

The EQUAL study: Utilizing plasma EGFR cfDNA detection as an accessible screening tool for lung cancer in underserved patients ineligible for routine screening.

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Background: Lung cancer (LC) among non-tobacco-users is increasing in the United States, with no routine screening available. Among those patients, EGFR mutations (EGFRm) are common, with the highest prevalence seen in East Asian and Hispanic women. Delays in diagnosis and treatment are exacerbated in these marginalized groups and women, negatively impacting their cancer outcomes. At Dana-Farber Cancer Institute's (DFCI) Belfer Center for Applied Science, we developed a novel droplet digital PCR ctDNA assay to detect EGFR del19 and L858R mutations, which comprise 85–90% of total EGFRm in LC. Here, we report the methodology of EQUAL, a study assessing the feasibility of a diagnostic assay among non-tobacco using, historically marginalized East Asian and Hispanic populations at high risk for EGFRm-LC. **Methods:** To assess the feasibility of our ctDNA screening tool, the EQUAL study is recruiting two cohorts of participants. Cohort 1 (n=500) includes 50–80-year-olds who self-identify as East Asian or Hispanic from the general population, while Cohort 2 (n=500) includes 40–80-year-olds of the same backgrounds with an additional risk factor for LC, with a focus on direct family members of patients with EGFRm-LC. Recruitment is beginning with these family members of patients with EGFRm-LC at DFCI main campus, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, DFCI Merrimack Valley, DFCI regional campuses, and will expand to primary care clinics and community events. Blood samples are collected in clinics or at home via mobile phlebotomy. Positive results are verified in a government-certified CLIA laboratory; a complementary chest CT will be arranged for those with positive assay results, and patients will receive navigation until resolution. Patients with a positive assay but negative chest CT will be followed for 12 months and will receive a second annual chest CT. Recognizing how cultural beliefs and tobacco's association with LC may hinder screening participation, EQUAL includes an optional survey and focus groups to explore perceptions and barriers surrounding LC screening with our tool for future optimization efforts. The study is available in 8 languages including Spanish, Portuguese, Korean, Vietnamese, Japanese, Chinese (simplified and traditional), and Creole. EQUAL is the first study to implement EGFRm-LC blood-based screening for historically marginalized populations who are not eligible for LC screening, thereby allowing for LC identification that can be effectively treated with targeted therapy approved for stages IB–IV. This pilot study seeks to lay the groundwork for future sensitivity and specificity trials that will confirm the value of the assay and expand the scope of current screening guidelines to reduce health disparities and delays in LC diagnosis. Clinical trial information: NCT06716580. Research Sponsor: Dana-Farber Cancer Institute Philanthropic Funds.