

Real-World Evidence Methodology for Economic Evaluation of Clinical AI: Cost-Effectiveness of an Imaging Algorithm for Incidental Detection of Heart Failure with Preserved Ejection Fraction

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INTRODUCTION

Heart Failure with preserved Ejection Fraction (HFpEF) is associated with substantial morbidity, mortality, and healthcare costs [1-3].

Prevalence	Missed Cases	Annual Health Care Costs
6.7M	66%	5x higher
Americans currently live with heart failure (HF), projected to reach 8.7M by 2030 [2].	Of HFpEF patients are missed under Standard of Care diagnosis [4]	For patients with HF versus those without HF, driven largely by hospitalizations [5]

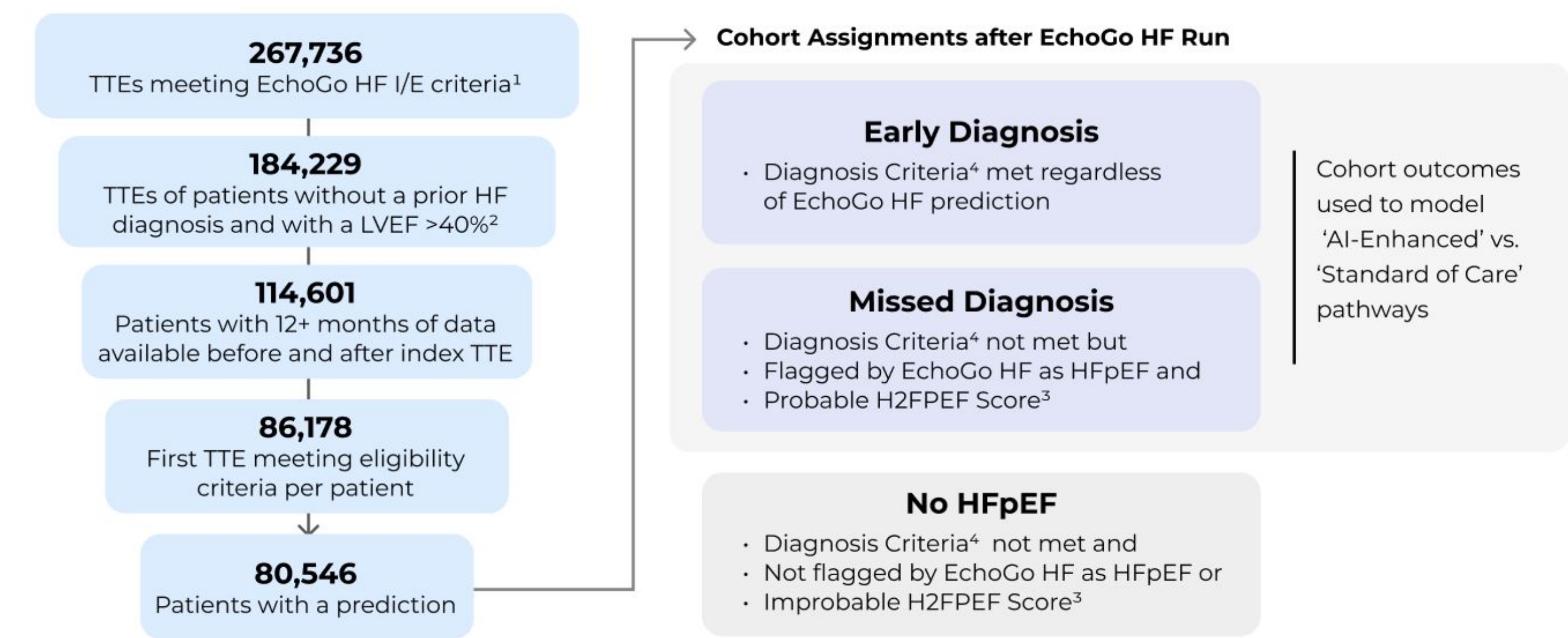
Objective: Assess the incremental clinical and economic benefits of improved HFpEF detection, reflected in fewer missed or delayed diagnoses, using the EchoGo Heart Failure algorithm compared with Standard of Care.

METHODS

EchoGo Heart Failure (HF) by Ultromics Ltd is a computer vision algorithm that detects HFpEF on transthoracic echocardiograms (TTE).

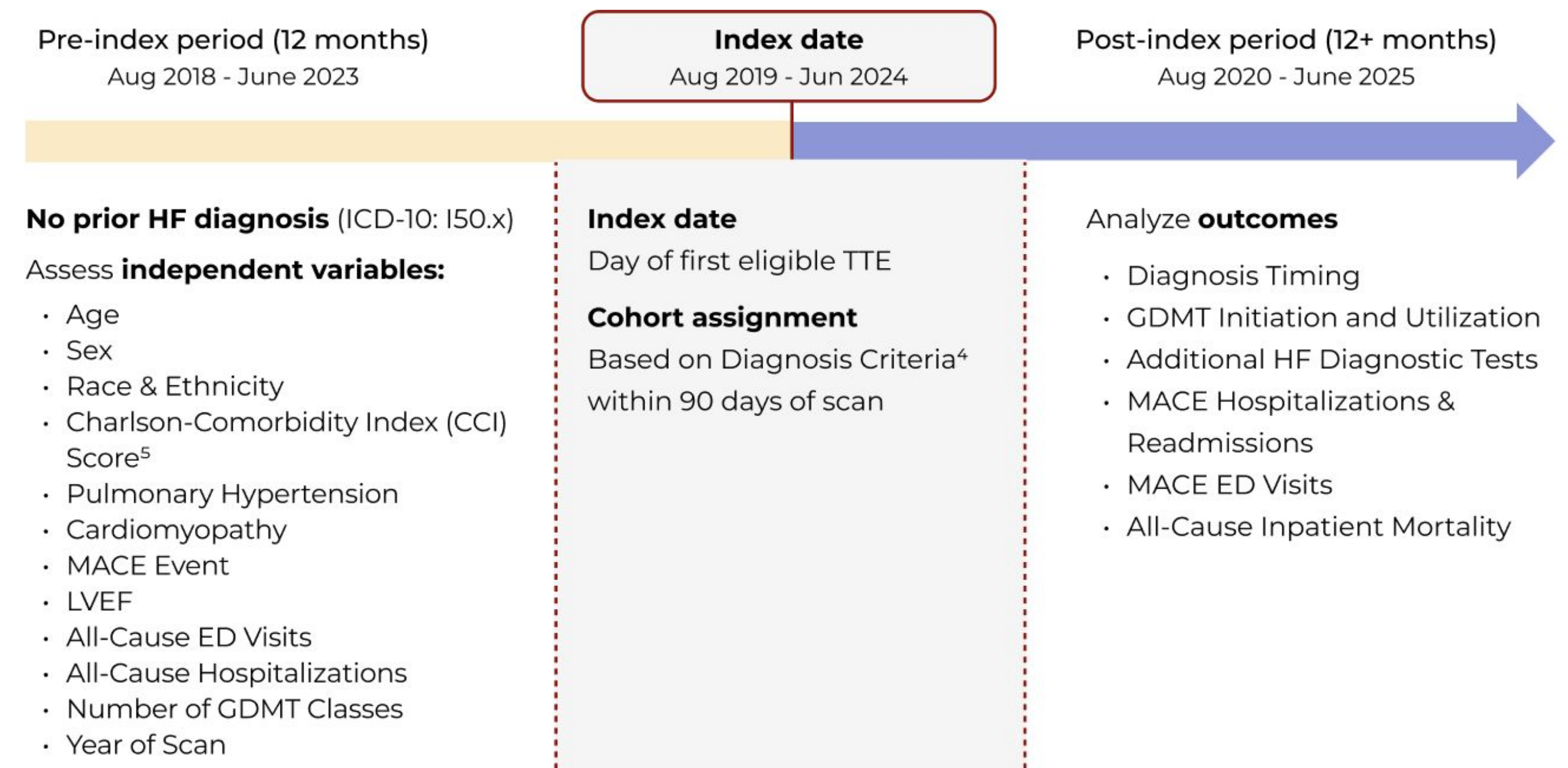
1. Run the Algorithm

EchoGo HF algorithm was run on all TTE scans from eligible patients within the **Dandelion Health environment**.



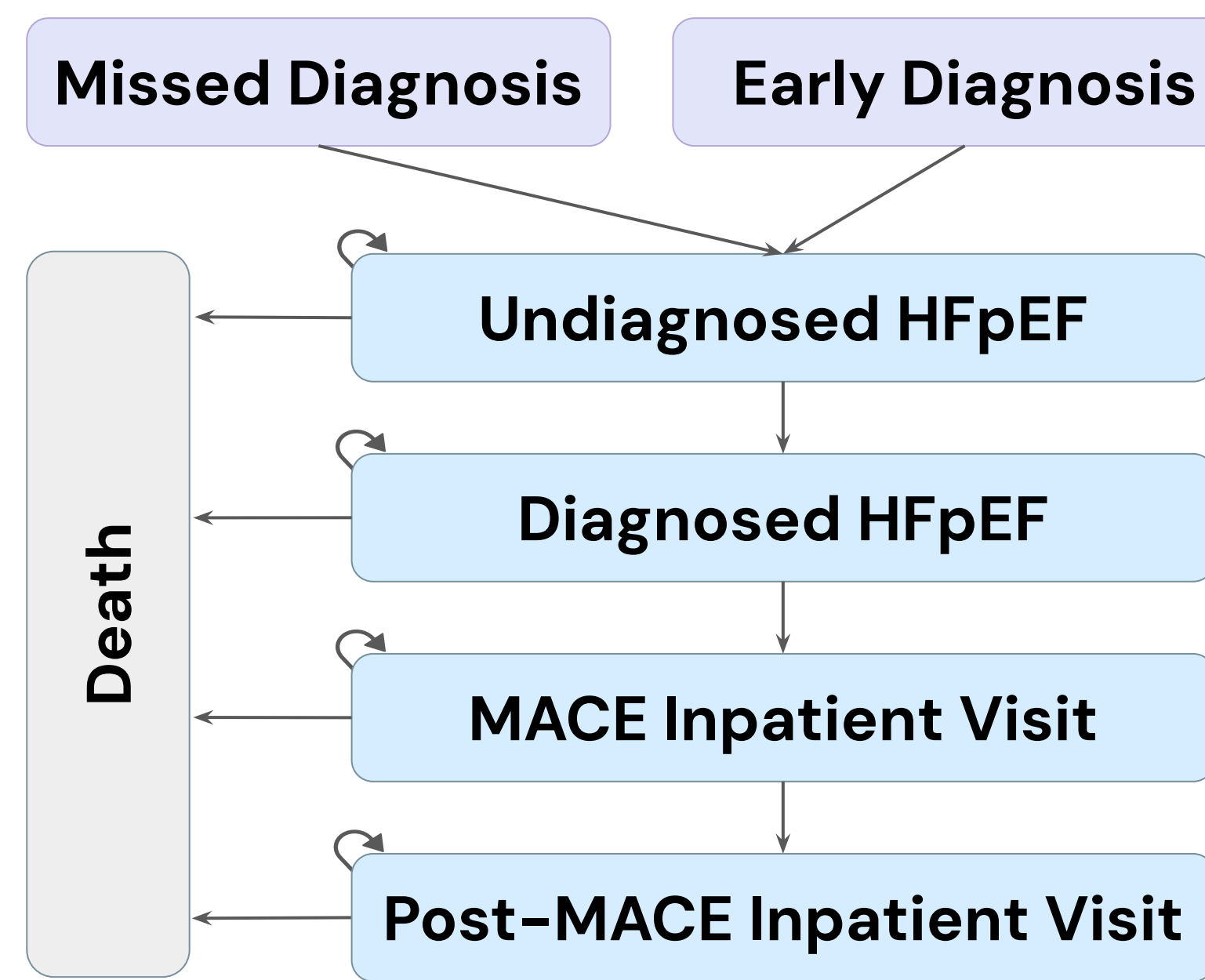
2. Retrospective Assessment on Respiratory Outcomes

Patients' real-world HF and Major Adverse Cardiac Event (MACE)-related healthcare resource utilization were compared after balancing cohorts on baseline characteristics using inverse probability treatment weighting.



1. Inclusion & Exclusion criteria were applied to TTEs characteristics, including adult, non-contrast, non-stress, non-3D TTEs with apical-4 chamber clips.
 2. EchoGo Heart Failure is FDA-approved for use in LVEF > 50%.
 3. H2FPEF Score: Clinical risk score used to estimate the likelihood of HFpEF based on obesity, hypertension treatment, atrial fibrillation, pulmonary hypertension, age, and elevated filling pressures.
 4. HFpEF Diagnosis Criteria: i. First ICD-10 for I50.x within 90 days, ii. Newly initiated GDMT within 90 days, iii. Elevated BNP or NT-proBNP 90 days before or after index TTE, iv. Diastolic dysfunction measured on index TTE.

3. Markov Model Structure



Inputs

- Transition Probabilities & Resource Utilization:** Directly derived from retrospective cohort in Dandelion Health platform.
- Mortality Rates:** US Census Data, Dandelion Health mortality, & published MACE mortality rates [6, 7]
- Utility Values:** Published literature review derived from HFpEF & MACE hospitalizations [8]
- Costs:** Mapped from retrospective cohort utilization to HCUP NEDS + NIS, CMS Physician Fee Schedule, and VA Federal Supply Schedule [7, 9-11]. All costs were adjusted to the 2025 USD.

Time Horizon

- 5 Year Horizon
- 30 day cycle lengths
- Half-cycle corrections applied
- 3% Discount applied to costs & utilities

Key Assumptions

- Timely HFpEF impacts resource utilization
- Willingness-to-pay threshold of \$150,000 per QALY.
- Base case utilized severity-adjusted trajectories (**Figure 2 below**)

RESULTS

Ground Truth	Algorithm Prediction		EchoGo HF Algorithm	Standard of Care [4]
	Positive	Negative		
Positive	3,713 True Positives	688 False Negatives	Sensitivity: 84.4%	34%
Negative	14,866 False Positives	61,259 True Negatives		
		Specificity: 81%		83%

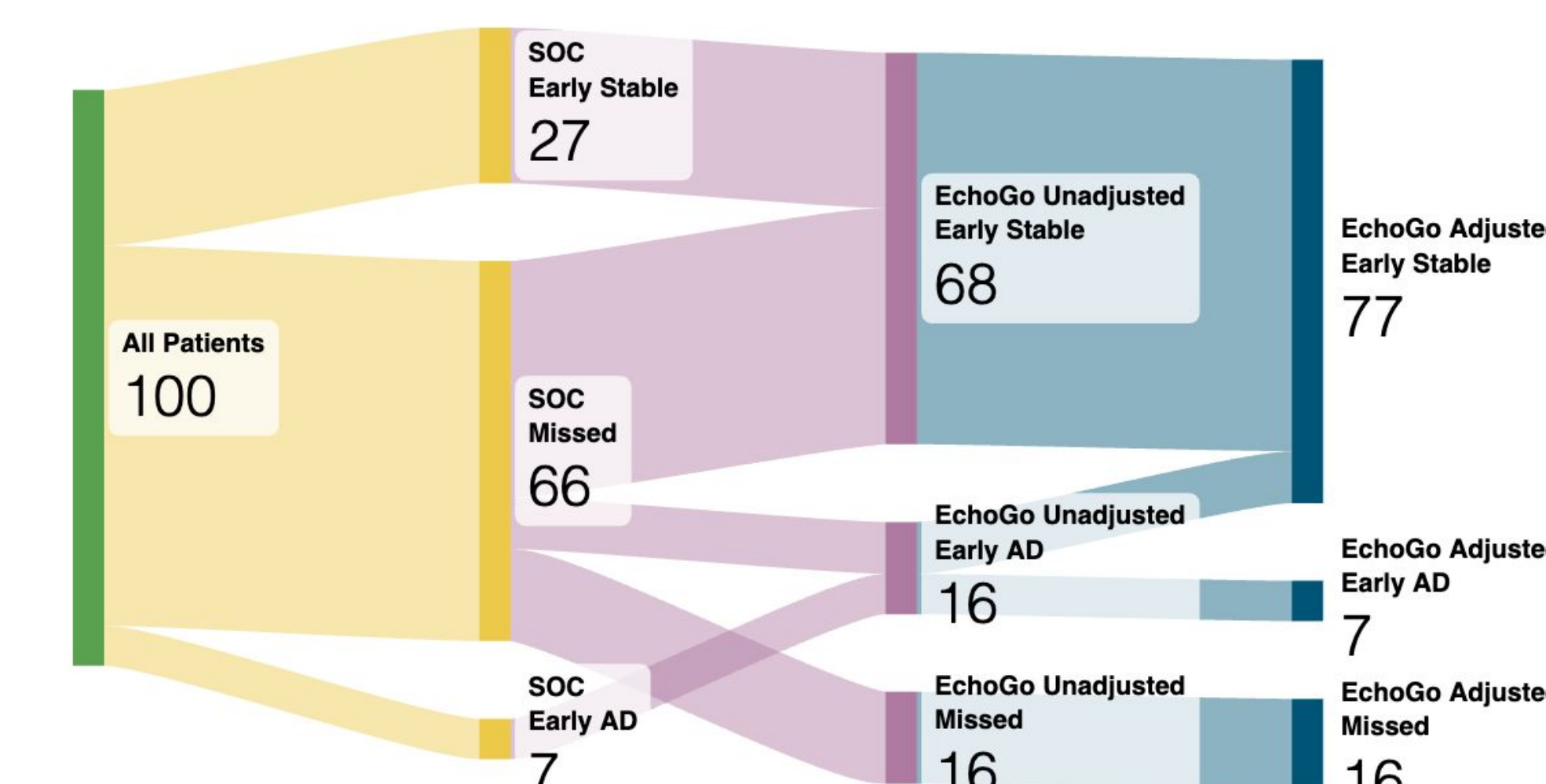
Validation Data: Dandelion Health Data November 2025
 Ground Truth: Established by retrospective EHR events, when predictions disagreed with EHR labels, by calculated H2FPEF Scores

Figure 1. EchoGo HF Algorithm Performance Metrics.

EchoGo HF Algorithm has 50% absolute improvement in early detection compared to conventional care.

Figure 2. Severity-Adjusted Trajectory & Cohort Assignments Standardized per 100 patients

Sensitivity estimates (shown above) were used to determine the proportion of patients projected to have an Early versus Missed diagnosis under Standard of Care (SOC) and the EchoGo HF modeled pathway. The model assumed the algorithm would primarily identify patients who would otherwise have been missed under SOC. Therefore, the number of patients diagnosed only at acute decompensation (AD) was assumed to remain the same as SOC, and the additional Early diagnoses in the algorithm pathway were assumed to occur among stable patients. Additionally, analyses were restricted to patients who received an ICD-10 heart failure diagnosis after the index TTE to ensure both cohorts consisted of patients whose disease became clinically recognized to account for HF severity.



This assumption and the corresponding proportions were varied in one way and probabilistic sensitivity analyses.

Key Clinical Outcomes Attributable to Earlier Diagnosis of HFpEF from the EchoGo HF Algorithm.

23.4% Reduction in MACE-related ED visits per 10,000 patients over 5 years	17% Reduction in MACE-related hospital readmissions Per 10,000 patients over 5 years	263 EchoGo could have led to diagnosis of HFpEF 263 days before clinically recognized in the EHR record among Missed Diagnosis patients.
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Subgroups	Deterministic Result	Net Monetary Benefit	Probability of Cost-Effectiveness
Base Case	\$122,714/QALY	\$9,485	67%
Sex			
Male	Dominant	\$10,818	65%
Female	\$89K/QALY	\$1,450	51%
Age			
< 75 Years Old	Dominant	\$6,336	59%
>= 75 Years Old	\$133K/QALY	\$319	50%
Race & Ethnicity			
White, Non-Hispanic	Dominant	\$6,319	61%
Non-White [12]	Dominant	\$40,186	76%

Table 1. EchoGo Cost-Effectiveness is Highest in Male Patients, Younger Patients, and Non-White Patients.

Non-White patients had substantially higher hospitalization and readmission rates when diagnoses are delayed.

Note: Willingness-to-pay threshold of \$150,000 / QALY

Cost-effectiveness was most sensitive to EchoGo Heart Failure algorithm's ability to diagnosis HFpEF prior to decompensation.

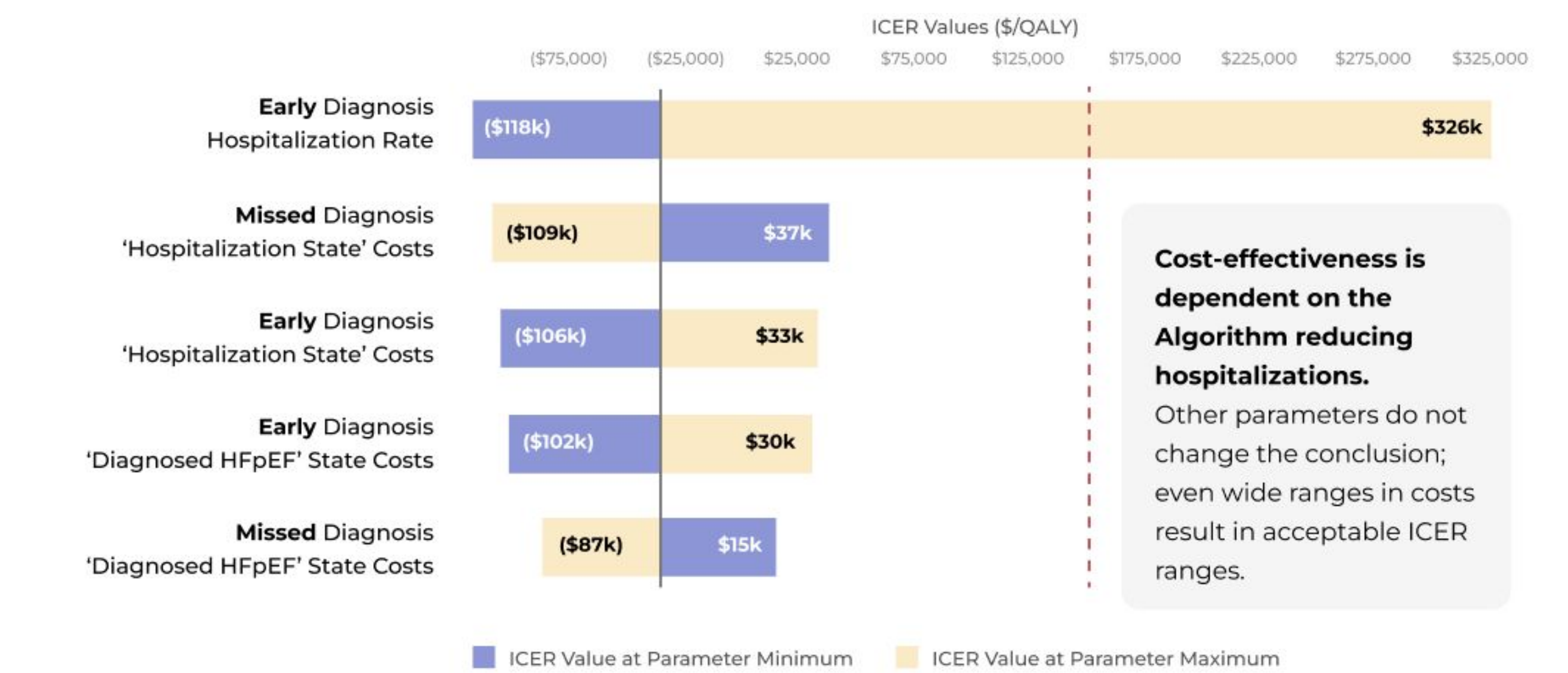


Figure 3. One-Way Sensitivity Analysis

CONCLUSIONS

Literature has reported a limitation of prior AI diagnostic economic evaluations is the insufficient inclusion of downstream outcomes data [13-16]. **This study demonstrates a novel real-world evidence methodology that retrospectively applies AI algorithms to historical imaging data and tracks subsequent patient outcomes within the same dataset.**



EchoGo HF algorithm offers improved performance on detecting HFpEF on TTE scans compared to literature-reported standard of care.

- 500 more patients could potentially receive a timely diagnosis of HFpEF among 10,000 patients screened.
- Beyond enhanced diagnostic accuracy, EchoGo HF enables earlier detection and treatment initiation, helping prevent disease progression.
- Missed diagnosis is associated with higher acute care utilization for MACE-related events and increased all-cause mortality.



The Algorithm was cost-effective in the base case (66.7% of 5,000 simulations were cost-effective) with the strongest evidence of this in the non-white subpopulations. By identifying patients before acute decompensation, EchoGo HF is **cost-effective** and improves patient's clinical trajectories.

This study establishes a framework for evaluating real-world value of AI through retrospective application of algorithms to imaging data that are linked to longitudinal outcomes.

ACKNOWLEDGEMENTS & REFERENCES



The American Heart Association AI Assessment Lab, Powered by Dandelion Health provides independent, scientifically rigorous evaluations of cardiology and stroke AI algorithms. Using the American Heart Association's gold-standard methodology, the Assessment Lab helps AI developers and healthcare stakeholders evaluate solutions for clinical performance, safety, and impact, ensuring innovation serves patients and healthcare systems with integrity.

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