Foundations of Economic Evaluation

Reviewing Key Concepts

Back to Website

Objectives/Outline

Back to Website

Outline

Before diving into decision trees and Markov models in Amua, I'll spend the next ~50 minutes reviewing key concepts in economic evaluation, covering the following topics:

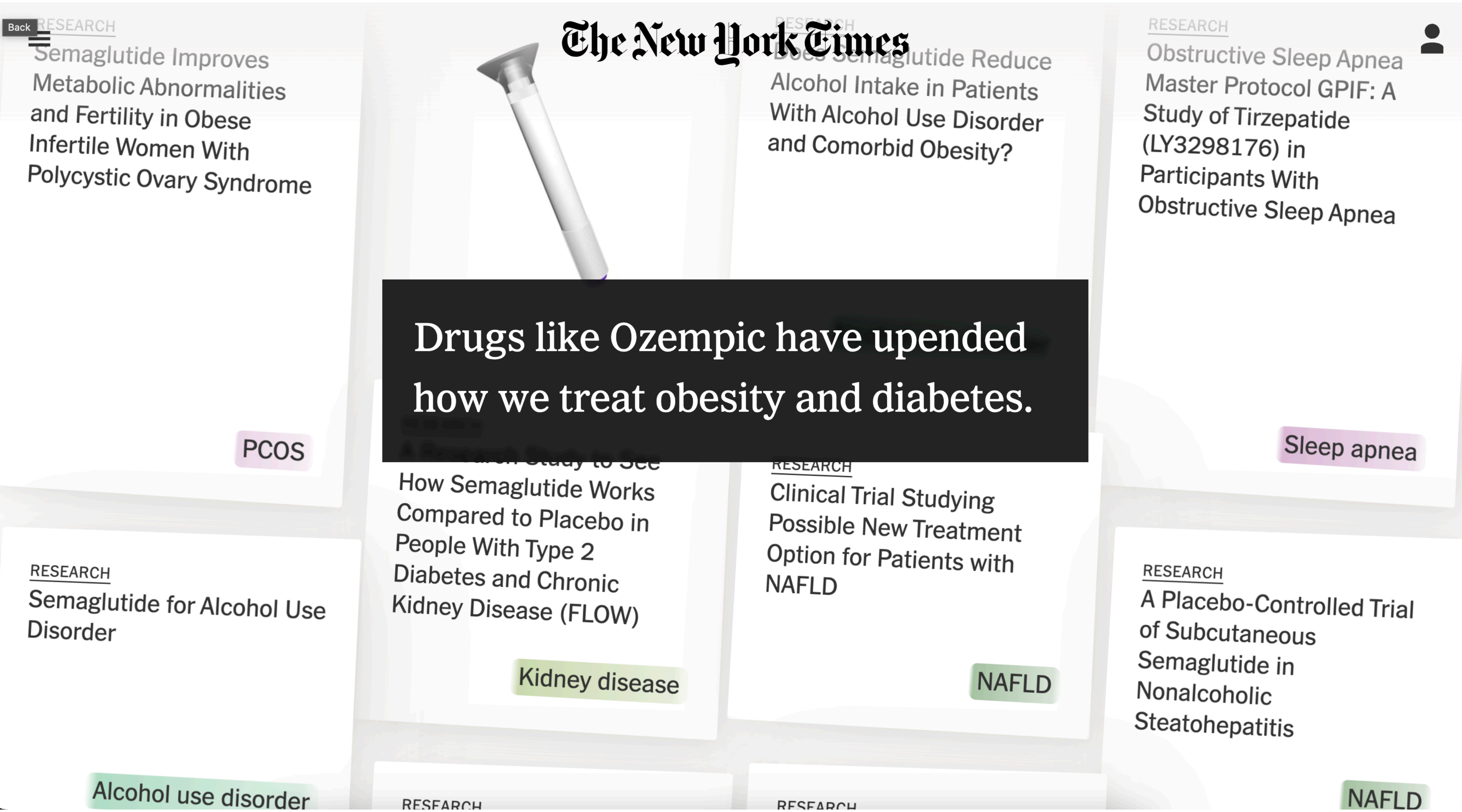
- An example research question that can be solved using economic evaluation methods (with a brief primer on decision trees)
- Types of Economic Evaluations
- Cost-effectiveness analysis alongside decision trees
- Competing choice problems/incremental cost-effectiveness analysis
- Beyond decision trees: A brief primer on Markov models

Back to Website

Example Patient

- Lisa is a 45 year old woman with obesity (BMI 32) who has struggled with weight management.
- She does not have diabetes but is concerned about her risk for cardiovascular disease due to weight, family Hx of heart disease, and elevated cholesterol levels.
- Lisa heard from a friend about Wegovy, and would like her national health program to cover it for her.

Back to Website



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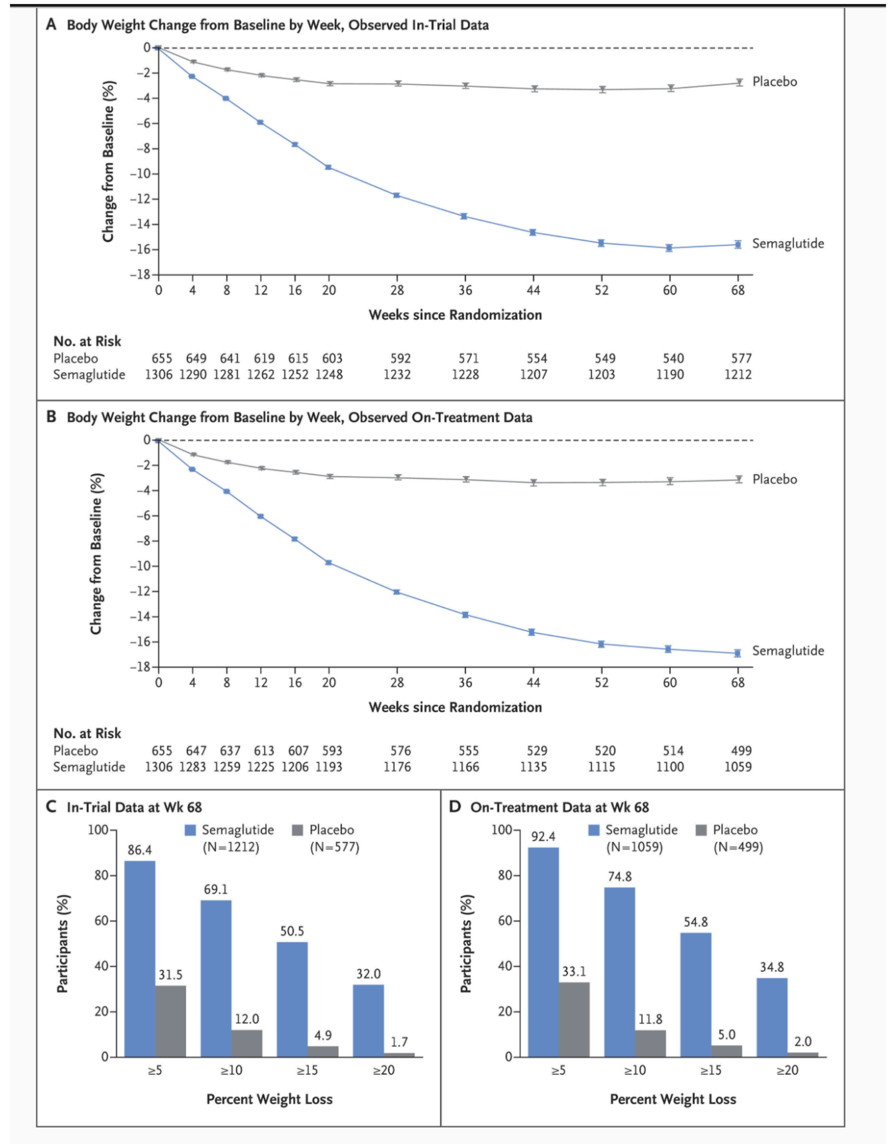
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MARCH 18, 2021 VOL. 384 NO. 11

Once-Weekly Semaglutide in Adults with Overweight or Obesity

John P.H. Wilding, D.M., Rachel L. Batterham, M.B., B.S., Ph.D., Salvatore Calanna, Ph.D., Melanie Davies, M.D., Luc F. Van Gaal, M.D., Ph.D., Ildiko Lingvay, M.D., M.P.H., M.S.C.S., Barbara M. McGowan, M.D., Ph.D., Julio Rosenstock, M.D., Marie T.D. Tran, M.D., Ph.D., Thomas A. Wadden, Ph.D., Sean Wharton, M.D., Pharm.D., Koutaro Yokote, M.D., Ph.D., Niels Zeuthen, M.Sc., and Robert F. Kushner, M.D., for the STEP 1 Study Group*



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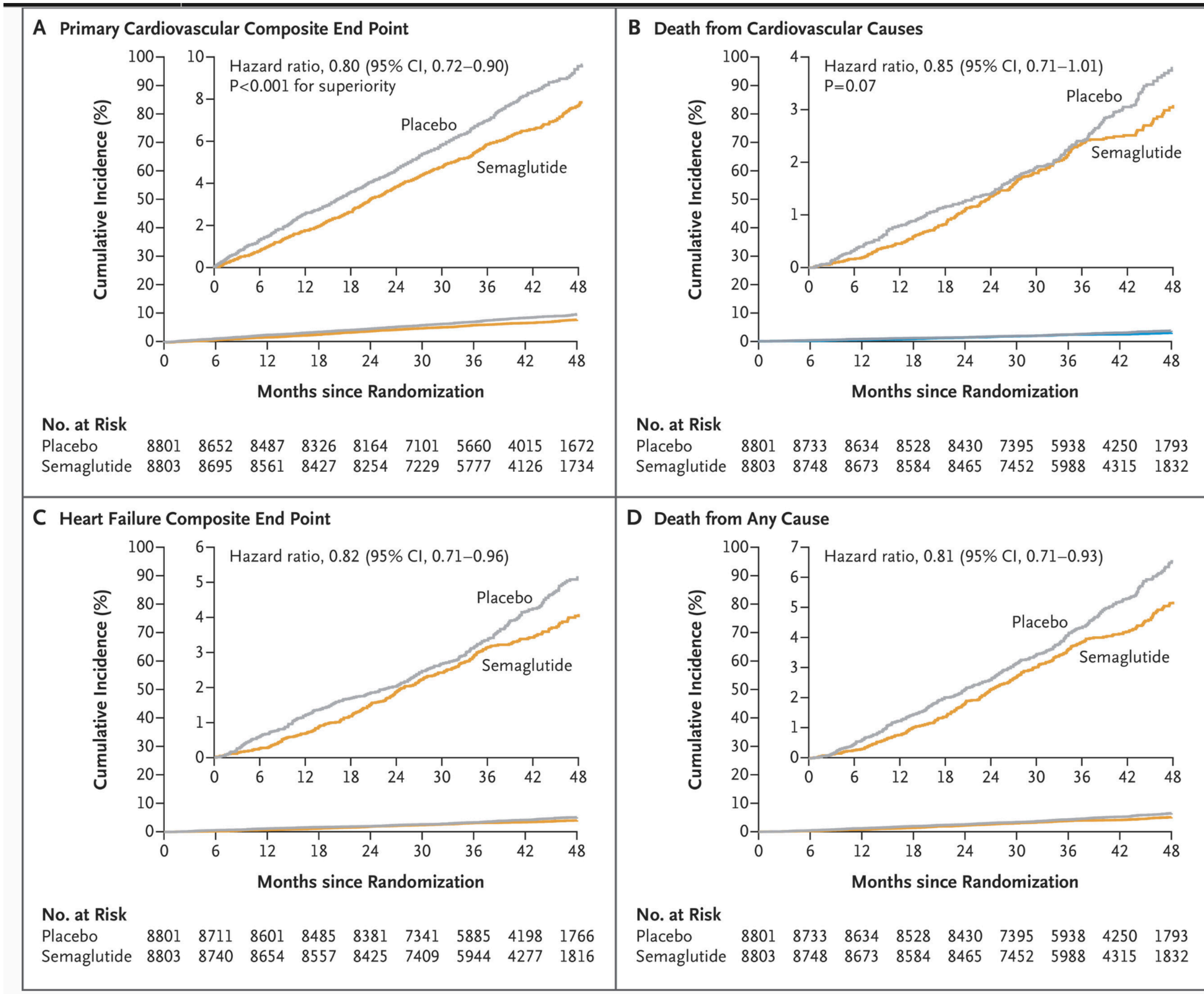
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 14, 2023 VOL. 389 NO. 24

Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes

A. Michael Lincoff, M.D., Kirstine Brown-Frandsen, M.D., Helen M. Colhoun, M.D., John Deanfield, M.D., Scott S. Emerson, M.D., Ph.D., Sille Esbjerg, M.Sc., Søren Hardt-Lindberg, M.D., Ph.D., G. Kees Hovingh, M.D., Ph.D., Steven E. Kahn, M.B., Ch.B., Robert F. Kushner, M.D., Ildiko Lingvay, M.D., M.P.H., Tugce K. Oral, M.D., Marie M. Michelsen, M.D., Ph.D., Jorge Plutzky, M.D., Christoffer W. Tornøe, Ph.D., and Donna H. Ryan, M.D., for the SELECT Trial Investigators*

Back to Website



Back to Website

WORK IN PROGRESS

The Weight-Loss-Drug Revolution Is a Miracle—And a Menace

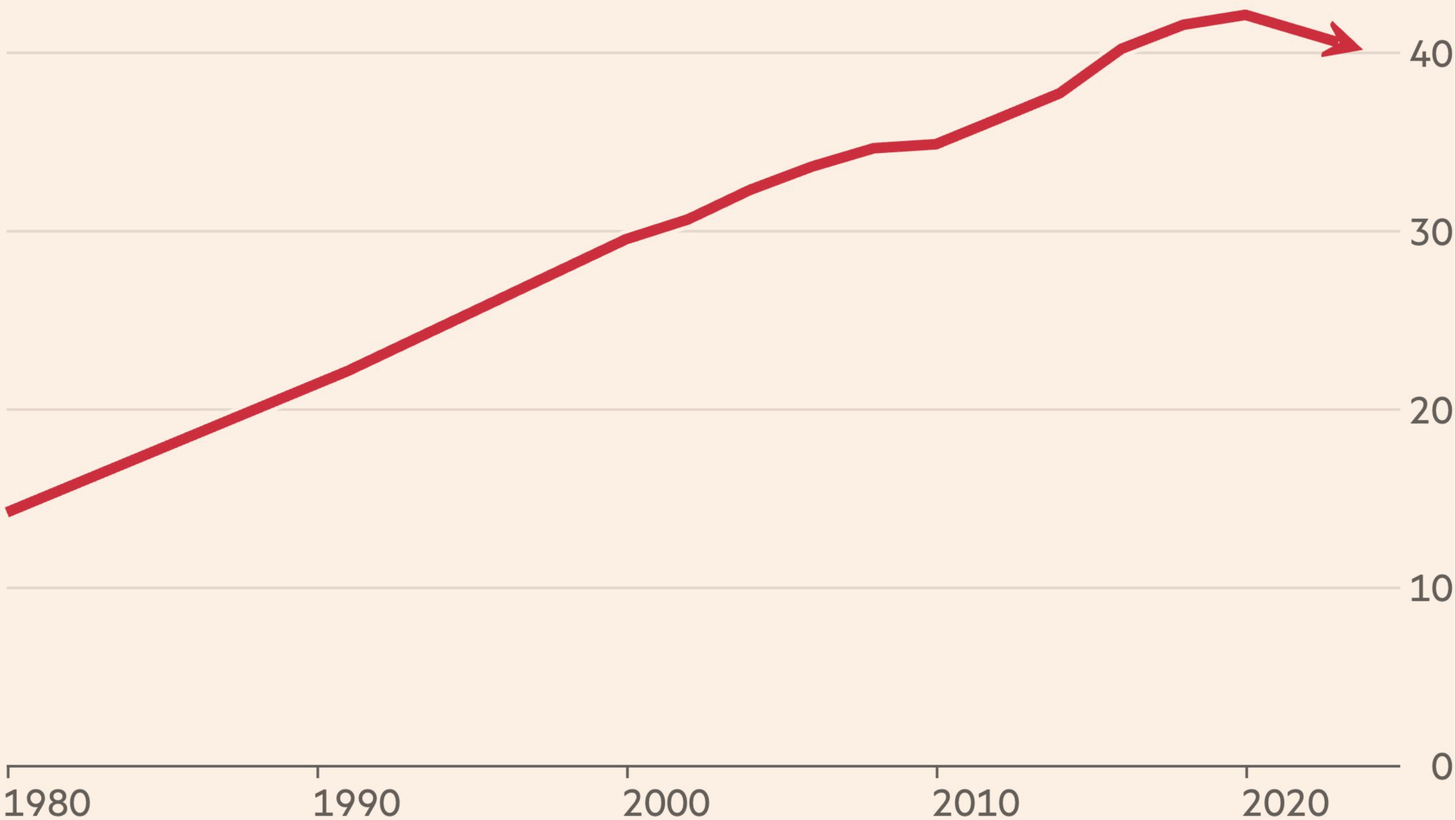
How the new obesity pills could upend American society

By Derek Thompson

Back to Website

The US obesity rate fell in 2023

Age-adjusted obesity rate among adults aged 20 and older (%)



Source: FT analysis of US National Health and Nutrition Examination Survey
FT graphic: John Burn-Murdoch / @jburnmurdoch

Back to Website

News

Signal: Novo Nordisk market cap higher than Danish GDP due to obesity drugs

Novo Nordisk's obesity drugs are driving Danish growth as well as record profits as the company becomes second-most valuable in Europe.

Isaac Hanson | September 1, 2023

Share this article

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Example Patient

- Lisa works as a nurse for one of the largest nonprofit health systems in the US, which recently dropped coverage of weight-loss medications due to concerns over “long-term outcomes, national coverage benchmarks, and cost-effectiveness.”
- Lisa’s predicament is not uncommon ...

Buried in Wegovy Costs, North Carolina Will Stop Paying for Obesity Drugs

Starting April 1, state employees in North Carolina will no longer have insurance coverage for costly weight-loss medications like Wegovy and Zepbound.

By Rebecca Robbins

PRINT EDITION Weight Drug Is Straining Health Funds | January 27, 2024, Page B1

Feb. 2

HEALTH

Six Reasons Why It's So Hard to Get Your Weight-Loss Drugs

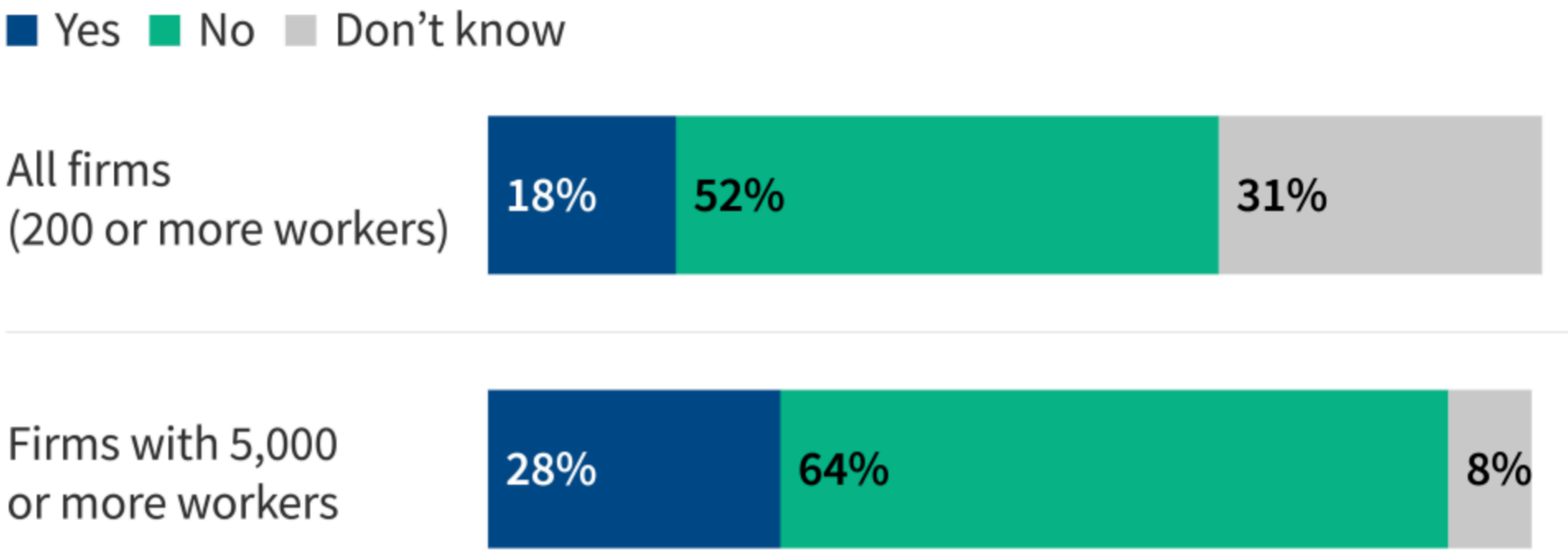
An array of obstacles makes it difficult for patients to obtain Wegovy or Zepbound. Finding Wegovy is "like winning the lottery," one nurse practitioner said.

By Reed Abelson and Rebecca Robbins

PRINT EDITION Why Weight-Loss Drugs Became So Hard to Find | February 3, 2024, Page A19

Back to Website

Most Large Employers Don't Cover GLP-1 Drugs for Weight Loss



2024 EMPLOYER HEALTH BENEFITS SURVEY

KFF

Back to Website

HEALTH AND SCIENCE

Weight loss drug Wegovy has launched in Germany — but users across Europe face a long and costly wait

PUBLISHED WED, JUL 26 2023•1:09 AM EDT | UPDATED MON, JUL 31 2023•5:06 AM EDT

Karen Gilchrist
@_KARENGILCHRIST

Back to Website

Example Patient

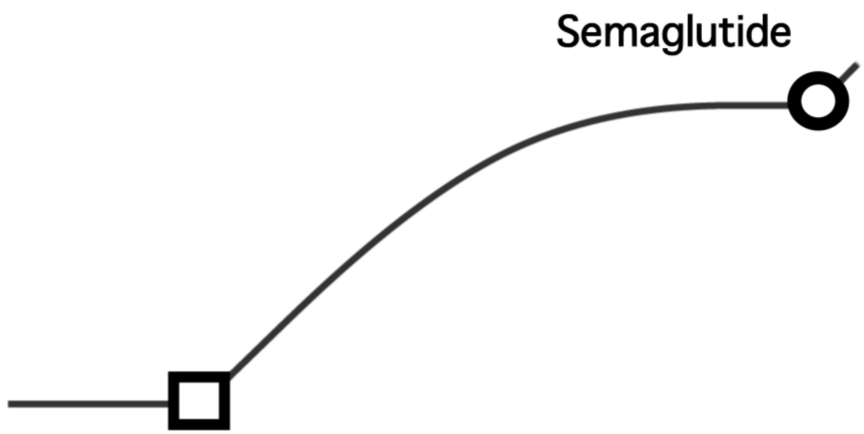
- If Wegovy is not covered by the National Health Programme, it will cost Lisa $1,349 per month.
- More broadly, how can we reconcile the health benefits of semaglutdie against the access and affordability challenges patients now face?

Decision Trees

Back to Website

What outcomes might Lisa experience?

Back to Website


Semaglutide

What alternative to Semaglutide might she also consider?

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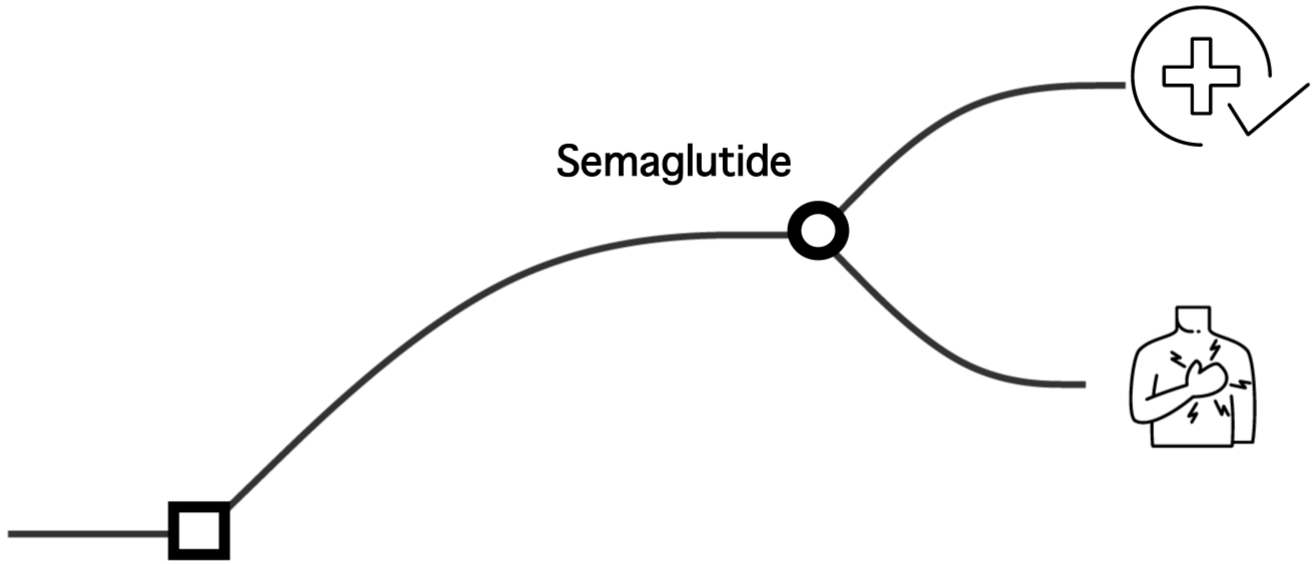


Back to Website

Let’s now quantify the possible health and cost outcomes in different states of the world …

Health Outcome

Back to Website

Health Outcome

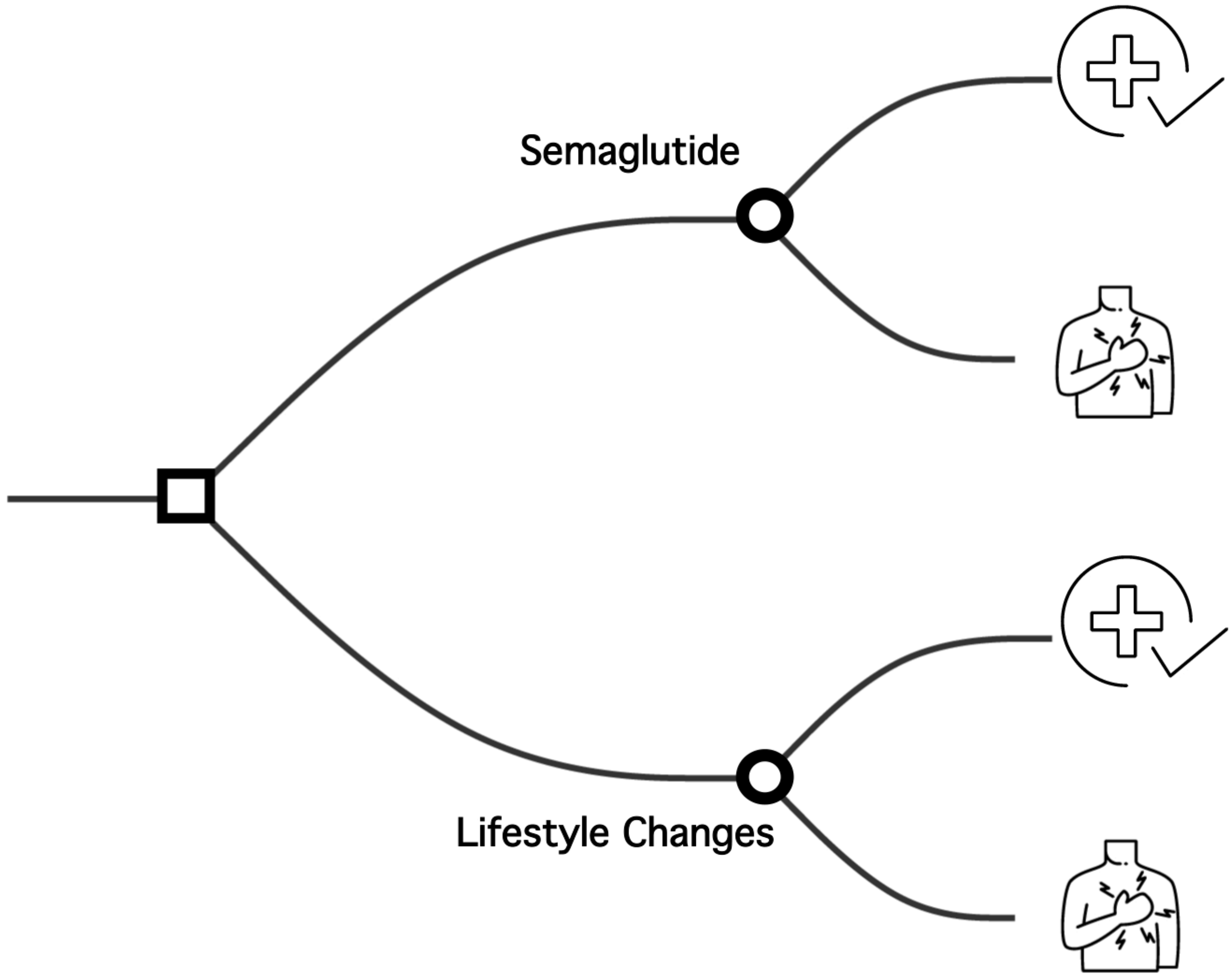
Back to Website

Back to Website

Cost Outcome

Back to Website

Back to Website



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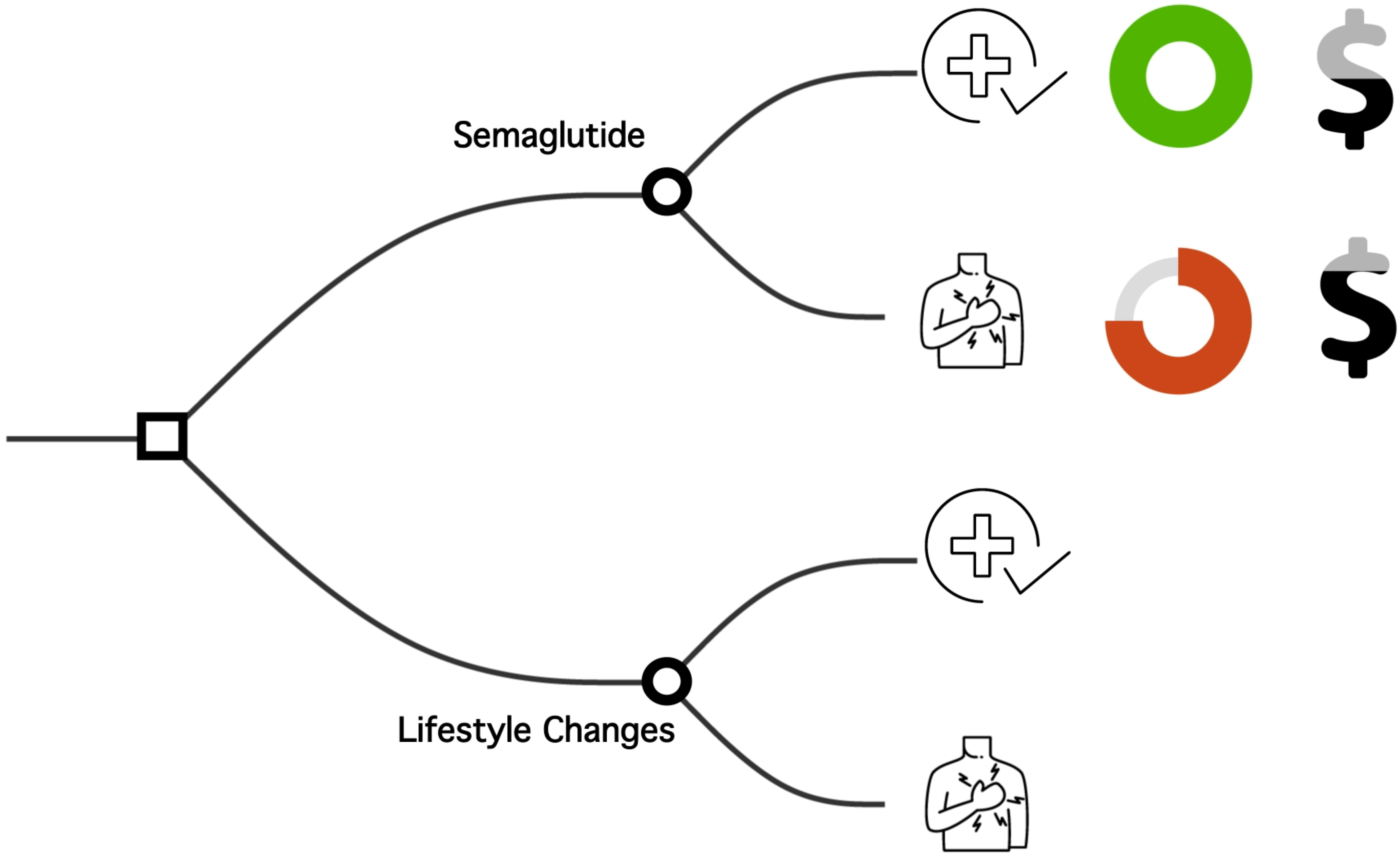
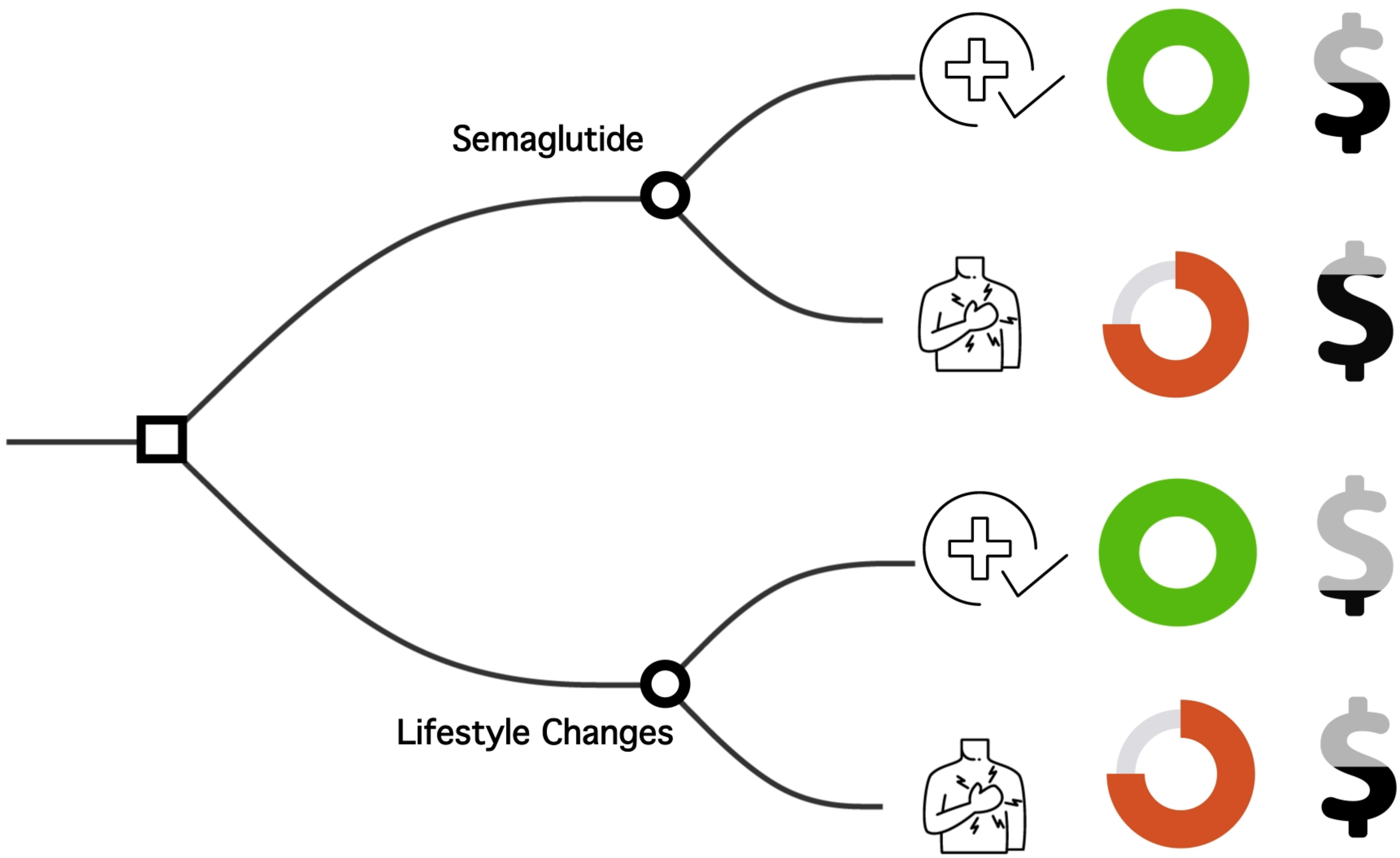


Back to Website

Let’s now summarize the overall health and cost outcomes

Back to Website



Back to Website

We can now map (average) health and cost outcomes to a plot

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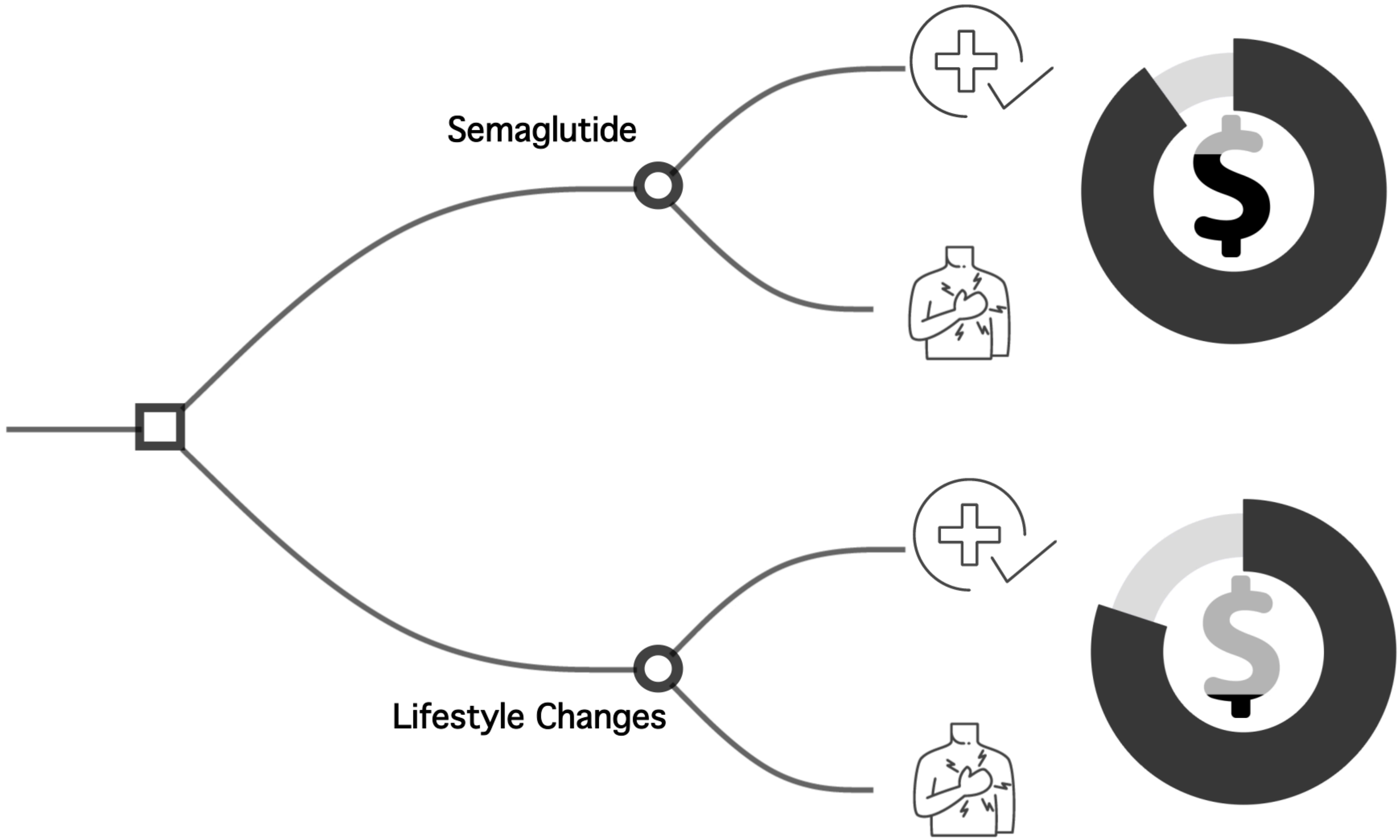

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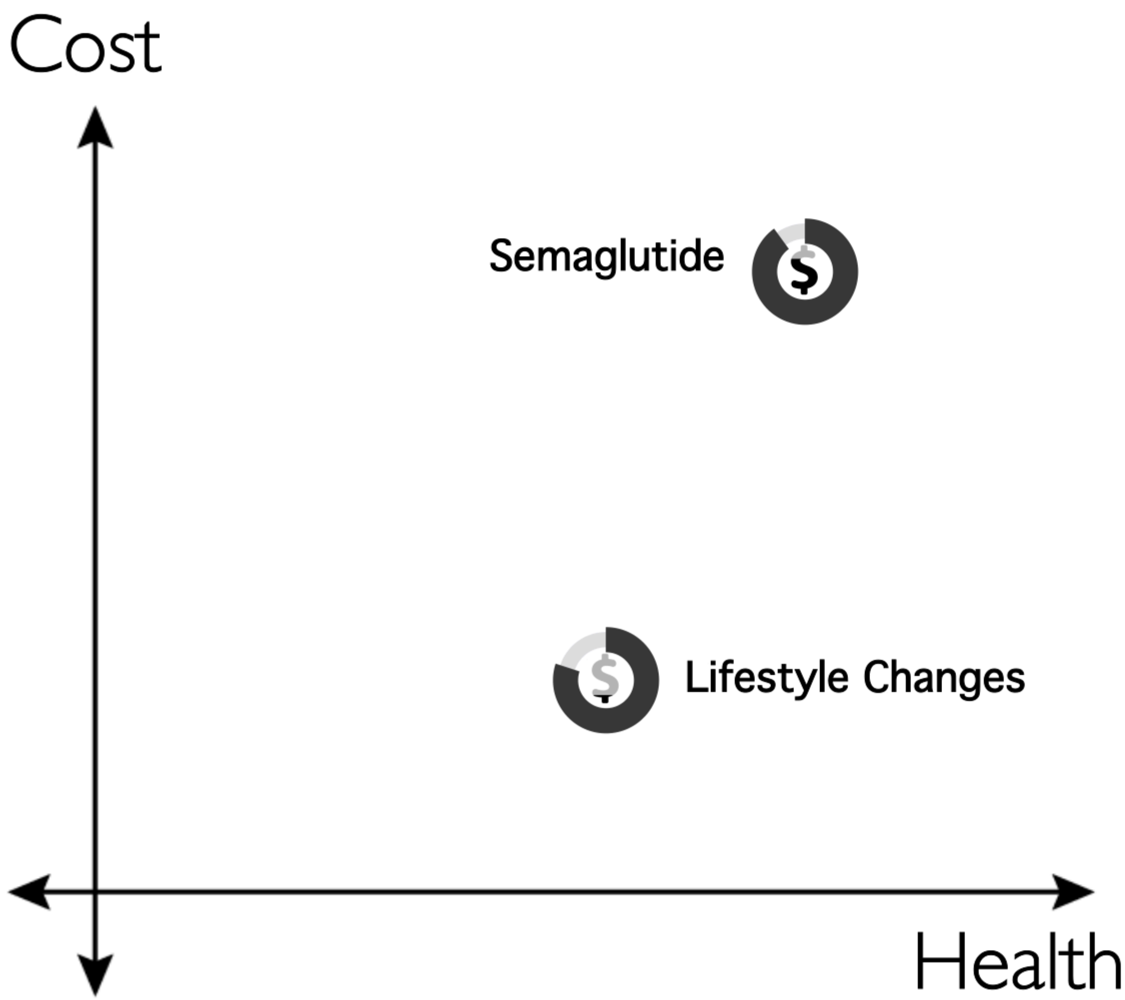
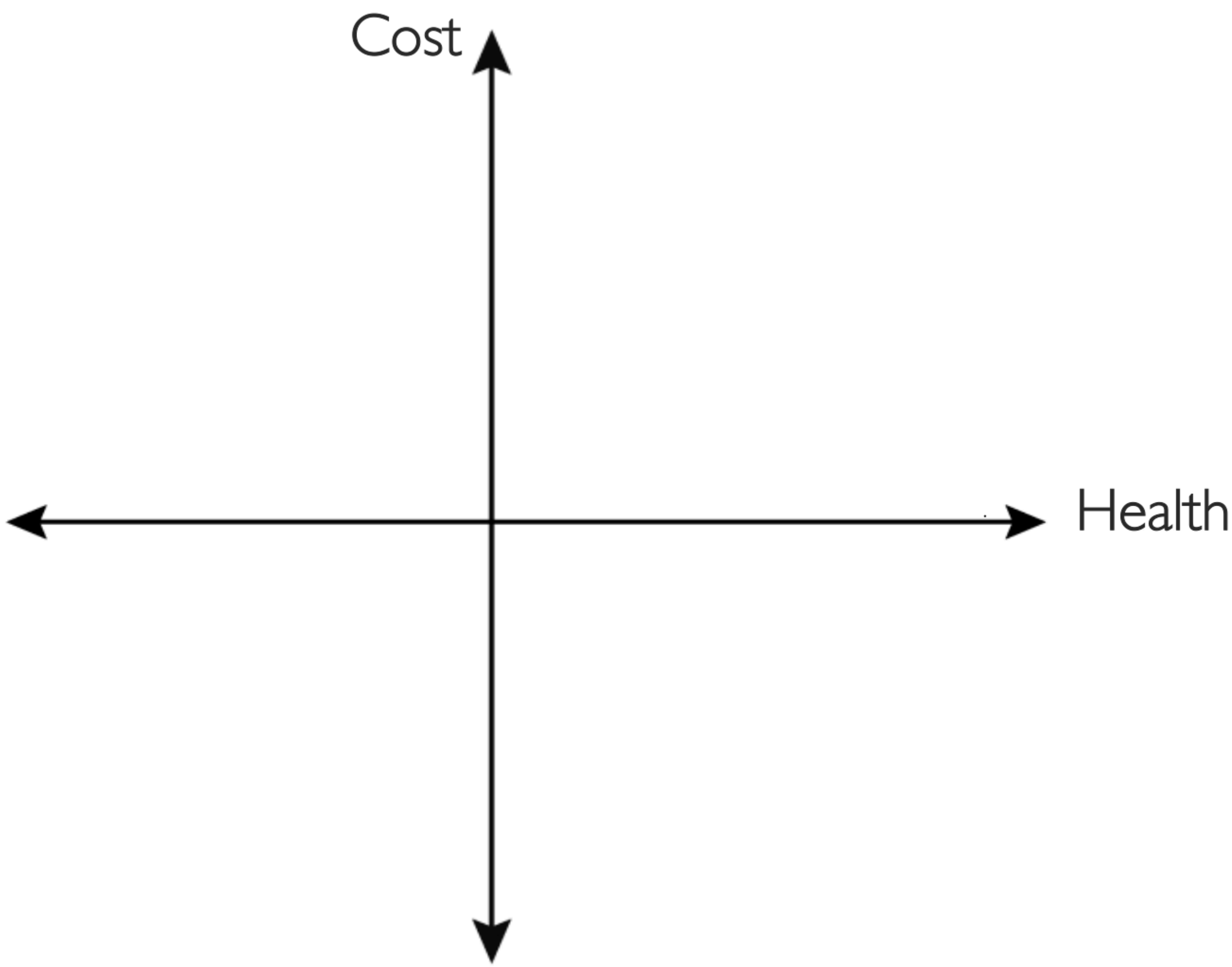


Back to Website

The Cost-Effectiveness Plane

Back to Website



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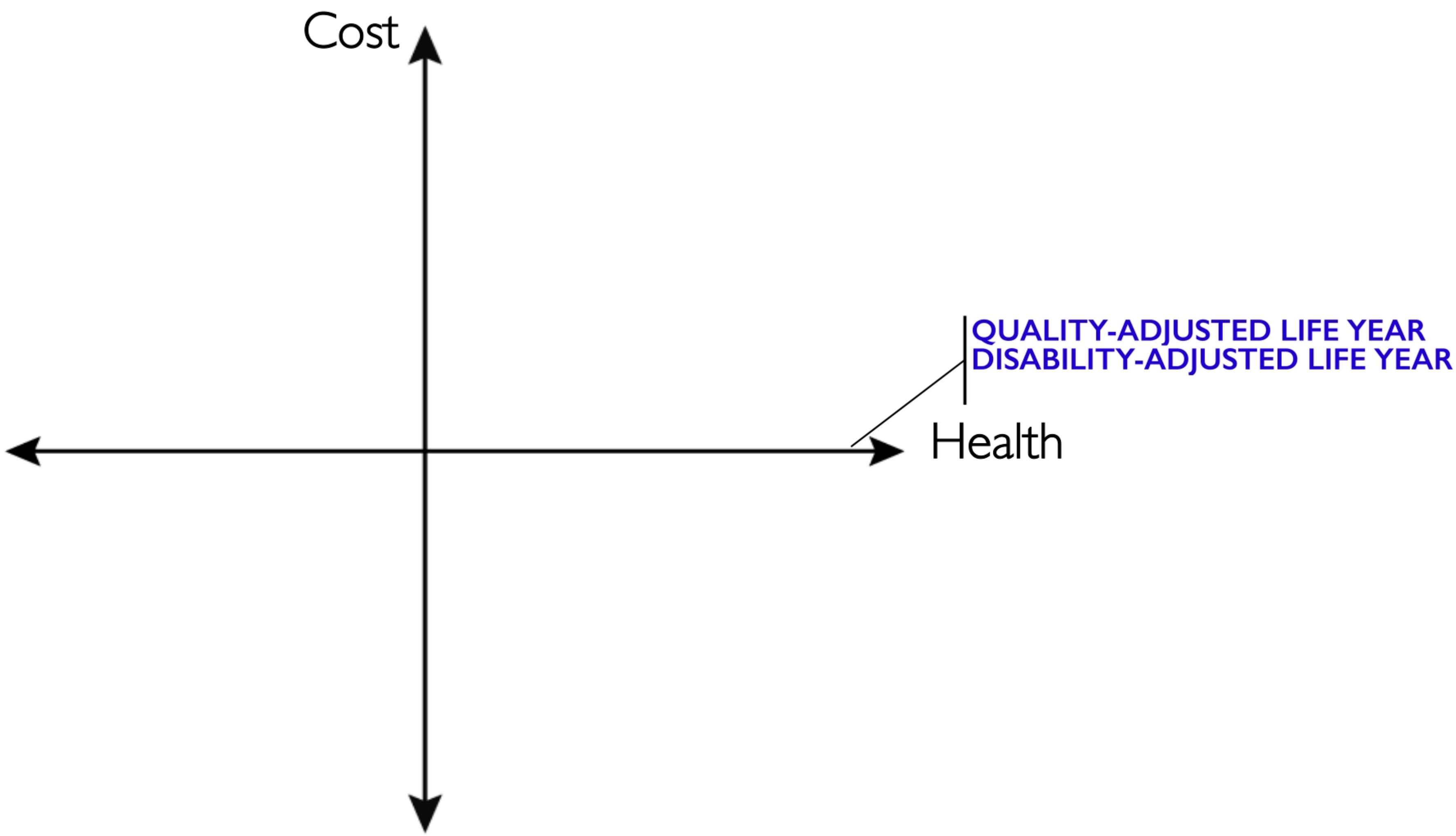

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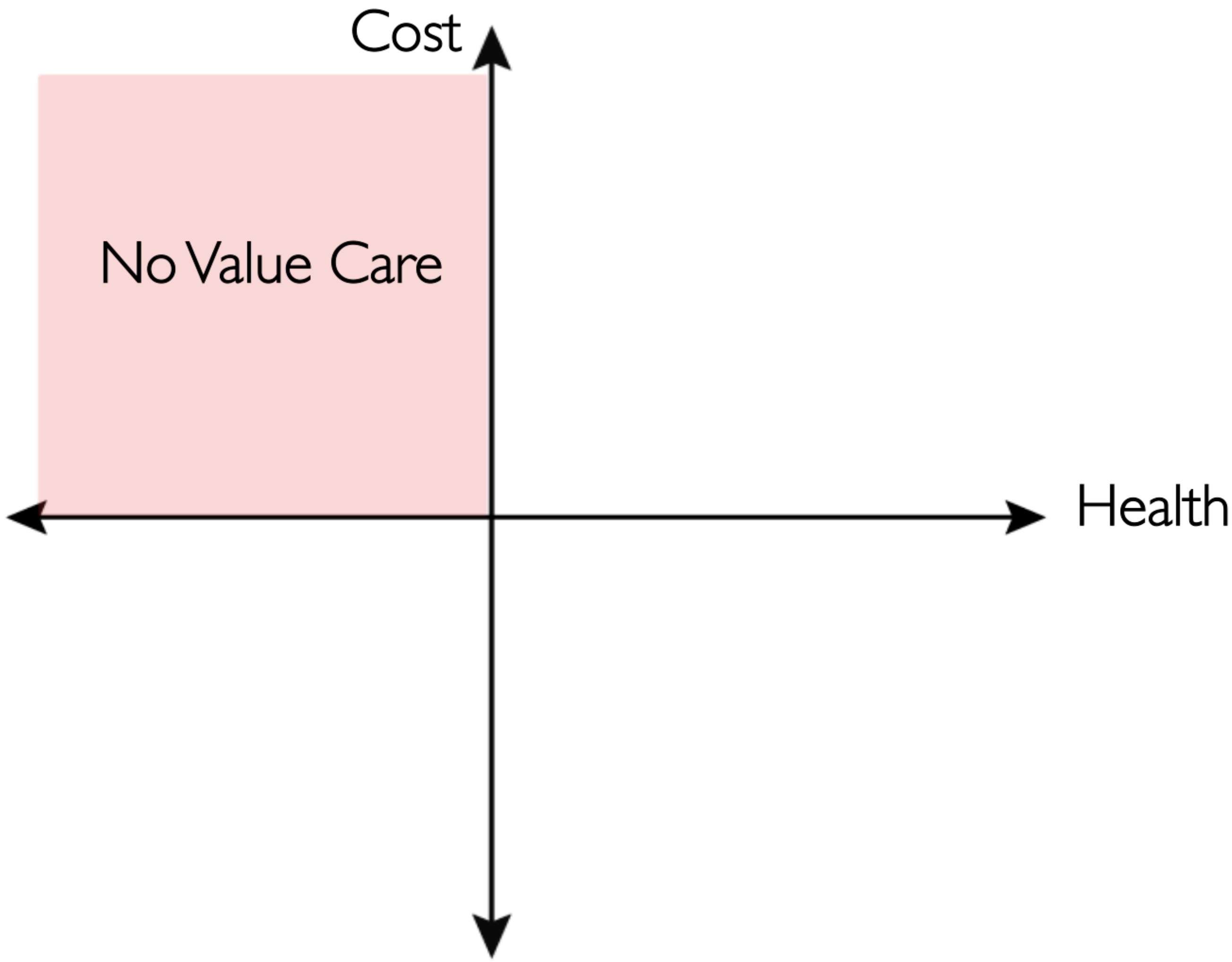

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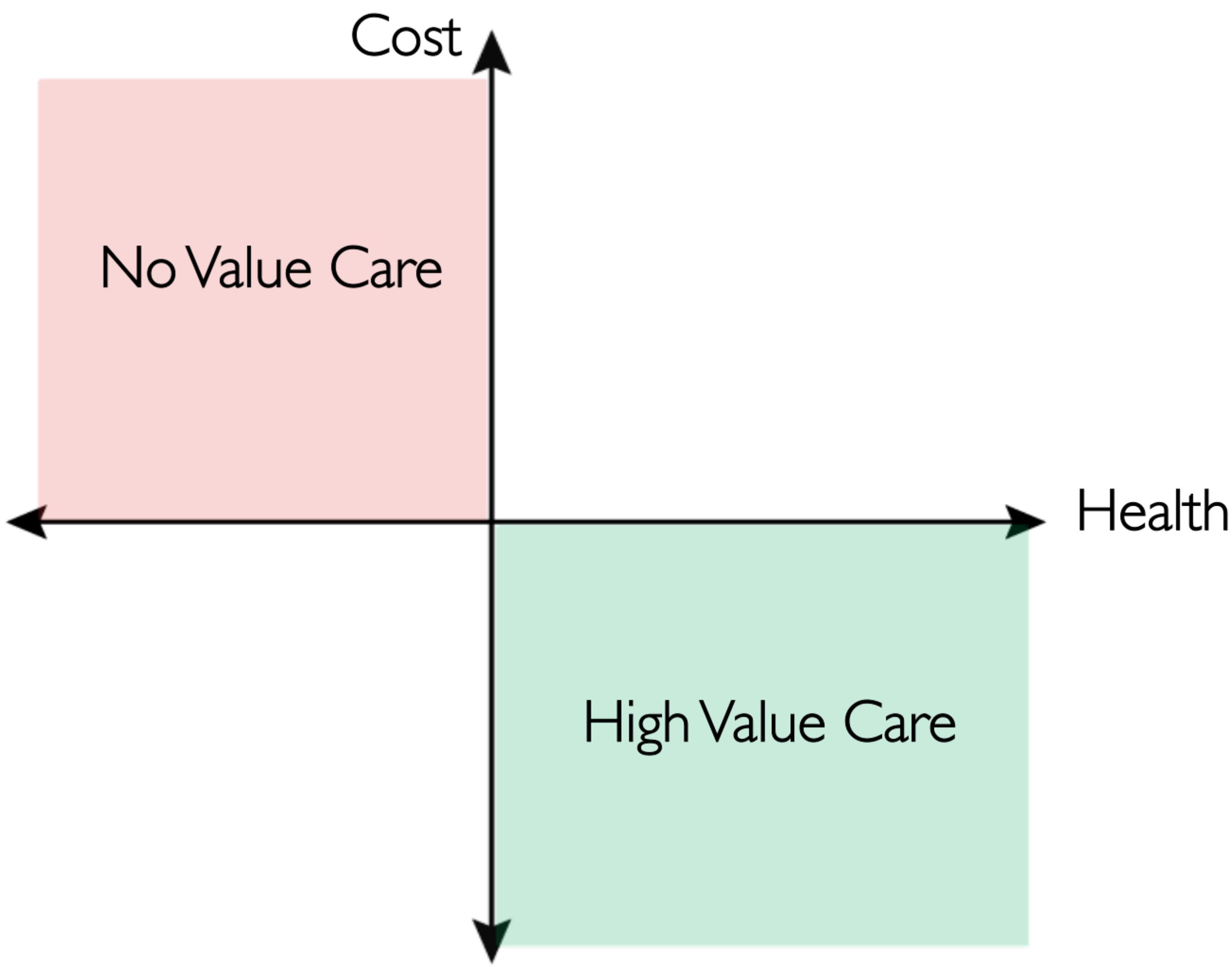

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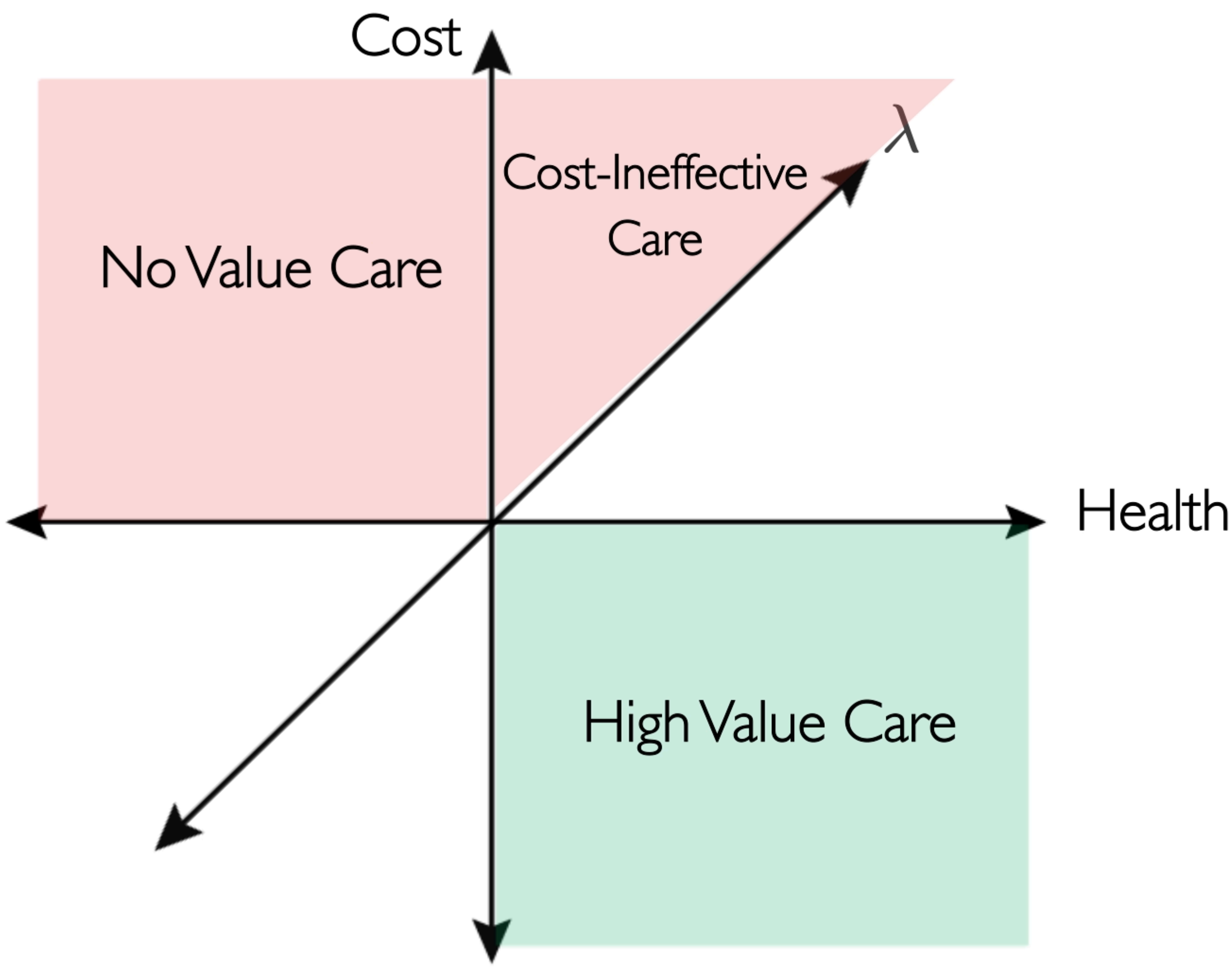

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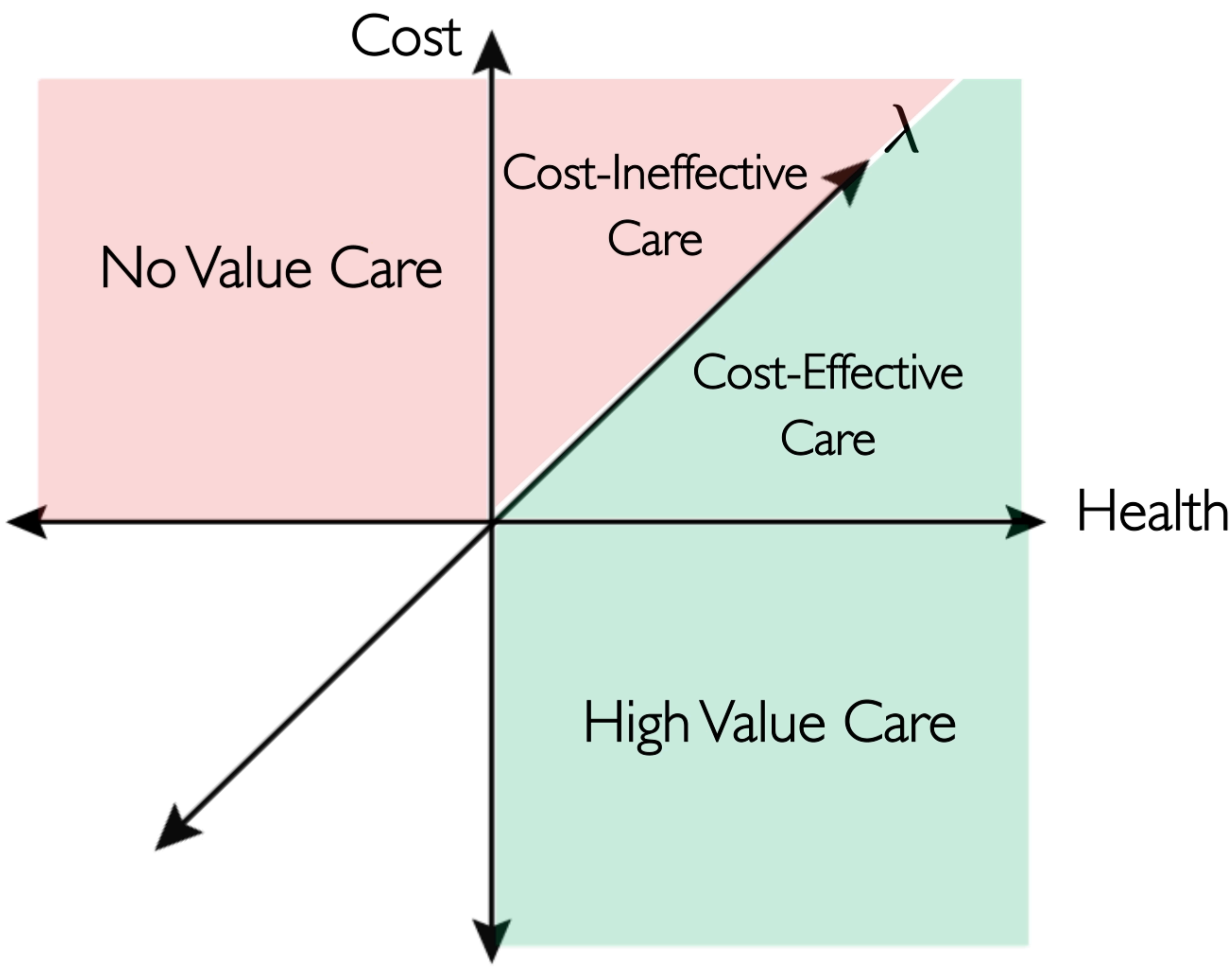

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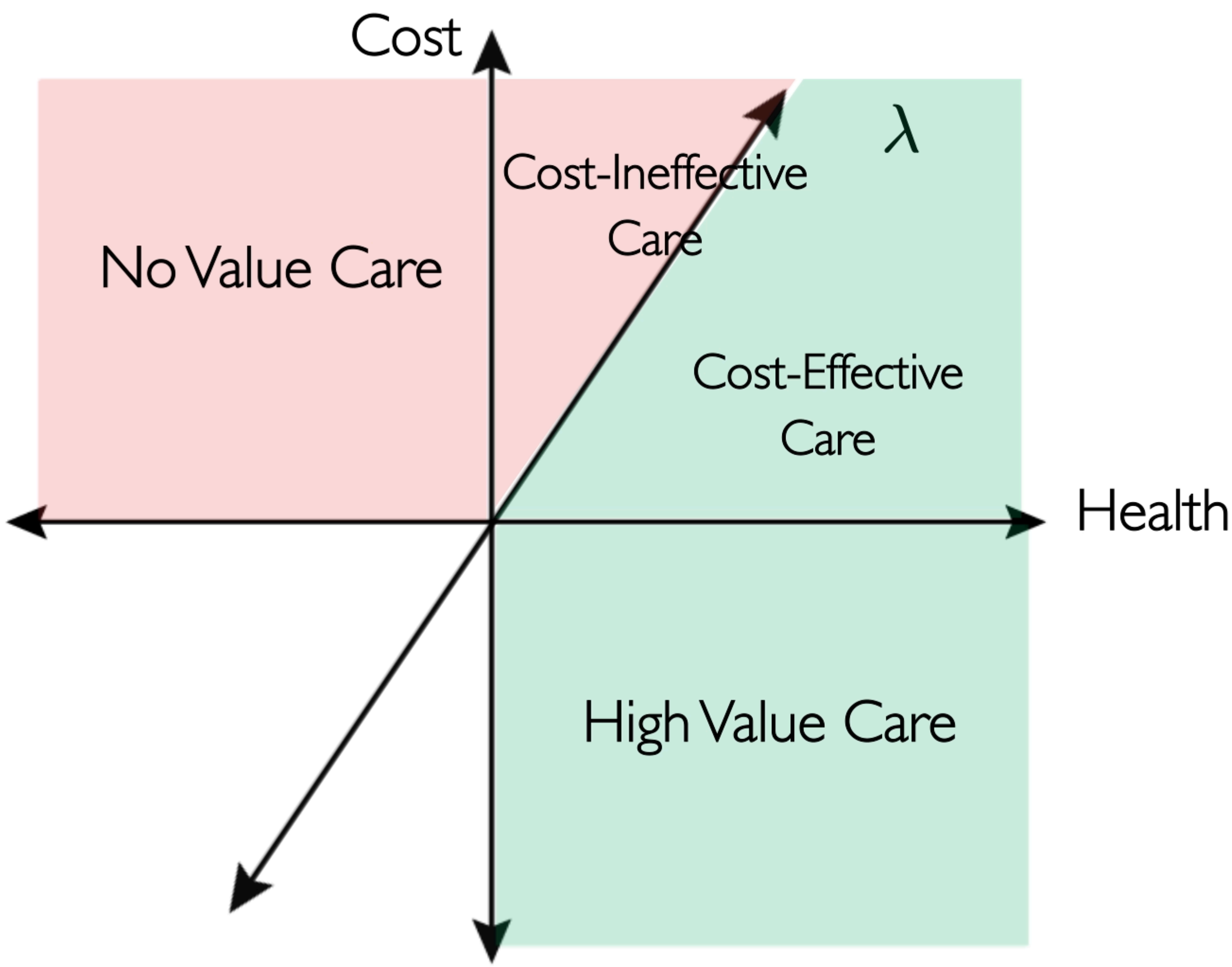


Back to Website

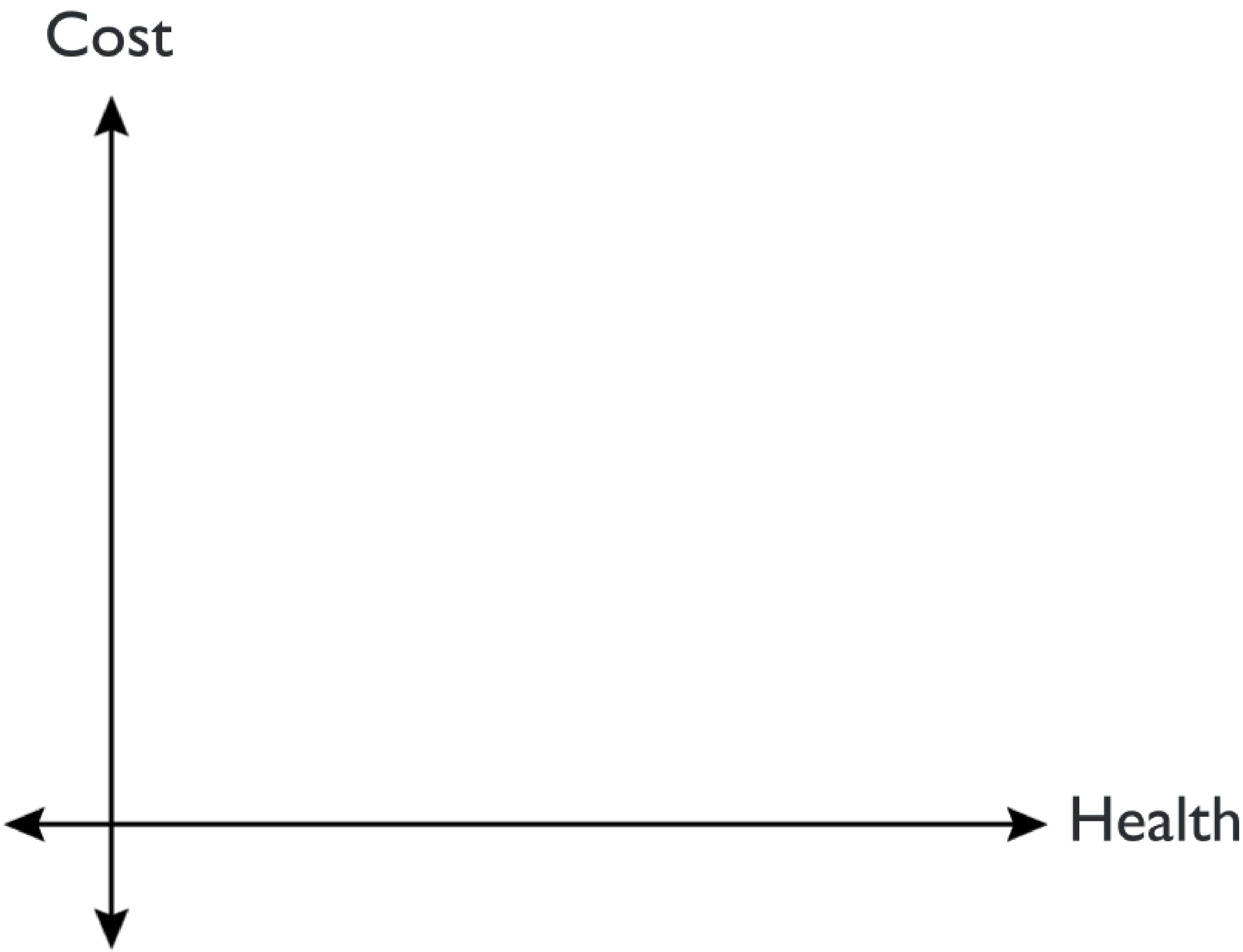
The Efficiency Frontier

Back to Website

Efficiency Frontier

- A key mechanism for decisions over how to efficiently allocate scarce resources.
- Allows us to identify the set of *potentially* cost-effective treatments.
- Strategies *off* the frontier cannot provide the same health benefits at equal or lower cost.

Back to Website



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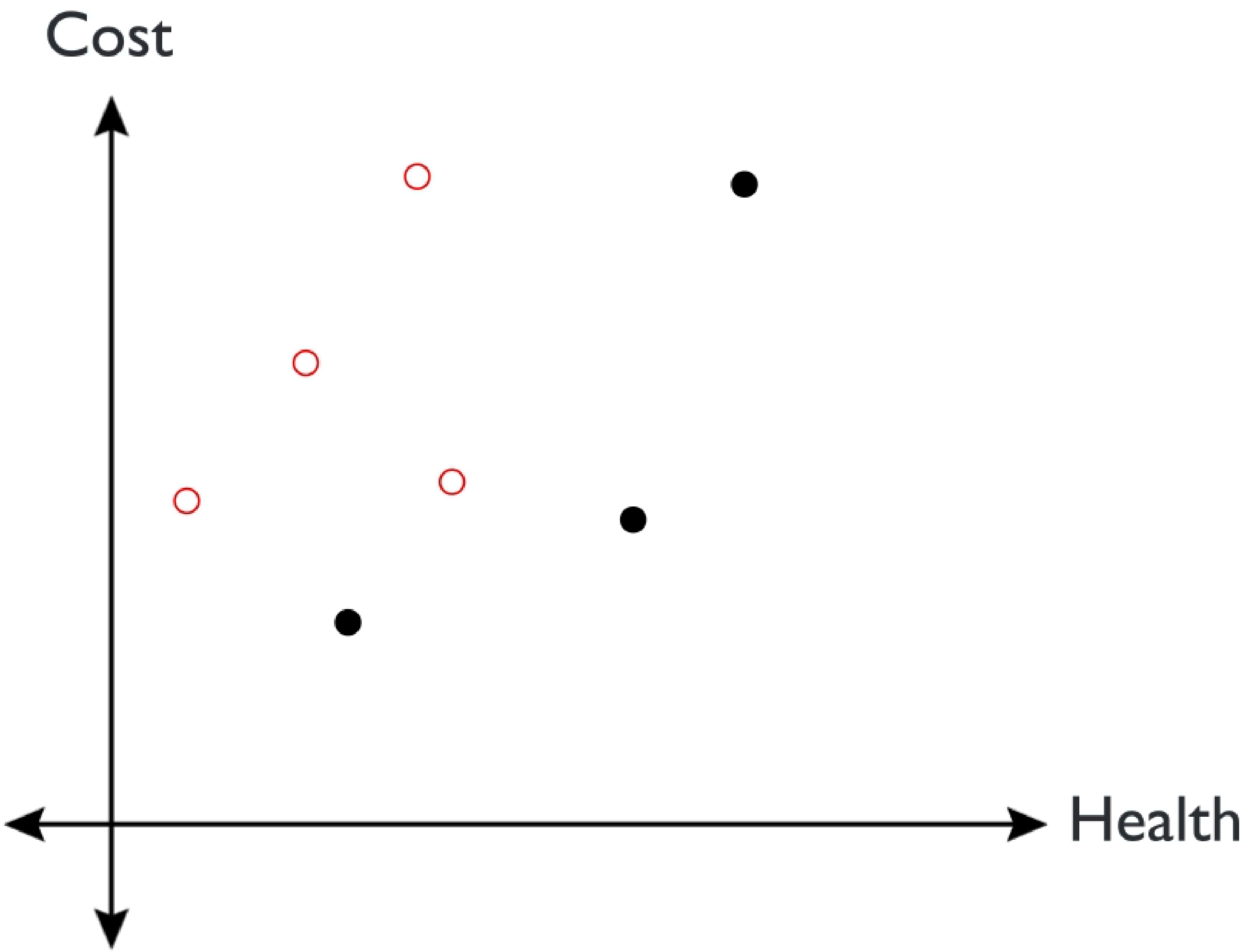

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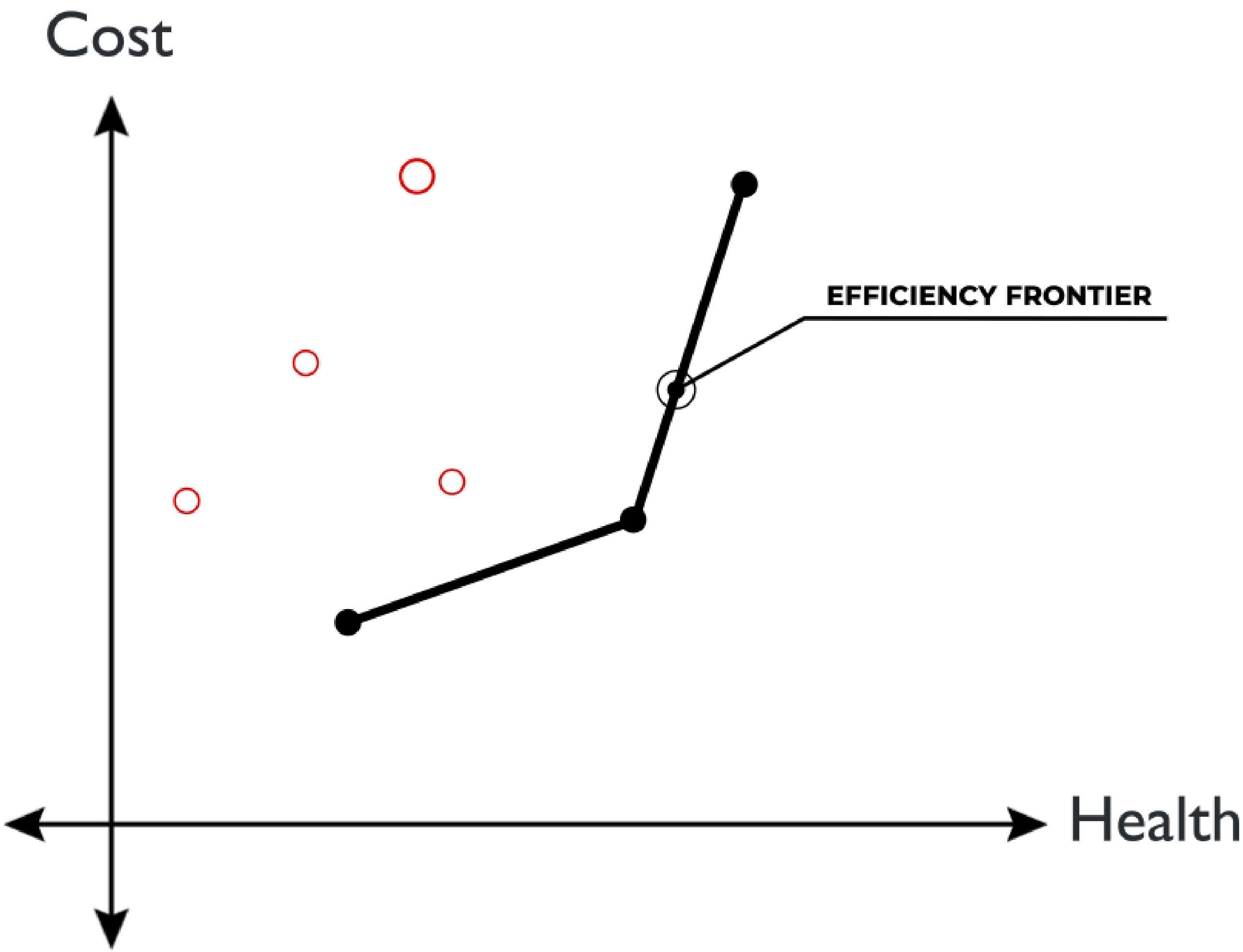

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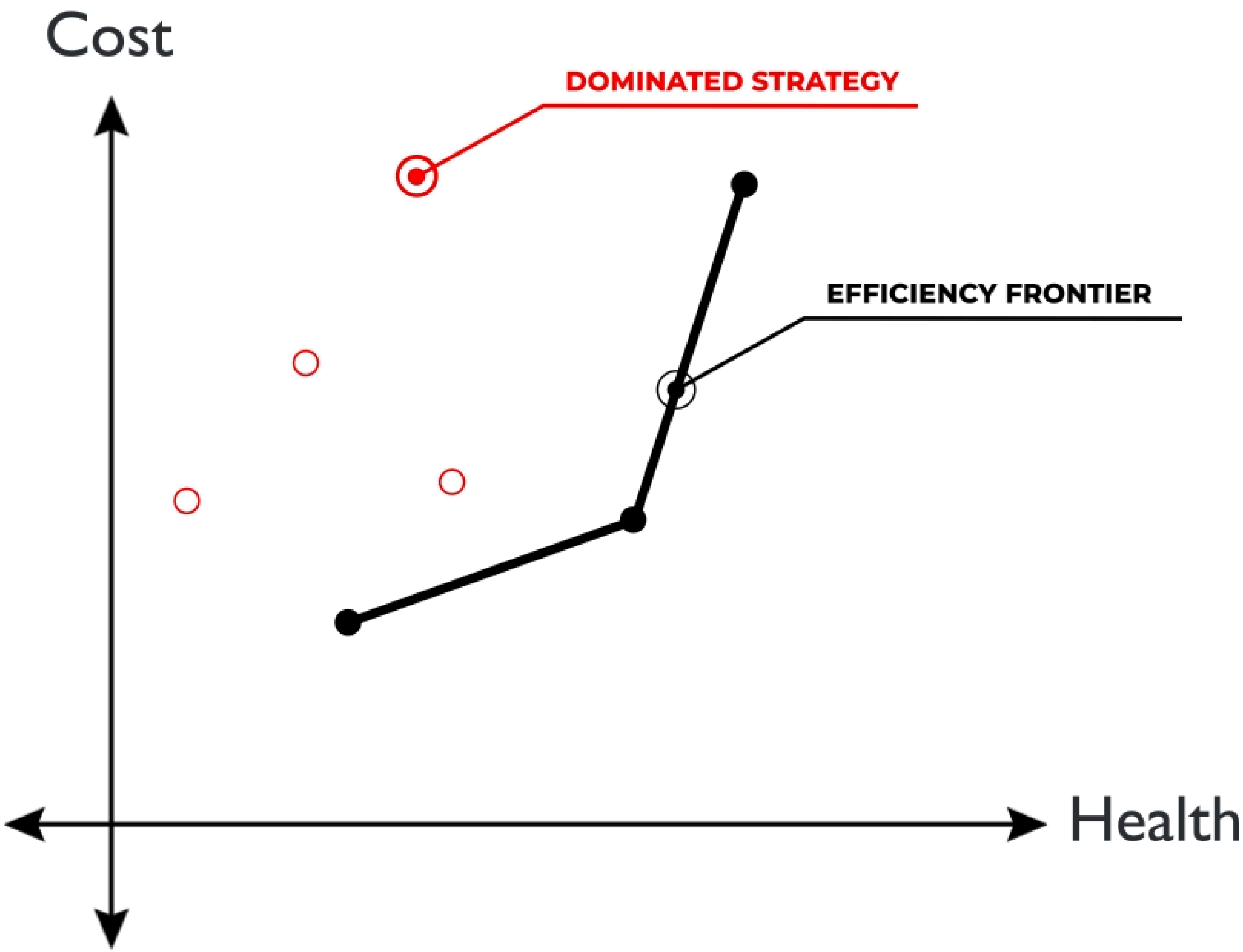

Back to Website

Opportunity Costs

- Under a constrained budget we would have to divert resources from other worthy activities (e.g., education services, income assistance programs, other medical treatments) to cover a treatment that achieves, at best, the same health outcome.
- If we select a strategy off the frontier, there is an ***opportunity cost*** and a potential loss in social welfare.

Introduction to Economic Evaluations

Back to Website

Economic Evaluation

- Relevant when decision alternatives have different costs and health consequences.
- We want to measure the relative value of one strategy in comparison to others.
- This can help us make resource allocation decisions in the face of constraints (e.g., budget).

Features of Economic Evaluation

- Systematic quantification of costs and consequences.
- Comparative analysis of alternative courses of action.

Back to Website

Techniques for Economic Evaluation

Type of study	Valuation of costs	valuation of consequences	Major features
Cost analysis	Monetary units; goal to minimize cost	None	Might be useful when options are equally effective; rarely the case

Techniques for Economic Evaluation

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Techniques for Economic Evaluation

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Cost-utility analysis	Monetary units	Healthy years (quality-adjusted life-years)	Use of summary measure of health; variant of CEA

Back to Website

Techniques for Economic Evaluation

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Cost-utility analysis	Monetary units	Healthy years (quality-adjusted life-years)	Use of summary measure of health; variant of CEA
Cost-benefit analysis	Monetary units	**Monetary units**	Not making comparisons across strategies; only comparisons of costs & benefits for the same strategy (e.g., “we quantify the mortality benefits associated with the reduction in sulfates in the Indian power sector)

Back to Website

Cost-Effectiveness Analysis

Back to Website

Cost-Effectiveness Analysis

- Quantifies how to maximize the quality & quantity of life from among competing alternatives, given restricted resources.
- It's an explicit measure of value for money.
- A POPULATION-LEVEL decision-making tool.

Cost-Effectiveness Analysis IS NOT

- Indiscriminate cost-cutting
- Downsizing
- Intended to override individual-level decision-making.
- The only tool for decision-making

Incremental Cost-Effectiveness Ratio

Most often used, since for most conditions there is already some available treatment.

- C_1: net present value of total lifetime costs of new treatment
- C_0: net present value of total lifetime costs of default treatment
- E_1: effectiveness of new treatment, measured in expected life expectancy, quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs), or some decision-relevant health outcome.
- E_0: effectiveness of default treatment

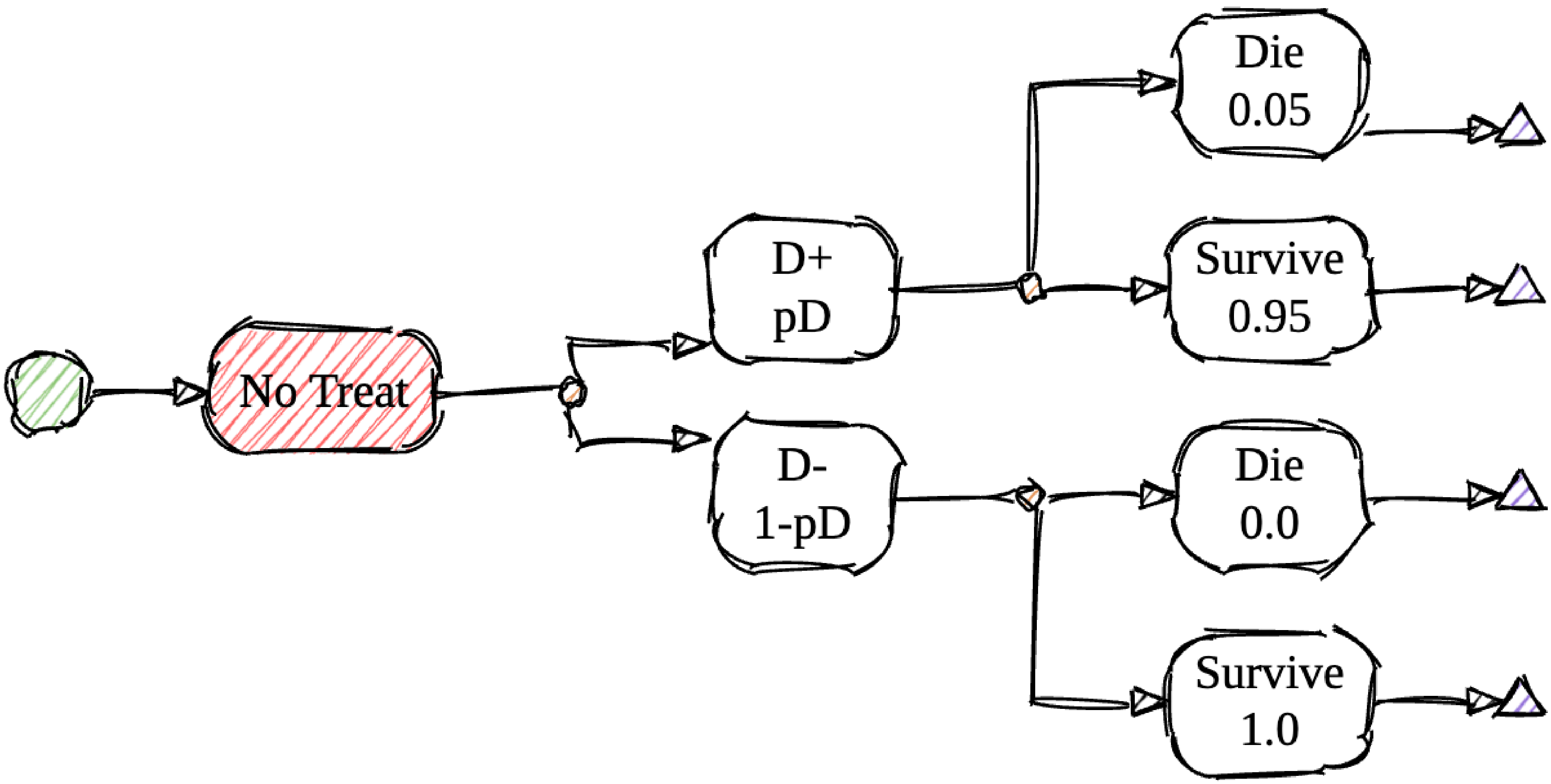
$$\frac{C_1 - C_0 \quad (\Delta C)}{E_1 - E_0 \quad (\Delta E)}$$

Back to Website

Conducting a CEA

Back to Website

Neurologic Disease Decision Tree



Back to Website

Outcomes

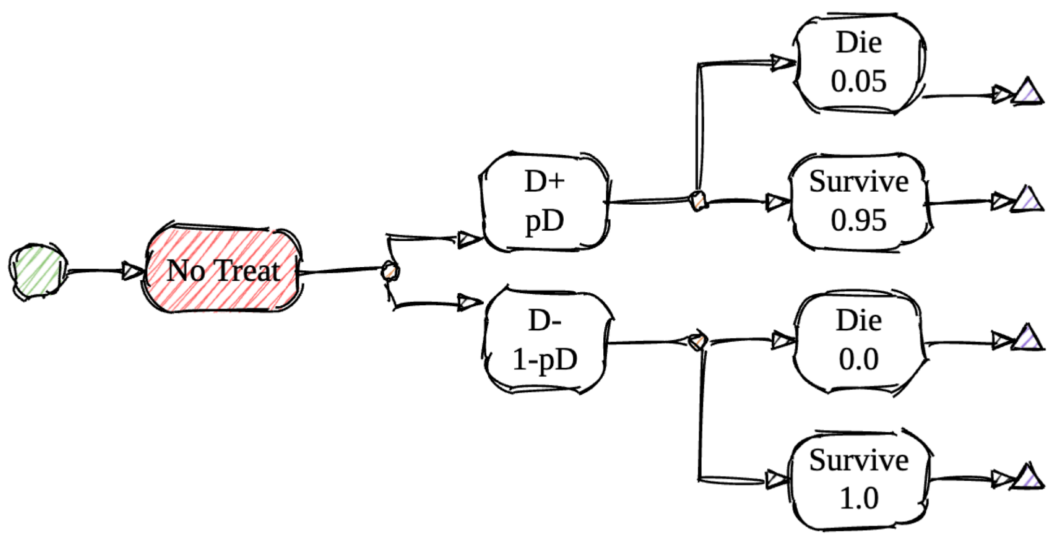
- C_{treat} = expected cost of treat everyone strategy.
- $C_{notreat}$ = expected cost of treat *no one* strategy.
- C_{biopsy} = expected cost of biopsy strategy.

Outcomes

- C_{treat} = expected cost of treat everyone strategy.
- $C_{notreat}$ = expected cost of treat *no one* strategy.
- C_{biopsy} = expected cost of biopsy strategy.
- E_{treat} = expected life expectancy of treat everyone strategy.
- $E_{notreat}$ = expected expectancy of treat *no one* strategy.
- E_{biopsy} = expected expectancy of biopsy strategy.

Treat All vs. Treat None

Strategy: Treat No One

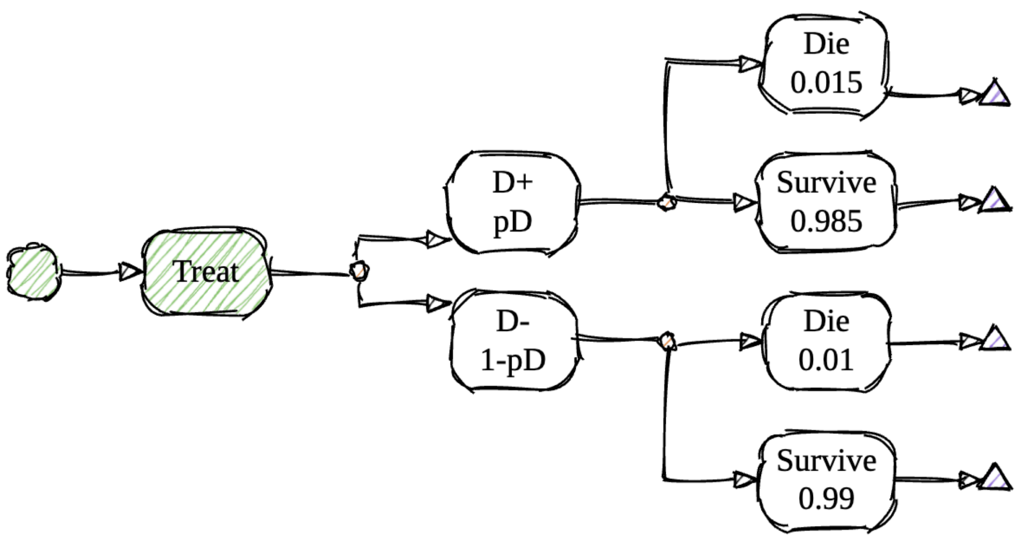


Life Expectancy	Cost
0y	$0
15y	$10,000
0y	$0
25y	$0

Back to Website

Treat All vs. Treat None

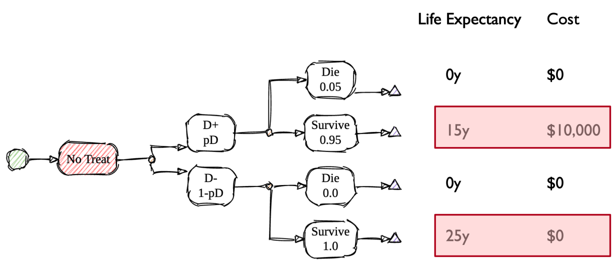
Strategy: Treat All

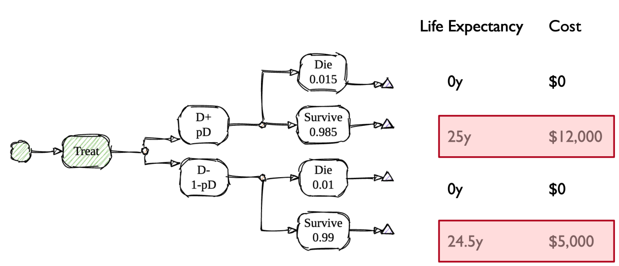


Life Expectancy	Cost
0y	$0
25y	$12,000
0y	$0
24.5y	$5,000

Back to Website

Key Takeaways (For Now)





- Treatment yields *higher* life expectancy for those with disease, but comes at a cost.
- Treatment yields *lower* life expectancy for those without the disease, *and also* comes at a cost.
- Biopsy can help balance these two outcomes by better targeting treatment, but also comes with risks and costs.
- Incremental CEA provides a transparent framework for quantifying and weighing these considerations.

Back to Website

Average Cost-Effectiveness Ratio

Special case where C_0 and E_0 are assumed to be zero.

- C_1: net present value of total lifetime costs of new treatment
- C_0: Assumed zero
- E_1: effectiveness of new treatment, measured in expected life expectancy, quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs), or some decision-relevant health outcome.
- E_0: Assumed zero

$$
\begin{aligned}
ICER &= \frac{C_1 - 0}{E_1 - 0} \\
&= \frac{C_1}{E_1}
\end{aligned}
$$

Non-Competing vs. Competing CEAs

Back to Website

Use of CEA in two situations

1. **Shopping Spree**: Decision problem has non-competing programs/interventions.

- Each program is compared to a null alternative; therefore, you're calculating an "average" cost-effectiveness ratio.
- What can fit into the budget; breast cancer screening vs. childhood vaccination program

Use of CEA in two situations

2. **Competing Choice**: Decision problem has competing programs/interventions for the same purpose; these choices are mutually exclusive.

- Two or more active alternatives in addition to the null option.
- You need to calculate an “incremental cost- effectiveness ratio”, which gives us the added cost per unit of added benefit of an option, relative to the next less expensive choice.

Beyond decision trees: A brief primer on Markov models

Back to Website

A Simple Disease Process

- Suppose we want to model the cost-effectiveness of alternative strategies to prevent a disease from occurring.
- We start with a healthy population of 25 year olds and there are three health states people can experience:

1. Remain **Healthy**
2. Become **Sick**
3. **Death**

A Simple Disease Process

- Remaining healthy carries no utility decrement (utility weight = 1.0 per cycle in healthy state)
- Becoming sick carries a 0.25 utility decrement for the remainder of the person's life (utility weight = 0.75)
- Death carries a utility value of 0.0.

A Simple Disease Process

- There is no cost associated with remaining healthy.
- Becoming sick incurs $1,000 / year in costs.
- Becoming sick increases the risk of death by 300%.

A Simple Disease Process

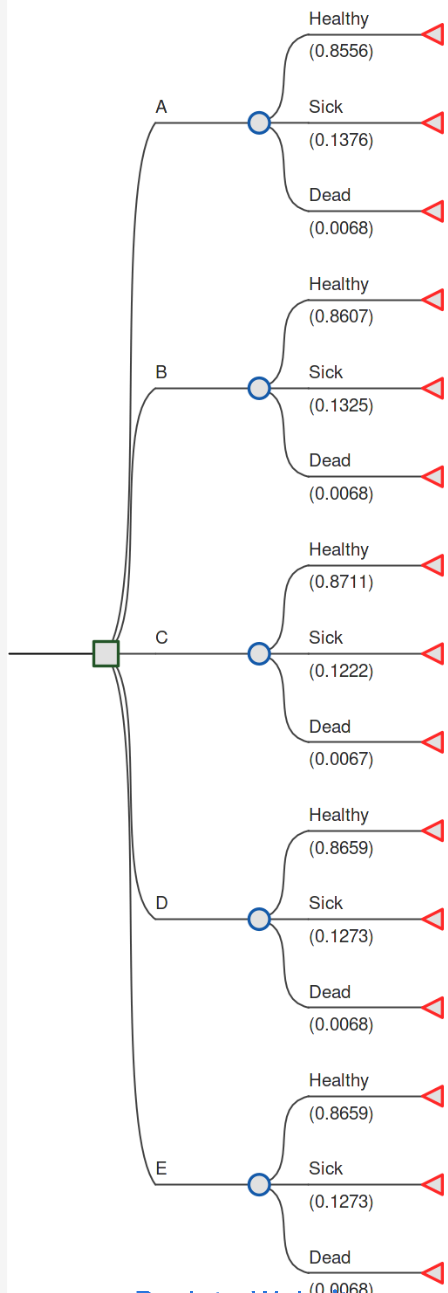
A country's health institute is considering five preventive care strategies that reduce the risk of becoming sick:

Strategy	Description	Cost
A	Standard of Care	$25/year
B	Additional 4% reduction in risk of becoming sick	$1,000/year
C	12% reduction in risk	$3,100/year
D	8% reduction in risk	$1,550/year
E	8% reduction in risk	$5,000/year

Back to Website

Model Option 1: Decision Tree

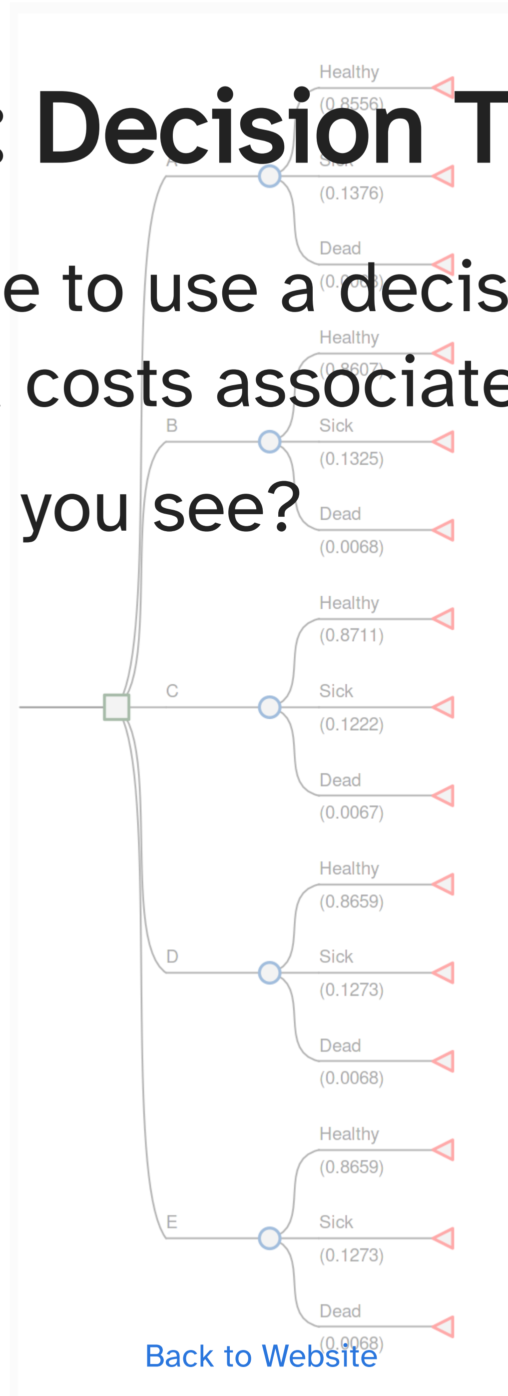
- One option would be to use a decision tree to model the expected utility and costs associated with each strategy.



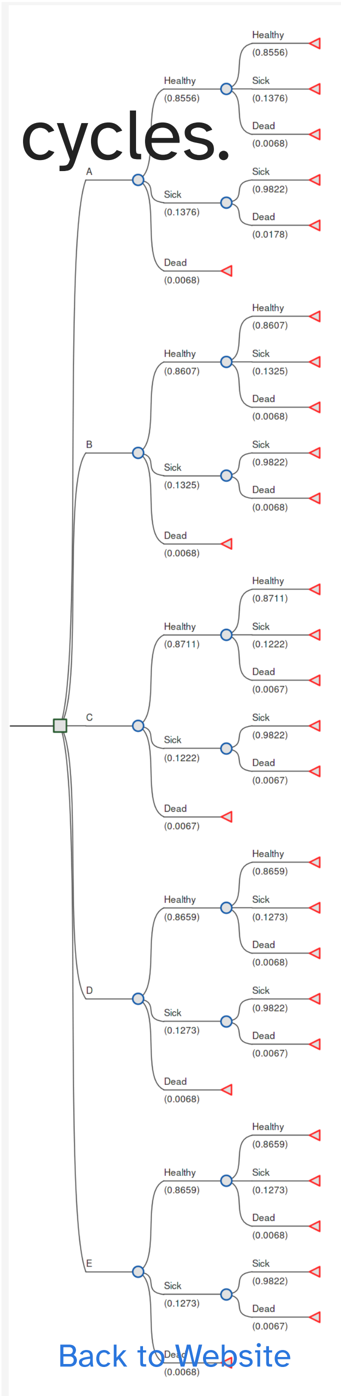
Back to Website

Model Option 1: Decision Tree

- One option would be to use a decision tree to model the expected utility and costs associated with each strategy.
- What limitations do you see?

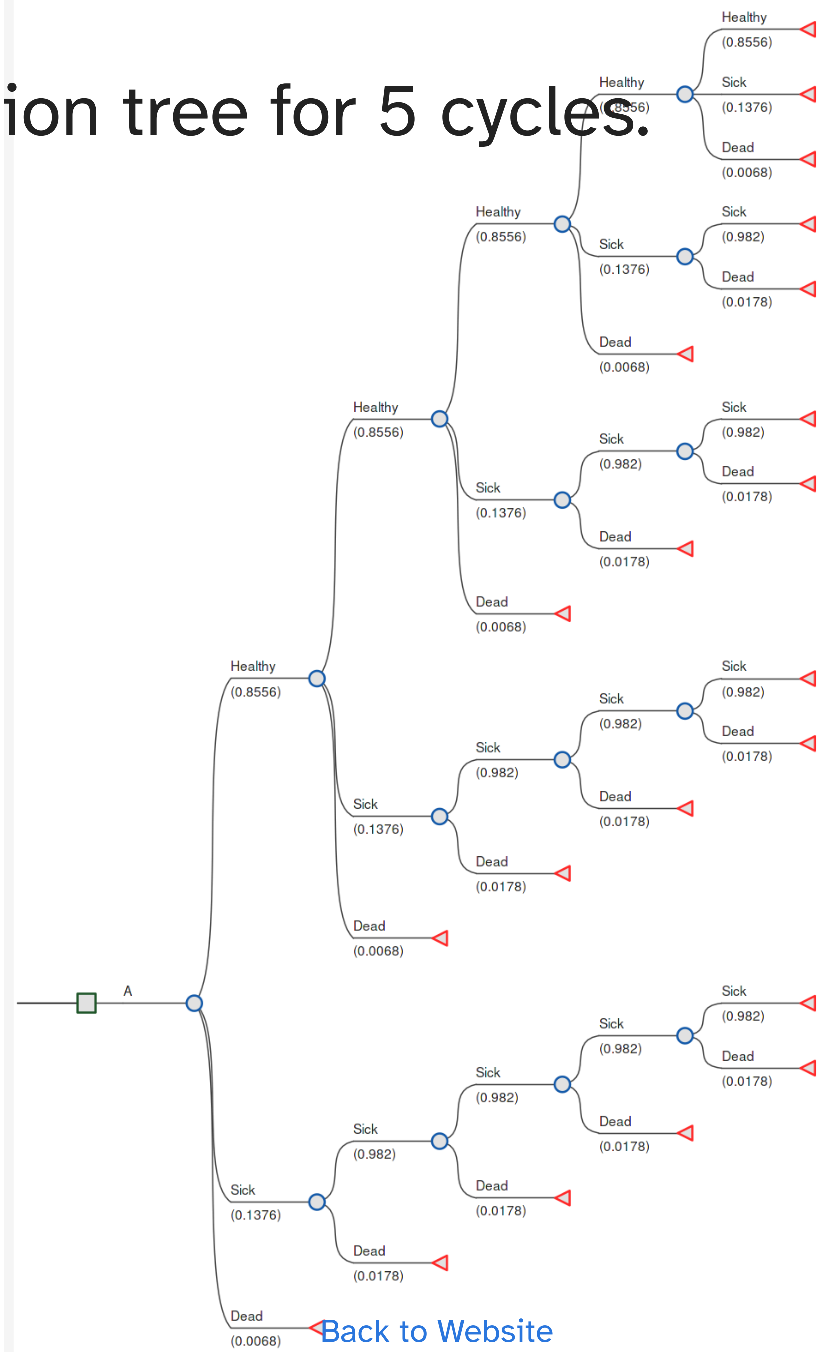


Decision tree for two full cycles.



Back to Website

Strategy A decision tree for 5 cycles.



[Back to Website]

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	
Easy to describe & understand	

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	
Easy to describe & understand	
Works well with limited time horizon	

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	Difficult to include clinical detail
Easy to describe & understand	
Works well with limited time horizon	

Back to Website

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	Difficult to include clinical detail
Easy to describe & understand	Elapse of time is not readily evident.
Works well with limited time horizon	

Decision Trees

Pros	Cons
Simple, rapid & can provide insights	Difficult to include clinical detail
Easy to describe & understand	Elapse of time is not readily evident.
Works well with limited time horizon	Difficult to model longer (>1 cycle) time horizons

Back to Website

Decision Trees

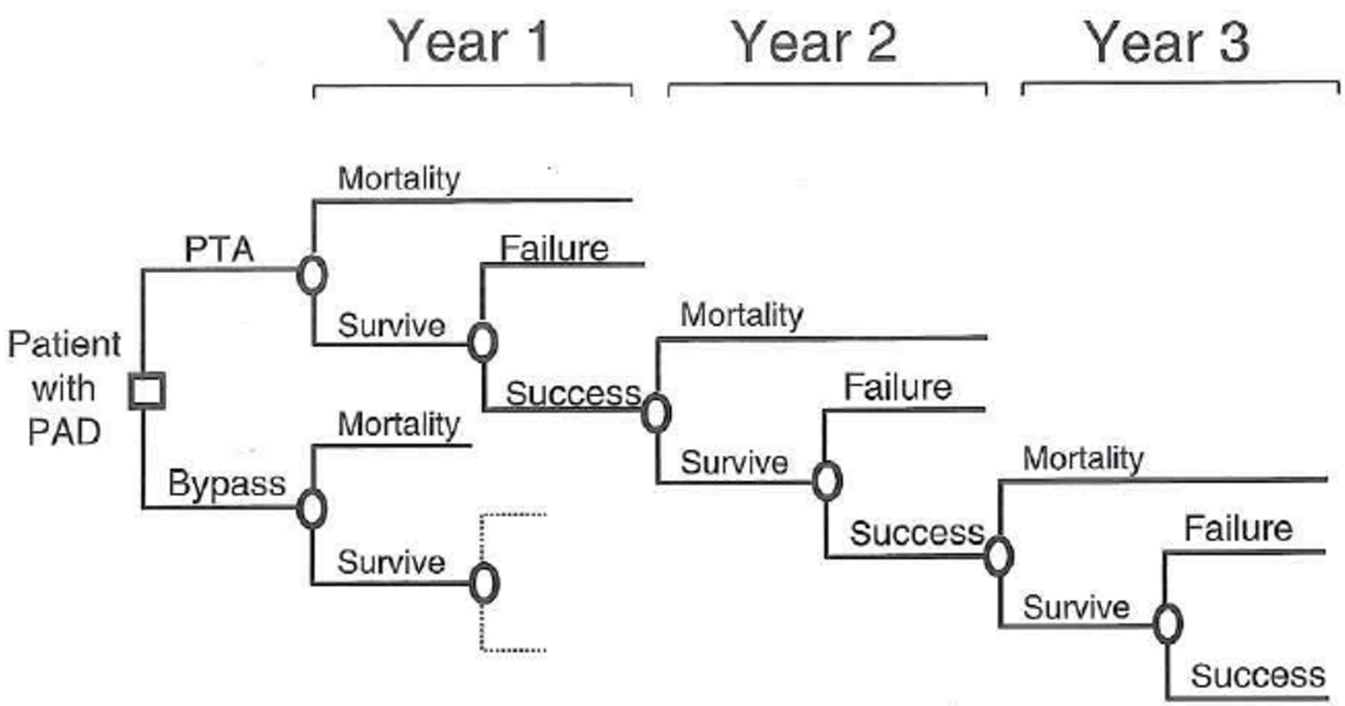


Figure 10.2 Decision tree for peripheral arterial disease (PAD) with a 3-year time horizon. PTA, percutaneous transluminal angioplasty.

Back to Website

Next Steps

- Ideally we want a modeling approach that can incorporate flexibility and handle the complexities that make decision trees difficult/unwieldy.

Markov Models

Back to Website

Markov Models

Common approach in decision analyses that adds additional flexibility.

Pros	Cons
Can model repeated events	

Markov Models

Common approach in decision analyses that adds additional flexibility.

Pros	Cons
Can model repeated events	
Can model more complex + longitudinal clinical events	

Markov Models

Common approach in decision analyses that adds additional flexibility.

Pros	Cons
Can model repeated events	
Can model more complex + longitudinal clinical events	
Not computationally intensive; efficient to model and debug	

Back to Website

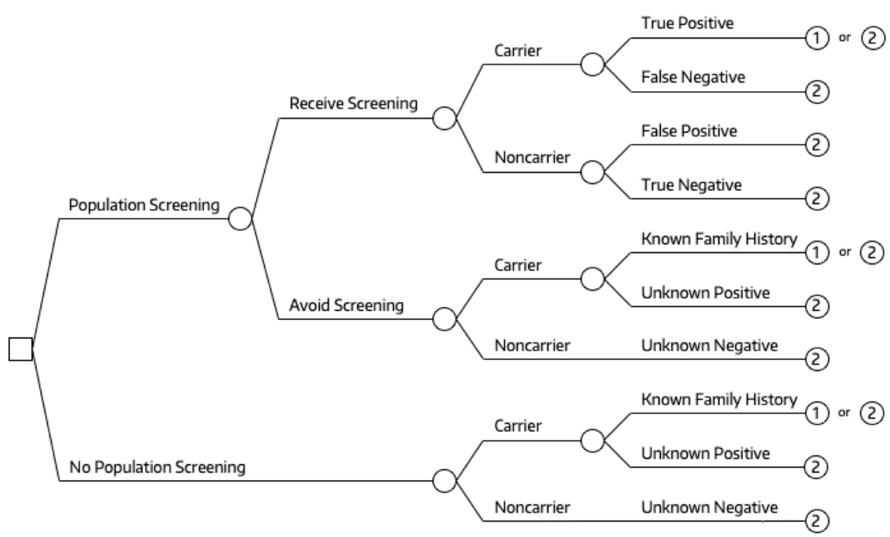
Markov Models

- The advantages of Markov models derive from their structure around mutually exclusive disease states.
- These disease states represent the possible states or consequences of strategies or options under consideration.
- Because there are a fixed number of disease states the population can be in, there is no need to model complex pathways, as we saw in the decision tree “explosion” a few slides back.

Back to Website

Markov Trees

It is also common to pair a Markov model with a decision tree.[1]



Back to Website

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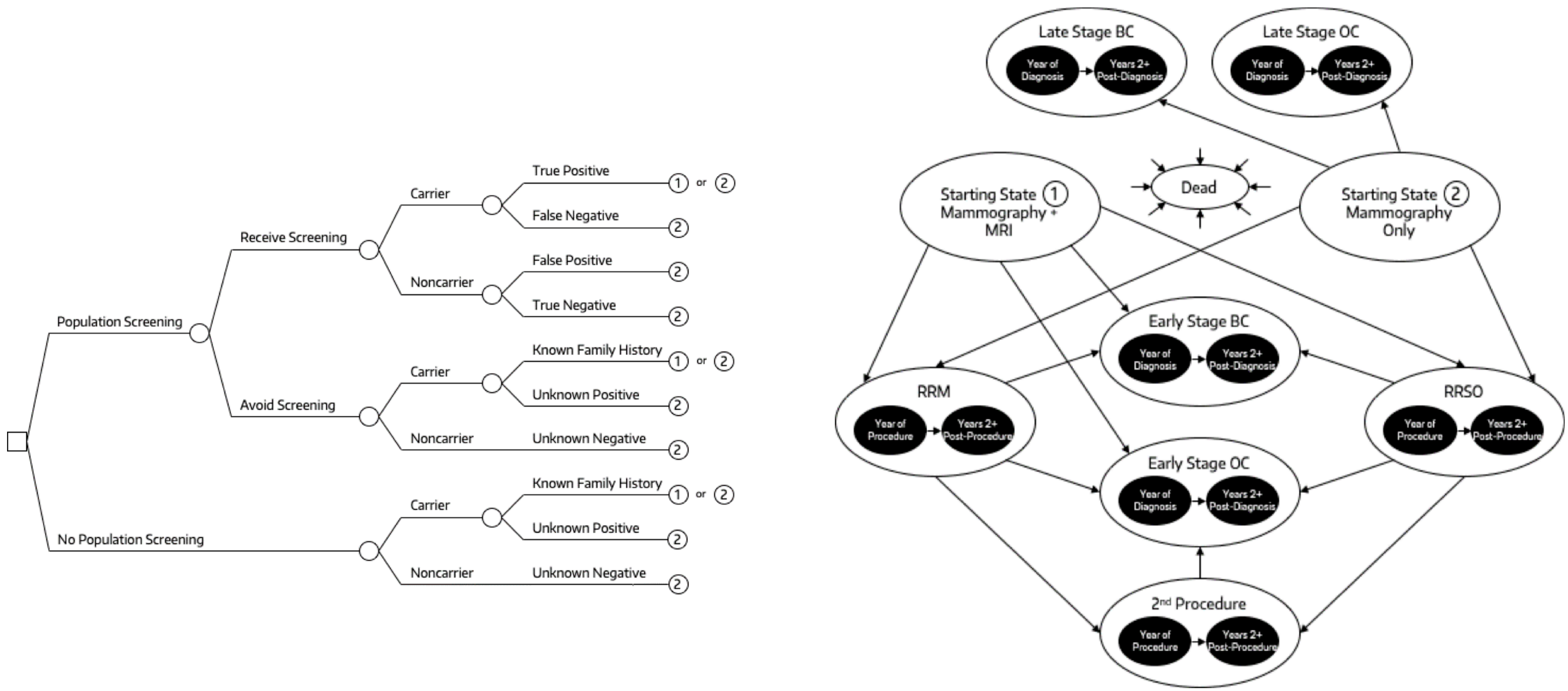
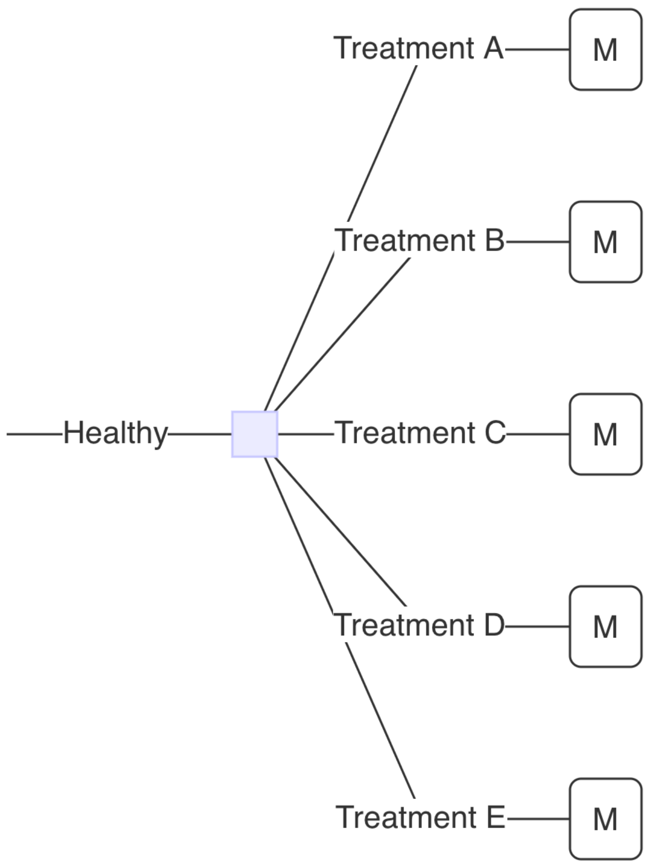


Back to Website

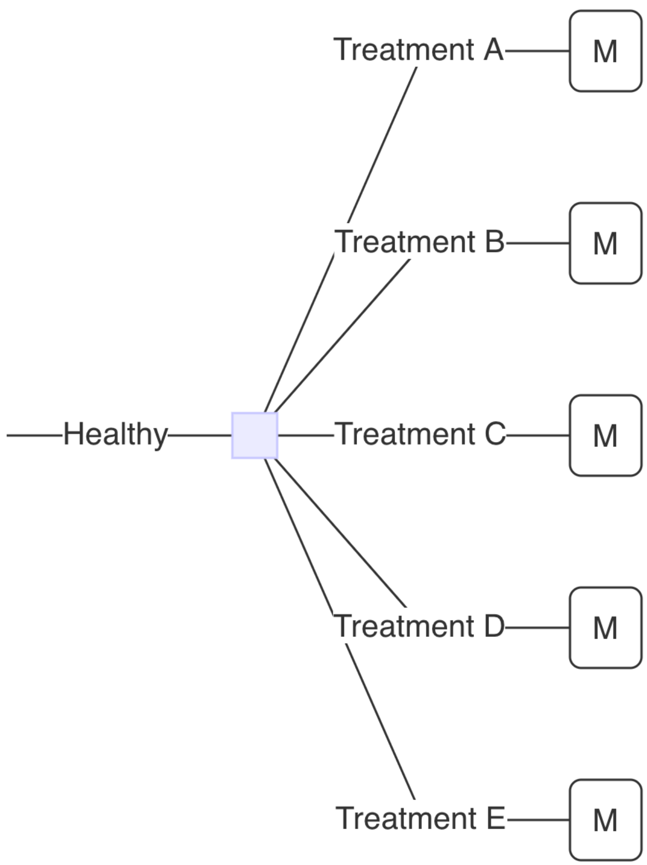
Markov Tree

A simple decision tree is implicit in nearly every decision analysis.

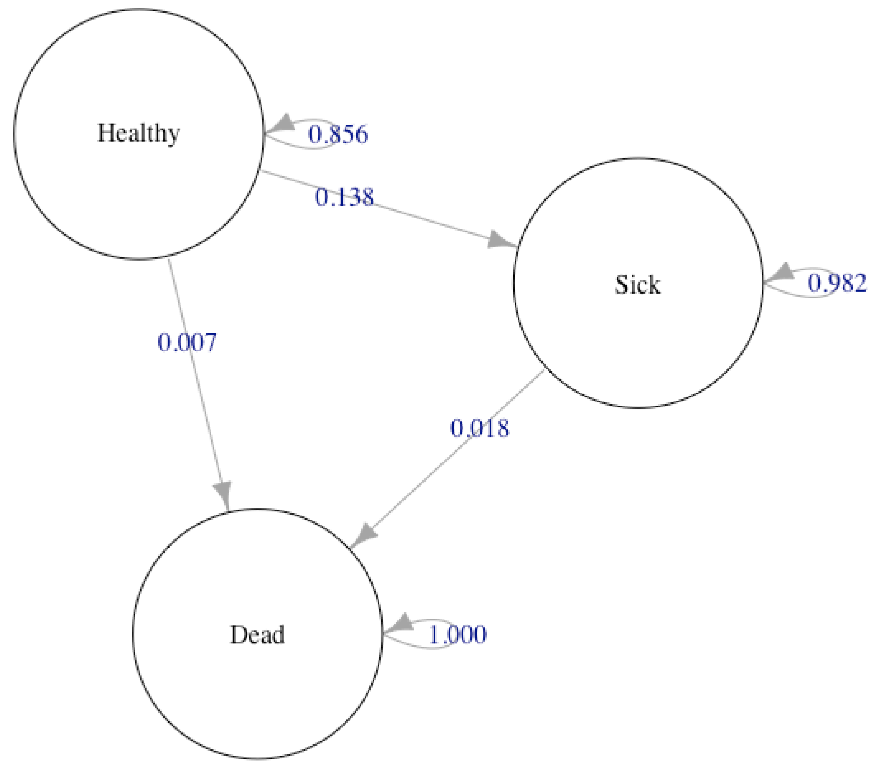


Back to Website

Markov Tree: Example

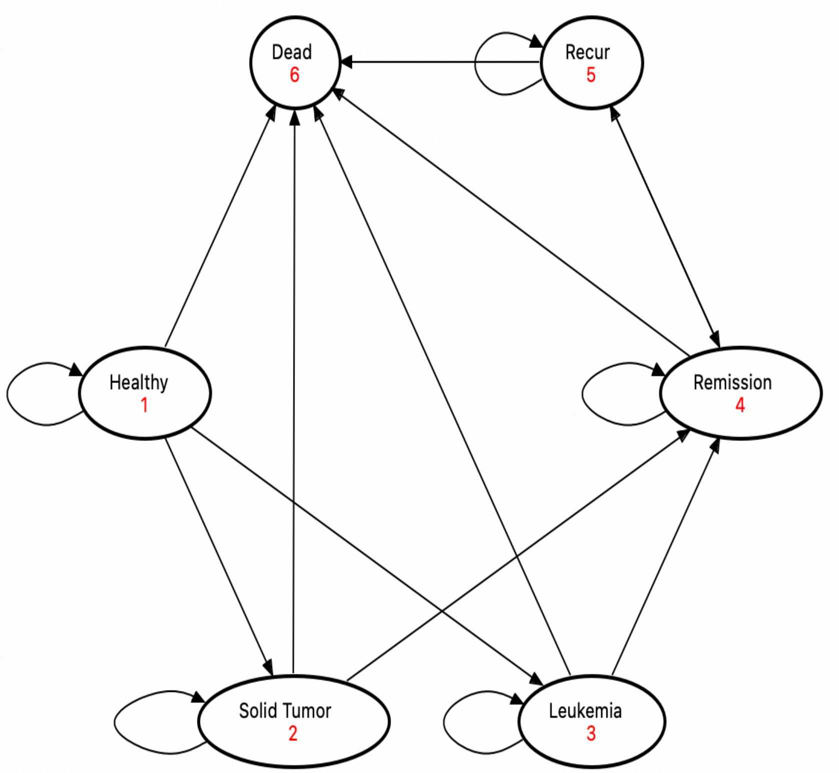


Treatment A:

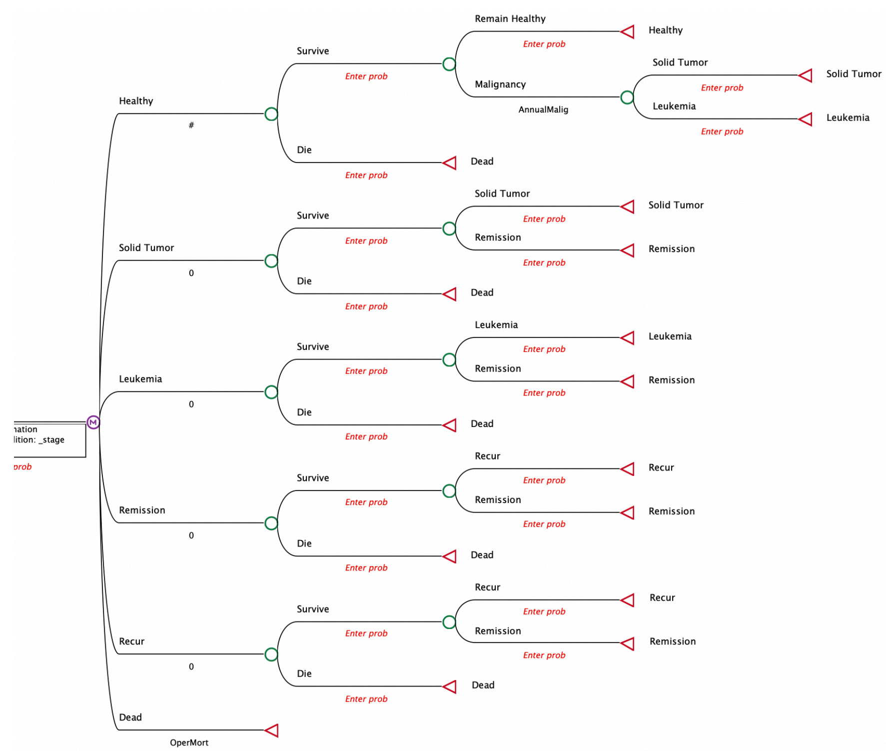


Back to Website

Markov Tree: Example



Treatment A:



Back to Website

When choosing a model structure...

> “Things should be made as simple as possible, but not simpler” - paraphrased by a lecture given by Albert Einstein at Oxford in 1933

In essence, science/models should be as simple as possible but without losing essential truth or necessary complexity.

Back to Website

Constructing a Markov Model

Back to Website

Key characteristics

- Allows for health state transitions over time
- Individuals can only exist in one state at a time (mutually exclusive health states)
- At the beginning or end of each cycle, patients transition across health states via transition probabilities & individuals stay in health state for entire cycle length
- Probability of transitioning depends on the current state ("no memory"), not on how you got there or how long you've been there; (though tunnel states can account for this potential limitation)
- Transition probabilities typically remain constant over time (apart from embedded lifetables); though you can always add complexity & allow for more dynamic behavior (e.g., risks that change with age or treatment effects decaying)
- Results report "average" of cohort

Key characteristics

> “CYCLE” = Minimum amount of time that any individual will spend in a state before possible transition to another state

Back to Website

Steps

1. Define the decision problem
2. Conceptualize the model
3. Parameterize the model
4. Calculate or define the transition probability matrix.
5. Run the model

1. Define the Decision Problem

Back to Website

Step 1: Define the Decision Problem

We defined the decision problem earlier in this lecture, so we'll repeat the basic objectives briefly here.

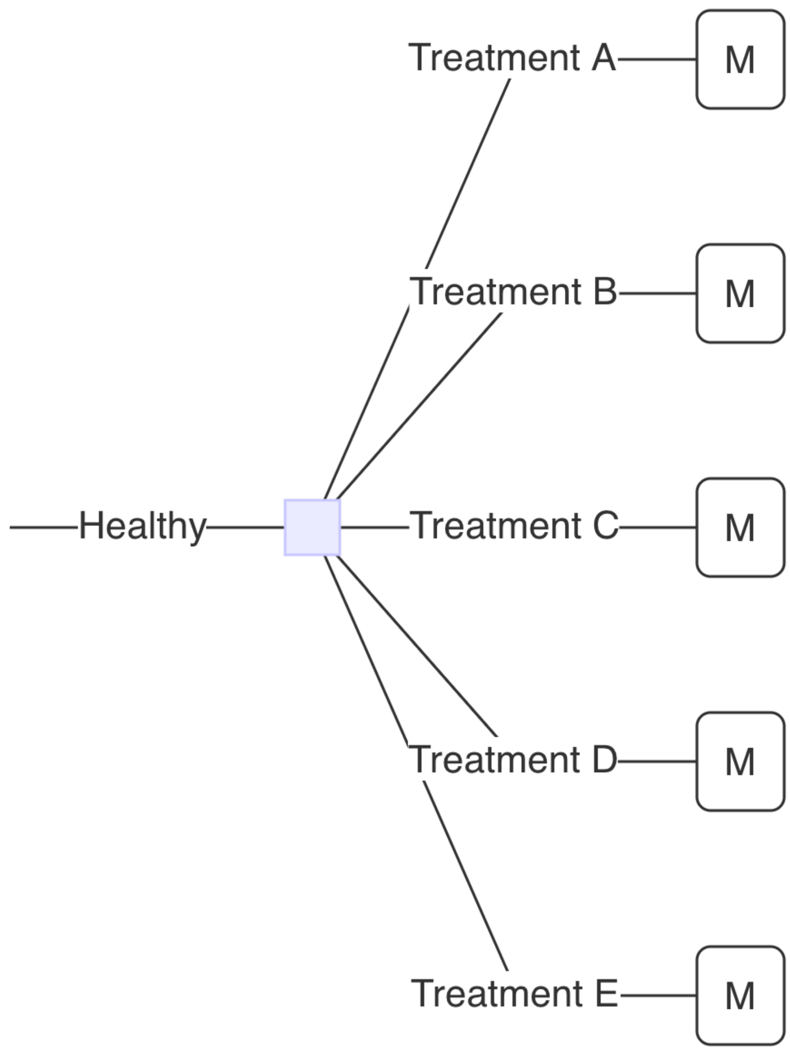
Step 1: Define the Decision Problem

Goal: model the cost-effectiveness of alternative strategies to prevent a disease from occurring.

Strategy	Description	Cost
A	Standard of Care	$25/year
B	Additional 4% reduction in risk of becoming sick	$1,000/year
C	12% reduction in risk	$3,100/year
D	8% reduction in risk	$1,550/year
E	8% reduction in risk	$5,000/year

Back to Website

Step 1: Define the Decision Problem



Back to Website

2. Conceptualize the Markov Model

Back to Website

2. Conceptualize the Markov Model

Two major steps:

2a. Determine health states

2b. Determine transitions

Step 2: Conceptualize the Model

2a. Determine health states

- There are three health states people can experience:
  1. Remain **Healthy**
  2. Become **Sick**
  3. **Death**

Step 2: Conceptualize the Model

2a. Determine health states

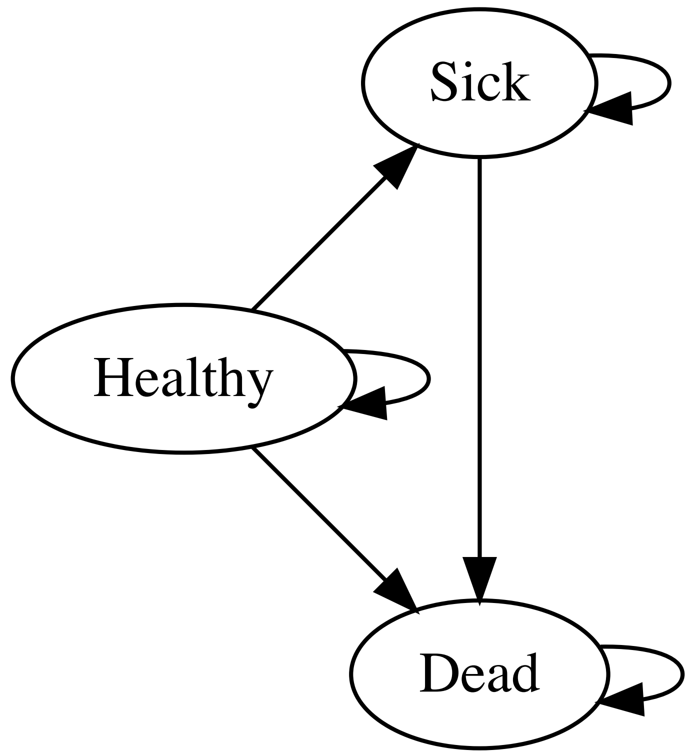
There are three health states people can experience: 1. Remain **Healthy** 2. Become **Sick** 3. **Death**

2b. Determine transitions

Individuals who become sick cannot transition back to healthy.

Back to Website

Step 2: Conceptualize the Model



Back to Website

3. Parameterize the Model

Back to Website

3. Parameterize the Model

Basic steps

3a. Determine basic model parameters

3b. Curate and define model inputs

3. Parameterize the Model

Basic steps

3a. Determine basic model parameters

- Define the population (e.g., 25 year old females)
- Define the Markov cycle length (e.g., 1-year cycle)
- Define the time horizon (e.g., followed until age 100 or death)

3a. Define the Markov Cycle Length

- Fundamentally, we're modeling a continuous time process (e.g., progression of disease).
- A discrete time Markov model "breaks up" time into "chunks" (i.e., "cycles").
- A consequence is that the model will show us what fraction start out a cycle in a given state, and what fraction end up in each state at the end of the cycle.

3a. Define the Markov cycle length

- Suppose we used a one-year cycle for the healthy-sick-dead model.
- Think about the underlying (continuous time) disease process.
  - Recall that becoming sick substantially increases the likelihood of death.

Back to Website

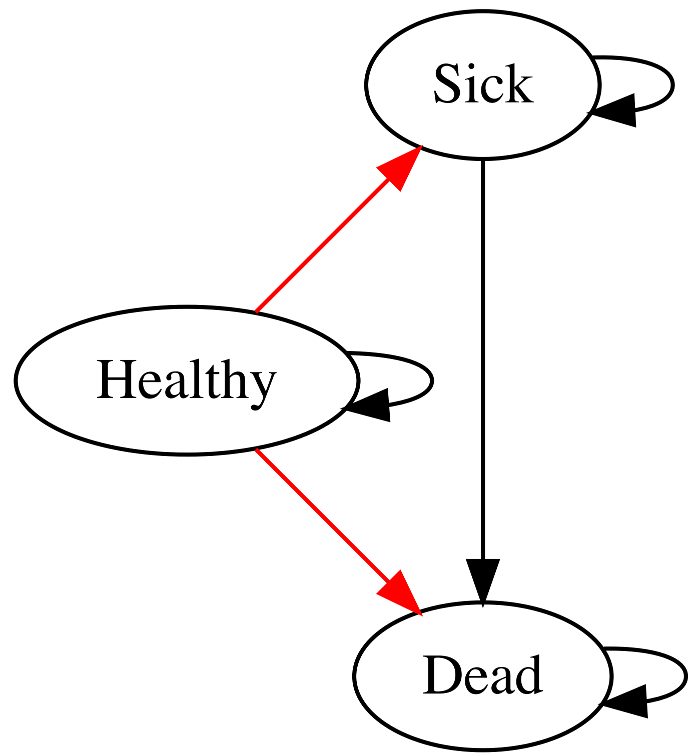
3a. Define the Markov Cycle Length

Back to Website

3a. Define the Markov Cycle Length

The challenge of selecting an appropriate cycle length boils down to how we deal with **competing risks.**

- Competing risks: individuals can transition from their current health state to two or more other health states.

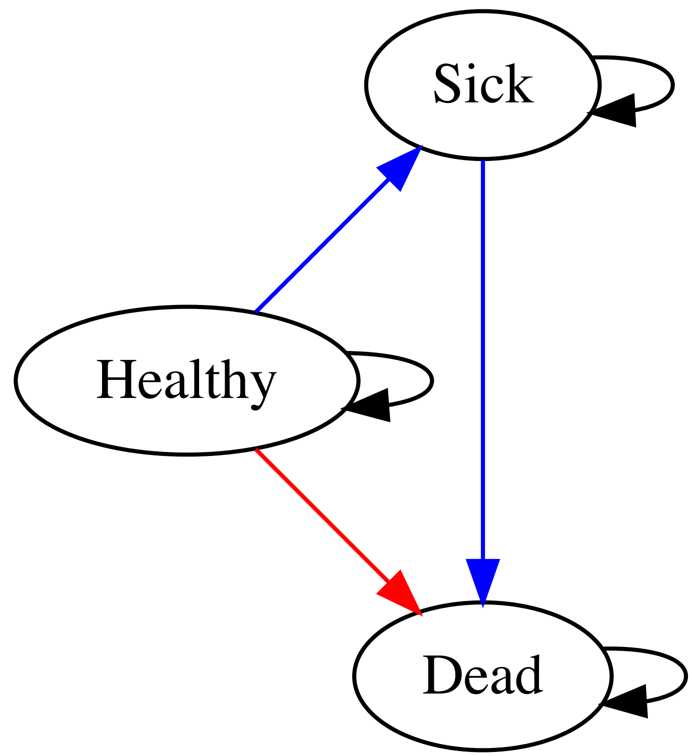


Back to Website

3a. Define the Markov Cycle Length

The challenge of selecting an appropriate cycle length boils down to how we deal with **competing risks**.

- If we're not careful, we could effectively rule out the possibility of Healthy – Sick – Dead within a cycle.
- The model would *look like* a basic Healthy – Dead transition, but they took a detour through Sick along the way!



3a. Define the Markov Cycle Length

Pros	Cons
Can model repeated events	Competing risks are a challenge
Can model more complex + longitudinal clinical events	
Not computationally intensive; efficient to model and debug	

Back to Website

3a. Define the Markov Cycle Length

- It may be tempting to simply shorten the cycle length (e.g., use 1 day cycle vs. 1 year cycle).

- For a 75 year horizon, how many cycles would that be?
  - 27,375!!!
- Any possible issues with this?

3a. Define the Markov Cycle Length

- Shortening the cycle creates a computational challenge.

- Base case requires 27,375 daily cycles.
- Now suppose we want to run 2,000 probabilistic sensitivity analysis model runs.
  - We now have 54,750,000 cycle runs to contend with!

3a. Define the Markov Cycle Length

Pros	Cons
Can model repeated events	Can only transition once in a given cycle
Can model more complex + longitudinal clinical events	Shortening the cycle can create computational challenges.
Not computationally intensive; efficient to model and debug	

Back to Website

3a. Define the Markov Cycle Length

More challenges ...

3a. Define the Markov Cycle Length

More challenges …

- Markov models are "memoryless" – they don't remember what happened before the current cycle.
  - If your risk of transition to a sicker health state depends on events that happened earlier in time, the model can't explicitly account for this.

3a. Define the Markov Cycle Length

More challenges …

- There are workarounds known as “tunnel states” to get around this problem, though these are difficult to do and present their own challenges
  - We won’t cover them here but can provide references if you want to explore!

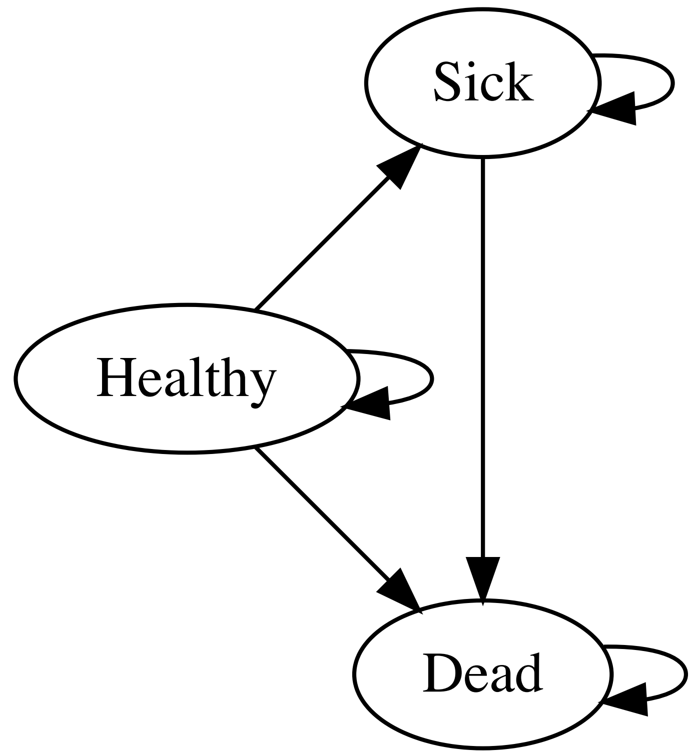
3a. Define the Markov Cycle Length

Pros	Cons
Can model repeated events	Can only transition once in a given cycle
Can model more complex + longitudinal clinical events	Shortening the cycle can create computational challenges.
Not computationally intensive; efficient to model and debug	Shortening cycle can cause “state explosion” if tunnel states are used

Back to Website

3a. Define the Markov Cycle Length

- It's also advisable to pick a cycle length that aligns with the clinical/disease timelines of the decision problem.
  - Treatment schedules.
  - Acute vs. chronic condition.
- Another option is to incorporate "short-run" events that happen early in the course of a disease/intervention within the decision tree, then allow the Markov model to model longer-term health consequences (pediatric appendicitis & CT scan example).



3. Parameterize the Model

3b. Curate and define model inputs

3b.i. Source and define the base case values.

3b.ii. Source and define sources of uncertainty.

Back to Website

3. Parameterize the Model

3b. Curate and define model inputs

- Rate of disease onset
- Health state utilities and costs
- Hazard ratios, odds ratios or relative risks for different strategies.
- … and so on.

3. Parameterize the Model

We defined many of the underlying parameters earlier in this lecture, so we'll repeat them briefly here.

Back to Website

3. Parameterize the Model

- We start with a healthy population of 25 year olds and follow them until age 100 (or death, if earlier).

- Remaining healthy carries no utility decrement (utility weight= 1.0)
- Becoming sick carries a 0.25 utility decrement for the remainder of the person's life (utility weight = 0.75)
- Death carries a utility weight value of 0.0.

Back to Website

3. Parameterize the Model

- There is no cost associated with remaining healthy.
- Becoming sick incurs $1,000 / year in costs.
- Becoming sick increases the risk of death by 300%.

3. Parameterize the Model

Each strategy has a different cost and impact on the likelihood of becoming sick.

Strategy	Description	Cost
A	Standard of Care	$25/year
B	Additional 4% reduction in risk of becoming sick	$1,000/year
C	12% reduction in risk	$3,100/year
D	8% reduction in risk	$1,550/year
E	8% reduction in risk	$5,000/year

Back to Website

3. Parameterize the Model

> ! It is **critical** to follow a formal process for parameterizing your model.

- Often, parameters are drawn from the published literature, and it is important to track the source (published value, assumption, etc.) for each model parameter.
  - For example, the percent risk reduction parameter for each strategy may come from different clinical trials.
  - The parameter governing death from background causes may be derived from mortality data.

Back to Website

3. Parameterize the Model

> ! It is **critical** to follow a formal process for parameterizing your model.

- Some parameters may just be values (e.g., cost of Strategy A is $25/yr)
- Some parameters may be functions of other parameters.
  - For example, suppose we want to follow a cohort of 25 year olds until age 100 or death, if it occurs earlier.
  - In that case we have two “fixed” parameters: the starting age, and the maximum age.
  - We can use these two parameters to infer the total number of cycles we need to run.

3. Parameterize the Model

ⓘ It is **critical** to follow a formal process for parameterizing your model.

- Parameters also have various “flavors”:
  1. Probabilities
  2. Rates
  3. Hazard ratios
  4. Costs
  5. Utilities
  6. etc.

Back to Website

3. Parameterize the Model

> ! It is **critical** to follow a formal process for parameterizing your model.

- All of the above highlight the importance of adopting a formal process for naming and tracking the value, source, and uncertainty distribution of **all** model parameters in one place.
- We recommend a structured approach based on parameter naming conventions and parameter tables.

Back to Website

3. Parameterize the Model

Naming conventions:

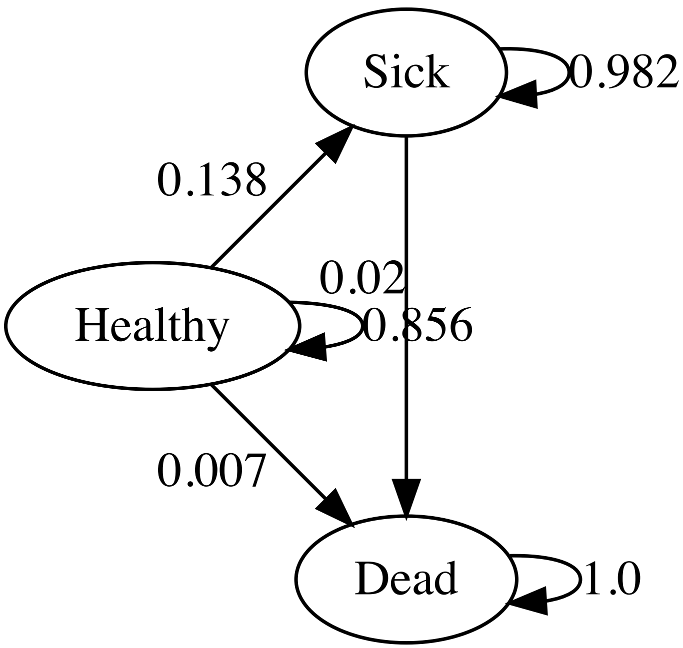
type	prefix
Probability	p_
Rate	r_
Matrix	m_
Cost	c_
Utility	u_
Hazard Ratio	hr_

Back to Website

4. Calculate or Define the Transition Probability Matrix

Back to Website

Transition Probability Matrix



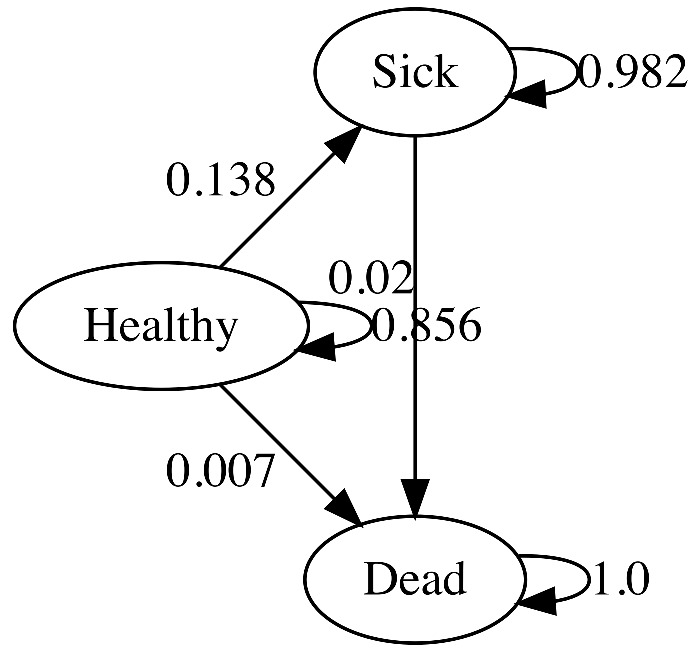
	Healthy	Sick	Dead
Healthy	0.856	0.138	0.007
Sick	0	0.982	0.02
Dead	0	0	1

Back to Website

Transition Probability Matrix

- It is **rarely** the case that you will have access to *all* necessary transition probabilities.

- Often, you will curate or define various quantities (e.g., rates, hazard rates, etc.) to construct the transition probability matrix for each strategy under consideration.



Back to Website

4. Run the Model

Back to Website

4. Next up: Decision Trees in Amua

Back to Website