as small nodules (5 or 6mm) yields a five-year survival rate of 85%. Accurate detection of small nodules requires precise quantitative imaging.

Calibration phantoms can be used to develop high quality imaging protocols and avoid CT quality issues.

Spatial warping is a CT quality issue that can significantly impact lung cancer screening. Based on studies using calibration phantoms, up to a 44% change in volume of same size spheres was detected due to spatial warping. Many studies have shown evidence of spatial warping and due to this CT quality issue, 16 slice scanners should not be used for lung cancer screening—especially for large patients. However, the FDA continues to approve these model scanners for lung cancer screening and the AAPM continues to provide lung cancer screening protocols. These are issues which should be addressed and avoidance of specific 16 slice scanner models is recommended for lung cancer screening based on calibration phantom data.

To ensure precise imaging for lung cancer screening, Accumetra, in collaboration with RSNA and QIBA, developed the CTLX1 phantom. This is a low-cost phantom that measures fundamental properties of a CT scanner to produce 3D mathematical models. More recently, the CTLX2 phantom also became available. This is a water-fillable phantom developed to support radiation dose vs. image quality studies and is also used to check software for volumetrics.

A network of CTLX1/CTLX2 phantoms now exists around the world. The network monitors, optimizes and shares crowd-sourced protocols for lung cancer screening. As an example, over 1,400 CT scans from around the world have been evaluated based on phantom data and this data was used to publish recommendations for scanning parameters for quantitative analysis of COVID-19.

There are many supporting studies about the efficacy of the phantoms and their performance is sound. However, there are no accepted standards to compare against for measuring 3D resolution. It is of absolute critical importance to develop such a standard to allow for verification of scanner performance and allow research to document the quality of scans in terms of 3D resolution.

Additional benefits of phantom use include:

- Development of precision follow-up times. When considering the baseline nodule diameter and precision of the scanner, the appropriate time to schedule follow-up scanning based on volume doubling times can be determined.
- Optimizing radiation dose and resolution
- Ways to measure the software bias

- Lifting the requirement to use the same scanner for a patient across visits by modifying the imaging protocol to bring the scanner performance into alignment.

New innovations continue to arise, including more AI image reconstruction. A global image quality safety network, as we have today, will continue to be important for maintaining high quality imaging.

Link to session recording: https://www.youtube.com/watch?v=wuqZxUb7TLA

Mario Silva, M.D., Ph.D., University of Parma (Italy)

Overview: Mario Sliva, M.D., Ph.D. presented from the point of view of a physician reading cancer screening images while using software and the importance of the balance between visual quality and quantitative quality. A low-dose CT reconstruction and reading model was proposed.

Summary: Image quality is conditioned by slice thickness and the reconstruction algorithms. Inadequate image quality leads to increases in false positives and false negatives during lung cancer screening. Verifying image quality using calibration phantoms is a possible solution. Software performance can be verified for quality based on image quality parameters including edge enhancement, 3D resolution, spatial warp, 3D resolution aspect ratio, HU bias and noise.

The impact of CT scanner kernels and how they influence the number of false positives when evaluated using software is an important consideration and point for further discussion.

The screening program developed at University of Parma is called the PEOPLHE program and utilizes two low-dose CT reconstructions selected based upon verified image quality data points. One reconstruction is for quantitative reading and another is for visual reading. A third reconstruction is also presented for visual and quantitative reading that is specific to evaluation of mediastinal structures. The visual read requires the review of CAD detected nodules to determine if the finding is a true nodule.

One drawback with this reconstruction and reading method is that the volume of storage increases with this method of reconstruction. However, the benefits outweigh this.

Development of reading models are important steps toward standardization of lung cancer screening via CT.

Link to recording: https://www.youtube.com/watch?v=hnrRwWPmxz0

Sean Fain, Ph.D., Functional Lung Imaging Laboratory, Iowa Institute for Biomedical Imaging, University of Iowa

Overview: Sean Fain, Ph.D. made a few points based on the presentations thus far during this panel.

- There will continue to be higher demand on scanner performance and harmonization. The role of phantoms and phantoms that can be shipped to multiple sites is an advantage for the field to understand how much variability there is.
- Standardization of CT kernels is a critical issue that is emphasized by the need for quantitative imaging. It would be helpful to identify a sub-set of kernels across vendors that perform similarly and are specific to quantitation.
- As we move forward with Quantitative Imaging Biomarker Alliance (QIBA) and development of profiles that are standardized, this opens the door to multi-parametric measures.
- Iterative reconstructions, Artificial Intelligence and machine learning are all on the horizon and will only increase the demand on harmonization.

Stephen Lam, M.D., FRCPC, British Columbia Cancer Agency and Pan-Canadian Lung Cancer Screening Network (Canada)

Overview: Stephen Lam, M.D., FRCPC provided a pulmonologist's perspective about the importance of being able to measure nodules accurately and consistently over time.

Summary: Quantitative measurements are an important feature of lung cancer screening via CT and mean diameter changes have been shown to no longer be adequate given the higher incidence of part-solid nodules. Solid core, maximal diameter and total nodal volume are shown to be more demonstrative of nodule growth.

Currently, there are more previous smokers with lung cancer than patients who are current smokers. In the next 20-30 years it is expected that most lung cancer patients will have never smoked. The TALENT study conducted in Taiwan screened 'never' smokers with a family history of lung cancer and other risk factors and found that 'never' smokers present with a higher detection rate of invasive lung cancer, predominantly non-solid nodules (where solid nodules are predominant in smokers), and higher frequency of multiple primary lung cancers. The different presentation of disease in newer international populations confirms the need for additional quantitation of nodules ieg., more measurement options.

Personalized screening should be pursued to reduce unnecessary scans and prevent lung cancer from going undetected during the interval. Consistency in image acquisition and measurement will be important. Also, stability of image quality is important for sub-solid nodules in terms of volume and density measurements.

Discussion: The discussion focused on the point made regarding the lack of a 3D resolution standard in CT. The panelists agree there is no accepted phantom and analysis method used by all CT scanner vendors or sites around the world. However, there are elements for evaluating in plane resolution, including line response function, line pairs, etc. Given the critical role that resolution plays in developing quantitative methods, and especially since the role of CT scanning is moving toward being a quantitative tool, the need for defined standards for measuring resolution, especially in 3D, is critical and needs urgent attention. This will greatly aid in facilitating the introduction of advanced imaging approaches in clinical settings across the vast number of imaging centers providing CT scanning for lung cancer screening.

The point regarding CT kernel standardization was also discussed and it was agreed that further action should be taken to resolve this issue for lung cancer screening via CT to be successful.

Conclusion: Image quality and standardization are important for development of a successful lung cancer screening program. The demand for quantitative data from CT scans will continue to increase, placing even more importance on scan quality. There is an urgent need to develop a simple and well understood 3D resolution standard, including reporting and CT kernel standardization.

ESTABLISHING A TECHNICAL GUIDANCE FOR COPD AND LUNG CANCER IMAGE ACQUISITION PROTOCOL

Moderator: Raúl San José Estépar, Ph.D., Brigham and Women's Hospital and Harvard Medical School

Panel Overview: The goal of this session was to discuss current practices and future developments that will help to establish a technical guidance document for a single COPD and lung cancer image acquisition protocol. The topics discussed include quantitative assessments for COPD and lung cancer screening programs, biomarkers, accommodating radiologist preference, and

scanning parameters that maintain standards for quantitative protocol requirements, including reconstruction and post-processing of images.

Charles Hatt, Ph.D., Imbio LLC and University of Michigan

Overview: Charles Hatt, Ph.D. discussed how Quantitative Imaging Biomarker Alliance (QIBA) committees are working together to establish a technical guidance document for COPD and lung cancer image acquisition.

Summary: QIBA's mission is to improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, sites, patients and time.

The QIBA small lung nodule committee is committed to understanding and improving the accuracy of detecting true volume changes of lung nodules on screening CT scans, which is important for early detection.

The QIBA lung densitometry committee works on establishing standards for lung density measurements used to quantify emphysema and phenotypes of COPD.

In 2020, the small lung nodule committee and lung densitometry committee wrote a guidance document on optimal protocols for quantitative assessment of COVID. This publication was possible because of committee members' deep experience in quantitative imaging of lung cancer and COPD and as a result, the process for publishing the COVID guidance document can be applied to a guidance document for COPD and lung cancer.

Next steps toward development of a guidance document for lung cancer and COPD is establishing a standardized method for automated quantitative COPD/emphysema screening. Published data demonstrates that visual detection of COPD is associated with increased odds of lung cancer, however this association does not hold with automated emphysema detection. QIBA's hypothesis for this lack of association is image acquisition protocol standardization.

This hypothesis was pursued, and it was found that indeed many image quality factors impact the relationship. Therefore, improvements to image quality and standardization of image acquisition should improve automated detection for COPD/emphysema. The fissure completeness score was discussed as an example quantitative imaging biomarker which is known to be impacted by image quality and standardization to further strengthen this point.

A technical guidance document that will benefit a screening program for lung cancer will be critical for allowing for quantitative detection of COPD on CT scans in the setting of lung cancer screening.

Link to session recording: https://www.youtube.com/watch?v=pzZ7ZxTCwPE

Panelists:

Ella Kazerooni, M.D., MS, Michigan Medicine/ University of Michigan Medical School

Nicholas Petrick, Ph.D., Division of Imaging, Diagnostics and Software Reliability, U.S. Food and Drug Administration

George R. Washko, MMSc, M.D., Brigham and Women's Hospital and Harvard Medical School

Discussion: The following questions were posed to the panel:

- How can we accommodate radiologists' preferences in scanning parameters while maintaining standards for quantitative protocol requirements?
- What are the clinical application targets of a combined CT image acquisition protocol for COPD and lung cancer?

- What studies will be necessary to demonstrate effectiveness of a combined protocol?
- How do we move beyond statistically significant association between biomarkers and disease and demonstrate concrete examples of how the biomarkers can be used clinically?
- Do we have enough data to support the role and impact of doing expiratory imaging in LCS?
- What is the best way to disseminate and achieve acceptance of such a document?

In response the panelist discussed as follows:

All processing steps for imaging data should be considered by the committee developing the technical guidance document. This includes acquisition, reconstruction and post-processing. It will be important to consider that variability can be reduced at any step. The reconstruction step can be used to accommodate radiologist preference and automated assessments by creating different reconstructions for each need.

Regarding acquisition, this is the most difficult step to control. Defining optimal slice thickness with optimal data storage approach are recommended for the acquisition protocol so that different downstream image reconstructions are possible as needed to meet the need of the radiologist as well as the needs for more in-depth computational image analysis. This is just one example of parameters that could be used with the goal of a universal acquisition protocol.

The panel then discussed how the goal of screening is to detect disease and not to treat and follow the patient over time. However, it will be important for the committee to consider the benefits that could be gained by a screening program which follows millions of patients over many years. The committee should consider developing multiple protocols where one is for standard screening and another is for screening of patients with prior findings or other scenarios.

Conclusion: Ricardo Avila, MS is leading the effort to develop a technical guidance document for lung cancer and COPD screening and the committee will consider points made by Dr. Hatt and the panelists.

FINAL GENERAL DISCUSSION & FEEDBACK

James L. Mulshine, M.D., Rush University Medical Center

- Albert Rizzo is committed to writing a white paper on clinical management and implications of an integrated screening between lung cancer and COPD and will be happy to hear from individuals who would like to support him.
- We look forward to the technical guidance document for integrated lung cancer COPD screening.
- The need for community engagement and developing specific tools and the process for implementing screening across all the communities of the world will be pursued.