

**Use Case 1**  
**Pragmatic Trial of More versus Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules**

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**Background:** Guidelines now recommend that smokers and former smokers undergo lung cancer screening, which can identify small growths. These pulmonary nodules are typically then monitored with serial CT scans that look for changes suggesting the nodules are cancerous. However, the optimal frequency of such scans has not been determined. The proposed research will compare more intensive versus less intensive protocols for CT surveillance.

**Objectives:** Among individuals with small pulmonary nodules that progress beyond the most curable stage of lung cancer, we will compare two protocols for CT surveillance, both of which are supported by existing guidelines from professional societies and are consistent with current standards of care. We consider patient-reported outcomes of emotional distress, anxiety, general health status, and satisfaction with the evaluation process; resource utilization and exposure to diagnostic radiation; adherence to the recommended protocols for surveillance; and adherence to use of low-radiation-dose techniques.

**Methods:** Using automated methods for identification, notification, and registration into the study, we will enroll eligible patients at each of 26 hospitals within 14 healthcare systems. We estimate that almost 47,000 patients will be passively enrolled over 20 months and followed for two years. We will perform analyses to determine which protocol works best for specific subgroups of patients.

**Patient Outcomes:** Lung cancer tumor stage T1a, the most curable stage of cancer; timeliness of lung cancer treatment; survival from lung cancer; emotional distress, anxiety, and general health status during surveillance; overall satisfaction with evaluation; number of tests and procedures performed during the surveillance period; number of procedure-related complications during the surveillance period; adherence to recommended surveillance, for both patients and providers; and exposure to potentially harmful radiation.

**Anticipated Impact:** Surveillance imaging and downstream invasive testing can be inconvenient, costly, and potentially harmful. By comparing two existing options for surveillance in the context of routine clinical practice, our trial will have a large and immediate impact on clinical care. By collaborating with stakeholders from health systems, professional societies, and advocacy groups, we will disseminate our findings widely and facilitate implementation in diverse practice settings.