Implementation of a Lung Cancer Screening Program in a Community Setting

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ung cancer is the leading cause of cancer mortality in the United States, greater than the deaths from breast, colorectal, and prostate cancers combined.¹ The American Cancer Society (ACS) estimated that 238,340 people would be diagnosed with lung cancer, and 127,070 people would die from this disease in 2023.¹ The lifetime risk of developing lung cancer is approximately 1 in 16 for men and 1 in 17 for women. The risk is 25-fold higher for those with a history of smoking,² accounting for about 80% of cases and deaths, and this risk increases with age.³

Eligibility for Lung Cancer Screening

In 2011, the National Lung Cancer Screening Trial screened high-risk individuals (ages 55 to 74 years with a 30+ pack-year smoking history) with low-dose computed tomography (LDCT) and saw a 20% reduction in lung cancer mortality compared to chest radiography.^{4,5} Two European trials reported even greater mortality reductions among participants with more moderate disease risk.^{6,7} Based on these and other data, ACS and the US Preventive Services Task Force (USPSTF) began recommending lung cancer screening using LDCT for high-risk individuals in 2013. Expanded criteria include people ages 50 to 80 years with a 20+ pack-year smoking history who currently smoke or have quit within the past 15 years.⁸ With these criteria, approximately 8.5 million adults were eligible for lung cancer screening in 2020.

Low Enrollment in Lung Cancer Screening Programs

Despite these advances, the nationwide lung cancer screening rate of eligible high-risk individuals was only 6.5% of 8.5 million eligible persons in 2020.⁹ Screened individuals tend to be older, female, and current smokers.¹⁰ The greatest barriers to screening exist among Black and socioeconomically disadvantaged individuals.¹¹ Patient and provider education is required to increase uptake among eligible adults.¹²

The Lung Cancer Screening Program at Providence Holy Cross Medical Center

Providence Holy Cross Medical Center (Providence Holy Cross) is an essential care provider in the San Fernando, Santa Clarita, and Simi Valley communities situated North of Los Angeles. The medical center offers both inpatient and outpatient health services, including a state-of-the-art cancer center, with a holistic and familycentered approach to care. The lung cancer screening program is The patient navigator provides emotional support, answers questions, and acts as a liaison between patients, PCPs, and specialists to facilitate communication and care coordination.

dependent on the close affiliation between Providence Holy Cross and the Facey Medical Group. Facey has over 100 primary care physicians (PCPs) in the region, extending the reach of Providence Holy Cross to approximately 170000 patients and making the screening program accessible to a broader population. The combined referral, screening, and treatment pathway is advantageous in reducing patient travel.

LDCT examination is the foundation of the Providence Holy Cross-Facey lung cancer screening program. Before program implementation, it was determined that the specifications and performance of the 4 existing multidetector helical CT scanners met state, federal, and applicable American College of Radiology (ACR) practice parameters and technical standards for lung cancer screening. The Providence Holy Cross-Facey lung cancer screening program was initiated in October 2016. The program received ACR Lung Cancer Screening Center designation and Lung Cancer Screening Alliance Center of Excellence designation on December 31, 2016.

The program has grown with time. Since 2017, about 3000 patients have been screened at Providence Holy Cross using low-dose CT scans, improving the detection of early lung cancers. Today the lung cancer screening program includes preimaging risk-benefit counseling, protocoled and approved low-dose imaging of the chest from the lung apices to the upper abdomen, structured reporting of the findings (Lung-RADS), a structured call-back process, structured results communication with providers and patients, and data acquisition and reporting as required by the ACR and the Center for Medicare & Medicaid Services (CMS).

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Power to Go Further







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(Continued from page 20.) Physician Pioneer and Champions

A Providence Holy Cross radiologist pioneered the lung cancer screening program and served as a *physician champion* along with a Facey pulmonologist. The lung cancer screening program provides education both to Providence Holy Cross physicians at medical staff meetings and to the Facey Medical Group Utilization Management team who is committed to expediting referrals. Physician education includes the lung cancer screening workflow, how to make referrals, and how to communicate with patients. Patient education includes information from PCPs, educational brochures placed in physician offices (Figures 1 and 2), presentations at health fairs, and other community outreach. Spanish versions of the patient education brochures are available. Education brochures are also distributed by the Providence Holy Cross business development team.

An overview of the lung cancer screening process is shown in Figure 3 and described below.

Step 1. Patient Selection and Referral *The Role of the Primary Care Physician*

Patients who are appropriate for screening may be identified by their PCPs or by a pulmonologist. Hence, it is imperative to provide support to enable PCPs to identify high-risk individuals and know how to refer them to the lung cancer screening program. To aid in this effort, targeted letters (Figure 4) were sent to local health care providers, along with educational materials. Appropriate screening candidates include people aged 50 to 80 years with a history of smoking and patients with signs and symptoms compatible with a diagnosis of lung cancer. Patients who are candidates for low-dose CT screening are referred to the lung cancer screening patient navigator.

The Role of the Patient Navigator

The patient navigator for the lung cancer screening program is vital in guiding individual patients through the screening process to ensure that they receive timely care, understand their results, and can navigate the health care system for additional evaluation and treatment. The patient navigator provides emotional support, answers questions, and acts as a liaison between patients, PCPs, and specialists to facilitate communication and care coordination. The patient navigator also works to remove financial, transportation, and insurance-related barriers that may impede patient access to screening and follow-up care. The involvement of the patient navigator at community outreach events raises awareness of the Providence Holy Cross lung cancer screening program and encourages eligible individuals to participate.

Figure 1. Patient Education Leaflet for the Lung Cancer Screening Program





Figure 2. Patient Q&A for the Lung Cancer Screening Program



Lung Cancer Screening Program

Saving lives with early detection

ung cancer kills more people-men and women-than sny othe of cancer. In 2021, the foan Cancer Society American Canada Society estimated that by the end of the year more than 255,000 would be diagnosed with Long cancer in the LLSL and more than 131,000 would dia more than 131,000 would dia from the diagnose. In light of the fact that there are 35 bellion and facebear million adult smoken ountry, screening is unt. We talked with ialist ITTSL about the ence Haly Cross lung screening program

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Lung Cancer Screening Algorithm

To facilitate the continuum of care, the radiology medical director and the patient navigator developed a lung cancer screening algorithm composed of 3 components:

- 1. Eligibility assessment and program referral. Once a patient is referred, along with LDCT authorization from the referring physician, the patient navigator verifies eligibility and contacts the patient to provide education and smoking cessation counseling (if appropriate), to discuss next steps, and to direct eligible patients toward the LDCT screening process.
- 2. Patient education. Shared decision-making elements are discussed and documented. These include the potential harm and benefits of screening, follow-up diagnostic testing, false positive rates, and total radiation exposure. Patients are educated about lung cancer risk factors, the benefits of early detection through screening, and the screening process itself. The patient navigator helps individuals understand the importance of regular screenings, particularly for those at high risk, such as current or former smokers.
- 3. Smoking cessation counseling. The patient navigator is a certified tobacco treatment specialist. Individuals are counseled on the importance of maintaining smoking abstinence or smoking cessation. They are provided with information about smoking cessation interventions and resources, if appropriate.

Step 2. LDCT Screening The Role of the Radiologist

The radiologist plays a key role in lung cancer screening. Responsibilities include:

- The lung cancer screening program offers preimaging risk-benefit counseling for low-dose imaging of the chest.
- Low-dose imaging of the chest is performed from the lung apices to the upper abdomen. The imaging protocol for specific lung cancer screening of a standard size patient (5 feet, 7 inches, 154 pounds, using a 32-cm diameter CTDI phantom) was used. Radiation exposure levels were consistent with low-dose lung cancer screening protocols, not routine CT chest scans, and the protocols all met the required CTDI volume of less than 3 mGy for a standard size patient. Exposure values were reduced for smaller patients and increased for larger patients using either manual or automated methods such as automatic tube current modulation and/or kV selection.
- The team adopted a data acquisition Lung-RADS reporting template for structured reporting by all interpreting radiologists. In addition to the findings and conclusion section of the report, which is included in every primary interpretation, the template includes pertinent Lung-RADS categories, required verbiage specifying recommendations for follow-up, a link to the ACR Lung-RADS assessment categories, and disclosure that the examination was performed at a facility meeting the criteria for an LDCT screening program, as required by ACR and CMS.
- **Communication with patients and providers.** This approach to structured reporting of the findings (Lung-RADS) extended to the call-back process and structured results communication with providers and patients.

The Role of the Pulmonologist

The pulmonologist plays a key role in lung cancer screening. Responsibilities include:

- Once there is a highly suspicious lesion on CT chest imaging, the pulmonologists use patient history in conjunction with examination and imaging to consider a differential diagnosis of the nodule(s) or lesions. Because not all lung nodules or lesions on CT chest imaging are considered malignant, it is important to review all the history when determining the differential diagnosis. Based on the size and imaging characteristics of the nodules, unnecessary biopsies of benign lesions are avoided, which alleviates escalating costs of screening.
- If a **biopsy** is appropriate, the pulmonologist decides how to approach sampling the nodule or lesion. The many different modalities to sample lung tissue include surgery, interventional radiology CT-guided lung biopsy, and advanced bronchoscopy techniques for differential diagnosis and exclusion of infection or inflammation. A newer technology, ION navigational bronchoscopy, can facilitate the previously challenging biopsy of lung nodules in the periphery of the lung.
- Endobronchial ultrasound may also be used in the staging of the lung cancer to see if mediastinal lymph nodes also harbor malignancy. Navigational bronchoscopy and endobronchial ultrasound procedures are usually done during the same anesthetic event.

Figure 3. Lung Cancer Screening Program Workflow



Step 3. Treatment and Follow-Up

The patient navigator facilitates a review of Lung-RADS category 4 scans at a multidisciplinary tumor board, and the patient is referred to the oncology treatment teams. This navigation helps to significantly reduce the time from screening to diagnosis. Specific data elements are also collated and transmitted to the CMS-approved national registry.

The navigator helps patients move through the health care system and ensures follow-up with recommended treatments. Where appropriate, using the electronic medical record (EHR), the patient navigator generates a letter to the patient notifying them of their next LDCT. The patient navigator makes phone calls concerning information on incidental findings and referrals to appropriate specialists, and notifies the PCP of recommendations from the multidisciplinary tumor board. In addition, the patient navigator is available to the patient to facilitate the treatment phase.

Dear Provider:

Providence Holy Cross Medical Center is pleased to announce a new lung cancer screening comprehensive program. This applies to patients who are considered high risk for lung cancer as defined by the NCCN, USPSTF, and CMS. A lung cancer screening program includes preimaging risk-benefit counseling, protocoled low-dose CT imaging of the chest, structured reporting of the findings (Lung-RADS), structured call-back process, structured process for result communication to the patient and the primary care provider, and data acquisition and reporting as defined by the ACR and CMS. Referring providers can bill Medicare for the shared decision-making.

Enclosed you will find the following:

- Lung cancer screening form (eligibility for screening, shared decision-making, and order form)
- Educational rack card regarding lung cancer screening for your patients
- Patient instructions for scheduling
- · Educational handout regarding smoking cessation for your patients

NSCLC

Our goal is to reduce deaths associated with lung cancer and low-dose CT screening has been shown to reduce mortality for high-risk patients. Thank you for your consideration of participating in this program.

Sincerely,

Providence Holy Cross Cancer Program

National Lung Screening Trial

- 20% relative reduction in mortality from lung cancer with low-dose CT screening
- <u>http://www.nejm.org/doi/pdf/10.1056/NEJMoa1102873</u>
- http://www.nejm.org/doi/pdf/10.1056/NEJMoa1209120

NCCN = National Comprehensive Cancer Network USPST = US Preventive Services Task Force CMS = Centers for Medicare & Medicaid Services ACR = American College of Radiology

Thoracic Surgery

Thoracic surgery plays an important role in the management of early-stage lung cancer. Early detection, made possible with a robust lung cancer screening program, not only increases the feasibility of surgical resection, but improves the overall prognosis for patients diagnosed with lung cancer.

Surgical resection of the anatomic segment of the lung involved may include lobar and sublobar resections, depending on the size and anatomy of the lesion. In addition, mediastinal lymph node evaluation during surgery allows for accurate staging, which guides potential adjuvant therapies.

Surgical resection for stage I and II non-small cell lung cancer

(NSCLC) offers the best opportunity for long-term survival.¹³ Lobectomy is generally accepted as the optimal treatment in early-stage lung cancers. However, sublobar resections, like segmentectomies, are at least equivalent to lobectomy in patients with small peripheral NSCLC.¹⁴ Similarly, limited-stage small cell lung cancer (SCLC), which includes patients with a solitary pulmonary nodule and no evidence of lymph node or distant metastasis, may be treated with surgery.¹⁵

Radiation Therapy

Radiation is important in the local management of early-stage NSCLC, as patients may be considered inoperable due to age, cardiovascular,

pulmonary, or other comorbidities associated with smoking. Historically, conventionally fractionated radiotherapy was used for patients who were too frail for surgery. This treatment entailed 5 to 6 weeks of daily radiation treatment and had high rates of local failures.¹⁶⁻¹⁹ Technological developments now allow for the delivery of ablative doses of radiation precisely delivered to a lesion over 1 to 5 days of treatment. Stereotactic body radiation therapy (also known as stereotactic ablative radiotherapy) is now standard of care for inoperable, local lesions. This allows for a highly effective and safe treatment option for medically vulnerable patients.²⁰

Medical Oncology

The medical oncologist is critical in the overall treatment and management, conferring with pulmonologists, thoracic surgeons, radiologists, radiation oncologists, and the patient navigator to devise the optimal treatment plan, such as surgery, radiation therapy, chemotherapy, and nonmedical interventions. The patient is provided with an explanation of the diagnosis, staging, and treatment options. The medical oncologist oversees all treatment stages, monitors and adjusts therapy, manages the symptoms and adverse effects of therapy, and discusses continuing care with the patient navigator.

Evaluation of the Lung Cancer Screening Program

Figure 5 illustrates the growth of the program since its 2017 inception, while **Table 1** shows the number of patients gradually increasing year over year. Recruitment was lower in 2020 due to the COVID-19 pandemic.

The tumors detected were primarily stage I and stage II, fulfilling the purpose of the lung cancer screening program to detect early cancers, since early detection of LR1 and LR2 lesions can be addressed in a timely manner before they become L3 and L4 lesions. Benefits to early detection and ongoing surveillance with low-dose CTs for high-risk individuals include increased survival rates, better outcomes, overall improved community health, and reduced health care costs. The financial and economic benefits are related to the avoidance of intense and costly treatments. The incidental detection of other diseases and conditions beyond lung cancer is another benefit that allows for early intervention and treatment.

Initial LDCT studies resulting in Lung-RADS scores of 1 or 2 may create a false sense of security about the absence of lung cancer, and patients may no longer continue with their annual screenings. Our lung cancer screening program was successful from the outset because of the commitment of all stakeholders to continued patient screening at both 3 months and annually, including repeat screenings when necessary.

Barriers and Challenges to Implementation of the Lung Cancer Screening Program Screening Expertise

All aspects of lung cancer screening including interpretation, communication, continuity of care, and documentation are practiced. Initially, a pool of 3 designated lung cancer screening readers were selected from radiologists with the most experience and interest in interpretation of thoracic CT examinations and with documentation for training in interpretation and reporting according to Lung-RADS requirements. Over the years, the pool of radiologists was expanded to include additional readers for the growing program load.

Creating a Structured Lung-RADS Reporting Template

A template was drafted by 1 of the radiologists and adopted for structural reporting by all interpreting radiologists. In addition to the findings and conclusion section of the report, which is included in every primary interpretation, the structured Lung-RADS reporting template includes pertinent Lung-RADS categories, required verbiage specifying recommendations for follow-up, a link to the ACR Lung-RADS assessment categories, and disclosure that the exam was performed at an approved facility meeting the criteria for LDCT screening and data submission to an approved registry.

Funding of the Patient Navigator Position

Funding the dedicated patient navigator position was a barrier; it was challenging to justify the salary at the beginning of the lung cancer screening program. The role of an existing bilingual navigator was restructured to spend 25% to 30% of her time on the lung cancer screening program, primarily to review the patients who were Lung-RAD category 3 and above, and to refer patients to the interdisciplinary tumor board. Other tasks, such as data entry, obtaining referrals, and sending letters to patients, were delegated to a registrar.

Improving Identification of Lung Cancer Screening Candidates

In larger medical groups or health systems, the use of patient population data, including best practices and/or clinical pathways that connect primary care and specialty providers, may facilitate identification of qualifying patients. Radiology integration or diagnostic imaging integration into the EHR make the ordering of imaging for screening more seamless and allows further capture of eligible patients. Large group practices or health systems that use the same diagnostic radiology service may also provide a steady volume to support a lung cancer screening program and help to maintain appropriate program resources.

Enrollment in Antismoking Programs

Patients were encouraged to enroll in a smoking cessation program, such as the California Smokers' Helpline (1-800-No-Butts), a free telephone program that provides counseling and materials, such as nicotine patches. However, the patient navigator did not have the resources to follow up with each patient by telephone at regular intervals to ensure compliance.

Concluding Remarks

Despite the evidence that lung cancer screening in high-risk populations is associated with reduced mortality, enrollment has been low.²¹ Many patients who qualify for lung cancer screening per guidelines do not undergo screening due to poor access to screening programs or provider failure to identify appropriate patients. In particular, California has struggled to enroll patients or provide appropriate screening for lung cancer.²² This unmet need was a major driver of the lung cancer screening program initiative.

An integral part of our lung cancer screening is increased awareness and education, including health fairs and offering free screenings, empowering individuals to take a proactive (self-care) approach. Patients who have undergone lung cancer screenings are recruited to enter a smoking cessation program. The lung cancer screening program advances our knowledge of lung cancer and new treatment modalities.

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Figure 5. Lung-RADS Findings in Lung Cancer Screening Patients

Note: The number of individuals screened in each year is shown. The number of screenings was reduced in 2020 due to the COVID-19 pandemic.

 Table 1. Lung-RADS Findings in Patients Enrolled in the Providence Holy Cross-Facey Lung Cancer Screening

 Program

Lung-RADS	2017	2018	2019	2020 ⁻	2021	2022	2023
LR 1 negative	66	110	167	135	197	363	425
LR 1S negative and significant NLC	2	3	7	1	9	6	1
LR 2 benign	41	75	122	112	165	270	332
LR 2S benign and significant NLC	7	11	2	3	8	6	0
LR 3 probably benign	13	27	16	10	37	38	57
LR 3S benign and significant NLC	0	3	3	1	1	0	0
LR 4A suspicious	2	4	10	6	5	17	18
LR 4B suspicious	2	7	6	3	6	14	10
LR 4X suspicious	0	1	1	0	3	0	6
Total Patients Screened	133	241	334	271	431	714	849

* Recruitment was impacted in 2020 because of the COVID-19 pandemic.

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The Providence Holy Cross-Facey lung cancer screening program is holistic and multidisciplinary, offering individuals access to specialized care, including designated lung cancer screening radiologists, pulmonologists, oncologists, radiation oncologists, oncology nurses, and navigators. Our specialists work together to ensure appropriate treatment, disease management, education, follow-up, continuous monitoring, and supportive care. This multidisciplinary approach is a patient-centered model of care employing joint decision-making between the team of experts and the patient.

Looking to the future, we remain focused on growing and improving the program, addressing barriers to care, reporting outcomes data at cancer committee meetings, and engaging in continued community outreach and PCP education. Creation of an easily accessible website is a top priority.

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