



Hutchinson Institute for
Cancer Outcomes Research

MCD Testing in the United States Estimating Cost-Effectiveness and Budget Impact

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Disclosures

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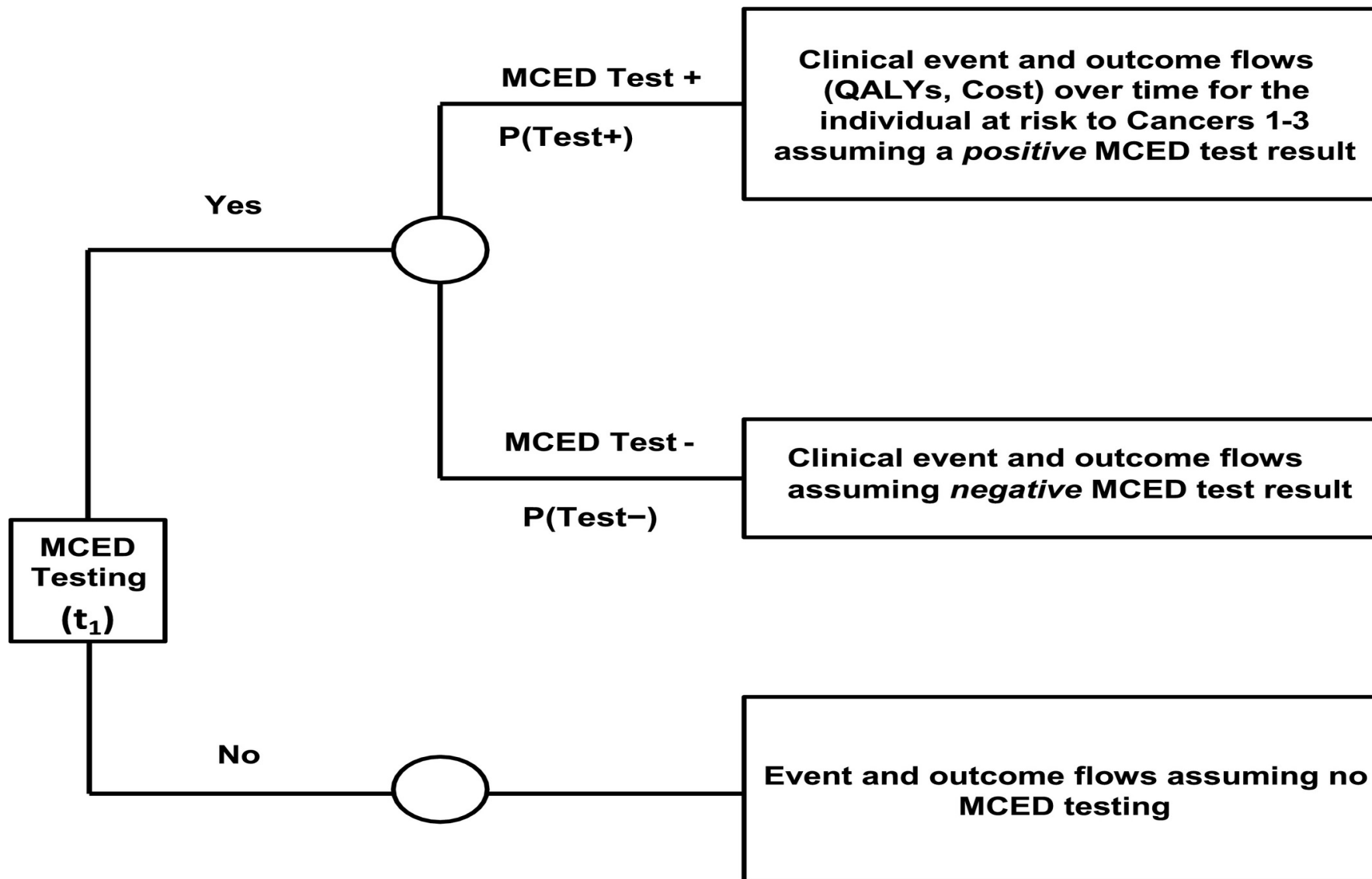
Definitions

Cost-effectiveness analysis

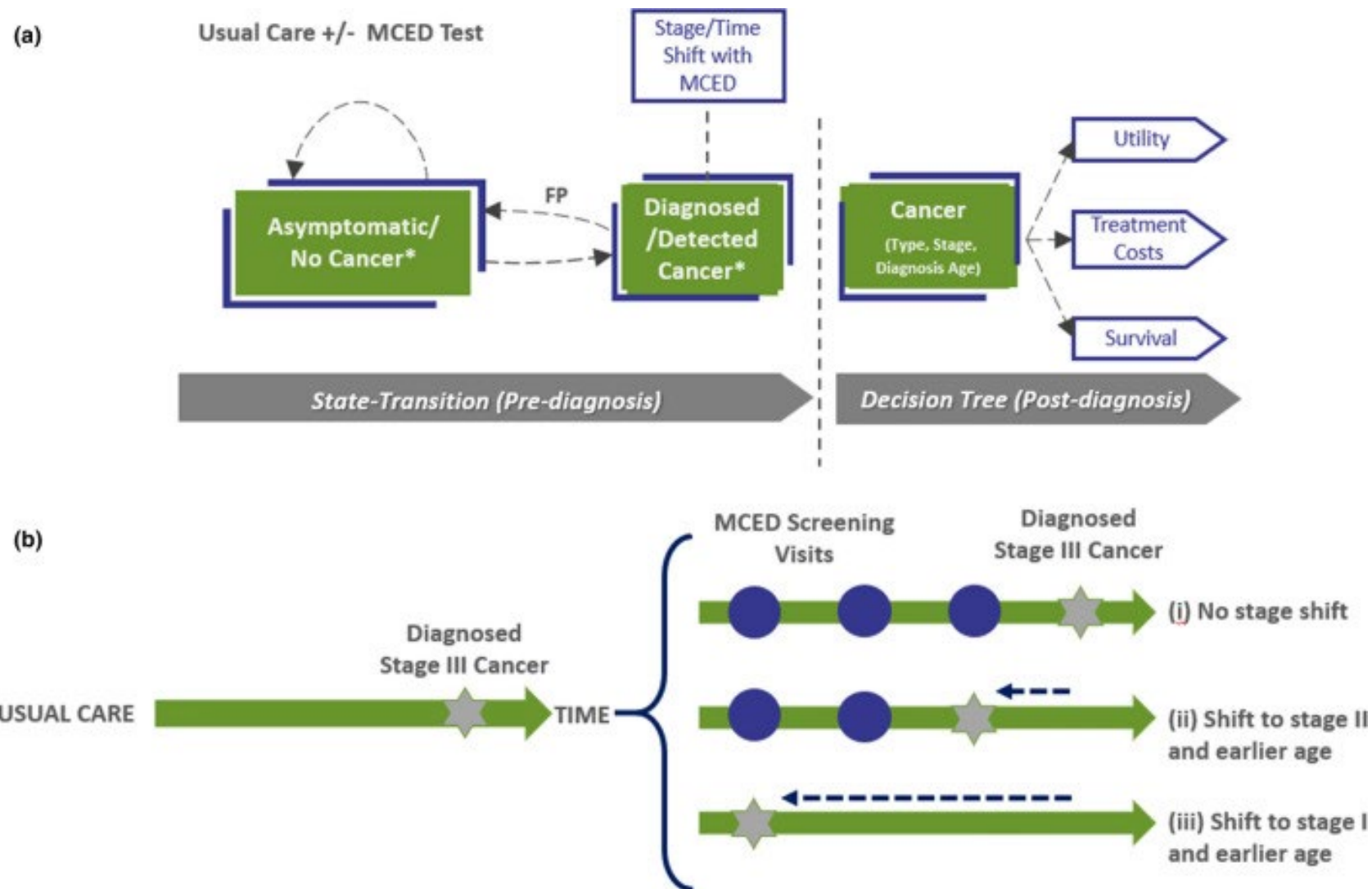
- Compares the costs and effectiveness of two or more alternatives
- Expressed as a ratio of the difference in costs divided by the difference in effects (ex: life years, quality adjusted life years (QALYs))
- Ratio used to determine **value**: whether the incremental benefits of an intervention justifies its cost relative to the alternative
 - Compare to cost-effectiveness of other interventions
 - Compare to a value threshold (e.g. \$50,000 per QALY)

Budget impact analysis

- Estimates the financial consequences of adopting a new intervention from the health insurer perspective
 - Focus is on intervention-related costs (e.g., screening test cost) and associated downstream impacts on cost (e.g., evaluation of false positive tests, savings from treating earlier stage cancer)
 - No explicit consideration of health effects



Model structure with an example of stage and time shifting of diagnosed cancers due to MCD testing



Factors That Will Influence the Cost-effectiveness and Budget Impact of MCD Testing

- 1. Eligible patient population**
 - Cancer risk profile of patients being screened
- 2. Natural history of the cancers included in MCD test**
- 3. MCD Screening strategy**
 - Cadence
 - Follow-up procedures for positive tests
 - Use in relation to existing screening programs
- 4. Test performance**
 - Sensitivity for detecting early-stage cancers
 - Specificity
- 5. Patients' willingness and ability to participate in MCD screening programs**
- 6. Healthcare system's ability to accommodate willing patients**
- 7. MCD program cost**
 - Test cost
 - Evaluation of positive tests
- 8. Cost of cancer treatment (early vs late stage)**

MCD + SoC vs SoC Screening: Cost-effectiveness Studies

Study	MCD Cancers Included	Cost/QALY vs SoC Screening	Value Based Price, WTP \$100,000/QALY	Most Influential Parameters, OWSA
Lewis et al, 2024	8 cancers	CDN\$143,369/QALY*	CDN\$451	MCD test cost MCD specificity
Tafazzoli et al, 2022	19 solid cancers	US\$100,000/QALY	US\$1196	Cancer incidence MCD sensitivity
Lipscomb et al, 2021	Pancreatic, uterine, lung cancer**	US\$22,494/QALY	N/A	Cancer Prevalence MCD sensitivity

*\$500 per test

**Single screening test

Annual Cost of Cancer Screening in the US

Screening Test	Overall Total Cost (\$M)	Private Insurance		Medicare, Medicare Advantage, Dual Enrollment		Medicaid, Other Government, Uninsured	
		Cost per Screening Test (\$)	Persons Screened (M)	Cost per Screening Test (\$)	Persons Screened (M)	Cost per Screening Test (\$)	Persons Screened (M)
Mammography	\$8,802	\$327	23.3	\$134	6.0	\$105	3.5
Cervical cancer	\$5,542	\$212	25.1	\$35	0.81	\$27	7
CRC (all tests)	\$27,467	-	13.8	-	6.3	-	2.3
Lung cancer	\$656	\$498	0.78	\$179	1.1	\$136	0.55
Prostate	\$702	\$110	6.1	\$18	1.8	\$12	0.52
Total (Pop-\$M)	\$43,169	\$38,128		\$3,679		\$1,362	

Adapted from Halpern et al. Ann Intern Med. 2024;177:1170-1178.

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Estimated Annual Budget Impact Under Universal MCD Coverage

Cost component	Overall Total Cost \$M	Private Insurance		Medicare, Medicare Advantage, Dual Enrollment		Medicaid, Other Government, Uninsured	
		<i>Cost per impacted person (\$)</i>	<i>Persons (Millions)</i>	<i>Cost per impacted person (\$)</i>	<i>Persons (Millions)</i>	<i>Cost per Impacted person (\$)</i>	<i>Persons (Millions)</i>
MCD		\$711	29.4	\$380	7.8	\$285	4.02
Positive MCD tests*		\$4,500	0.412	\$3,000	0.1092	\$2,500	0.056
Cancer shift to earlier stage		\$(40,000)	0.0188	\$(20,000)	0.00498	\$(15,000)	0.0026
Total (Pop-\$M)							

- Positive test rate (Pathfinder) - 1.4%; % of positive tests w cancer (Pathfinder) - 38%;
- % of detected cancers shifted to earlier stage 12% (Tafazzoli et al); Cost savings for stage shift, year 1
- Retail price MCD test \$949 (Grail); Test discounts: Commercial - 25% Medicare - 60% Medicaid - 70%

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		Cost per impacted person (\$)	Persons (Millions)	Cost per impacted person (\$)	Persons (Millions)	Cost per Impacted person (\$)	Persons (Millions)
MCD	\$ 25,031	\$711	29.4	\$380	7.8	\$285	4.02
Positive MCD tests*	\$ 2,321	\$4,500	0.412	\$3,000	0.1092	\$2,500	0.056
Cancer shift to earlier stage	\$ (889)	\$(40,000)	0.0188	\$(20,000)	0.00498	\$(15,000)	0.0026
Total (Pop-\$M)	\$ 26,462	\$22,027		\$3,189		\$1,247	

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		Cost per impacted person (\$)	Persons (Millions)	Cost per impacted person (\$)	Persons (Millions)	Cost per Impacted person (\$)	Persons (Millions)
MCD	\$ 30,625	\$806.65	29.4	\$616.85	7.8	\$521.95	4.02
Positive MCD tests*	\$ 2,321	\$4,500	0.4116	\$3,000	0.1092	\$2,500	0.05628
Cancer shift to earlier stage	\$ (889)	\$40,000	0.01877	\$20,000	0.0050	\$15,000	0.00257
Total (Pop-\$M)	\$ 32,057	\$24,817		\$5,039		\$2,200	

- Positive test rate (Pathfinder) - 1.4%; % of positive tests w cancer (Pathfinder) - 38%;
- % of detected cancers shifted to earlier stage 12% (Tafazzoli et al); Cost savings for stage shift, year 1
- Retail price MCD test \$949 (Grail); Test discounts: **Commercial - 15% Medicare - 35% Medicaid - 45%**

Factors That Will Influence Budget Impact

- Without insurance coverage, uptake of MCD testing will be modest at current prices (e.g. Galleri test list price: \$949)
- USPSTF rating of MCD evidence is pivotal for insurance coverage
 - A or B ranking mandates coverage with 0% copay
- If covered, mitigating budget impact comes down to
 - Aggressive price negotiation
 - May be possible if multiple tests are on the market
 - Further risk stratifying*
 - Lengthening covered screening intervals*

**Will entail restrictions beyond the FDA label.*

Balancing Fairness Against Budget Impact

- Risk informed screening will mitigate budget impact
- Risk stratification can raise concerns over fairness
 - All persons have a risk for cancer that increases with age
 - We accept age-adjusted risk stratification
 - Would we accept further stratification, which implies denying coverage for persons with lower (but nonzero) risks?

Takeaways

Cost Effectiveness

- The value proposition for MCD tests is uncertain
 - Test cost will be a primary factor
 - Survival impacts will matter more than cancer cost savings
- Need for harmonization of economic models
 - Validation against existing clinical trials (Pathfinder, Galleri-UK, Vanguard)

Budget Impact

- Primary driver of uptake—and budget impact—is insurer coverage policies
- If adopted widely, MCD testing is likely to be the costliest component of US screening
- In the short run, aggressive price negotiation is the most feasible path to mitigating budget impact
- In the long run, the economic return on trials focused on further risk stratification and/or less frequent screening schedules is likely to be **very large**



Thank you