

# Cost-Effectiveness Analysis of Stool-based CRC Screening Tests for Individuals Aged 45 Years

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## Background

- Colorectal cancer (CRC) is a major cause of cancer-related deaths globally.
- Two innovative stool-based CRC screening technologies (mt-sRNA and mt-sDNA 2.0) have recently emerged.
- This study evaluated the cost-effectiveness of innovative stool-based CRC screening tests compared to previously approved stool-based CRC screening methods (FIT, HS-gFOBT and mt-sDNA).

## Methods

- Perspective:** US payer's perspective
- Model:** A Markov model (Figure 1)
- Time horizon:** lifetime with yearly cycle
- Patient Population:** Individuals aged 45 years at average risk with undetected adenoma/CRC status and no CRC symptoms
- Intervention and comparator:** Nine screening strategies were evaluated: (1) annual FIT; (2) annual HS-gFOBT; (3) mt-sDNA every 3 years; (4) annual mt-sDNA; (5) mt-sRNA every 3 years; (6) annual mt-sRNA; (7) mt-sDNA 2.0 every 3 years; (8) annual mt-sDNA 2.0; (9) no screening.
- Primary outputs:** CRC cases, deaths, direct medical costs, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratios (ICERs).
- Sensitivity analyses:** One-way sensitivity analysis and probabilistic sensitivity analysis (PSA) were performed to explore the uncertainty in this model

## Base case results

- Comparing each strategy to the next less costly option, 6 of 9 strategies were dominated and eliminated from further cost-effectiveness analysis. Annual mt-sDNA 2.0 gained the highest QALYs (21.58 QALYs), followed by annual FIT (21.56 QALYs) and no screening (21.42 QALYs). The ICER of annual mt-sDNA 2.0 versus annual FIT was US\$463,088/QALY, exceeded the willingness-to-pay (WTP) of US\$10,000/QALY. Annual FIT emerged as the preferred strategy with an ICER of US\$952/QALY.

Strategy	Incremental cost (US\$)	Incremental QALY	ICER (US\$/QALY)
<b>Versus "no screening"</b>			
No screening	-	-	-
FIT every year	141	0.1484	952
HS-gFOBT every year	234	0.1456	1,605
mt-sDNA 2.0 every 3 years	2,463	0.1430	17,226
mt-sRNA every 3 years	2,604	0.1470	17,716
mt-sDNA every 3 years	2,626	0.1299	20,216
mt-sDNA 2.0 every year	8,079	0.1655	48,792
mt-sDNA every year	8,554	0.1600	53,480
mt-sRNA every year	8,556	0.1619	52,862
<b>Versus the next less costly strategy (dominated strategies excluded)</b>			
Strategy	Incremental cost (US\$)	Incremental QALY	ICER (US\$/QALY)
No screening			
annual FIT	141	0.1484	952
annual mt-sDNA 2.0	7,937	0.0171	463,088

## Sensitivity analysis

- Annual HS-gFOBT became the preferred cost-effective strategy when the sensitivity of FIT was below 21.3% or the specificity of HS-gFOBT exceeded 94.2% in the one-way sensitivity analysis.
- In probabilistic analysis, the probabilities to be preferred cost-effective option (at WTP US\$100,000/QALY) were 84.37% for annual FIT, 15.63% for annual HS-gFOBT and 0% for other screening strategies.

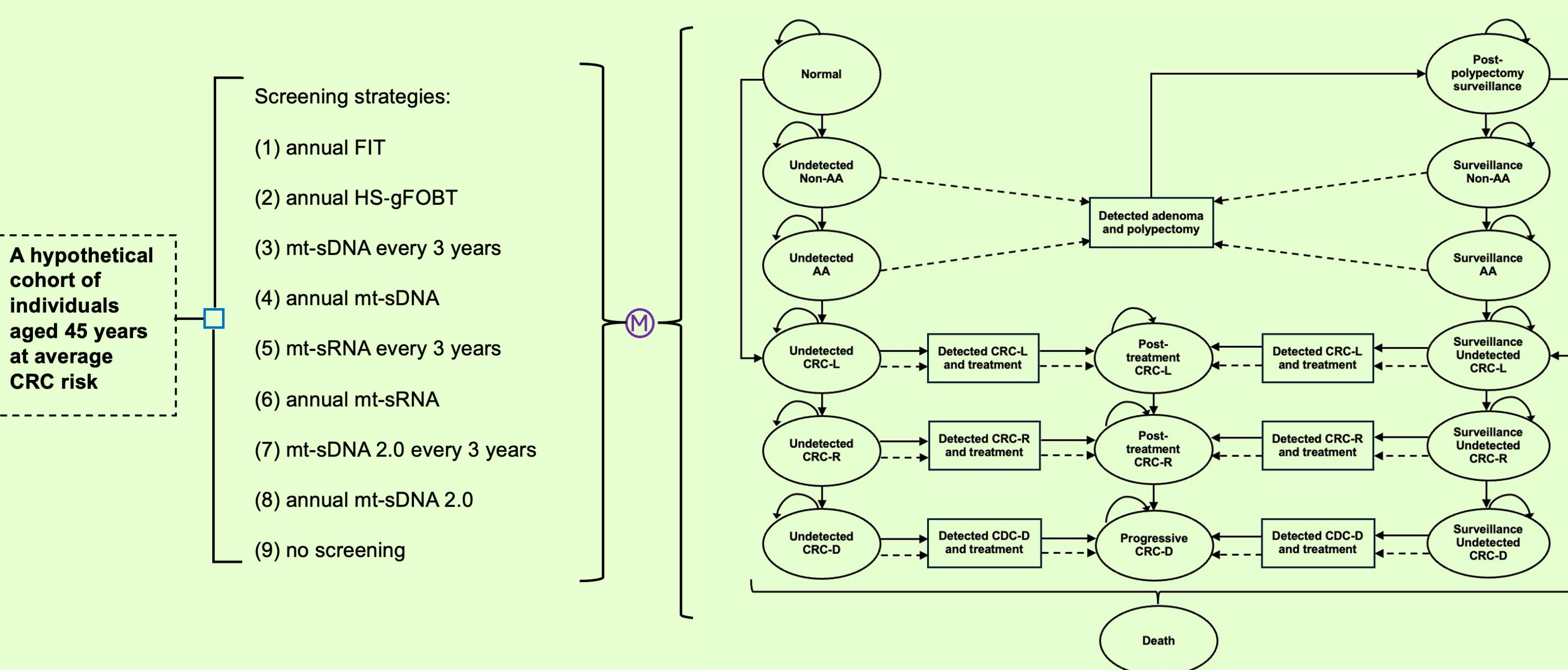


Figure 1 Simplified Markov model

Table 1 Clinical variable

Parameters	Value	Range
<b>FIT</b>		
CRC sensitivity (%)	73.3	60.3-83.9
Advanced adenoma sensitivity (%)	23.8	20.8-27.0
Non-advanced adenoma sensitivity (%)	7.6	6.7-8.6
Specificity (%)	96.4	95.8-96.9
<b>HS-gFOBT</b>		
CRC sensitivity (%)	70.0	50.0-87.0
Advanced adenoma sensitivity (%)	23.9	17.7-49.4
Non-advanced adenoma sensitivity (%)	10.0	10.0-26.2
Specificity (%)	92.5	90.0-95.0
<b>mt-sDNA</b>		
CRC sensitivity (%)	93.3	83.8-98.2
Advanced adenoma sensitivity (%)	42.4	38.9-46.0
Non-advanced adenoma sensitivity (%)	17.2	15.9-18.6
Specificity (%)	89.8	88.9-90.7
<b>mt-sDNA 2.0</b>		
CRC sensitivity (%)	93.9	87.1-97.7
Advanced adenoma sensitivity (%)	44.0	41.0-47.0
Non-advanced adenoma sensitivity (%)	29.0	26.1-31.9
Specificity (%)	92.7	92.2-93.1
<b>mt-sRNA</b>		
CRC sensitivity (%)	94.0	81.0-99.0
Advanced adenoma sensitivity (%)	47.1	46.3-50.0
Non-advanced adenoma sensitivity (%)	35.5	32.0-39.1
Specificity (%)	88.0	87.0-89.0

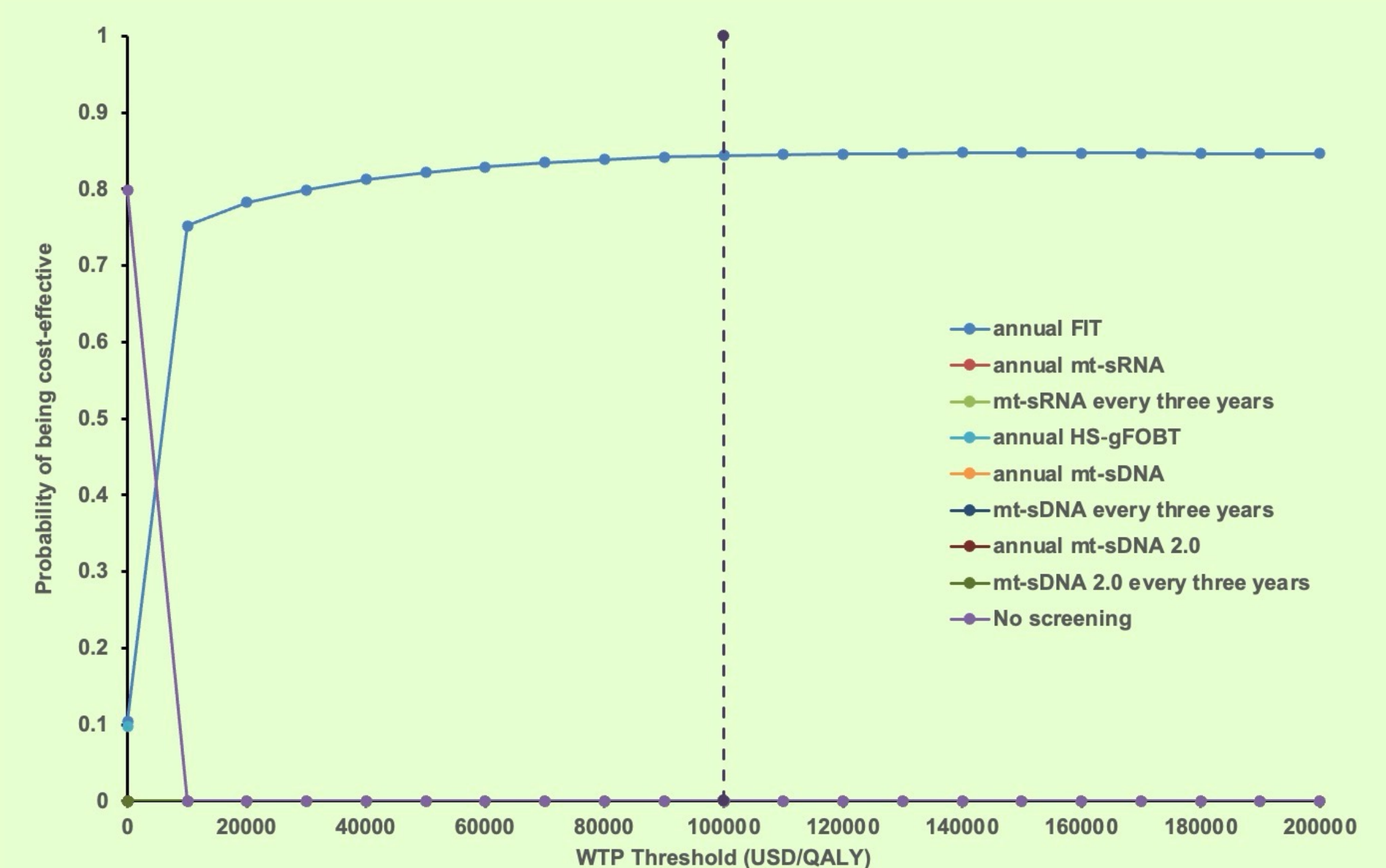


Figure 2 CEAC of all screenings compared to no screening

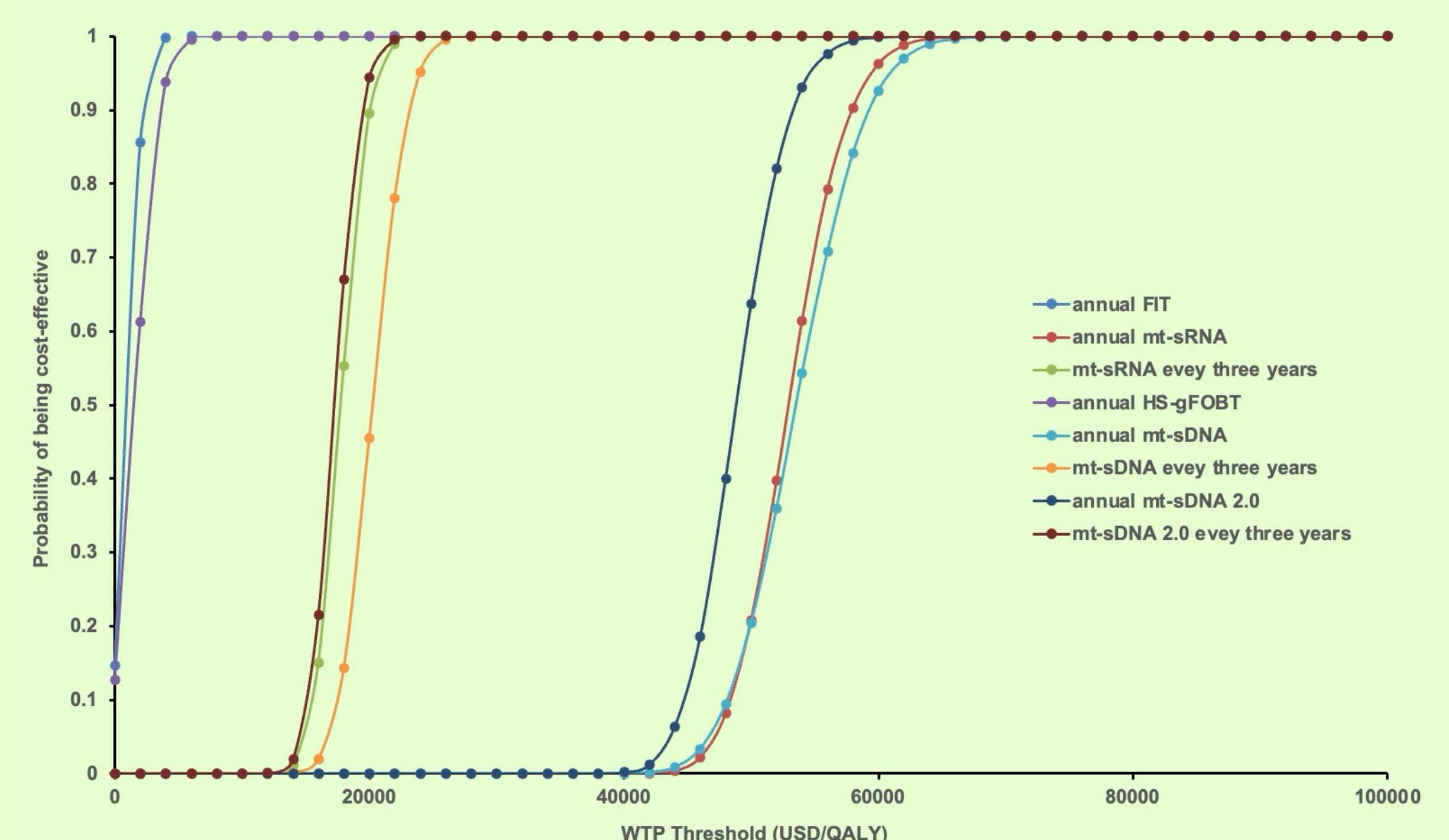


Figure 3 CEAC among all screenings

## Conclusion

- Annual FIT appeared to be the preferred strategy and the cost-effectiveness is subject to the sensitivity of FIT for advanced adenomas and the specificity of HS-gFOBT.