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Title: Cost Effectiveness of Automated 3D Sputum Cytology  
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#### Abstract

**Background:** The Lung Cell Evaluation Device (LuCED™) employs a high-resolution 3D cell-by-cell analysis of sputum cells, making it possible to achieve test performance superior to 2D sputum cytology. We estimated the cost-effectiveness ratio (CER) of a lung cancer screening protocol that uses LuCED as the primary test, combined with x-ray computed tomography (CT) as the secondary test.

**Methods:** We developed a Monte-Carlo natural-history model, EL-CID, to compute the costs and life-years saved over the course of 15 years from initiation of the screening protocol. The hypothetical screening population consisted of high-risk current and former smokers. We compared results for this population with (1) no screening, (2) x-ray CT screening, and (3) LuCED screening as the primary test, with x-ray CT as the secondary test. We applied multiple scenarios and a range of LuCED test accuracies. These scenarios were:

- (A) The default scenario with lung cancer incidence of 0.6% annually;
- (B) Faster disease progression;
- (C) Slower disease progression;
- (D) Higher background death rate, in which there is a greater chance of death from causes other than lung cancer;
- (E) Lower lung cancer incidence (0.45% annually);
- (F) Lowest lung cancer incidence (0.3% annually);
- (G) Lower early-stage cure rate;
- (H) Lowest early-stage cure rate.

The model was validated by comparing the results with known benchmarks in the unscreened case, including five-year survival by stage at diagnosis (Mountain, 1997), distribution by stage of detected cancers (Mountain, 1997), and treatment cost by stage (Hillner 1998; Riley 1995). We used a triage model in which detection of dysplasia led to increased testing frequency. We varied the sensitivity and specificity of the LuCED test for each scenario.

**Results:** The CER depended on the performance of the LuCED test as well as on the parameters of each scenario. The highest CER's were found for the scenarios characterized by a poor rate of early-stage treatment success (G and H), lowest lung cancer incidence (F), or slower rates of disease progression (C). The CER remained close to the default value (A) for scenarios with fast disease progression (B), annual incidence of 0.45% or higher (E), or an elevated background death rate (D). The cumulative CER was evaluated for each year; it fell below \$40,000 per life-year saved by year 10. After an initial spike in detected cancers, steady-state cost and life savings were reached within four years of screening implementation.

**Conclusion:** A screening protocol for high-risk patients that combines LuCED sputum analysis with x-ray CT can be comparable in cost-effectiveness to biennial mammography screening.