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ETHICS CASE

Close-Call Screening and Shared Decision Making

Commentary by Evelyn Chan, MD, MS

Dr. Samuelson is an internist employed by a large hospital system. As she walks into the office, a colleague greets her.

"Hey, Dr. Sam! You're looking a lot better than the last time I saw you!" Dr. Martin had seen Dr. Samuelson's last couple of patients for her one night the previous week, when she'd suddenly been laid low by what was probably the flu.

"Thanks for covering for me."

"No problem! Just don't make it a habit," Dr. Martin jokes. "By the way, while I was seeing Mr. Johnson and entering his visit info into the record, the little flag lit up reminding me that he met the criteria for lung cancer screening, so I went ahead and gave him a script to get the CT scan done. You saw the policy memo about the new core quality measures, right? They've really been pushing for 100 percent adherence to the USPSTF lung cancer screening guidelines in the EMR."

"Oh, OK. Well, I should get caught up on my work. Thanks again for seeing my patients."

As she walks to her office, Dr. Samuelson wishes she had told her colleague not to order any routine testing for her patients—only tests that were indicated by their present concerns. She did not automatically order even the recommended scans for her patients because of the unintended consequences of false-positive and false-negative results, incidental findings, and radiation exposure. She had seen it time and time again with mammography and worried that the USPSTF recommendations ended up causing trouble and pain for more patients than were helped.

Commentary

The ethical dilemma in the case concerns the hospital's guidelines and US Preventative Services Task Force (USPSTF) quality measures that endorse annual low-dose CT screening for lung cancer in patients ages 55 to 80 with a history of smoking [1], despite evidence suggesting a "close call" between benefits and risks [2, 3]. To manage this case, Dr. Samuelson should engage patients in shared decision making (SDM). This process allows clinicians to balance adherence to evidence-based guidelines with clinical judgment in patient care, particularly in situations in which screening tests offer potential

benefits and harms. The ethical justification for shared decision making resides in respecting patient autonomy while upholding the principle of nonmaleficence or "above all, do no harm" [4]. We will discuss the scope of the problem, the evidence in favor of and against CT screening, why shared decision making is the ethical "solution," and how to implement it while considering system-level and patient-level issues.

Evidence and Guidelines

Lung cancer is the leading cause of cancer-related mortality in the United States with about 158,040 expected deaths in 2015, accounting for about 27 percent of all cancer deaths [5]. The strongest risk factors for lung cancer are age over 55 years and a history of smoking. About 20 percent of the population smokes and only 15 percent of smoking cessation efforts succeed [2]. Outcomes in lung cancer depend on the stage of diagnosis. Because only about 15 percent of lung cancer cases are currently diagnosed at stage 1 [2], screening has been explored as a way to improve lung cancer survival. In the 1970s, three randomized controlled trials funded by the National Cancer Institute did not support routine chest x-ray or sputum cytology as effective screening tests for reducing lung cancer mortality [6]. As a result of the National Lung Screening Trial (NLST), low-dose CT has emerged as a potentially superior screening method with 55 percent to 85 percent of cancers detected in stage 1 [2].

The NLST was launched in 2002 to determine whether screening with low-dose CT (LDCT), as compared to chest x-ray (CXR), would reduce mortality from lung cancer among persons aged 55-74 at high risk for lung cancer [7]—those with a 30-pack-year history of cigarette smoking who, if they had quit, had done so within the previous 15 years. Participants were invited to undergo three annual screenings. Over the follow-up period, the median duration of which was 6.5 years, there were 20 percent fewer deaths from lung cancer in the LDCT group, but the absolute risk reduction was just 0.33 percent [7]. In all three rounds, a higher rate of positive screening test results was found with LDCT than with CXR. About 320 high-risk smokers or former smokers would need to be screened for every life saved, which compares well with other screening tests—to save one life from breast cancer, 2,000 people have to be screened; for colon cancer, 1,200 people [8]. However, false positive rates for these other tests are much lower. Age-related subgroup analysis showed that NLST participants age 65 years or older had not only a higher rate of false positive results than those younger than 65, but also a higher cancer prevalence [5].

Although comparative modeling [9] has been done and other European randomized controlled trials are in progress [10] to examine further the efficacy of LDCT as a screening method for lung cancer, the NLST remains the primary evidence base for screening guidelines. Drawing on this evidence, the USPSTF issued guidelines in 2013 giving LDCT a grade "B"—meaning that it is likely to offer moderate to substantial net benefit—to screening with LDCT for high-risk current and former smokers [1]. These

guidelines recommend annual screening with LDCT in patients aged 55-80 years who have a 30 pack-year smoking history and who currently smoke or have quit within the past 15 years. Screening should be stopped when a patient has not smoked for 15 years or has a health problem that limits life expectancy or the ability or willingness to undergo curative lung surgery.

Approximately 10 million people in the US would qualify for annual LDCT screening based on these criteria [10, 11]. Under the Affordable Care Act (ACA), a grade B from USPSTF means that private health insurers are required to cover LDCT at no cost to their eligible beneficiaries in 2015 [12]. The Centers for Medicare and Medicaid Services (CMS), on the other hand, can expand coverage based on A or B recommendations but is not required to do so [13]. In April 2014, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) reviewed the evidence base for LDCT and expressed low to intermediate confidence that "there is adequate evidence to determine if the benefits outweigh the harms" for patients covered by Medicare [14]. In February 2015, CMS ultimately decided that the evidence was sufficient to support annual LDCT under the Medicare program, if the following criteria are met: age 55-77 years, no symptoms of lung cancer, tobacco smoking for at least 30 pack-years, and a current smoker or one who has quit within the past 15 years. Additionally, smoking cessation materials have to be available for patients and the initial order and subsequent orders for LDCT screening have to include screening counseling and shared decision making with a physician, physician assistant, nurse practitioner, or clinical nurse specialist [15].

Other professional organizations, such as the American Cancer Society [5] and the National Comprehensive Cancer Network [16] have generally recommended eligibility criteria similar to that of the USPSTF with smoking cessation referral and screening in facilities with multi-disciplinary expertise for follow-up.

The different objectives of the USPSTF and MEDCAC illustrate some of the difficulties of implementing evidence-based policy on a population level. The USPSTF places the greatest weight on the evidence from randomized controlled trials. Such trials evaluate whether a preventive service works in a narrow population of patients under tightly controlled circumstances. However, the results of randomized controlled trials do not predict how well an intervention will perform in practice. For payers, including Medicare, the effectiveness of a preventive service is defined as the ratio of real-world benefits to harms for its population and is more relevant than findings derived from a selected population in a randomized controlled trial.

Other difficulties in implementing screening are the out-of-pocket costs some patients can expect to bear for follow-up studies to investigate false positive LDCT screening results [3, 11, 12, 14] and that the NLST participants, and therefore the results, were not representative of the population for which screening is recommended. Lower screening

uptake might be expected in those with socioeconomic or geographic barriers to health care or specialty follow-up [3].

Implementing Evidence-Based Recommendations on the Individual Level

Evidence-based recommendations cannot be applied at an individual level without clinical judgment. An individual patient may have more comorbidities than the NLST study participants, leading to a higher ratio of harms to benefits for the patient. Screening an individual patient also brings a high risk of false positive test results, anxiety, radiation exposure, and potentially numerous diagnostic workups and complications from these procedures. There is a real risk of psychological harm from receiving news about a lung nodule that might be cancer when workups might involve invasive diagnostic procedures before producing a benign result [3]. About 39 percent of patients who had an LDCT had at least one abnormality in three annual screenings. Fully 96.4 percent of abnormal results were false positives, 72.1 percent of which required workups [7]. More than 90 percent of the positive screening tests in the first round of screening led to a diagnostic evaluation, usually further imaging. But other workups included invasive procedures such as bronchoscopy and other surgeries. Additionally, invasive diagnostic procedures after a false positive LDCT were modestly more frequent [7].

Implementing Shared Decision Making

The USPSTF, CMS, the American Cancer Society, and the National Comprehensive Cancer Network all recommend shared decision making about lung cancer screening. As the USPSTF puts it, "the decision to begin screening should be made through a shared decision-making process whereby patients and providers discuss the potential benefits, harms, and uncertainties of screening" [1].

Clinicians can support shared decision making through a multi-step process. The clinician can assess the availability of LDCT in the geographical area, the patient's eligibility for screening, the time required for shared decision making over one or more visits, the patient's knowledge, and the patient's preferences for engagement—active, collaborative, or passive—in the decision making process. The clinician can then counsel the patient about the purpose of annual LDCT screening, smoking cessation programs, the potential benefits and harms of screening (including radiation exposure and patient costs for follow-up testing and diagnostic interventions), the scientific uncertainties (including false-positive test results and workups related to that), and how results and follow-up might be reported and conducted [3, 10, 11, 14]. Discussions might differ depending on the patient's age and race, due to the previously described limitations of the NLST trial results.

On an annual basis, clinicians might assess any change in patient preferences and review the decision making process. Clearly documenting the initial discussion and follow-up

discussions [11, 15], including the use of educational materials or decision aids [3, 10, 11, 14], can possibly safeguard the clinician from medical-legal consequences (if, e.g., a case of lung cancer is detected before a decision has been made about lung cancer screening or a patient has major downstream complications from screening) [11].

On a system level, accountable care organizations (ACOs) may want to develop cancer care groups of cancer specialists and primary care physicians to provide guideline-concordant, patient-centered, coordinated care. They may also want to coordinate lung cancer screening with smoking cessation programs and shared decision making. Low-risk patients who inquire about screening should be informed about the potential harms and that there is no evidence to indicate that the benefits of screening outweigh the risks. Patient-centered medical homes can identify patients eligible for lung cancer screening with LDCT. Additionally, the electronic medical record can be used to evaluate the performance and quality of a lung cancer screening program with LDCT and notify the responsible clinicians about abnormal imaging results that need followup [11]. Some systems, such as the Veterans Health Administration, are embarking upon demonstration projects [17] to determine whether they can provide screening and followup with accuracy, efficiency, and safety similar to that achieved in the NLST. New processes may be needed to monitor quality, ensure adequate capacity, and track outcomes in different regions of the country in different practice settings. Such demonstrations might inform other health care organizations and affect the manner in which health care providers offer LDCT to patients.

In summary, Dr. Samuelson needs to consider the hospital environment in which she is practicing—both system-level issues and patient-level issues—to promote shared decision making about LDCT screening. On an individual level, she might promote shared decision making by offering a decision aid to her patients and then discussing the decision with them in a clinic visit. A Cochrane review of 115 randomized clinical trials of patient decision aids concluded that they help increase patients' knowledge, improve their risk perceptions, and stimulate patients to take a more active role in decision-making processes [18]. By drawing upon the resources of a coordinated health care system and offering a decision aid to her patients, Dr. Samuelson will be able to uphold patient autonomy and the principle of nonmaleficence through shared decision making. She just needs to remember that the USPSTF guidelines that the hospital system supports also explicitly promote shared decision making. "Adherence" to the guidelines means adherence to this process that acknowledges patient preferences in determining whether it is appropriate to order an LDCT.

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