Projected Benefit and Cost-Effectiveness of Offering a Choice of Blood-Based Screening Versus Existing Screening Tests for Colorectal Cancer in Two Real-World Settings

Reinier G.S. Meester,[1,2] Andy Piscitello,[1] Lance Baldo,[1,a] Noelle M. Griffin,[1,a] Peter S. Liang[3,4]

[1]Freenome Holdings Inc., South San Francisco, CA, US; [2]Stanford University School of Medicine, Stanford, CA, US; [3]VA New York Harbor Health Care System, New York, NY, US; [4]NYU Langone Health, New York, NY, US

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INTRODUCTION

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- Screening for colorectal cancer (CRC) reduces CRC-associated incidence and mortality[1] and is recommended for average-risk adults starting at age 45 years[2,3]
- Recent CRC screening statistics reveal that only 59% of eligible individuals are up to date, which is well below the US nationwide goal of 80%[1,4]
- Emerging blood-based tests for CRC detection, free from some of the drawbacks associated with existing tests, such as bowel preparation, sedation, and stool-handling, could potentially improve screening rates[5-9]
- However, there is concern that replacing existing tests with blood tests could adversely impact health outcomes and costs due to the lower sensitivity of current blood tests for advanced precursor lesions[10-12]
- Two recent studies in patients who previously declined screening found that offering a choice between blood-based screening vs existing screening options (colonoscopy or stool testing) increased overall adherence, with limited replacement of existing screening[8,9]

OBJECTIVE

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- To estimate the long-term clinical and economic impact of adherence patterns observed for CRC screening with blood-based tests vs existing tests in two real-world studies

MODEL ASSUMPTIONS

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- An established Cancer Intervention and Surveillance Modeling Network (CISNET)[13] model was replicated, validated, and then used to evaluate the observed mix of screening patterns across the studies' control and intervention arms
- The assumed performance for blood testing was 74% CRC sensitivity and 90% specificity (**Table 1**), satisfying the minimum US coverage criteria as defined by the Centers for Medicare and Medicaid Services (CMS)[14]; a 10% advanced adenoma sensitivity was conservatively assumed
- Assumed costs were based on CMS reimbursement rates, using stool-DNA (sDNA) costs as a proxy for blood-based tests
- Outcomes assessed were deaths averted, projected life-years gained (LYG), and incremental cost/quality-adjusted life-years (QALY) for offering the choice of blood testing

Table 1. Inputs on test performance

Test characteristic	Colonoscopy	Fecal test (FIT)	Blood test[a] (CMS minimal requirements)
Specificity	-	0.97	0.90
Sensitivity for non-AA[b]	0.75-0.85	0.07	0.10
Sensitivity for AA	0.95	0.22	0.10
Sensitivity for CRC	0.95	0.74	0.74

[a]The input test performance for blood testing was defined as the minimum coverage criteria outlined by CMS.[14]
[b]The model defines non-AA as adenomas <10 mm in size and AA as adenomas ≥10 mm.
Colonoscopy sensitivity differs for adenomas of 1-5 (75%) vs 6-9 mm (85%).
AA, advanced adenoma; CMS, Centers for Medicare and Medicaid Services; CRC, colorectal cancer; FIT, fecal immunochemical test.

Model inputs for screening patterns

- Assumed adherence to colonoscopy every 10 years, annual fecal immunochemical test (FIT), and triennial blood testing were based on observed utilization in Liang et al.[8] and Coronado et al.[9] (**Table 2**)
- In both studies, a significantly higher proportion of participants underwent screening in the intervention arm (OR 1.96, *P*=.04; and, OR 3.08, *P*<.001), which offered blood-based testing as a screening option, compared with the control arm, which did not offer blood-based testing[8,9]
- Colonoscopy and FIT utilization were similar between study arms in both studies
- In the model, adherence to screening was assumed to remain at observed levels

Table 2. CRC screening patterns

Patients screened, n (%)	Liang et al., 2023[8]			Coronado et al., 2024[9]		
	Control[a] n=178	Intervention[b] n=181	OR (*P* value[c])	Usual care[a] n=1003	Intervention[b] n=181	OR (*P* value[c])
Colonoscopy	2 (1.1%)	4 (2.2%)	1.99 (0.68)	15 (1.5%)	12 (1.2%)	0.80 (0.70)
Fecal testing	15 (8.4%)	18 (9.9%)	1.20 (0.72)	115 (11.5%)	99 (9.9%)	0.85 (0.28)
Blood testing	- (0%)	9 (5.0%)	-	- (0%)	204 (20.4%)	-
Total	17 (9.6%)	31 (17.1%)	1.96 (0.04)	130 (13.0%)	315 (31.5%)[d]	3.08 (<0.001)

[a]Did not include blood-based testing as a screening option.
[b]Included blood-based testing as a screening option.
[c]Fisher's exact test.
[d]Coronado et al. reported n=305 screened with intervention (OR 2.94), but test-specific numbers and visual data from the study suggest n=315 (OR 3.08).
CRC, colorectal cancer; OR, odds ratio.

Model inputs for adherence patterns for follow-up colonoscopy

- In both Liang et al. and Coronado et al., 50% of the individuals who had a positive blood test result completed a follow-up colonoscopy, while the follow-up rate for fecal tests ranged from 0% to 70%[9,10] (**Table 3**)
- As differences were not statistically significant, we assumed a rounded follow-up rate of 50% for both blood and fecal testing based on the overall average of 51.4%
- To account for uncertainty, higher reported rates in literature, and potential future improvements, we also evaluated scenarios with 75% and 100% follow-up

Table 3. Adherence pattern for follow-up colonoscopy

Patients, n (%)	Liang et al., 2023[8]			Coronado et al., 2024[9]		
	Fecal testing	Blood testing	*P* value[a]	Fecal testing	Blood testing	*P* value[a]
Screened	33	9		214	204	
Positive	3	2		10	22	
Followed up[b]	0 (0%)	1 (50%)	0.40	7 (70%)	11 (50%)	0.45

[a]Using Fisher's exact test.
[b]Current clinical guidelines state all positive results for non-colonoscopy tests should be followed up with a timely colonoscopy.[2,3]

RESULTS

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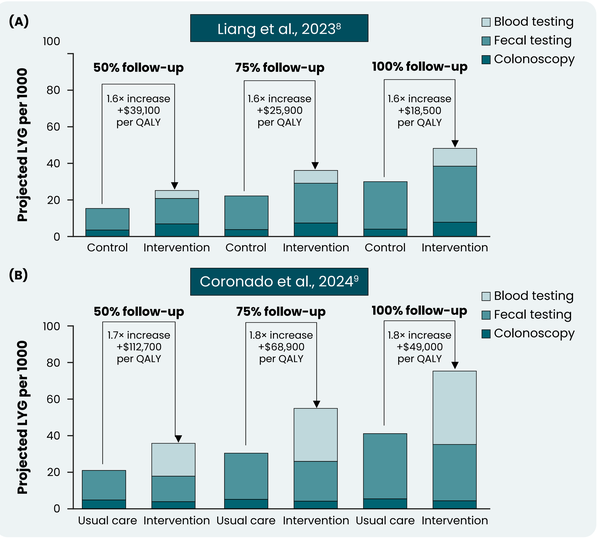
Projected clinical and cost-effectiveness of blood-based testing using observed adherence patterns for screening and follow-up colonoscopy

- With 50% assumed adherence to colonoscopy follow-up and with observed screening patterns from Liang et al., offering blood testing in addition to existing tests was projected to result in 1.6 additional CRC deaths averted per 1000 persons, and to increase the LYG by 1.6 times, at a cost of $39,100/QALY gained (**Figure 1A**)
- With observed screening patterns from Coronado et al., offering blood-based screening resulted in 2.9 projected CRC deaths averted per 1000 persons, and increased the LYG by 1.7 times, at a cost of $112,700/QALY (**Figure 1B**)

Projected clinical and cost-effectiveness of blood-based testing with higher assumed adherence to follow-up colonoscopy

- With assumed follow-up adherence of 75% and 100% and observed screening patterns from Liang et al., offering blood-based screening resulted in a steady increase in LYG per 1000 persons at a cost of $25,900/QALY and $18,500/QALY, respectively (**Figure 1A**)
- At 75% and 100% assumed follow-up adherence and observed screening patterns from Coronado et al., offering blood-based testing resulted in a steady increase in LYG per 1000 persons at a cost of $68,900/QALY and $49,000/QALY, respectively (**Figure 1B**)

Figure 1. Projected benefit and cost-effectiveness of blood-based testing by adherence pattern for follow-up colonoscopy



Projected benefit and cost-effectiveness of offering a choice between blood-based screening vs existing tests for colorectal cancer in Liang et al. (A) and Coronado et al. (B).
LYG, life-years gained; QALY, quality-adjusted life-years.

KEY FINDINGS AND CONCLUSIONS

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- Trial data and modeling suggest that offering patients a choice between blood-based CRC screening vs existing tests may substantially improve outcomes at an acceptable cost
- Adequate follow-up of positive screening results with colonoscopy is essential, especially when blood testing replaces some of the existing screening, such as observed in Coronado et al.[9]
- Our analysis extrapolated observed test utilization patterns from studies with a single screening round in patients who previously declined standard screening
- More research is needed to understand the impact of first-line blood testing and longitudinal adherence on projected benefits and cost-effectiveness

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Disclosures

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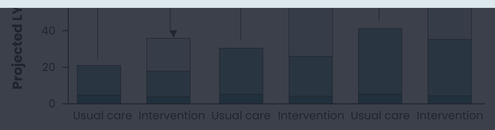

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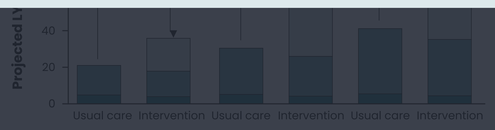

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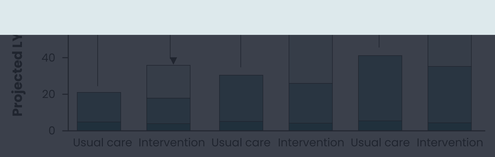

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Test characteristic	Colonoscopy	Fecal test (FIT)	
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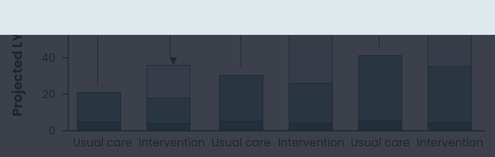

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MODEL ASSUMPTIONS

Back

Model inputs for screening patterns

- Assumed adherence to colonoscopy every 10 years, annual fecal immunochemical test (FIT), and triennial blood testing were based on observed utilization in Liang et al.[8] and Coronado et al.[9] (**Table 2**)
- In both studies, a significantly higher proportion of participants underwent screening in the intervention arm (OR 1.96, *P*=.04; and, OR 3.08, *P*<.001), which offered blood-based testing as a screening option, compared with the control arm, which did not offer blood-based testing[8,9]
- Colonoscopy and FIT utilization were similar between study arms in both studies
- In the model, adherence to screening was assumed to remain at observed levels

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AND CONCLUSIONS

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MODEL ASSUMPTIONS

Table 2. CRC screening patterns

	Liang et al., 2023[8]			Coronado et al., 2024[9]		
Patients screened, n (%)	**Control[a] n=178**	**Intervention[b] n=181**	**OR (*P* value[c])**	**Usual care[a] n=1003**	**Intervention[b] n=181**	**OR (*P* value[c])**
Colonoscopy	2 (1.1%)	4 (2.2%)	1.99 (0.68)	15 (1.5%)	12 (1.2%)	0.80 (0.70)
Fecal testing	15 (8.4%)	18 (9.9%)	1.20 (0.72)	115 (11.5%)	99 (9.9%)	0.85 (0.28)
Blood testing	- (0%)	9 (5.0%)	-	- (0%)	204 (20.4%)	-
Total	17 (9.6%)	31 (17.1%)	1.96 (0.04)	130 (13.0%)	315 (31.5%)[d]	3.08 (<0.001)

[a]Did not include blood-based testing as a screening option.
[b]Included blood-based testing as a screening option.
[c]Fisher's exact test.
[d]Coronado et al. reported n=305 screened with intervention (OR 2.94), but test-specific numbers and visual data from the study suggest n=315 (OR 3.08).
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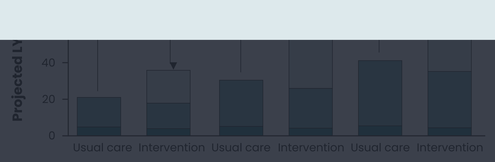

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MODEL ASSUMPTIONS

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Model inputs for adherence patterns for follow-up colonoscopy

- In both Liang et al. and Coronado et al., 50% of the individuals who had a positive blood test result completed a follow-up colonoscopy, while the follow-up rate for fecal tests ranged from 0% to 70%[9,10] (**Table 3**)
- As differences were not statistically significant, we assumed a rounded follow-up rate of 50% for both blood and fecal testing based on the overall average of 51.4%
- To account for uncertainty, higher reported rates in literature, and potential future improvements, we also evaluated scenarios with 75% and 100% follow-up

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Patients, n (%)	**Fecal testing**	**Blood testing**	***P* value[a]**	**Fecal testing**	**Blood testing**	***P* value[a]**
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Positive	3	2		10	22	
Followed up[b]	0 (0%)	1 (50%)	0.40	7 (70%)	11 (50%)	0.45

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Back

MODEL ASSUMPTIONS

Table 3. Adherence pattern for follow-up colonoscopy

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OBJECTIVE

- To estimate the long-term clinical and economic impact of ad observed for CRC screening with blood-based tests vs existing studies

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- An established Cancer Intervention and Surveillance Modeling model was replicated, validated, and then used to evaluate th screening patterns across the studies' control and interventio
- The assumed performance for blood testing was 74% CRC sen specificity (**Table 1**), satisfying the minimum US coverage crite Centers for Medicare and Medicaid Services (CMS)[14]; a 10% ad sensitivity was conservatively assumed
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- Outcomes assessed were deaths averted, projected life-years incremental cost/quality-adjusted life-years (QALY) for offerin blood testing

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Test characteristic	Colonoscopy	Fecal test (FIT)	
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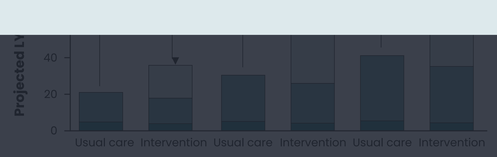

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RESULTS

Back

Projected clinical and cost-effectiveness of blood-based testing using observed adherence patterns for screening and follow-up colonoscopy

- With 50% assumed adherence to colonoscopy follow-up and with observed screening patterns from Liang et al., offering blood testing in addition to existing tests was projected to result in 1.6 additional CRC deaths averted per 1000 persons, and to increase the LYG by 1.6 times, at a cost of $39,100/QALY gained (**Figure 1A**)
- With observed screening patterns from Coronado et al., offering blood-based screening resulted in 2.9 projected CRC deaths averted per 1000 persons, and increased the LYG by 1.7 times, at a cost of $112,700/QALY (**Figure 1B**)

Projected clinical and cost-effectiveness of blood-based testing with higher assumed adherence to follow-up colonoscopy

- With assumed follow-up adherence of 75% and 100% and observed screening patterns from Liang et al., offering blood-based screening resulted in a steady increase in LYG per 1000 persons at a cost of $25,900/QALY and $18,500/QALY, respectively (**Figure 1A**)
- At 75% and 100% assumed follow-up adherence and observed screening patterns from Coronado et al., offering blood-based testing resulted in a steady increase in LYG per 1000 persons at a cost of $68,900/QALY and $49,000/QALY, respectively (**Figure 1B**)

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AND CONCLUSIONS

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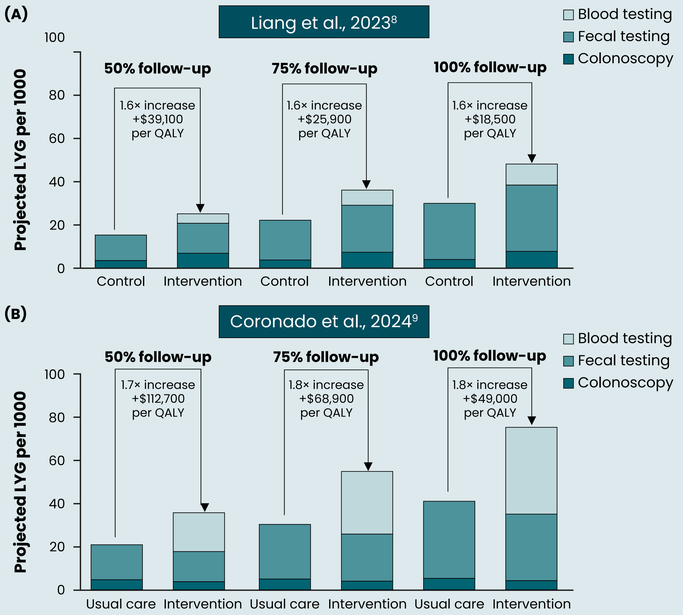

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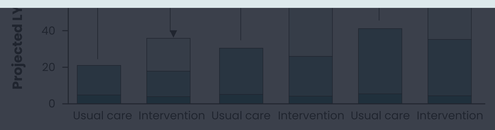

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KEY FINDINGS AND CONCLUSIONS

Back

- Trial data and modeling suggest that offering patients a choice between blood-based CRC screening vs existing tests may substantially improve outcomes at an acceptable cost
- Adequate follow-up of positive screening results with colonoscopy is essential, especially when blood testing replaces some of the existing screening, such as observed in Coronado et al.[9]
- Our analysis extrapolated observed test utilization patterns from studies with a single screening round in patients who previously declined standard screening
- More research is needed to understand the impact of first-line blood testing and longitudinal adherence on projected benefits and cost-effectiveness

…S AND CONCLUSIONS

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