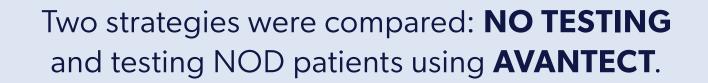


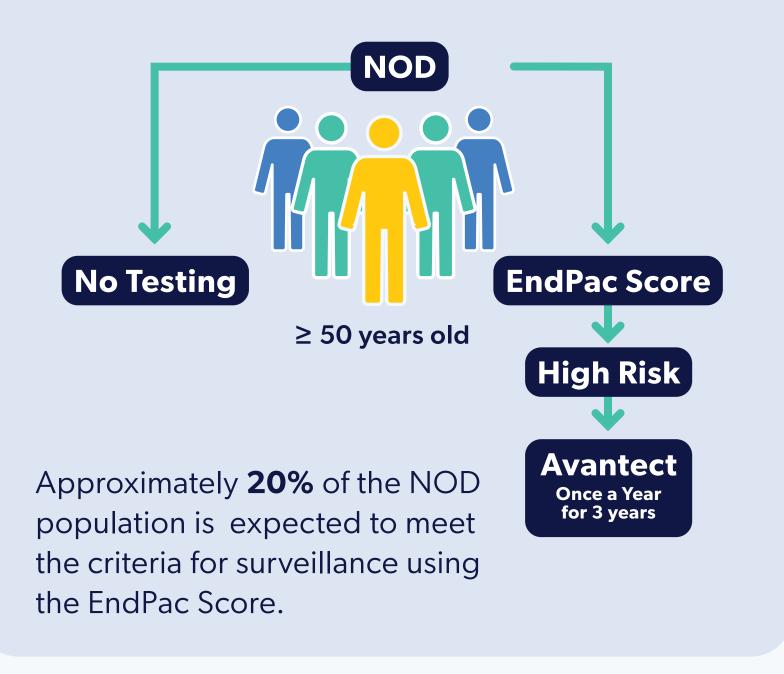


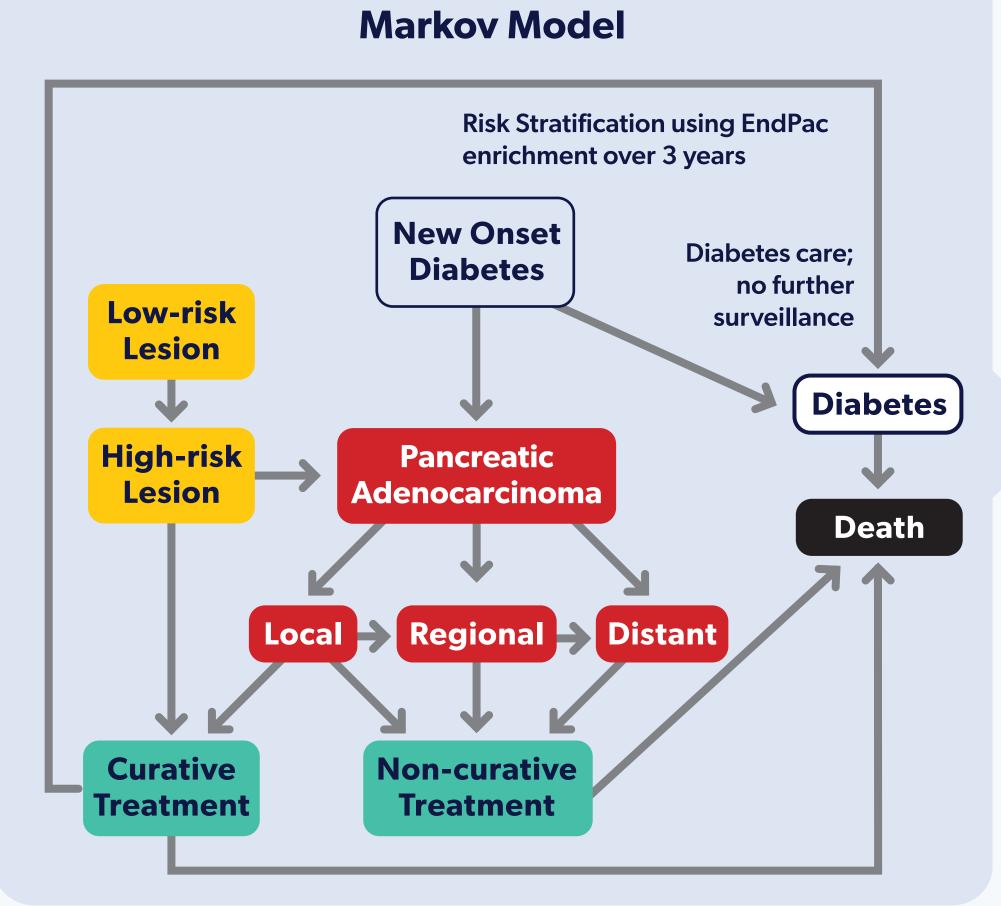
Cell-Free DNA Epigenomic-Based Test is Predicted to Be Cost Effective to Manage New-Onset Type 2 Diabetes (NOD) Patients for Risk of Pancreatic Cancer

Adrian Vilalta, PhD¹, Ananya Das, MD², Michael B. Wallace, MD, MPH³

1. ClearNote Health, San Diego, CA 2. Arizona Centers for Digestive Health, Phoenix, AZ 3. Mayo Clinic, Jacksonville, FL







Results

Avantect is cost-effective when used as a monitoring test modality in NOD high-risk patients, with an Incremental Cost-Effectiveness Ratio (ICER) of \$5,173 and a Willingness to Pay of \$100,000.

The model predicts that 1% NOD patients would be diagnosed with PC in the **no surveillance strategy; only 7.1% of cases treatable with surgery. Avantect arm 0.71% PaC cases detected**; these cases could be more likely to be detected at an earlier, more treatable stage, with **32.4% eligible for surgical resection**.

Avantect Quality-Adjusted Life Expectancy (IQALE) of 0.02485

Risk of PC, survival, and cost data from the SEER and Medicare databases.

OBJECTIVE

This study aims to assess the clinical and economic benefits of early detection of pancreatic cancer (PC) in patients with new-onset type 3c diabetes (NOD) using a blood-based, cell-free DNA epigenomic test (Avantect; ClearNote Health, CA). Recent findings indicate that NOD increases the risk of PC by 6-8 times within the first three years post-diagnosis.

METHODS

A Markov model was created to compare two strategies: no surveillance and surveillance of higher-risk NOD patients using a blood-based cell-free DNA epigenomic test. Using criteria from Sharma et al. (EndPac; Gastroenterology 2018), approximately 20% of the NOD patients were considered at higher risk for PC. The risk for developing PC, survival, and cost data were obtained from the US Surveillance, Epidemiology, and End Results (SEER), and Medicare databases.

RESULTS

The cell-free DNA epigenomic test (Avantect Pancreatic Cancer Test) proves cost-effective in NOD high-risk patients, with an Incremental Cost-Effectiveness Ratio (ICER) of \$5,173 and a Willingness to Pay of \$100,000.

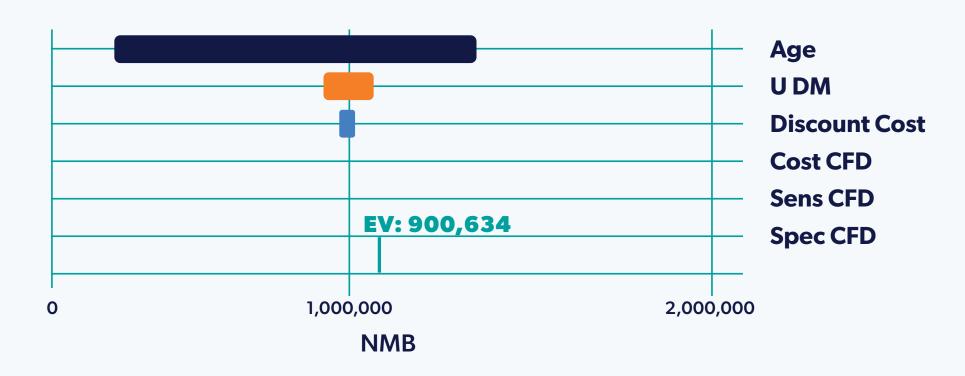
The model predicts that in a cohort of 10,000 patients with NOD, 1% would be diagnosed with PC in the no-surveillance strategy, with only 7.1% of cases treatable with surgery. In contrast, 71 PC cases are predicted to be detected with cfDNA testing. These cases would be more likely to be detected at an earlier, more treatable stage, with 32.4% eligible for surgical resection.

The clinical benefit of using the Avantect test in NOD vs. no surveillance is reflected in an IQALE of 0.02485.

Results of the Baseline Analysis

STRATEGY	COST (4)	IC (\$)	QALE	IQALE	ICER	NMB (\$)





The Tornado diagram shows the results of 1-way sensitivity analyses using key variables and the range of change of Net Medical Benefit (NMB) with each variable with respect to the Willingness to pay (WTP). **Age at entry into the model has the largest impact on NMB**.

Definitions:

U DM: Utility Value of Diabetes CFD: cell-free DNA test



No Surveillance	114,283		10.12560			898,278
Avantect Surveillance	114,411	129	10.15045	0.02485	5,173	900,634
NOD Screening MR	114,511	100	10.15079	0.00033	300,473	900,568

IC = incremental cost; IQALE = incremental adjusted life year



CONCLUSIONS

Testing higher-risk NOD patients for pancreatic cancer using the Avantect Pancreatic Cancer epigenomic test is predicted to be cost-effective compared to the standard of care (no testing). Testing with Avantect annually across 3 years post diabetes diagnosis likely increases the detection of treatable pancreatic cancer cases, thereby potentially improving patient survival outcomes.

•		
• •		•
		•
	• • • • • • •	
		•
		•
		·
• • • •		•
	•••••••••••••••••••••••••••••••••••••••	
	· •••••••••••••••	

.....

•	• • • • •		•
	• • • • • •	• • • • • • • • • •	•
			•
			•
			•
, ,			
•			
2			
		· · · • • • • • • • • • • • • • • • • •	