BUDGET IMPACT MODEL OF ENHANCED LUNG CANCER SCREENING WITH AI/ML TECH-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ON A US COHORT AND PRIVATE PAYER PERSPECTIVE

OP9

A. DISSET[1], C. VOYTON[1], D. QUACH[2,3], E. LAM[3]

[1] Median Technologies, eyonis® USA, [2] – Pharmacy Systems, Outcomes, and Policy, University of Illinois at Chicago College of Pharmacy, [3] Avania, USA

BACKGROUND

Lung cancer remains a leading cause cancer death worldwide.

Current standard of care, screening based on Low-Dose Computed Tomography (LDCT), has improved early detection, yet false positives and late-stage diagnoses persist.

There is a need for innovative, cost-effective screening approaches that improve diagnostic accuracy and optimize healthcare resource use and cost.

CADe/CADx are computer-aided tools that help radiologists detect and diagnose abnormalities in medical images.

OBJECTIVES

To evaluate the budget impact and resource use of implementing a CADe/CADx, an AI/ML tech-based Software as a Medical Device (SaMD), in lung cancer screening compared to standard LDCT-alone, from a US private payer perspective.

METHODS

A five-stage Markov model simulated lung cancer progression, comparing two screening strategies:

- LDCT + CADe/CADx SaMD (AI alone)
- LDCT-only (Radiologist alone)

Patient management followed Lung-RADS (Pinsky et al), incorporating real-world sensitivity and specificity inputs.

Disease progression was based on 1-year stage transitions (Pan) and 5-year mortality (Pan & Kay).

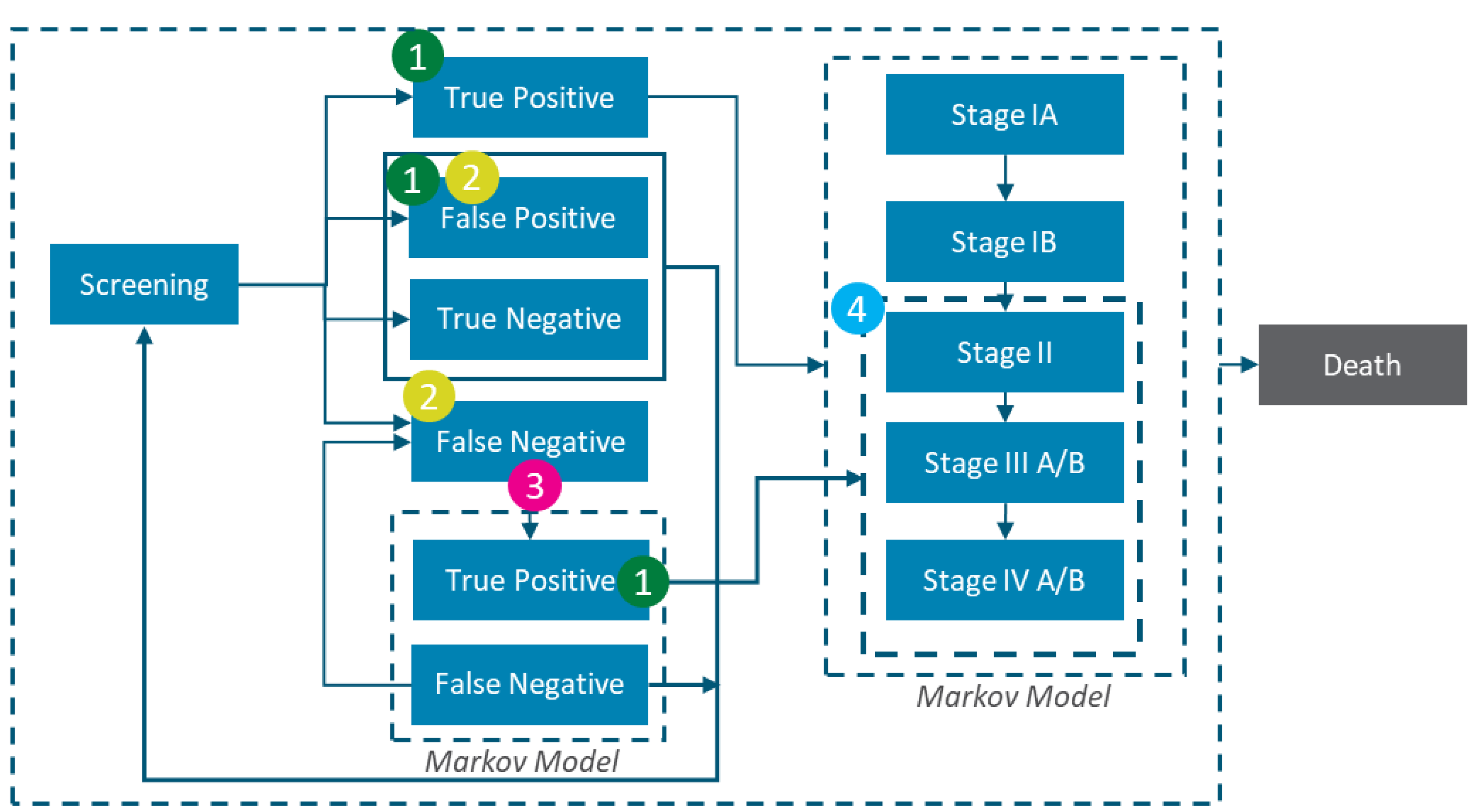
Cost elements included diagnostic procedures (LDCT, PET-CT, biopsies) based CPT codes tariffs 2024, treatments by cancer stage based on CMS tariff 2017 *(Sheenan et al - excluding immunotherapy)* and downstream clinical management.

Diagnostic accuracy & impact on Lung-RADS and disease stage were estimated relative to radiologist and SaMD performance

Outcomes were calculated Per Member Per Month (PMPM) over a 5-year horizon for a 1-million-member health plan

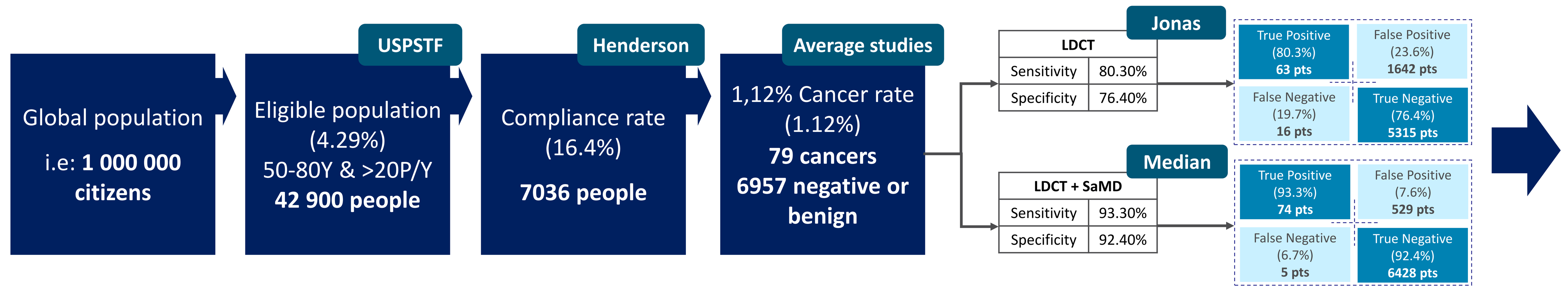
RESULTS

Lung cancer screening pathway and disease progression in the Markov model



1. Incorporation of a granular diagnostic pathway that accounts for the high costs associated with testing (i.e., biopsy, PET-CT etc.)
2. Differentiated screening program / timing / tests used according to the LUNG-RADS classification and guidelines
3. Creates a separate Markov Model for False Negative patients, as well as a differentiated pathways for subsequent True Positive / False Negative patients
4. False Negative patients enter into staging at a higher classification (Pan et al)

From population to diagnosis – Patient flow & performance: LDCT + SaMD alone vs LDCT only



LDCT + SaMD vs LDCT only	Change (%)
True Positive	+ 16%
False Negative	- 67%
True Negative	+ 21 %
False Positive	- 68%

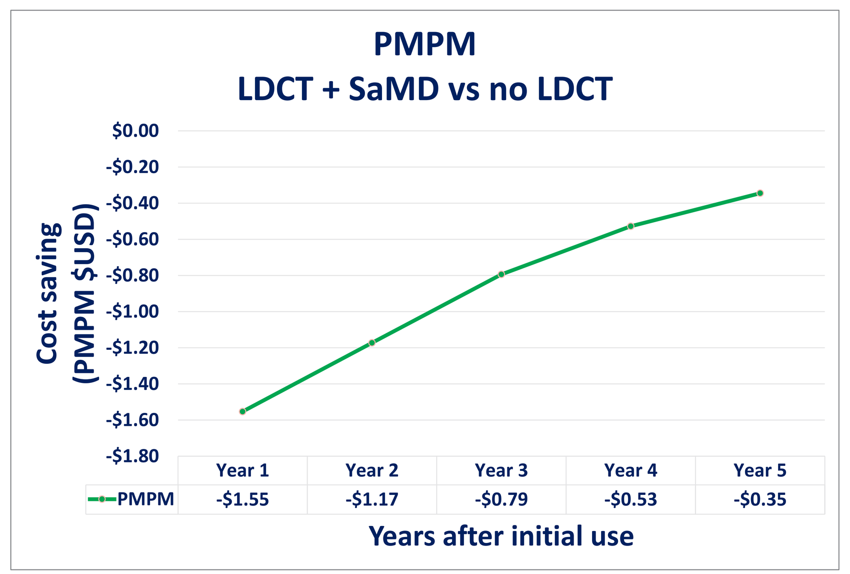
CADe/CADx AI-based screening improves diagnostic accuracy, optimizes procedures & reduces costs for health insurers:

- ❑ - 67% false negatives & - 68% false positives
- ❑ - 16.5% CT-Scan, −89% PET-CT scans, −89% biopsies, -65% complications
- ❑ 5-year cumulative cost savings
- ❑ - $1.55 PMPM savings in year 1 and - $52.70M over 5 years, mainly from earlier detection & diagnosis and reduced late-stage treatment
- ❑ Biggest impact in Year 1 due to stage shift
- ❑ Cost savings diminish overtime as early cancer deaths accumulate whilst screening use, decision-making, and SaMD declines

Procedure rates per patient

Based on 7036 pts screened	LDCT + SaMD	LDCT Only	Variance
Procedure type	N/ patient	N/ patient	%
SaMD	1.11	0	NA
Screening	1.11	1.33	-16.5%
Shared decision making	1.11	1.33	-16.5%
Invasive diagnostic procedure (biopsy)	0.012	0.109	-89%
PET scan	0.018	0.166	-89%
Complications for biopsy	0.0016	0.0047	-65%

5-Year PMPM budget impact



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CONCLUSIONS

CADe/CADx SaMD enables earlier lung cancer detection & characterization, reduces invasive and useless procedures, and delivers meaningful cost savings for US payers. These findings advocate for integrating CADe/CADx SaMD into routine lung cancer screening programs.

DISCUSSION

Sensitivity and specificity were the most influential inputs. Over time, stage 3 and 4 to death transitions increasingly impacted outcomes. Findings show the technology is cost-effective, but real-world validation and research is needed to confirm these findings.