

Expediting Lung Nodule Evaluations: Experience from the VA Pittsburgh Healthcare System

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This VA facility dramatically reduced the average interval between nodule detection and lung cancer diagnosis by establishing an algorithm-based program that is coordinated by a nurse practitioner and administered by a multidisciplinary team outside of the traditional clinic setting.

Lung cancer is the leading cause of cancer death in the United States, where it was newly diagnosed in 213,380 patients and led to 160,390 deaths in 2007 alone. It causes more deaths annually than breast, prostate, and colon cancers—the second, third, and fourth leading causes of cancer death, respectively—combined. Lung cancer's overall five-year survival rate of 16% rises to about 49% for cancers that are found and treated while still localized. Only 16% of patients with lung cancer, however, are diagnosed at such an early stage.¹

Lung cancer is a major health problem in the VHA. In 2006, 7,251 cases of lung cancer were diagnosed in the VHA nationwide (unpublished data, VA Central Tumor Board, 2007), and 105 cases were diagnosed in the VA Pittsburgh Healthcare System (VAPHS), Pittsburgh, PA (unpublished data, VAPHS Tumor Board, 2007). Like the overall U.S. vet-

eran population, the VAPHS patient population has a high rate of heavy smokers. In addition, due to its location in the Ohio Valley, the VAPHS treats many patients who have been exposed to carcinogenic chemicals while working in the coal mining or asbestos industries. Therefore, VAPHS clinicians commonly evaluate patients with abnormal chest imaging results that may represent cancer, and these patients often require follow-up and long-term management.

In 1999, leadership at the VAPHS became aware of delays in the system's evaluations of possible lung cancer and began looking for ways to expedite these evaluations. A chart review determined that, for patients with lung nodules, the interval between abnormal imaging results and diagnosis of lung cancer was 45 days on average and up to four months in some cases. In response to these findings, the system conducted a pilot study to determine whether evaluating patients with lung nodules outside of a traditional clinic setting and with a designated case manager would lead to more expeditious evaluations. For the 40 patients included in this pilot study, the average interval between nodule detection and lung cancer diagnosis was only 21 days.

Encouraged by this result, the VAPHS acted in 2001 to implement an expanded version of the pilot study called the Lung Nodule Evaluation Program (LNEP). In this article, we describe how the pilot study and, subsequently, the LNEP attempted to improve upon the traditional clinic model historically employed at the VAPHS to evaluate lung nodules, the specific procedures by which lung nodules are evaluated in the program, the program's impact thus far, and the ongoing challenges we face in expediting lung nodule evaluations.

ADDRESSING THE PROBLEM

In 1998, the British Thoracic Society (BTS) published guidelines that proposed timeliness standards for diagnostic evaluation and treatment initiation in patients with suspected lung cancer.² According to these guidelines, patients with suspected lung cancer should undergo an initial evaluation within one week of primary care referral, receive diagnostic tests within two weeks of the decision to perform a biopsy, and be informed of the biopsy results as soon as possible. For patients with early stage, localized, non-small cell lung cancers who may be candidates for surgery, the BTS recommends a timeline of four to eight weeks from the

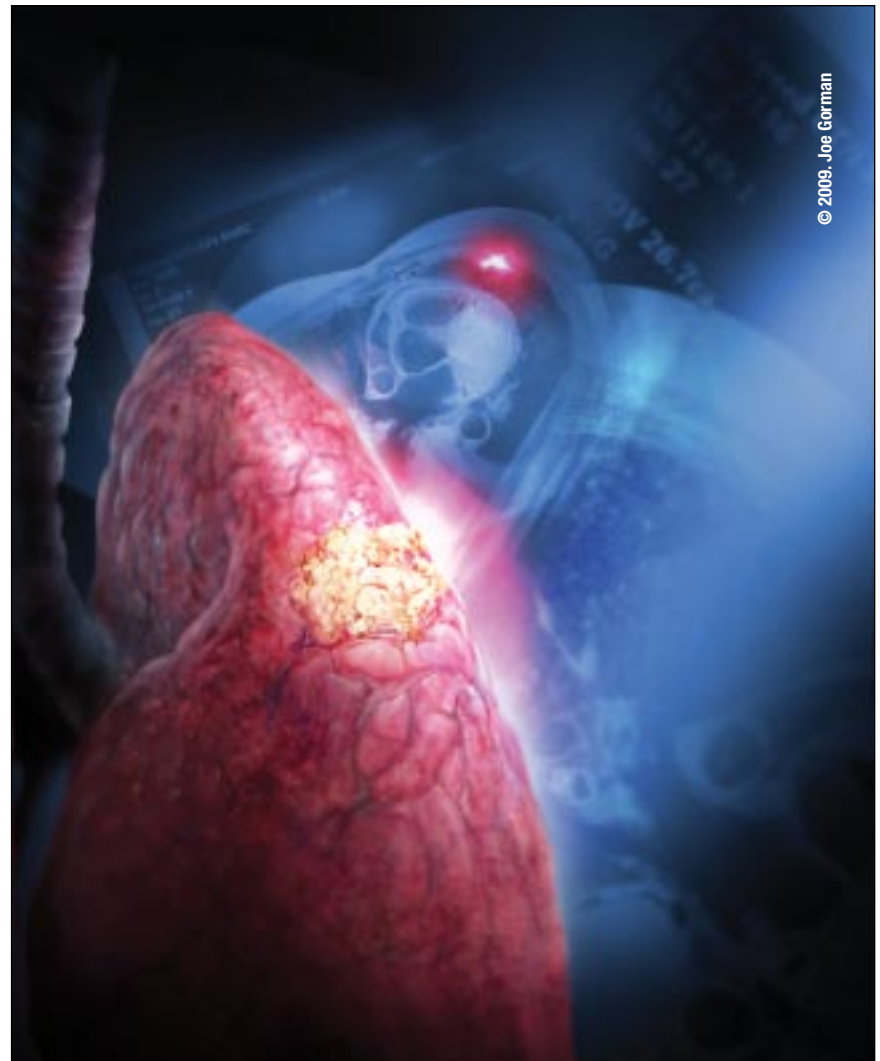
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initial consultation to surgical resection—unless the resection is delayed for neoadjuvant therapy. For patients who are not surgical candidates, the BTS recommends beginning treatment within two weeks of referral to a radiation or chemotherapy service.²

Before initiation of the pilot program, multiple factors contributed to the situation at the VAPHS in which the intervals between nodule detection, diagnosis, and treatment initiation exceeded the standards set by the BTS guidelines. Chief among these factors was the complex series of tests and procedures most patients needed to undergo prior to diagnosis. Under the traditional clinic model, VAPHS primary care providers were responsible for organizing these tests and procedures, and they often found it difficult to help their patients get to multiple appointments in a timely fashion. Frequently, patients would be admitted to VAPHS inpatient units simply to facilitate the coordination of testing and to bypass repetitive trips to this facility.³ In addition, as a teaching institution, the VAPHS places emphasis on the education of its medical residents, who rotate in and out of the primary care service line on an ongoing basis. This mode of health care delivery meant that, oftentimes, important findings were not passed along to patients in a timely fashion and, when alerts required immediate action and planning, no one was available to institute them or to execute the required plan of care efficiently.

Piloting a new approach

The pilot study, conducted in 1999, attempted to improve on this process by establishing a caregiver-patient relationship focused specifically on directing patients through the lung nodule evaluation process in a structured manner—thus removing them from the traditional clinic setting and



avoiding unnecessary inpatient admissions. An experienced registered nurse (RN) case manager was assigned to coordinate the evaluation process for the 40 patients participating in the study, with the support of a pulmonary physician committed to the project.

At the outset of this pilot study, a very rough algorithm was created that showed how a patient with a newly diagnosed nodule on an x-ray or computed tomography (CT) scan should be moved through the system in a specific manner. After the RN case manager reviewed each patient's

case with the physician preceptor, patients were contacted and scheduled for their evaluation, including biopsy procedures, pulmonary function tests, and any other recommended tests.

Patients enrolled in the pilot study stayed in temporary lodging (known as a “hoptel”) located on the grounds of the main VAPHS medical center in Pittsburgh and were given pagers so that, as information pertaining to their case became available, the nurse could arrange to meet with them to update them and inform them of the next step in the process (after discussing plans with the physician).

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LUNG NODULE EVALUATIONS

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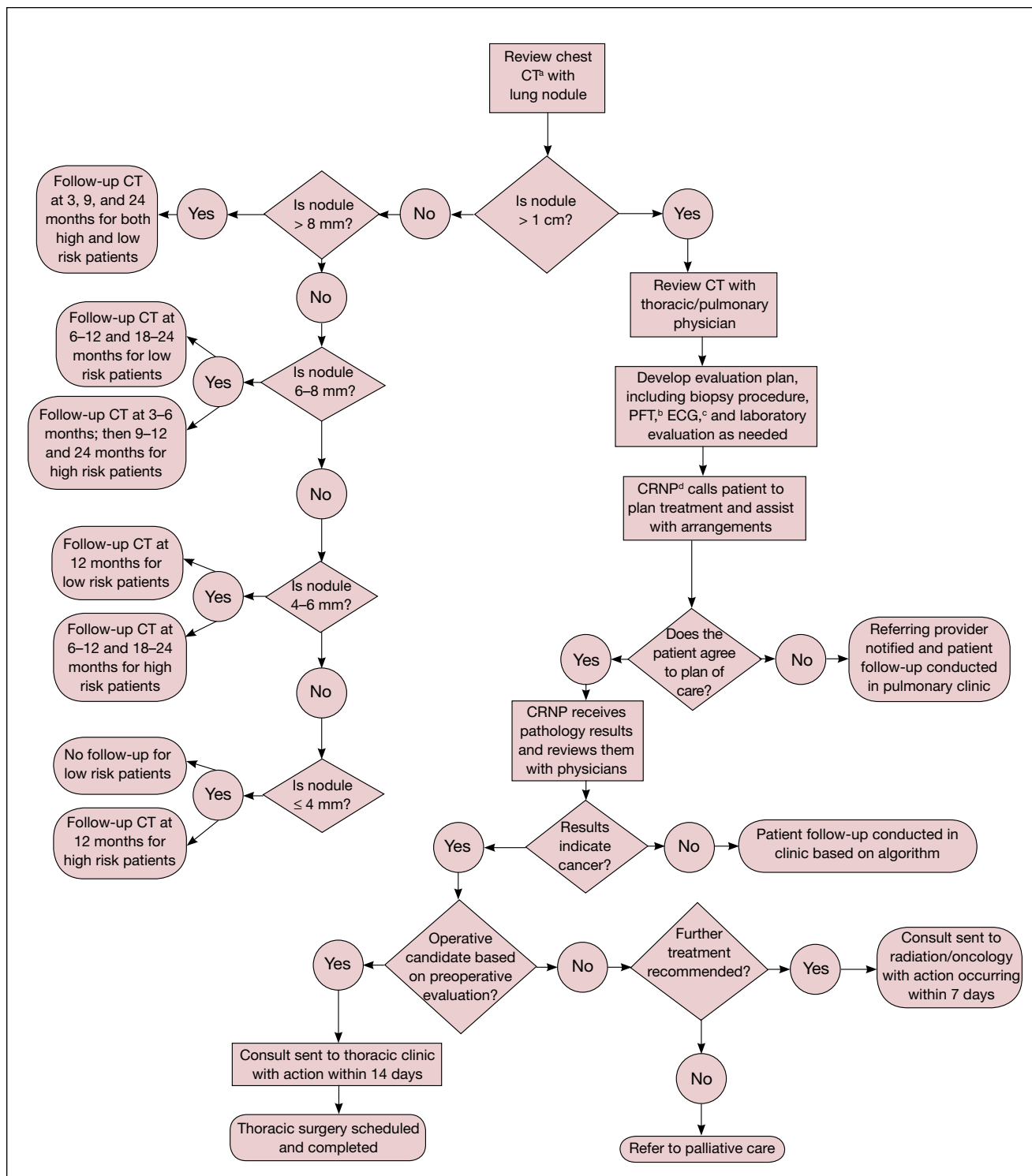


Figure 1. Algorithm used for patients referred to the VA Pittsburgh Healthcare System's Lung Nodule Evaluation Program, based in part upon the 2005 Fleischner Society guidelines⁴ and the 2007 American College of Chest Physicians guidelines.⁵ ^aCT = computed tomography. ^bPFT = pulmonary function test. ^cECG = electrocardiography. ^dCRNP = certified registered nurse practitioner.

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The hoptel unit was created for any patients who required access to the acute care hospital but did not require an inpatient admission. (All of the biopsy procedures can potentially cause complications that might require an inpatient stay after the procedure.)

Another intervention that was implemented for this cohort of patients was tracking of data by the RN case manager. This greatly helped to expedite a timely process for patients simply by keeping plans clear and organized.

Establishment of the LNEP

Based on the dramatic reduction in the average time to diagnosis (from 45 to 21 days) accomplished by the pilot study, the VAPHS implemented the project more widely as the LNEP, which officially began in 2001. The overall goal of the program is to expedite the evaluation of patients with abnormal radiology findings. The LNEP is staffed by a multidisciplinary panel, which includes primary care physicians, pulmonologists, radiologists, thoracic surgeons, and a certified registered nurse practitioner (CRNP) who serves as the program coordinator. When expanding the pilot program into the LNEP, the decision was made to use a nurse practitioner in this role rather than an RN because the coordination of patients could occur more seamlessly with an individual who could write orders, perform assessments, and make autonomous decisions as needed throughout the evaluation process. There always would be interaction with the physician preceptor about evolving patient scenarios, but the use of a CRNP coordinator provided for even more expeditious evaluations for the patient.

In most cases, patients are referred to the LNEP by VAPHS primary care providers or by providers from

“spoke” VA facilities (other VA medical centers in the surrounding area that refer patients to the VAPHS). In order to be scheduled for an outpatient evaluation through the LNEP, patients must be medically stable and able to care for themselves. This is because most LNEP patients are housed in the Outpatient Diagnostic Center (ODC), an outpatient nursing unit located at the main VAPHS acute care facility for the purpose of providing lodging, meals, support, and minimal nurse monitoring to patients undergoing certain diagnostic procedures (such as those involving conscious sedation). Although some patients undergoing LNEP evaluations stay in the hoptel unit at the main VAPHS facility (which offers no nursing support) while undergoing their outpatient testing, we have found that most patients require frequent directions and oversight in order to get to their appointments and procedures at the correct times. Additionally, ODC staff can relay messages to patients and provide them with written documentation of their follow-up plan before they leave. In this way, the ODC facilitates timely evaluation without the need for patients to occupy VAPHS inpatient beds. Patients with comorbidities who require a direct inpatient admission to the VAPHS are not considered to be enrolled in the LNEP and, thus, are not included in the program’s statistics.

THE EVALUATION PROCESS

Patients referred to the LNEP are evaluated according to an algorithm, developed using recent consensus guidelines,^{4,5} that stratifies patients according to the size of the nodule (Figure 1). Patients with nodules smaller than 1 cm are evaluated in an outpatient lung nodule clinic and then referred back to their primary care provider or spoke VA facility for

follow-up monitoring. Patients with nodules that are 1 cm or larger undergo an immediate review and evaluation through the ODC. Patients eventually diagnosed with either non-small cell or small-cell lung cancers have been evaluated through the LNEP, although the fact that small-cell lung cancer tends to present at a more advanced stage results in more of these patients being admitted to an inpatient unit (such as for management of Pancoast tumor symptoms) at the time of evaluation. And virtually all patients with small-cell lung cancer will present with nodules or masses larger than 1 cm.

Evaluation of subcentimeter nodules

The majority of patients referred to the LNEP have subcentimeter nodules. These nodules can be either solitary or multiple, and they frequently are detected as an incidental finding on a CT scan (or other chest imaging) ordered for a reason unrelated to lung cancer screening. Historically, the appropriate follow-up for these nodules—which may or may not progress to cancer—has been controversial. While the debate on this issue has not been resolved completely and practice continues to vary among providers and from case to case, the 2005 Fleischner Society⁴ and 2007 American College of Chest Physicians⁵ guidelines both provide evidence-based, expert consensus recommendations that we at the VAPHS have found useful and have incorporated into our LNEP algorithm.

Patients referred to the LNEP with subcentimeter nodules are seen initially by a supervised pulmonary fellow and receive pulmonary function tests within six months of their visit. The fellow places into the patient’s medical record a preestablished, templated note that dictates when the

next CT scan should be scheduled, based on the Fleischner Society criteria and recommendations. This follow-up scan often is performed at one of the spoke VA facilities with follow-up by the patient's primary care provider. Input from the LNEP team is always available should the patient's situation change or the referring provider desire further review and recommendation from the LNEP. Patients who receive their follow-up imaging at the main VAPHS facility generally continue to be monitored by the LNEP coordinator.

According to the Fleischner Society guidelines, patients with sub-centimeter nodules are divided into two groups: those who are at high risk and those who are at low risk for developing lung cancer. Cigarette smokers are at increased risk for lung cancers. This risk increases in proportion to the degree and duration of tobacco use. Other significant risk factors include a history of lung cancer in a first-degree relative and exposure to asbestos, radon, or uranium. Patients with any of these risk factors are classified as high risk and require a slightly shortened CT scan follow-up schedule to prove stability of the lung nodules over time. The guidelines also identify three groups of patients for whom its recommendations do not apply: (1) patients with known malignant disease, in whom follow-up should be consistent with treatment protocols for the underlying malignancy; (2) those who are younger than 35 years, in whom the risks associated with radiation exposure from multiple follow-up imaging scans likely outweigh the benefits; and (3) those with unexplained fever, in whom the appearance of a nodule could indicate active infection, thus necessitating more short-term follow-up imaging.⁴

In the low risk category, patients with nodules that are 4 mm or smaller require no follow-up. A low risk patient with a nodule between 4 and 6 mm requires a follow-up CT scan at 12 months. If there is no change, no further follow-up is necessary. A low risk patient with a nodule between 6 and 8 mm should receive a follow-up scan at six to 12 months and, if there is no change, again at 18 to 24 months.⁴

For high risk patients, nodules that are 4 mm or smaller require a follow-up scan at 12 months, with no further follow-up for unchanged nodules. A high risk patient with a nodule between 4 and 6 mm requires a follow-up scan at six to 12 months. If there is no change by then, the patient should have another follow-up scan at 18 to 24 months. A high risk patient with a nodule between 6 and 8 mm should receive a follow-up scan at three to six months, with subsequent follow-up scans at nine to 12 months and 24 months for unchanged nodules.⁴

For a nodule that is greater than 8 mm but less than 1 cm, both low and high risk patients require follow-up scans at three, nine, and 24 months. Clinicians also are advised strongly to consider ordering a positron emission tomography scan; a dynamic, contrast-enhanced CT scan; or, if feasible, a biopsy for these patients.⁴

Evaluation of larger nodules and masses

Patients referred to the LNEP who have a pulmonary nodule that is 1 cm or larger, as well as those with subcentimeter nodules that exhibit growth or change on follow-up imaging, enter the more "active" phase of the program, which departs from the traditional clinic model and utilizes the ODC. For these patients, the LNEP's CRNP reviews the patient's history and CT scan with the attending pulmonologist or

thoracic surgeon, who determines the appropriate diagnostic procedure for the patient based on the location of the nodule and other factors.

Most often, arrangements are made for bronchoscopy- or CT-guided biopsy procedures. Other procedures included in the diagnostic workup typically include pulmonary function tests; a thorough laboratory evaluation, which includes a complete blood count, chemistry panel with albumin, and coagulation panel; and a baseline electrocardiogram.⁶ Based on a preliminary discussion of possibly surgical candidacy, arrangements also may be made at the outset for specific pre-operative tests, such as cardiac stress tests and positron emission tomography scans. Occasionally, patients are referred directly to the thoracic clinic for surgical evaluation. Following this consultation, patients are contacted by the CRNP, who arranges for them to come to the ODC for their diagnostic workup.

When the patient presents to the ODC for a biopsy procedure, he or she is seen by the CRNP. If it is determined that the patient needs to be seen by the oncologist, arrangements are made for a same-day visit. Such visits often are initiated if the patient needs immediate radiation therapy or is a candidate for palliative therapy. A visit by the oncologist on the day of the diagnostic procedure reduces the need for the patient to return to the facility in an expedited manner. When patients cannot be seen by the oncologist or thoracic surgeon on the same day as their procedure, arrangements are made for them to visit the appropriate specialty clinic (hematology/oncology or thoracic) for follow-up within 14 days.

Generally, a member of the pathology staff is present during fine needle aspirate biopsy procedures to provide immediate pathology results. This

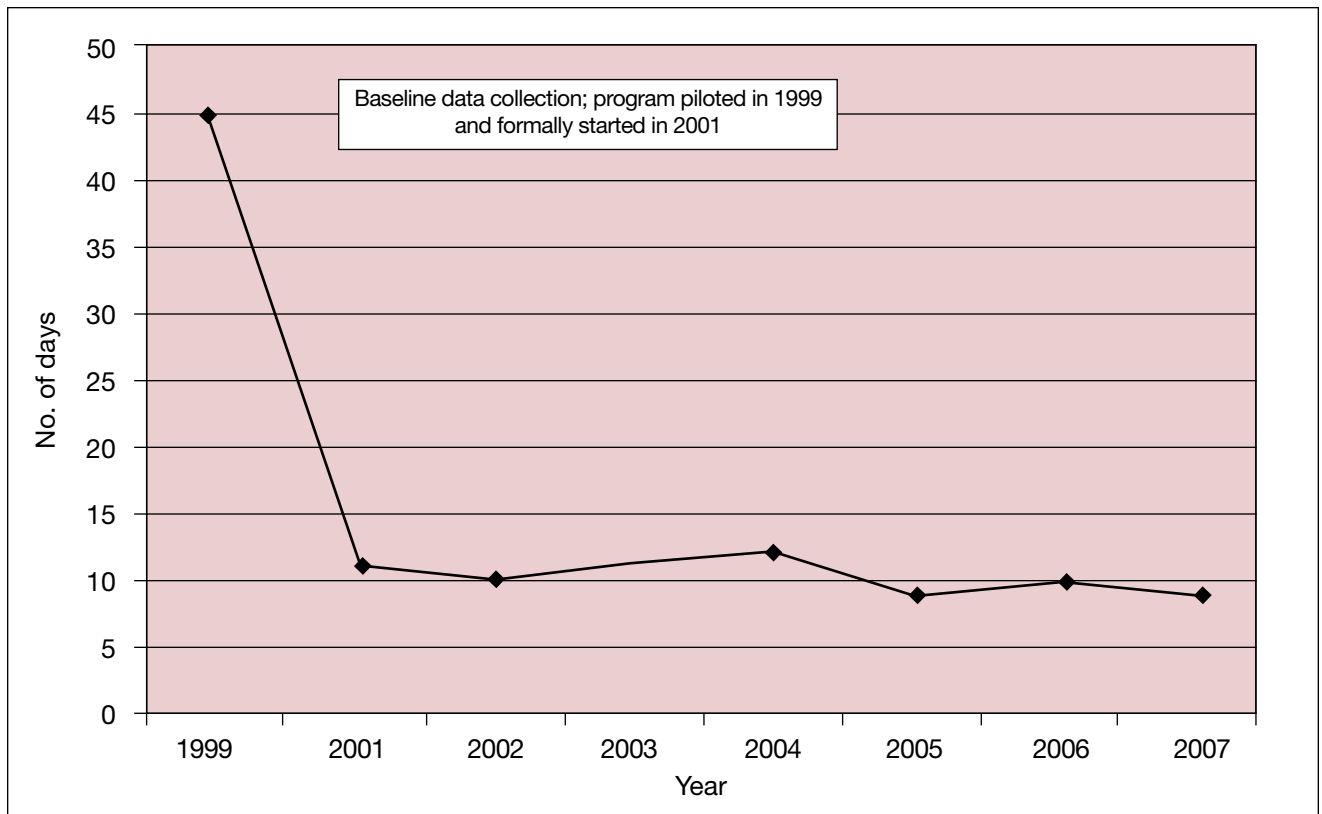


Figure 2. The average number of days from detection of a lung nodule (1999 data) or referral to the VA Pittsburgh Healthcare System's Lung Nodule Evaluation Program (2001 through 2007 data) to diagnosis of lung cancer.

ability to provide preliminary same-day findings facilitates a more timely response and helps to “fast-track” the patient for treatment, especially if he or she requires radiation for treatment or palliative care.

LNEP OUTCOMES

To date, we have collected seven years of data, from April 2001 through December 2008, on outcomes of patients evaluated through the LNEP. During this time, the program screened 2,283 patients with abnormal chest CT scan results (both subcentimeter and larger lung nodules). Of these patients, 660 have undergone a biopsy procedure and 450 have been diagnosed with lung cancer (59 with small-cell and the rest with non-small cell).

During the LNEP's first year, we were able to reduce the average interval between detection of a nodule and diagnosis from 45 to 11 days simply by streamlining the process by which these patients were evaluated (Figure 2). Since then, we have maintained a range of eight to 12 days from program referral to diagnosis. Although the latest data don't include patients evaluated in the inpatient setting (who are not part of the LNEP), it is unlikely that the inclusion of these patients would result in longer average intervals between lung nodule detection and diagnosis, since inpatient evaluation of lung nodules generally occurs relatively rapidly.

Between 2001 and 2007, the average interval between initial consult referral to initiation of treatment

(chemotherapy, radiation therapy, or thoracic surgery) ranged from 16 to 26 days annually (Figure 3). Average values for this range are a bit misleading because of occasional outliers who required a very cumbersome and lengthy process—as long as 120 days from initial consult referral to treatment. The fact that, despite these atypical patients, the average has remained as low as it has is a testament to the program's success in managing the evaluation process for the majority of patients within 30 days.

ONGOING CHALLENGES

The barriers that we have encountered in implementing the LNEP have remained consistent over the years in which we have tracked patient data. These barriers stem from the difficul-

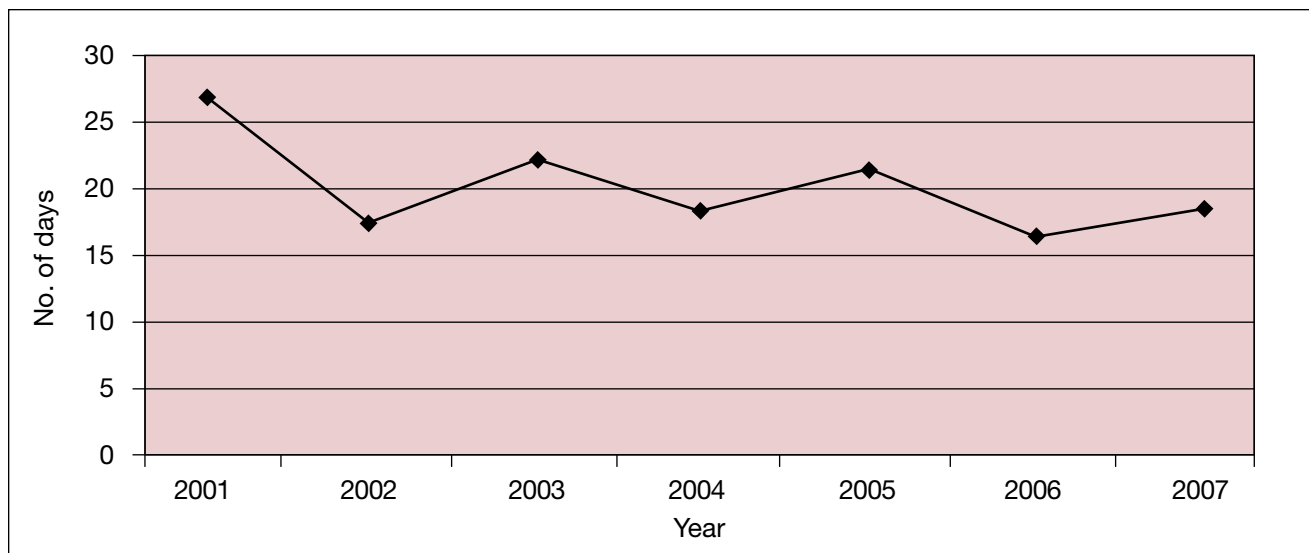


Figure 3. The average number of days from referral to the VA Pittsburgh Healthcare System's Lung Nodule Evaluation Program to the initiation of a treatment plan (thoracic surgery, radiation therapy, or chemotherapy), 2001 to 2007.

ties of evaluating and treating patients with complex conditions, and are not unique to patients with lung cancer. Determining the best treatment course for certain patients referred to the program (such as those with multiple cancers) requires so many different tests, visits, and, sometimes, hospitalizations that it is almost impossible to expedite the process. We have found, however, that certain aspects of the LNEP—such as personal telephone calls with detailed explanations and an ongoing, personal relationship with a consistent provider—may help patients to be more cooperative with complicated evaluations.

We also have faced challenges in reaching all patients who could potentially benefit from the LNEP. Despite efforts to educate primary care and other services within the VAPHS and at the surrounding VA medical centers that refer patients to the VAPHS about the existence of the LNEP, we have found it virtually impossible to track all patients referred to the VAPHS for evaluation of a newly discovered lung nodule. Chiefly, this is

due to the multiple routes by which such patients can undergo diagnostic workup for lung cancer without coming to the attention of the LNEP team. For instance, the lung nodule may be discovered while the patient is hospitalized for another condition, in which case the evaluation and diagnosis usually is conducted in the inpatient setting. Or, he or she may be an established patient of the hematology/oncology or radiation services (due to a previous cancer diagnosis) when the lung nodule is detected, in which case it is likely the respective service will oversee evaluation of the suspicious nodule. Of the 105 patients who were diagnosed with lung cancer at the VAPHS in 2006, for instance, only 46 had their evaluations managed by the LNEP. The rest were evaluated through one of these other routes.

At the VAPHS we are addressing this issue through ongoing provider education. When new interns start at the VA primary care clinics, for example, they receive a blurb about the LNEP, and we send letters periodically

to the spoke VA facilities. Additionally, the LNEP is now part of the National Lung Cancer Care Collaborative, and this affiliation may generate more ideas about better streamlining of patient evaluations.

IN CONCLUSION

The purpose of establishing the LNEP was to expedite the lung nodule evaluation process by removing patients from the traditional clinic setting, providing diagnosis and treatment through a multiservice team, and establishing a consistent caregiver-patient relationship to direct patients through the process. Despite continuing challenges, we have found the LNEP to be effective in achieving this goal.

Anecdotally, patients referred to the LNEP have expressed satisfaction with the care they receive through the program—both with the shortened wait time for information about their lung nodules and the expeditious manner in which they were given peace of mind and counseling about appropriate follow-up. Patients

also have communicated their appreciation of the program's accessibility and its use of a CRNP coordinator, who is familiar with their case from start to finish, to organize their cancer evaluation and answer any medical questions that arise as they progress through this stressful experience. Additionally, various service lines within the VAPHS have benefited from knowing that a designated individual is available for contact and consultation and that results may be obtained in a timely manner.

Overall, while the LNEP isn't always able to change the course of lung cancer, we have seen that having the disease evaluated more thoroughly from the outset enables patients to have a more positive experience and to have their care managed more efficiently in the long run. ●

Author disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

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