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Provider Work Up of Positive Findings in CT Lung Screening
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>> MURLEAN TUCKER: Welcome to the "Provider Work Up of Positive Findings in CT Lung Screening".   My name is Murlean Tucker and I'm running this Dialogue4Health dial with my colleague Tonya Hammond thank you for our partners for today's event the Lung Cancer National Training Network at the University of Louisville and the Bristol-Myers Squibb Foundation.

And now I would like to introduce Celeste Worth, the moderator of this event, Celeste Worth has over 20 years of experience in cancer control and provider education and is the director of the LuCa National Training Network at the University of Louisville. She is also a tobacco treatment specialist and master certified health Education Specialist.

She was previously a co-investigator for the provider education component of the KY Leads collaborative and the professional education and training manager for the Kentucky Cancer Program at the University of Louisville.   And I would like to say, welcome to Celeste.

>> CELESTE WORTH: Thank you so much, Murlean.   Hello and welcome to the fourth webinar in the LuCa National Training Network series.   We appreciate you taking the time to join us today for what promises to be a very informative and eye-opening look at some of the latest data related to lung cancer screening and management of positive findings.

As we begin, I want to share how LuCa National Training Network at the University

of Louisville can be a free resource for you.

The LuCa National Training Network, which also goes by LuCa is funded by a grant from the Bristol-Myers Squibb Foundation in addition to providing education and training directly to providers and other health professionals with webinars like this and an online course you'll get access for information on later we also provide assistance, materials and other resources for those who are educating health professionals on topics related to care at risk for lung cancer or who have been diagnosed.

Our website at LuCatraining.org recently received a national award and has over 300 tools and resources for both providers and patients.   We encourage you to check it out.   And please contact us at the email on this slide.   We also want to make sure that you're aware of the various resources that are available.   So you can go with any questions or requests to LuCatraining@Louisville.edu.

To get important updates and announcements about new offerings, tools and other resources, we invite you to follow us on Facebook and Twitter.   And for the first time today we are conducting live tweeting during today's webinars so please feel free to follow us on Twitter and add comments with #LuCaWebinar.   And make sure you have the capital L and capital C and capital W for webinar.

And with that, we will go out of the polls and I will introduce our first speaker.

I'm very pleased and privileged to be able to have this person participate with our webinar today Dr. Andrea McKee is a senior partner at Radiation Oncology Associates PA former chief of the Division of Radiation Oncology at the Lahey Hospital & Medical Center, Sophia Gordon Cancer Center in Burlington and Peabody, Massachusetts and current President of the Rescue Lung Rescue Life Society.   An independent 501(c)(3) organization established to eliminate barriers to CT lung screening adoption through public and provider education, advocacy, research and development of novel tools which streamline high quality program implementation and management Dr. McKee is actively involved in CT lung screening advancement on a local and national level as a member of the National Lung Cancer Roundtable several New England based patient Advisory Councils as a member of the Massachusetts State Cancer Control Steering Committee, Co-Chair of the State Lung Cancer Subgroup and is Advisory Board member to the Lung Cancer Alliance and the American Lung Association.

Dr. McKee, welcome and I'll turn the mic over to you.

>> DR. ANDREA McKEE: Thank you, Celeste.   Good afternoon and thank you, everyone, for joining us today for a discussion of positive findings in CT lung screening.

You saw my disclosures.

Lung cancer screening with low-dose CT improves outcomes in high-risk individuals with a 20% risk reduction -- 20% relative risk reduction and 24% risk reduction in men and 48% risk reduction in women published in the NELSON trial.   Concern over false-positive results and iatrogenic harm continue to limit LCS implementation and a challenge for shared decision making a requirement for reimbursement by CMS.

Possible positive finding categories in a lung screening exam include both in the lungs specifically.   Which can be a true positive.   In people who actually have lung cancer.   Or a false positive in those who have a lung finding that turns out not to be lung cancer.

Of note this definition also excludes other types of cancers spread to the lung or serious lung infection and thus false   positives can be of significant clinical relevance to the patient which will be touched upon later today I will be discussing workup of positive lung findings and my colleague Shawn Regis will be discussing the other category of positive findings those outside of the lung field these include incidental and significant incidental findings.   Shawn will also speak to the importance of tracking or navigating positive findings in CT lung screening.

Let's start with what defines a positive in the NLST.   As a reminder in the NLST patients were randomized to low-dose CT versus chest X-ray baseline prevalence scans were performed followed by 2 additional screens so 3 scans over two years. Positive test was defined as a non-calcified nodule greater than 4 millimeters in diameter or other findings suspicious for lung cancer like adenopathy or   effusion workup was determined by the patient's primary care physician not the NLST investigators however the NLST radiologist's recommendations were available.   It is very important to note that this is no longer how a positive exam is defined today Lung-RADS uses a 6 millimeter threshold for non-calcified solid nodule and in the NELSON study two CT scans over a predetermined time period were used before assigning positive or negative to the exam with the exam being coded as indeterminate during that wait time NELSON therefore reports an exceptionally low false-positive rate of 2% using their definition.

Not surprisingly, low-dose CT is more sensitive.   Approximately three times more sensitive than chest X-ray.   On the first two screens there's a 27% chance for a lung finding.   After that, the rate decreases to 16.8%.   Any solid nodule that's been stable for two years is considered benign according to the NLST and Fleischner guidelines now of course we use Lung-RADS in these situations the risk for finding a significant incidental is 7.5%.   Dr. Regis will cover incidentals in the talk later today.

False-positives were handled non-invasively for the most part.   Sorry.   If we compare to mammography something we are all familiar with, the discovery rate or the chance that you will get a callback for additional imaging is 20 to 25% for low-dose CT and about 8 to 10% for mammography.   With low-dose CT the callback occurs in 3 to 6 months with mammography the patient is immediately called back the false discovery rate meaning the chance that you don't have cancer if you get called back is 96% for both low-dose CT in the NLST and mammography the false discovery rate of 96% stated in the NLST has been misstated by numerous medical experts in the field of CT lung screening to be the false-positive rate the Rescue Lung Rescue Life Society has been working hard to get the medical literature corrected on this point as we suspect

that understanding the correct false-positive rate is very important to provider and patient engagement in CT lung screening.

The false-positive biopsy rate meaning the chance that you have a biopsy when you do not have cancer is .4 to 2.4% for low-dose CT and 1.4% for mammography.

False-positives were handled non-invasively for the most part with chest X-ray, CT, or pet/CT for -- PET/CT for follow up. Invasive diagnostic procedures on patients with no cancer were rare at about 2.4%. Complication rate for patients who didn't have cancer was also rare at 1.4% the major complication rate for those without cancer was very rare at .06%. For patients who have cancer these are the true positives the risk for major complication was 11.2% and the surgical resection mortality was 1%. But remember, these patients actually have lung cancer. The deadliest cancer that we see in the United States. In the NLST with the 4 millimeter non-calcified solid nodule threshold the false-positive rate was 26.3% at baseline and 27.2 -- 15.9% at T2 for overall 23.3% when investigators applied the 6 millimeter Lung-RADS threshold to the NLST dataset, a 12.6% at baseline and 5% at T2 false-positive rate was seen for an overall rate of 7.8%. In clinical practice at our institution we published our false-positive rate on several thousand high-risk individuals using the Lung-RADS system originated at Lahey with a -- 5% at T2 for an overall rate of 7.6%. And false-positive of 10.6%.

One of the questions that was submitted prior to this meeting was whether COVID-19 has had an impact on false-positive rates. Early on we instituted a policy to contact patients immediately before their scheduled exam to ensure they remained symptom free and without recent upper respiratory infection after learning during the first year of our program that false-positive rates had increased during the flu season without such a policy. Since instituting this new policy using this approach, we have not seen an increase in false-positive rates relative to COVID-19. After now having screened over 700 individuals in the post-COVID surge environment.

It's important to recognize the false-positive rate over time goes down in a mature CT lung screening program. This is a busy slide so allow me to walk you through it. Baseline scans are the dark red. Interval scans are the pink and incident scans are the salmon color. In Year 1 when we started the program, we see only baseline and interval scans as patients have just enter the program. Over time, there are many more incident scans seen in the larger salmon colored bar by year 2018 as patients have been enrolled for many years. Similarly the dark blue represents cancers diagnosed at time of baseline scan at Year 1 all diagnosed cases were done off baseline scans but over time the majority of lung cancers diagnosed are done so off non-baseline studies this is seen in a light blue by year 2018 where 27 of the cases diagnosed were in the non-baseline studies.

And in a mature program we are more often picking up new cancer that develops between annual screens and these cancers are typically very small. Our current program rate of diagnosing Stage I lung cancer in these later rounds of screening is

now 90%.   So 90% of the time we're finding these new very small cancers that are arising between years of screening.   Similarly in a very mature program once you really reached your steady state approximately 90% of the patients are going to be in that annual screening rounds with only 10% entering and leaving the program at any given time.

Here is one of the published false-positive corrections brought out by Rescue Lung Rescue Life Society without such corrections we were continuing to see new publications requoting the wrong 96% false-positive rate which as stated in this JAMA correction here is actually the false discovery rate so hopefully we will stop hearing that information moving forward.

So we decided to look at what happens to positive suspicious findings in our large clinical lung ancestors screening program as of April of 2020 we had performed almost 20,000 lung cancer screening studies in 7521 high-risk individuals we retrospectively reviewed all Lahey lung cancer screenings results on 4490 patients who had complete follow-up available through January of 2019 and these were from January 2012 to June 2017.

Why did we stop in -- in June of 2017?   This graph demonstrates what happens to individuals with suspicious findings or Lung-RADS 4A, 4B or 4X findings over time, 5.0 is the suspicious finding after which one of two things can happen the patient can be found to have lung cancer or the finding is determined to be benign in which these cases are most often rendered Lung-RADS 2 the graphs above the central day's timeline represent those who are found to have lung cancer after a Lung-RADS 4A in blue a 4B finding in red a 4X finding in green and the purple represents all Lung-RADS 4 cases later found to have lung cancer so this is above the day's time lane that you're seeing in the center of this graph.

If you go to the below graph, these are patients who are eventually not found to have cancer and become Lung-RADS 2.   We are using the same color coding for the different categories of suspicious findings so blue is a 4A.   Red a 4B.   Green a 4X. Purple represents all the 4s.   Note that by 360 days if you look over to the right side, about 92% of patients found to have cancer have been diagnosed with the disease. And at 360 days, 75% of benign cases have been determined to be benign.   So if you look out only one year you would be missing about 8% of lung cancers in this analysis. And looking at the graphs, waiting a full 18 months to run such statistics in your program allows you to analyze both the positive and false-positive cases which have essentially come to resolution by that time point.

I would also like to point out in the green box that is above the midpoint of the graph, you see the suspicious predictive value at 365 days for Lung-RADS 4A case the suspicious predictive value is 26%.   One of the questions that we received from the audience is can a 4A case wait for the next year to undergo an incident scan to avoid a co-pay as a diagnostic follow-up scan.   I see two potential problems with this.   First

and most important is that at 90 days, 50% of the Lung-RADS 4A cases with cancer have had their cancer diagnosed.   You can see that on the green above the bar graph.

And as you see additionally on this slide, this predictive value is nearly 30% meaning that nearly 30% of these Lung-RADS 4A cases actually have lung cancer.

So I wouldn't want to wait out a full year because of that co-pay issue just from a clinical standpoint in patients with a 30% chance of actually having lung cancer.   The second issue, at least in our program, is that once we have a 4A finding, the next exam would still be a diagnostic study subject to co-pay until that actually becomes resolved to a Lung-RADS 2.

Other programs may not handle their coding in that sort of a situation.   As long as they are waiting 11 months from the Lung-RADS 4A study, they may be putting that next exam in as a screening incidence scan but that's not the way we handle it in our program.

We follow NCCN guidelines and screen by NCCN Group 1 and 2 patients with suspicious findings or Lung-RADS 4 cases were evaluated for interventions and outcomes.   The table shown here describes the characteristics of Lung-RADS 4 patients with fairly equal male and female numbers.   Median age of 65.   And age of 43 with -- pack years of 43.   80% of Lung-RADS 4 cases are in NCCN Group 1 and 20% are in NCCN Group 2, NCCN Group 2 is a high-risk population who haven't enjoyed a mandate for screening coverage although this appears this will be changing soon. They have reduced the screening from 50 to 55 and pack years from 30 to 20 pack years on the basis of the NELSON trial and most recent randomized data we hope to see the final decision from USPDF findings before the end of the year.

The 4490 cases of those 3280 had complete follow-up at Lahey of those 345 were found falling into Lung-RADS 4 category with 311 having complete follow-up for -- they went -- SBRT, 51 underwent lung resection and 161 were managed with continued screening.

Among the 86 patients undergoing one or more invasive diagnostic procedures, 42 had lung cancer.   There were 4 non-lung cancers including metastatic breast metastatic renal carcinoma large lymphoma and follicular lymphoma remember these findings here are characterized as false-positives because they weren't lung cancer in the lung they were cancer in the lung but from another primary there were 5 benign findings and there were 35 non-diagnostic cases.

This yielded a 41% non-diagnostic rate.   Which is actually slightly higher than what we tend to see in the non-screened population.

We suspect this is probably because the lesions in the screening population are smaller.   And for the fact that we have slightly more mixed solid/part solid lesions seen in the screening population.

5.8% had truly benign disease.   This included necrotizing granuloma, organizing pneumonia and hemartoma and nearly 50% had lung cancer treated with surgery,

chemoradiation therapy or SBRT 2 patients died of other causes before treatment not related to their lung cancer.

Looking at diagnostic interventions, PET/CT was obtained in 60% there was a question from the audience about the use of PET prior to interventional biopsy our response would be that most of our pulmonolgists like to have a PET prior to an interventional procedure however it is not always covered by insurance and they make the comment that it is not always going to change what they are going to do as they will be staging the nodes in either case with EBUS, biopsies were done in 7%. CT guided biopsy were done in 10% of Lung-RADS 4 cases and the rarer procedures such as mediastinoscopy and thoracentesis there have been no major complications and rate of diagnostic interventions for those with non-malignant disease for entire population is .95%.

In this table of therapeutic interventions it's shown that path proven cancer is in place only 20% of the time prior to surgery. With 80% of those taken to surgery having presumed lung cancer after multidisciplinary review.

SBRT was used in 8% of Lung-RADS 4 cases with path disease slightly higher in this group than those going to surgery at 24%. Palliative chemotherapy therapy rarely used and definitive chemo radio therapy in -- used in some cases.

In those undergoing lung resection near 50% underwent a lobectomy and 50% underwent a wedge resection. There were no pneumonectomies. And 90% received thorascopic resection with less than 10% undergoing thoracotomy.

Benign disease was seen in 14 cases or 16.9% of surgeries comparing favorably to the rate that was published in the NLST of 24%. Overall .43% of Lahey lung cancer screening patients screened underwent surgery for benign disease.

There were no deaths within 60 days of surgery. 6% had a major complication according to NLST criteria. Comparing favorably to that of the NLST of 11.9%.

The most common complication seen was atrial fibrillation which was managed with pharmacologic intervention 5 patients experienced a prolonged air leak and 5 patients experienced pneumothoraxes requiring chest tube replacement.

25 patients underwent SBRT 24% had path proven disease 76% had presumed lung cancer based on department policy of multidisciplinary team review patients being reviewed by IR and pulmonary for biopsy risk.

Patients known to be at high risk for lung cancer. PET staging and serial growth of the lesion over serial scans.

There were 8 recurrences following SBRT. All but one were distant with half of the recurrences seen in patients with initial path proven disease and half seen in those who were presumed to have lung cancer and later the biopsy of the distant site proved their lung cancer diagnosis.

So looking back at our initial NLST positive findings slide and comparing to what's been seen in clinical practice we see a 7.8% false-positive rate less than the NLST rate

of 20 to 25% and a favorable rate of intervention of benign disease of .4 to .95% in our in our program comparing to 2.4 in NLST we feel these numbers are favorable to what is seen in mammography.

Complication rates compare favorably.   Having a shared decision making conversation with patients has been challenged by the various reports on statistics surrounding CT lung screening the numbers listed here are all published false-positive rates in the literature being precise with the definition of positive based on the reporting structure used and the year of screening baseline versus incidents helps shed some light on the discrepancies however in the U.S. Lung-RADS is used false-positive rate is less than 10%.   Similarly published diagnostic listed here from anywhere to -- NLST data has ended this debate with a diagnosis rate of 3%.   Structured reporting with algorithmic follow-up recommendations and multidisciplinary team to evaluate suspicious finding has yielded rates of less than 1% likelihood of surgery or intervention on benign disease.   So the answer for our question was less than 10% and less than 1%.

And I think that was No. C.

I just put in an example of a quick shared decision making conversation that can help in the clinics with the patient you're at high risk for lung cancer essentially 2% of baseline is a good rule of thumb although there are calculators out there you can use to get more precise with your findings new screening guidelines recommend annual CT lung screening for someone like you.   We find early stage lung cancer about 85% of the time screen detected Stage I lung cancer is 90% curable with surgery.   There's a less than 10% chance nodule is found that is not cancer managed mainly with imaging follow up surgery for benign disease is rare at .43% and invasive diagnostic is rare at .95% if imaging follow-up is recommended and cancer ultimately found it would be early stage.   There's no co-pay for annual screening exam.   Radiation exposure is that of a mammogram.   Smoking cessation for current smokers as per usual practice.   And there is a small possibility we find something other than lung cancer requiring care escalation.

Dr. Regis is now going to cover that issue in detail.

>> CELESTE WORTH: Okay thank you so much Dr. McKee for an excellent presentation.   It's very interesting and compelling to hear statistics from such a mature lung screening program that I think really helps a lot of other programs that aren't quite as far along know what to expect and have more up-to-date information to share with their patients and with others in their health system

So at this point I can start our introduction for our next speaker that we're also very privileged to have share with some additional information tied into what Dr. McKee was describing at the beginning.   And give another key aspect to all of these considerations. Dr. Shawn Regis is a patient navigator and associate research scientist at Lahey Hospital & Medical Center.   Clinical Assistant Professor at Tufts University and current

director of the Rescue Lung Rescue Life Society. Dr. Regis manages a CT lung screening database with data on over 8,000 patients and greater than 19,000 scans. And is on the Massachusetts comprehensive cancer prevention and control beneath's secondary prevention subcommittee focused on lung screening and was a member of the Advisory Committee for an Association of Community cancer centers initiative to develop an optimal care coordination model for lung cancer patients with Medicaid. Dr. Regis has been invited to speak about various lung cancer screening topics and numerous sites and conferences across the country and we are fortunate to have him with us today. Dr. Regis, welcome and I'll turn it over to you.

>> DR. SHAWN REGIS: Thank you so much Celeste and everyone at the LuCa network for having me here today and thank you to everybody who is coming out to participate in the webinar, as well.

I'll be talking first about radiologist recommendations for incidental findings as Celeste mentioned those poll results with the majority of people not being sure of what their rate is in their program, not entirely surprising and that will be part of the focus of my talk today. There are major discrepancies in the reporting of incidental and insignificant incidental findings in CT lung screenings and that's because there's not a good consensus on what the standard definition would be as Dr. McKee mentioned it's easy to care lung screening with mammography but this is one of those instances where it's quite different in breast cancer screening you're doing an image of the breast in lung cancer screening you're scanning the lungs but getting a whole bunch of other things as well that can't be ignored so they have to be commented on in the report the question is what if those are significant findings versus just incidental findings that can be mentioned but don't need immediate action. Most of the sites in the U.S. are using Lung-RADS to do their screening. Which just kind of has this S modifier for any significant incidental finding. It's kind of left up to a radiologist and it basically just says it's a clinically significant or potentially significant non-lung cancer finding and the management would be appropriate to that specific finding. They do give an estimated prevalence in about 10%. But again, at this point there's no real extension on what exactly those significant incidental findings are.

In the NLST kind of the general idea behind the finding was similar to what we see in Lung-RADS where it's an abnormality that's not related to lung cancer but it's up to the radiologist to determine whether that's clinically significant.

And we saw on the baseline round of screening in the NLST it was about 10% and then in the annual screening rounds it does drop off a bit closer to 6%.

There was a study in JAMA internal medicine that noted a insignificant finding rate of 41% and this was quoted a lot in the literature. And you can see that in the range it goes anywhere from 20% up to 63% in this study. And again that's because there's no real standard definition here. The radiologist and the coordinators were basically left to decide what they felt was an incidental finding that would likely require some sort of

follow-up or further evaluation.   And because of that lack of specific guidance that's where we start getting this wide range of numbers for significant incidental findings.

In our program we have a very specific definition for significant incidental finding it is an unexpected finding which is either new or unknown and requires some form of clinical or imaging investigation before the next recommended CT lung screening exam.

And there are two big parts of that the first part is the unexpected part which I'll get to in a moment and the second part is the new and unknown part.   You'll see that at baseline, a little over 6% of our scans have a significant incidental finding.   And then that drops down dramatically in the annual screening rounds to closer to 2 to 3% and the reason for that is because we have this new or unknown part of our definition where on a baseline screening exam if there's say a lesion on a kidney that's seen it's noted as a significant incidental finding there's a recommendation given to follow up on it but if that patient comes back on their annual screening round and that lesion is still there and not changed then it's not considered new anymore and it was previously known so not recorded as a significant incidental finding it will still be noted on the report but no longer considered a significant incidental finding because it was previously known.

So the differences in the general or lack of a definition of a general insignificant incidental finding is an issue and even within specific definitions that do exist there's discrepancies as well so in the VA study I mentioned before in the top left half of their significant findings came coronary artery calcifications and emphysema and Lung-RADS as well if you look at this piece taken from the data entry form lists calcification as a insignificant incidental finding as well so they specify in their case it would be moderate or severe that would make it significant.

We took a look at the patients in our program.   We do comment on coronary calcifications and emphysema on every single scan that we do.   It is listed as an incidental and not a significant incidental and that kind of gets back to the unexpected part of that definition that we have.

Almost 90% of the patients -- have some level of coronary calcifications or emphysema these are patients who have smoked over 200,000 cigarettes in their lifetime so we expect to see these kinds of things in these scans we do report it on every single scan but it's reported as an incidental rather than a significant incidental our coronary calcifications break down roughly 25% in each group between none, mild, moderate and marked so even using the definition saying it's severe calcifications would still give us 50% of our patients having significant in-- significant incidental finding due to coronary calcifications and about a quarter of patients have marked coronary calcifications or emphysema or both so even that definition of a severe calcification or emphysema finding would still give us 25% significant incidental findings just based off of those things.

Another area of discrepancy would be in the infectious or inflammatory findings ACR Lung-RADS imply these would be labeled as Lung-RADS 4X and not treated as a

significant incidental finding the VA study did treat them as a significant incidental finding and the rate was about 25% of those significant findings were infectious or inflammatory in nature so if we take those findings and the coronary calcium and emphysema findings that's about 75% of those significant incidental findings that were reported in the VA study which explains why that number was all the way up at 41%.

In our program we have a way of kind of separately characterizing these scans as infectious or inflammatory in nature and consistently across the board whether it's baseline or annual screening we see a rate of about 7% of our scans come back with this finding.   So again if those are going to be included as a significant incidental finding you're going to see a good amount of them it's going to be a little bit higher than say what we have seen in the NLST or what we have reported in our program.

So it is unfortunate that there's no standard definition for what a significant incidental finding is or no general guidance really provided.   So it's important for the individual program to then make up an agreed-upon definition for their program and have recommendations as well.   This should be determined by the program management, the Steering Committee, something like that.   Where you're deciding ahead of time, this is what our significant incidental findings will be, here is what we're going to recommend for those significant incidental findings.

And you should consider things like coronary calcifications, emphysema, infection and inflammation and then what we would consider to be kind of the more straight-forward incidental findings like masses in other organs, aortic aneurysms things like that you need to keep in mind when setting these definitions what you do and don't include as significant that will change the percentages of your results, as well.   So if you're including all coronary calcifications, and then it's not going to be overly helpful to compare your results to the NLST results because it doesn't appear that they did that based on the low number of their findings.

So one of the things that we did when we presented this data at the World Conference on Lung Cancer in 2018 is we compared our program with the cosmos study which was an Italian lung screening study.   Which had a very similar definition of a significant incidental finding for what we use at Lahey and a duration that was the same as what we had for our patients and what we found was that less than 5% of the overall scans and less than 10% of patients reported a significant incidental finding over those five years.   But 6.2% we had the cancer detection rate for these significant incidental findings so these aren't nothing these are other cancers we're finding in other parts of the body that are still important to the patient and still saving lives by finding them.   For every 7 or 7.5 lung cancers that are found, we're finding one of these significant incidental cancers.   And unfortunately a lot of talk especially when this VA study came out there was a lot of talk about how these significant incidental findings were a risk and a harm of lung screening and all of these people are coming back in for no reason.   It should be viewed as a benefit.   Like I've said depending on how you'll

find your significant incidentals they are really much lower than what we have seen in some of the literature and you're saving lives even more so than just finding lung cancer so that's how I think we should be looking at these significant incidental findings rather than saying they are an additional harm for the patients because that isn't really the case.

Next I'll talk about the importance of bringing the patients back in.   We've already talked a little bit about how we know lung cancer screening saves lives now in a variety of ways but it only really does that if we can get the patients to come back for the recommended follow-ups that are given so how do we best do that?   The main point here is that we can't really rely on the healthcare providers to do it all.   They don't have enough time to do it with everything else that's already on their plate.   If we take an example primary care physician who has about 2500 patients about 75 of those will equal effectively for lung screening which means the PCP is explaining what lung cancer screening is they are confirming the patient's eligibility, talking about risks and benefits, talking about smoking cessation and abstinence they have to write the order for the patient and then of those patients the vast majority will be a negative scan in which the PCP will have to write a new order for 12 months from them, determine if the patient is still eligible.   For those patients who had a positive scan it's the same thing but in a shorter time period usually around six months they are writing a new order for that patient.   There will be some suspicious findings where primary care typically has to let the patient know what those findings were and refer the patient to the a specialist for further evaluation as we just talked about there will be varied level of significant incidental findings depending on how they are defined by the institution and that's a lot to try to put on a healthcare provider to remember for every one of those lung screening eligible patients on top of what they have to remember for the other patients that are not in lung screening in their panel.

So the healthcare providers are really the ones that get the patients into the program but it's up to the navigators and a program management system to keep the patients in.

The first big step goes back to the shared decision making conversation that Dr. McKee mentioned where the healthcare provider does need to inform them upfront that this is an   annual process it's not a one time scan to see if you have lung cancer and you're done if they can lay the groundwork during that shared decision making visit and let them know it's an   annual thing it makes things easier down the road as well but the heavy lifting needs to be done by the navigator and program management system the main two ways we do that at Lahey we send results letters to the patients for the a negative scan that basically just says we don't see any signs of active lung cancer we recommend you come back in about a year and for positive findings it's that there were some nodules that are likely benign but we would like you to come back in six months to

make sure that's the case in both cases we give a specific date and that puts it in the patient's mind already that they are expected to have a lung screening exam on that date in the future.

We can then start working with the ordering physician to get that new order, give the patient a call and get them scanned.

If they don't make an appointment or if they miss an appointment that they have had scheduled, 30 days after that date we'll send them a reminder letter that let's them know we expected them in on a certain date and if they could get us a -- give us a call to get set up that would be great 60 days after if we haven't heard them we send that letter again but also a version to the ordering physician try to get them on board with getting the patient back in the program as well 90 days after we'll send the same letters to the patient and ordering physician with the add the caveat that the patient is effectively discharged from the program which really just means we won't be sending then the letters anymore they are welcome to give us a call and get back to screening which hopefully primary care is talking to them about it every year anyway.

And in our program we see about 86% of our patients coming back and following up with these recommendations from the radiologists and a large part of that is because we have the program management software that can keep track of these things and we're sending reminder letters to patients and making sure they are getting in for their scans I would be very surprised if you could get a number that was even close to this if you were just relying on healthcare providers themselves to try to remember all of this information and manage all of these patients on their own.

Dr. McKee showed this slide a little bit earlier so I won't spend a lot of time on it I just want to point out as she mentioned as your program begins to mature you see a lot more annual scans than you do baseline scans and this is kind of the why we need to bring patients back in we talked about the how and the why is because as you bring them back in as they get back into annual screening that's where you see the real even increased mortality benefit.

On baseline screening our early stage lung cancers are a little 80% once you get into annual screening it's a little under 90% because during baseline you still have patients who are weeks or months away from maybe being symptomatic so there's still some bulky disease there but.

>> DR. ANDREA McKEE: You'll screening you're catching small cancers and that's where the benefit is.   We saw this in the randomized control trials as well the NLST showed a benefit but we actually show a greater benefit in NELSON and MILD studies they screened for longer and did follow-up at a longer period of time so if we can keep those patients in screening they will get more benefit than if they just do a one time scan.   And lastly if you have a way to track all of these patients, a system that will do that for you, you can provide feedback to your referring physicians you can let them know how many patients quit smoking how many of their patients were diagnosed with

lung cancer what stage that was you can tell them how many patients didn't come in for a scan or who came in but never came back so they can talk to those patients and you're basically telling them what happens to all of their patients that they refer into the program and it's such a success story that they are just going to keep referring more patients in. So if you have those tools in place you can help them out, you'll get more patients in, you'll be saving more lives and I think that's what we're all trying to do here. So I thank you again for the time and I'll turn it back over.

>> CELESTE WORTH: Thank you so much, Dr. Regis for a terrific presentation what you all had together was extremely beneficial while attendees have a chance to submit a few questions for our speakers I will quickly share information about a couple of key offerings from LuCa. In two previous webinars Dr. Katie Garfield at Harvard center for health law policy and innovation introduced and reviewed two new resources developed in partnership with LuCa which address coverage for lung cancer screening and tobacco cessation coverage those publications and the recorded webinars are available on our website at LuCatraining.org there you can also find the recording of our last webinar on June 24th by Dr. Fati on power of primary care across the care continuum with examples of the benefits of telehealth use with lung cancer screening and tobacco cessation.

I would especially like to share information quickly about our free award wing course lung cancer and the Primary Care Provider this video based course covers lung cancer care it provides free CME Nurse Practitioner specific credit or AAFP prescribed credit and available to anyone so you can access this on our website at LuCatraining.org/course. And now, as I switch things over, we will allow Drs. McKee and Regis to answer questions that have been submitted I'll start with questions that were sent in when participants registered for this webinar and moved to those submitted during the webinar as time allows so Dr. Regis, what systems are available to alert primary care providers to order annual low-dose CT for those patients who qualify? At our health system this person writes a BPA on Epic alerting the PCP to screen but what about subsequent years, anyone with a plan for this?

>> DR. SHAWN REGIS: Yeah that's a great question and EHR is a really great way to help our healthcare providers know when their patients are eligible and when they are due to come back to screening setting up a BPA like that is fairly straightforward to do if you can make sure you have all of the correct information in there the pack year history if and when the patient quit smoking. The thing that we add in that makes it a little bit different and applies to annual screening, as well as baseline, is we just kind of add in they can't have had any kind of chest imaging within the past year so now you're not necessarily looking if they have ever had a screening exam you just want to know do they meet screening guidelines have they had a CT in the past year if not the BPA will fire it doesn't matter what round of screening they are all we just need to get them in to get the chest CT in if they are -- as part of the program.

>> CELESTE WORTH: The next one is for Dr. McKee how would you help patients understand the importance of keeping their annual appointments?

>> DR. ANDREA McKEE: So I do think that Shawn and I both kind of touched on this.   The key really is in that shared decision making conversation where you're presenting their risk of having lung cancer at baseline and then also reinforcing that due to their risk factors, their body is essentially making lung cancer at a rate of about 1% per year.   That's what we're seeing is that these new lung cancers once a patient has been in their annual screening rounds are developing lung cancer at a rate of about 1%.

So when they hear that, I mean, I actually -- because I do a lot of referring patients myself into our program.   You can see their face kind of like wow.   Geez.

That's what's happening in my body.   And I think that that reinforces that that's when we can catch it early, when -- between scans, a new lung cancer develops it doesn't have enough time to really get going and that clicks in their head I tend to use parallels to mammography for particularly my female patients but even men understand the paradigm behind annual breast screening.   So drawing parallels to things they can relate to really helps allow them to ensure that staying in the program as long as they qualify will give us the best shot at finding that early stage curable lung cancer.   Is how we can get them to kind of come back and the tracking system is obviously critical so if you don't have a tracking -- a navigator who is tracking these findings and supporting you in this endeavor, it's a shame.   I know Shawn uses the comparison how do you ask a surgeon to go to the OR without a scalpel?   You know, it's -- you need tools to kind of -- to really do this in the way that we want to get it done.   But there are some examples I've heard where providers may actually keep track of these patients, their own patients themselves.   As Shawn presented, it's typically going to be about 75 patients in a primary care panel who are going to qualify for lung screening.   And whether or not you can kind of try to keep track of getting back those 75 patients for their annual exams through some resource within your office.   I realize it's a lot to ask.   But you know those are the things that some providers I've heard are doing.   They basically use an Excel spreadsheet.

>> CELESTE WORTH: Unfortunately in those cases, right.
(Chuckles).

>> DR. ANDREA McKEE: I know.

>> CELESTE WORTH: Thank you for that.   I wish we had more time today because there's so much more we would all like to ask that we have definitely recorded all of the questions that have been sent in earlier or during the webinar.   And we will get responses to those.

Thank you to everyone who did that.   And I want to also add there will be a brief evaluation when the webinar has ended we appreciate your response to those so we can continue to provide continuing education going forward a slide set as well as a recording of this webinar will be on the Dialogue4Health website in about a week if you

shared your email address with us during registration we'll be able to send a link when that becomes available so thank you again for your participation.   Please be on the lookout for the next webinar on our series which will be September 30th and ones after that and feel free to contact us for any further questions.

I will turn it over to Murlean if she has any follow-up remarks but otherwise have a wonderful afternoon.