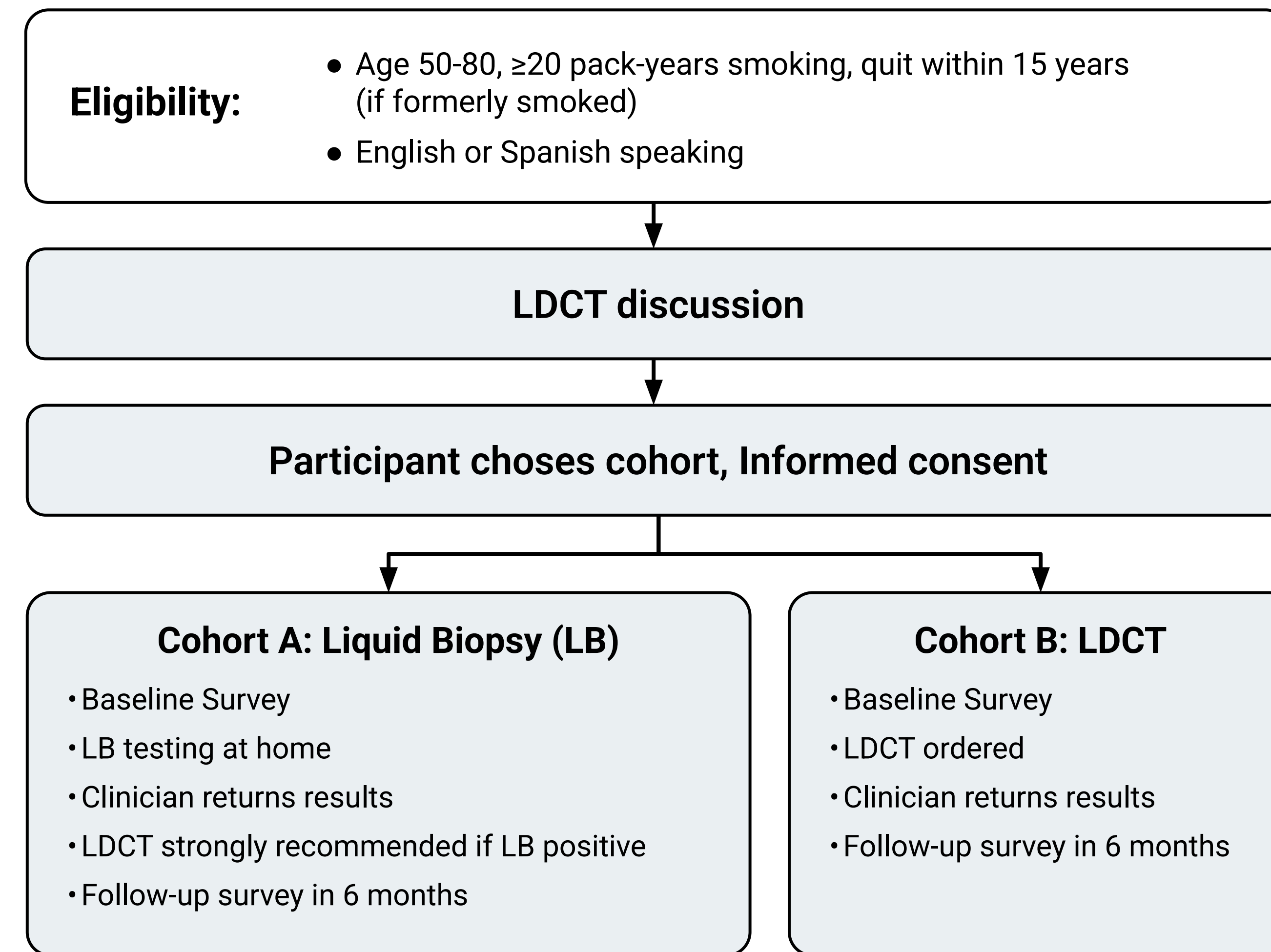


## BACKGROUND

Lung cancer screening (LCS) with low-dose computed tomography (LDCT) significantly reduces lung cancer mortality but remains severely underutilized.<sup>1,2,3</sup> Less than 19% of eligible adults undergo screening,<sup>3</sup> with even lower screening rates in under-resourced populations.<sup>4</sup> DELFI FirstLook™ Lung (FLL)<sup>5\*</sup> is a high sensitivity cell-free DNA (cfDNA) blood-based lung cancer screening test that can be collected at home, making it a potentially convenient option for individuals facing barriers to LCS. Results are returned as "Elevated", or "Not-elevated", where "Elevated" results require follow-up by LDCT. We evaluated the feasibility of FLL in an under-resourced population to identify characteristics of individuals interested in using blood-based testing as an initial step in LCS.

## STUDY DESIGN AND METHODS

- **Trial Design:** Non-randomized multi-center cohort study
- **Study sites:** An urban Federally Qualified Health Center (FQHC), a LCS program serving underserved populations, and community outreach.
- **Intervention:** Participants were offered either at-home FLL testing via mobile phlebotomy or LDCT.
- **Measurements:** Baseline surveys assessed screening history and barriers to LCS. Participants were recontacted 6-months after enrollment to evaluate acceptability and LDCT completion. Feasibility was defined as ≥30% preferring FLL.



**Outcomes:** Proportion of participants choosing LB, acceptability of home LB, LDCT rates if LB positive or negative, effect of barriers and socio-demographics on choice of testing

## STUDY RESULTS

**Table 1:** Sociodemographics and Characteristics of Study Participants

	BBT <sup>1</sup>	LDCT <sup>2</sup>	P value
Age, years (Median, IQR)	61 (57-66)	62 (58-65)	0.78
Sex (N,%)			0.71
Male	22 (50%)	11 (55%)	
Female	22 (50%)	9 (45%)	
Race/ethnicity (n,%)			0.19
White Non-Hispanic	15 (34%)	8 (40%)	
Hispanic/Latino	19 (43%)	6 (30%)	
Black/African American	3 (7%)	4 (20%)	
Asian/Pacific Islander	2 (5%)	1 (5%)	
Native American	0	1 (5%)	
Multi-racial/Other	5 (11%)	0	
Highest Education Level (n,%)			0.43
Some high school	8 (20%)	7 (35%)	
High school/GED	12 (29%)	5 (25%)	
Some College	15 (37%)	4 (20%)	
Completed College	2 (5%)	3 (15%)	
Post-college education	4 (9%)	1 (5%)	
Did not answer	3	0	
Annual household income			0.7
<\$25,000	20 (57%)	11 (73%)	
\$25-50,000	4 (11%)	1 (7%)	
\$50,000-\$100,000	9 (26%)	2 (13%)	
>\$100,000	2 (6%)	1 (7%)	
Did not answer	9	5	
Smoking History			0.75
Currently Smokes (n,%)	29 (66%)	14 (70%)	
Formerly Smoked (n,%)	15 (34%)	6 (30%)	
Pack-years smoked (Median, IQR)	44 (30-66)	37 (26-58)	0.49
Prior Cancer Screening			0.92
Chest CT for Lung Screening			
Yes	4 (9%)	2 (10%)	
No	33 (75%)	13 (65%)	
Other*	7 (16%)	5 (25%)	
Breast cancer screening (Women only)			0.72
Yes	18 (82%)	10 (53)	
No	3 (14%)	0	
Other*	1 (5%)	0	
Colon Cancer Screening#			0.73
Yes	19 (43%)	9 (45%)	
No	22 (50%)	9 (45%)	
Other*	3 (7%)	1 (5%)	

<sup>1</sup>Blood-Based Test; <sup>2</sup>Low-dose chest computed tomography  
 \*Other includes does not know, does not apply, or did not answer  
 #Includes colonoscopy, sigmoidoscopy, or stool-based test

**Table 2:** Participant Reported Reasons for Choosing Liquid Biopsy or LDCT

Liquid biopsy cohort	(n,%)
What were the reasons that you decided to get the blood test rather than the lung scan?	
The blood test is more convenient for me	24 (55%)
I can get the blood test completed faster than I can get a lung scan.	20 (46%)
I am worried I may need to pay money for the lung scan.	11 (25%)
I am worried about radiation exposure from a lung scan.	4 (9%)
The blood test seems like a good first step. I may still get a lung scan in the future.	12 (27%)
Other	3 (7%)
What is the single most important reason that you decided to get the blood test rather than the lung scan?	
The blood test is more convenient for me	16 (47%)
I can get the blood test completed faster than I can get a lung scan.	6 (18%)
I am worried I may need to pay money for the lung scan.	1 (3%)
I am worried about radiation exposure from a lung scan.	0 (0%)
The blood test seems like a good first step. I may still get a lung scan in the future.	10 (29%)
Other	1 (3%)
Did not answer	10
LDCT cohort	(n,%)
What were the reasons that you decided to get the lung scan rather than the blood test?	
A lung scan is better than the blood test at detecting cancer.	10 (50%)
A lung scan was recommended to me by my doctor or healthcare provider.	4 (20%)
I don't like blood tests.	4 (20%)
The blood test is new and still experimental.	1 (5%)
I have had a lung scan in the past and had a good experience getting one.	2 (10%)
Other/ did not answer	1 (5%)
What is the single most important reason that you decided to get the blood test rather than the lung scan?	
A lung scan is better than the blood test at detecting cancer.	8 (53%)
A lung scan was recommended to me by my doctor or healthcare provider.	3 (20%)
I don't like blood tests.	1 (7%)
The blood test is new and still experimental.	1 (7%)
I have had a lung scan in the past and had a good experience getting one.	1 (7%)
Other	1 (7%)
Did not answer	5

## SUMMARY:

- **64 participants were enrolled: 44 (69%) chose FLL while 20 (31%) chose LDCT.**
- Demographics, education, and prior cancer screening were similar between the groups (Table 1).
- **Participants choosing FLL more often reported barriers to LCS, including lack of a regular provider (P=0.008), cost concerns (p=0.02), and distrust in the health care system (p=0.11).**
- **Convenience and faster testing were the main reasons for selecting FLL (Table 2). Better cancer detection and physician recommendation motivated choosing LDCT.**
- Of those selecting FLL, 2 opted for LDCT prior to blood testing, and 3 did not complete testing.
- **49% (19/39) of FLL participants had "Elevated" or positive results, of whom 92% completed LDCT within 6 months.**
- Of those with "Non-Elevated" or negative results, 50% completed LDCT. **Among those choosing LDCT alone, 69% completed LDCT within 6 months.**

## CONCLUSIONS

In an underserved population, more than twice as many individuals selected at-home blood-based testing for LCS over LDCT, and nearly all individuals with an "Elevated" or positive result completed LDCT within six months. These results suggest that LCS rates could be improved in underserved populations if blood-based testing were an available option.



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\*DISCLAIMER: The FirstLook Lung test is a laboratory-developed test. This test was developed, and its performance characteristics were determined by DELFI Diagnostics. It has not been cleared or approved by the US Food and Drug Administration (FDA). The laboratory is regulated under the Clinical Laboratory Improvement Act (CLIA) as qualified to perform high-complexity clinical tests.