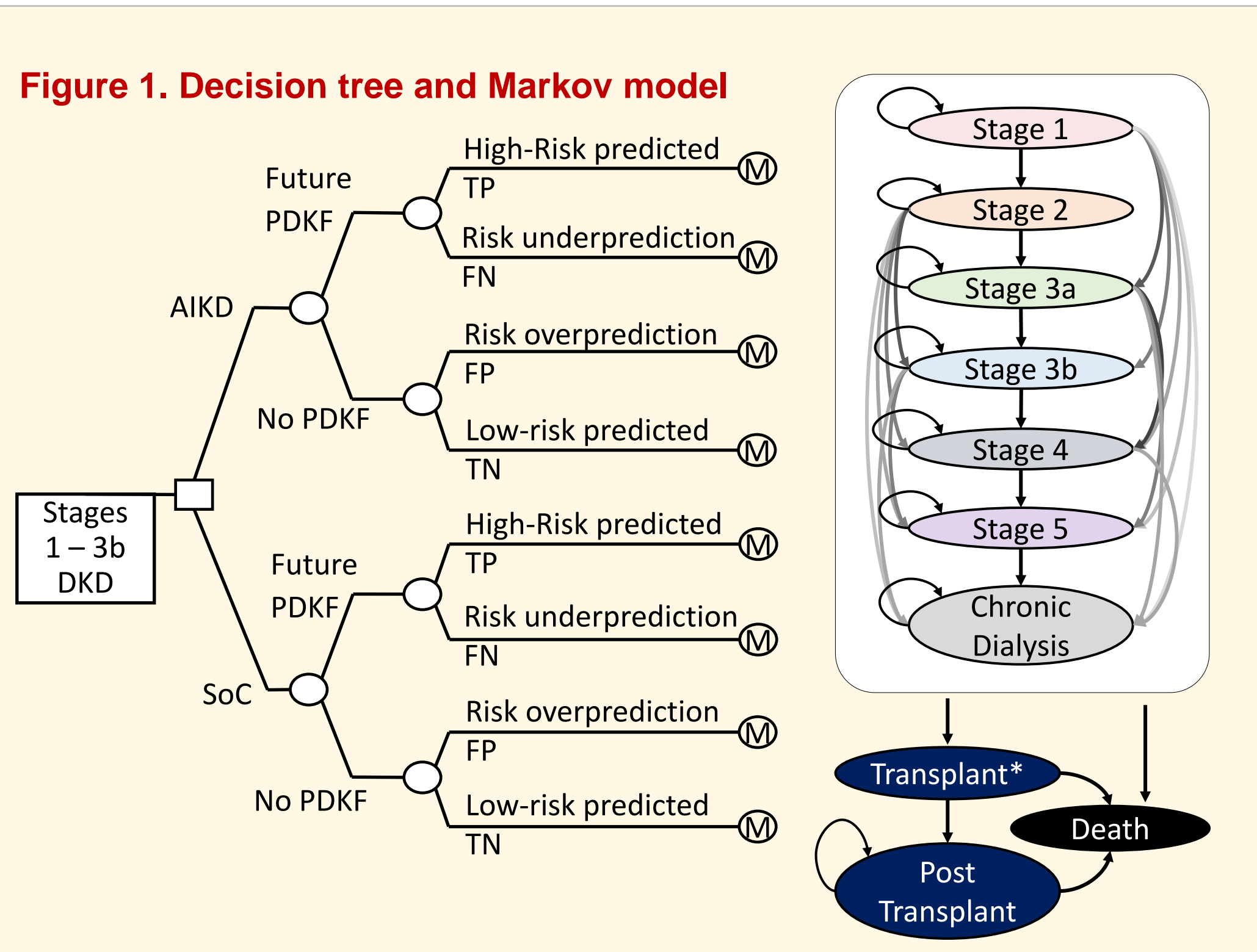


BACKGROUND and OBJECTIVE

- Artificial intelligence enabled kidney disease risk prediction (AIKD) can support decisions on the needs and use of comprehensive care for patients with early-stage diabetic kidney disease (DKD)
- Progressive Decline in Kidney Function (PDKF) is a composite predictive marker of rapid DKD progression.
- To evaluate the cost-effectiveness and budget impact of the artificial intelligence enabled kidney disease (AIKD) risk stratification among US veterans with diabetic kidney disease (DKD).

METHODS

- We developed a decision tree model to reflect the difference in the predictive performance of the AIKD and Standard of Care (SoC) in assessing the risk of PDKF. The model outlines the following treatment pathways and benefits among the patients at DKD stages G1A2 – G3b.
  - True Positive (TP): Comprehensive care delays progression
  - False Positive (FP): Comprehensive care gives nominal benefits
  - True Negative (TN): Normal progression on usual care
  - False Negative (FN): Expedited progression on usual care
- The decision tree was followed by Markov state transitions across various DKD stages where a proper renal-protective treatment given to the patients at elevated risk of DKD progression with true future PDKF would reduce the rate of stage progressions.
- Stage specific costs of care and annual transition rates were obtained from the analysis of Veterans Health Administration (VHA) electronic healthcare records and Managerial Cost Accounting data.
- We calculated the incremental cost-effectiveness ratio (ICER) for AIKD versus SoC over a 5-year time horizon, applying a 3% annual discounting rate to healthcare costs and quality-adjusted life years (QALYs).
- We ran one-way sensitivity analysis and probabilistic sensitivity analysis to assess the influence of varying inputs on the ICER calculation and decision.
- A five-year budget impact of AIKD was estimated for a cohort of 42,000 patients, representing about 10% of those eligible for AIKD and in stages 1 to 3b of DKD.



\* Transplant is a transient state where patients stay in a short amount of time while receiving kidney transplant and peri-surgical care. Upon survival, patients who received kidney transplant would transit to post-Transplant stage.

Table 1. Model Inputs, general

Input Parameter		Value	
Age <sup>1</sup>		65 years	
Initial % of each stage <sup>1</sup>	Stage 1	2.8	
	Stage 2	13.9	
	Stage 3a	68.9	
	Stage 3b	14.4	
Performance of Risk Prediction		Base Scenario	Liberal Scenario
AIKD	Sensitivity <sup>3</sup>	0.510	0.870
	Specificity <sup>3</sup>	0.930	0.540
SoC	Sensitivity <sup>3</sup>	0.280	0.670
	Specificity <sup>3</sup>	0.880	0.590
% patients with future PDKF out of each DKD stages		Base Scenario	High Risk Scenario
From Initial Stage 1 patients <sup>1</sup>		20.6	61.7
From Initial Stage 2 patients <sup>1</sup>		20.3	61.0
From Initial Stage 3a patients <sup>1</sup>		26.5	79.4
From Initial Stage 3b patients <sup>1</sup>		27.2	81.5

Table 2. Model Inputs, clinical

Annual rate of DKD stage progression or death		
From each initial stage	PDKF	No PDKF
Stage 1 <sup>1</sup>	0.110	0.184
Stage 2 <sup>1</sup>	0.088	0.175
Stage 3a <sup>1</sup>	0.105	0.166
Stage 3b <sup>1</sup>	0.150	0.197
From advanced stages		
Stage 4 <sup>1</sup>	0.242	
Stage 5 <sup>1</sup>	0.326	
Chronic Dialysis <sup>1</sup>	0.222	
Kidney Transplant <sup>1</sup>	0.040	
Post Kidney Transplant <sup>1</sup>	0.077	
Benefits of Comprehensive Care	True Positive	False Positive
Stage 1 <sup>4</sup>	0.370	0.950
Stage 2 <sup>4</sup>	0.600	
Stage 3a <sup>4</sup>	0.550	
Stage 3b <sup>4</sup>	0.700	

Table 3. Model Inputs, cost and utility

Stage Specific Inputs	Cost	Disutility
Stage 1 <sup>2,6,7</sup>	\$19,164	-0.150
Stage 2 <sup>2,6,7</sup>	\$21,264	-0.150
Stage 3a <sup>2,6,7</sup>	\$34,284	-0.200
Stage 3b <sup>2,6,7</sup>	\$44,664	-0.200
Stage 4 <sup>2,6,7</sup>	\$66,060	-0.260
Stage 5 <sup>2,6,7</sup>	\$83,988	-0.270
Chronic Dialysis <sup>2,6,7</sup>	\$147,576	-0.530
Kidney Transplant <sup>2,6,7</sup>	\$71,958	-0.530
Post Transplant <sup>2,6,7</sup>	\$79,632	-0.290
Cost Inputs, not stage specific		
Comprehensive care <sup>2</sup>	\$2,798	
Cost of AIKD <sup>2</sup>	\$1,050	
Utility inputs, not stage specific		
Population Utility Constant <sup>5</sup>	0.944	
Utility decrement per age <sup>5</sup>	-0.0007	

Table 4. Base case and scenario analyses results

	AIKD		SoC		ICER (/QALY)
	Cost	QALY	Cost	QALY	
Base Case	\$ 146,437	2.827	\$ 145,120	2.816	\$ 116,349
High risk scenario	\$ 148,478	2.721	\$ 145,466	2.686	\$ 85,130

High risk scenario: 50% of the target cohort with DKD stages G1 – G3b will eventually develop PDKF if additional comprehensive care is not given.

Figure 2. Tornado Diagram from one-way sensitivity analysis ICER from lower and upper input limits

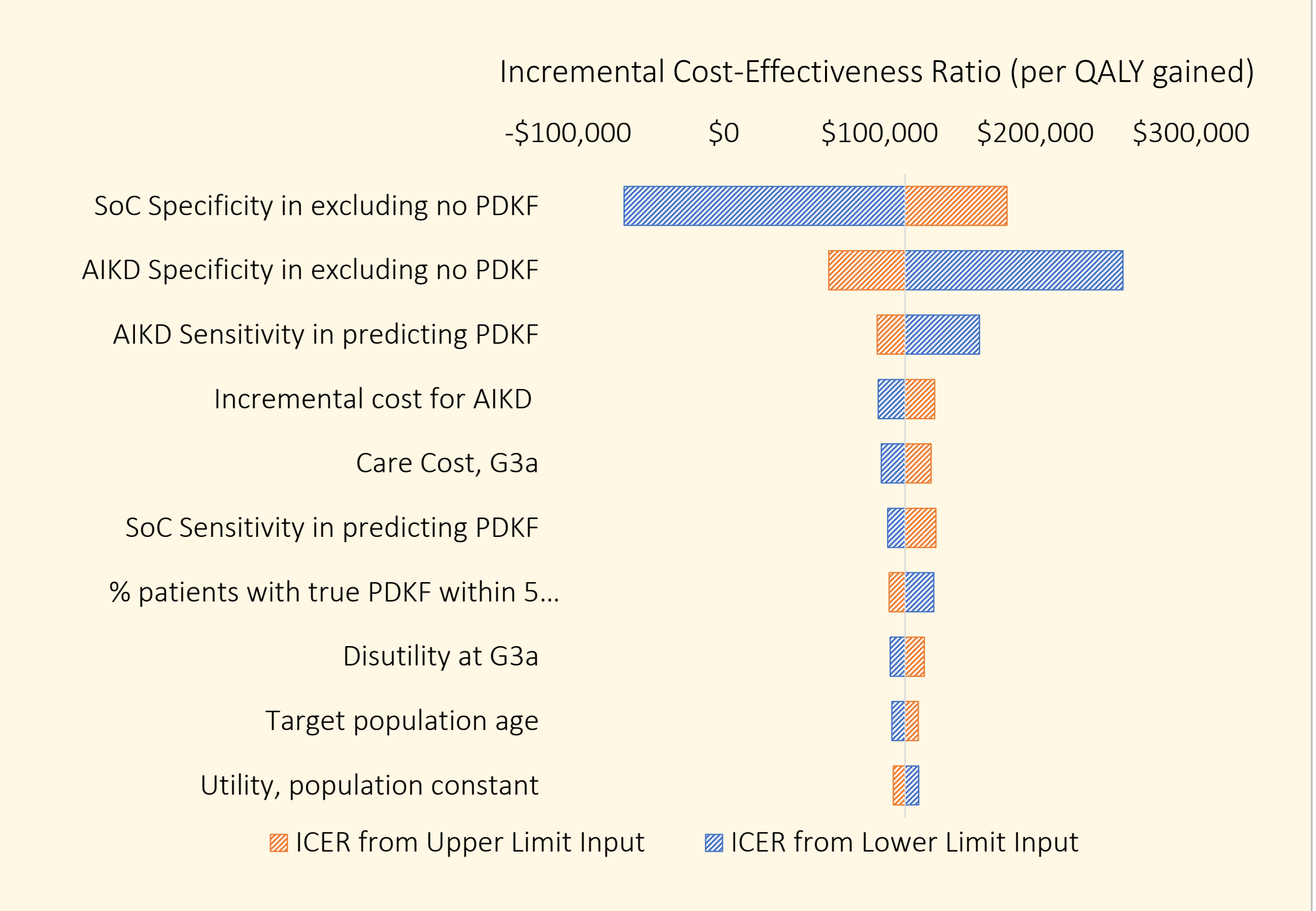
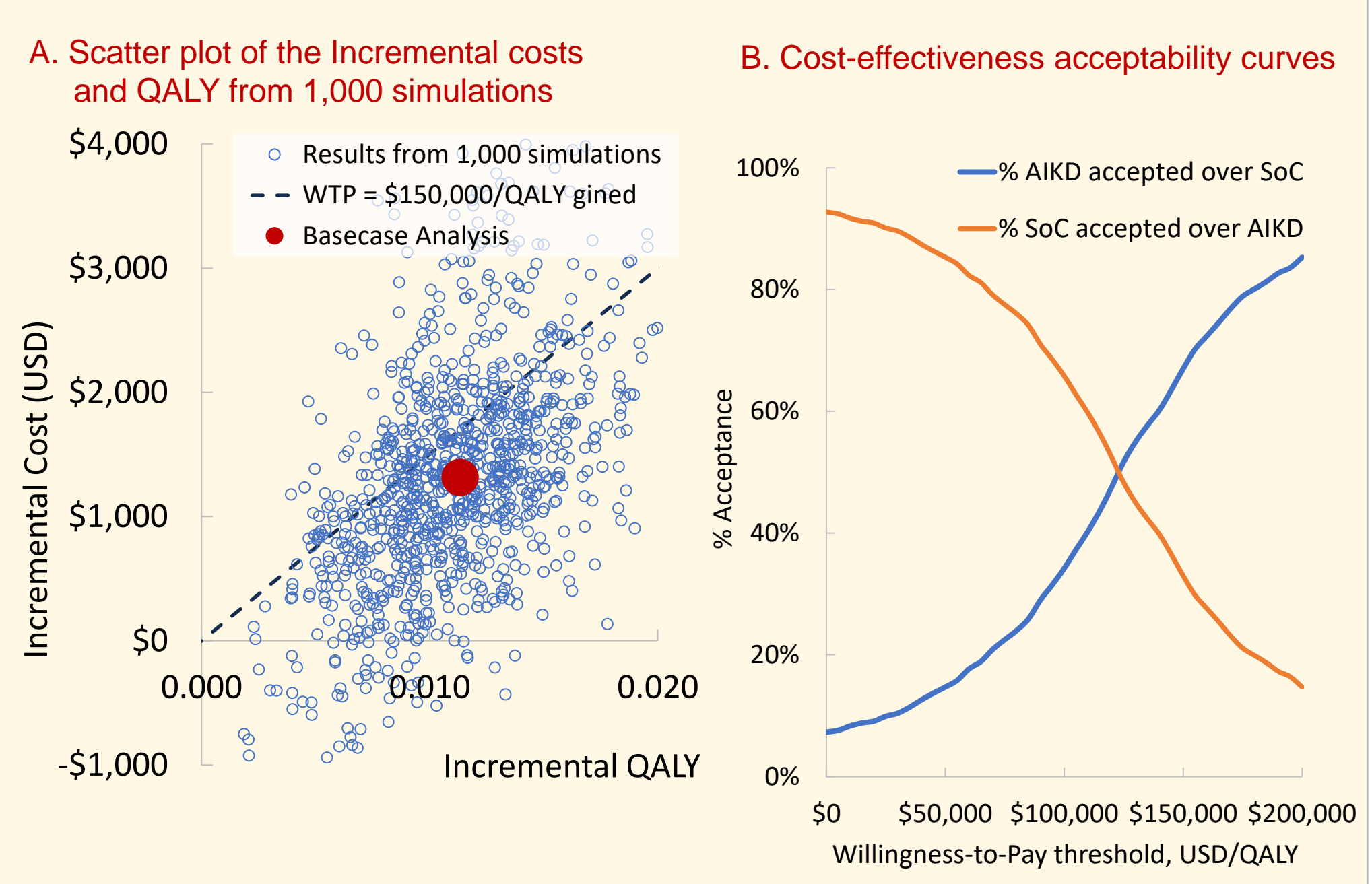


Figure 3. Results from probabilistic sensitivity analysis

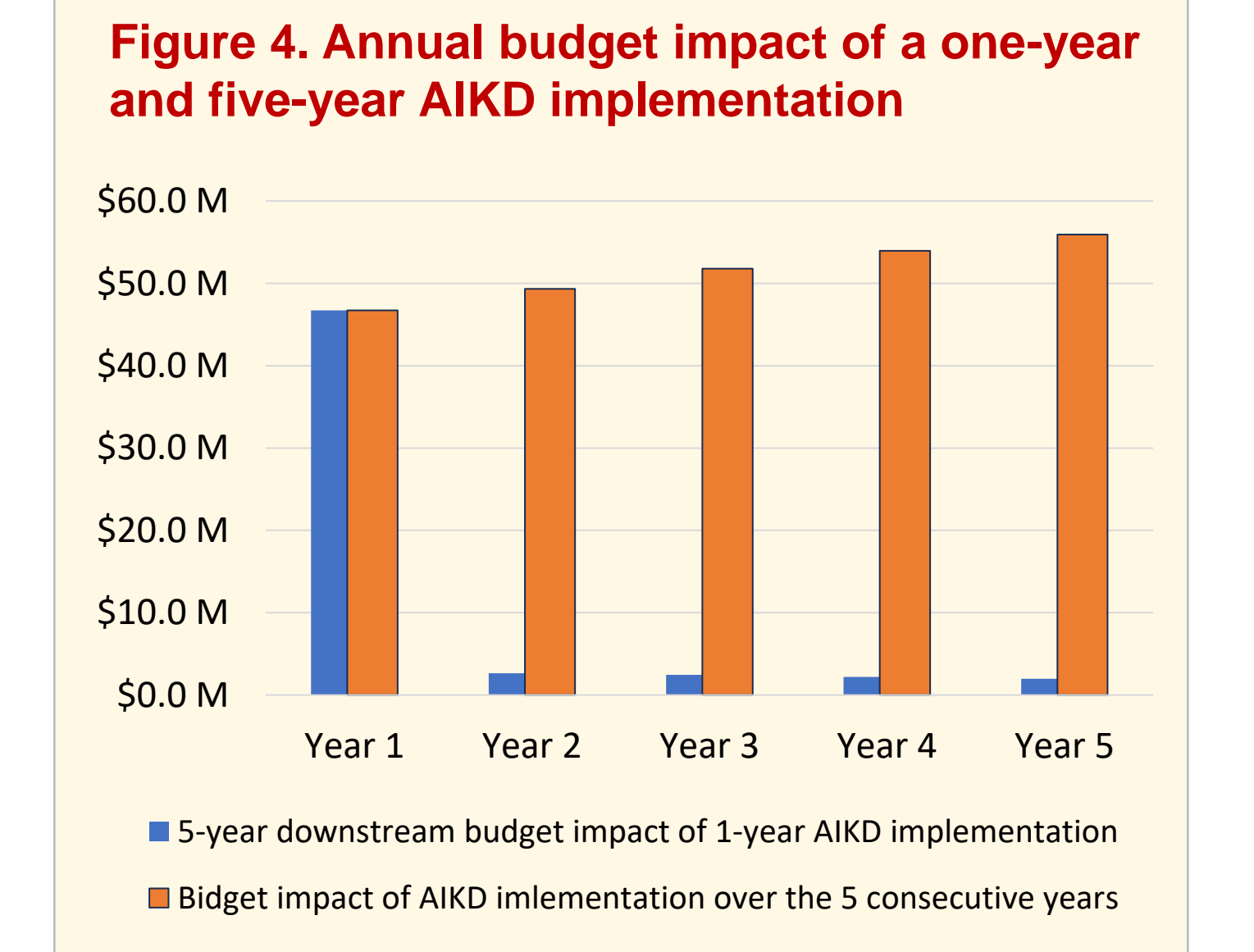


DISCUSSIONS

- For US veterans with early-stage DKD, AIKD emerges as a cost-effective strategy, given its ICER falls below the \$150,000/QALY threshold.
- Integration of AIKD into DKD management is projected to have a manageable five-year budget impact.

RESULTS

- The 5-year discounted costs for AIKD and SoC were \$146,437 and \$145,120, respectively. [Table 4]
- The QALYs were 2.828 for AIKD and 2.816 for SoC. [Table 4]
- This leads to an ICER of \$116,349 per QALY gained for AIKD. [Table 4]
- The ICER for the liberal decision and the high-risk scenario were \$192,930 and \$85,130 per QALY respectively. [Table 4]
- The model demonstrated robustness in sensitivity analyses. [Figure 2 and 3]
- The implementation of AIKD to the 10% of eligible DKD patients would have a downstream budget impact of \$56 million over five years and the aggregated budget impact is projected to be \$258 million. [Figure 4]



DISCLOSURE

This study was funded by Renalytix AI.

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