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Computed Tomography with Computer-Aided Detection for Lung Cancer Screening

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Several medical societies recommend annual lung cancer screening with low-dose computed tomography (LDCT) for certain individuals at high risk. However, the value of adding computer-aided detection to improve LDCT screening accuracy remains unclear.

Executive Summary: ECRI Perspectives

- In June 2011, the U.S. National Cancer Institute's (NCI's) National Lung Screening Trial (n = 53,454 current or former heavy smokers aged 55 to 74) reported these findings regarding screening with lowdose helical computed tomography (LDCT) compared with chest x-ray: individuals screened with LDCT had a 15% to 20% lower risk of dying from lung cancer than individuals screened using standard chest x-ray (National Lung Screening Trial Research Team 2011). This means that about 3 fewer deaths per 1,000 people screened occurred in the LDCT group than in the chest x-ray group over a period of about 7 years of observation (17.6 per 1,000 vs. 20.7 per 1,000, respectively).
- Study authors also reported that after 3 rounds of screening, on average, 24.2% of LDCT screens and 6.9% of chest x-rays were positive. These positive results usually led to additional testing.
- The authors also reported that certain types of lung cancer were detected more often at the earliest stage by LDCT (adenocarcinomas and squamous cell carcinomas) than by chest x-ray. However, small-cell lung cancers, which are very aggressive, were not often detected at early stages by either method.
- To improve LDCT screening accuracy, some developers have proposed using a class of pattern-recognition software called computeraided detection (CADe) to analyse radiologic images. The software is intended to identify patterns suggestive of disease and highlight them for radiologist review. Use of the technology requires additional staff time for interpretation and modestly increased data processing and storage capacity.
- Adding CADe capability to a computed tomography (CT) system could cost up to $65,000 (€57,250) per license (ie, for each radiologist user), but additional reimbursement for its use is not available, even though CADe has been available since 2006. Two studies report that CADe adds up to 80 seconds for LDCT image review (Matsumoto et al. 2013; Bogoni et al. 2012); additional data storage requirements for CADe use are considered to be small to negligible.
- Although several clinical guidelines recommend LDCT screening in the population defined in the NCI trial, they are silent on the role of CADe to improve LDCT screening accuracy (Detterbeck et al. 2013; Jaklitsch et al. 2012; Wender et al. 2013; American Lung Association Lung Cancer Screening Committee 2015; National Comprehensive Cancer Network (NCCN) 2015a; 2015b; Moyer VA; U.S. Preventive Services Task Force 2014)
- A primary safety concern about using CADe for LDCT screening is the risk of increasing the rate of false-positive results. False positives often lead to additional testing and potential harm from unnecessary treatment from overdiagnosis of lung lesions unlikely to cause clinical symptoms.
- Clinical trials are needed to determine whether CADe has an appropriate role for improving accuracy of LDCT for lung cancer screening. We identified one relevant ongoing study in China (Shanghai Changzheng Hospital), that may provide data in 2017 to further elucidate the role of CADe in LDCT screening.

Ratings and Rationales of Potential Impact

Note: *The following ratings and comments reflect the opinions and consensus of an expert panel convened by ECRI Institute to review information on this topic.*

Anticipated Utilisation: 1 (Expected to be used by 0% to 20% of eligible patients)

Clinical guidelines recommend low-dose computed tomography (LDCT) to screen high-risk patients for lung cancer; however, they are silent on enhancing LDCT with computer-aided detection (CADe) systems (Detterbeck et al. 2013; Jaklitsch et al. 2012; Wender et al. 2013; American Lung Association Lung Cancer Screening Committee 2015; National Comprehensive Cancer Network (NCCN) 2015a; 2015b; Moyer VA; U.S. Preventive Services Task Force 2014). Some manufacturers report that the slow initial adoption is unlikely to change without extra reimbursement or new clinical data showing that CADe improves outcomes or cost-effectiveness of LDCT. Over time, more radiologists might adopt software that automatically tracks changes to radiologistidentified lung nodules to facilitate lung cancer screening. However, that assumption would depend on ultimate patient demand for LDCT screening.

Estimated Adoption Status: 3 (Early adoption occurring – 0% to 25% of facilities that would be expected to adopt have adopted)

Before July 2012, the U.S. Food and Drug Administration (FDA) required companies to submit marketing applications for CADe software products under its premarket approval (PMA) application process. FDA granted Siemens AD (Munich, germany) a PMA for its syngo LungCAD product in October 2006 (United States Food and Drug Administration 2006). Since the change, FDA has not granted 510(k) marketing clearance to any software products that fully meet its definition of CADe: automatically identifying suspect lung nodules for radiologist review (ie, second reader mode).

Potential Health Impact: 2 (Expected to make a small improvement to patients' health and/or quality of life)
Few data are available to evaluate the potential effect of adding CADe to LDCT in lung cancer screening programmes. Several professional societies recommend LDCT lung cancer screening for certain older smokers and former smokers at highest risk of developing lung cancer. However, these guidelines generally do not address the addition of CADe to LDCT.

Potential Financial Impact: 2 (Expected to have a small financial impact)
Implementing CADe capability to a computed tomography (CT) system could cost up to $65,000 (€57,250) (PricePaid 2014), which is small relative to the overall cost of a CT system. Adding CADe to LDCT exams would likely lead to only a modest increase in data storage requirement. Additional reimbursement for adding CADe to LDCT exams is unlikely from third-party payers.

Potential Process and Infrastructure Impact: 2 (Expected to have a small process impact)
Adding CADe to LDCT exams is unlikely to cause major changes to existing lung cancer screening programmes. Implementing CADe for LDCT could incrementally increase radiologist workload by lengthening reading time per case. Increased data handling and storage requirements would likely be small. However, the potential downstream impact could be considerably greater if widespread use of CADe for LDCT lung cancer screening increases the number of false-positive findings, resulting in unnecessary additional testing and lung biopsies.

Note
The full article including overview, references and trial information is available through ECRI's Health Technology Assessment Information Service (HTAIS).

About ECRI

ECRI Institute, a nonprofit organisation, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover he best approaches to improving patient care. As pioneers in this science for nearly 45 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research.

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