Budget Impact Analysis (BIA) Methods & Scenario

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Contents

- Framework for thinking "Budget Impact Analysis"
  - Budget Impact Analysis
- Decision modeling: Designing Budget Impact Analysis
  - Framing: Conceptualize the problem
  - Structure
  - Parameters: probability and cost
  - Evaluation
  - Uncertainty (Test assumption)
- CHEERS Publication standard

Economic evaluation (REVIEW)

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- Type of economic evaluation (how to report costs and consequences)
  - Cost-analysis – reporting costs by intervention
  - Cost-minimization analysis – reporting costs to achieve same outcome, which is for minimization of cost
  - Cost-benefit analysis – reporting **monetary value on the health outcomes**, how much in total it is worth spending on an alternative given its projected effects
  - Cost-effectiveness analysis – reporting cost **per unit of health outcome**, incremental costs/effects, and ICER, resource allocation decision across different areas of health care
  - Cost-utility analysis – reporting **cost per QALY gained** (effects on survival measured in terms of life-years, and its effect on quality of life)
  - **Budget impact analysis - ?**

Economic evaluation

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- Connection between Cost-benefit and Cost-effectiveness/cost-utility analysis
  - CEA/CUAs compare ICERs to some threshold, which traditionally is measured in terms of **years of life gained or quality-adjusted life years** (QALY)
    - Threshold is the maximum WTP (willingness to pay) per unit of life or QALY
      - WTP depends on income and GDP
        - E.g. In US-based cost-utility analyses, 77.5% of all authors use either 50,000$ USD or 100,000$ USD per QALY as a reference point for cost-effectiveness*
  - After CEA/CUA:
    - If we have a new intervention that is considered cost-effective, what next?
      - ICER compared to traditional care is within WTP e.g. $35,000 per QALY. Do we implement?
    - The recommendation is to implement the intervention
      - The next logical question should be: **can we afford it?**

*Neumann PJ, Cohen JT, Weinstein MC. Updating cost-effectiveness — the curious resilience of the $50,000-per-QALY threshold. N Engl J Med. 2014;371:796–797.

Budget impact analysis

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- Budget impact analysis - Economic assessment to predict the financial consequences of the adoption of a new health care intervention within a specific health care setting given resource constraints
- While **BIAs focus on the financial impact of the new interventions (drugs, health program),** the value to the overall healthcare system is examined through other economic analyses, such as cost-effectiveness analyses (CEAs).

Budget impact analysis

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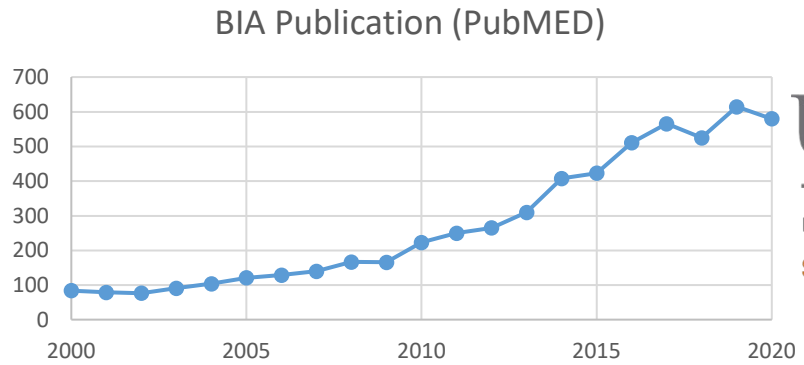
- BIA is usually performed in addition to CEA (**Complement of CEA, not substitute**)
- BIAs answer affordability, "Can we implement it?," based on budget
  - To understand the total budget
  - To inform influential implementation decision (Unit cost x target population)
    - How much their net annual budget is likely to increase/decrease by the new intervention in year 1, 2, and 3?
- BIA is a **financial decision** (resource allocation purpose)
- Emphasize 'relevance (timeliness)' of information -> Short-term analysis

Budget impact analysis



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- Growing recognition (ISPOR task force, Sullivan and Mauskopf et al, 2014)
- "Budget impact analysis (BIA) is an essential part of a comprehensive economic assessment of a health-care technology and is increasingly required, along with cost-effectiveness analysis (CEA), before formulary approval or reimbursement."
  - National regulatory agencies (Sullivan and Mauskopf et al, 2014)
  - National Institute for Clinical Excellence (NICE) in England and Wales
  - Pharmaceutical Benefits Advisory Committee (PBAC) in Australia
  - Managed care organizations (MCOs) in the USA

Budget impact analysis

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- The relevant question for a BIA study is the affordability of the interventions
- Take into account the actual number of people that would be affected by intervention
  - **Number of people * Cost per intervention**
- All the issues about perspective, time horizon, and relevance of costs for the decision are still valid.
  - Analysis of payer's expenditures for new intervention (drug, program or technology) over a short period (1 to 3 years)

Budget impact analysis

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	BIA	CEA
Information	Affordability	Value for money
Purpose	Financial impact of new intervention	Efficiency of alternatives
Time horizon	Short-term (1 to 5 years)	Long-term (life-time)
Perspective	Payer	Societal
Outcomes	Excluded	QALYs (quality-adjusted life years)
Discounting	No	4%
Results	Total and incremental annual costs	Incremental cost per unit

Budget impact analysis

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- Preferred comparators
  - Routine care vs. New/Intensive/Advanced intervention

- BIA topics (to address affordability)

  - Targeted drug therapy to adjuvant therapy
  - Routine to intensive cancer surveillance
  - Traditional to digital cancer screening
  - On-site to telemedicine care
  - Open surgery vs. Robotic surgery

Budget impact analysis

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- BIA Example
  - Routine/usual cancer care
    - Patients visit (Asymptomatic/Symptomatic) - Screening – Diagnostic procedure - Treatment
  - Intensive cancer prevention program by adding promotional elements significantly increased early detection and timeliness treatment
    - 'outreach' to population at risk of specific cancer
    - 'education' to inform how to receive screening and why it is important
    - 'reminder' by sending letters to receive screening

- **Intensive program was cost-effective, and now Public Health Officers are interested in implementing this program for community/city/state**

Decision modeling

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- How to design budget impact analysis?
  - We can not just guess. We need to apply modeling to estimate accurate financial consequences after implementation
  - **<u>Decision modeling is a set of analytic tools of economic evaluation</u>**
    - Framework to inform decision making under conditions of uncertainty
    - Widely used in a range of disciplines including business analysis, engineering, or healthcare evaluation in terms of informing clinical decisions at population and individual levels

Decision modeling

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- We need a systematic approach to decision making under uncertainty
- Mathematical relationships to define a series of possible consequences that would flow from a set of alternative options being evaluated
- Decision analysis is a quantitative description of the various choices and possible outcomes in a specific clinical situation
  - The important distinction in structuring problems as decision analyses is the term **quantitative**
  - This analytic technique requires that specific values be placed on the different possible outcomes so that an answer can be obtanined

Decision modeling

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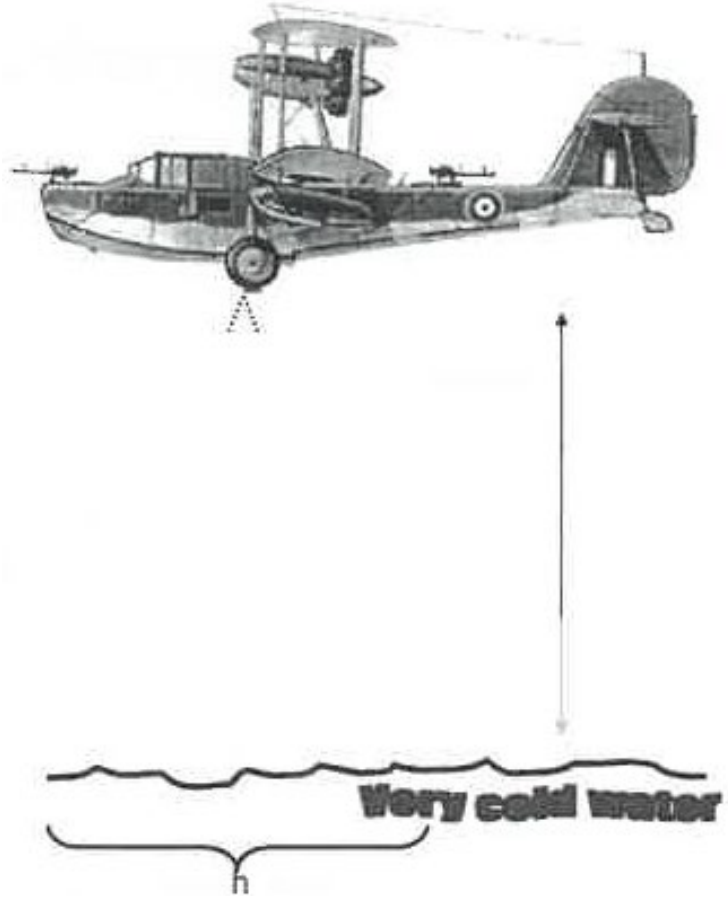
- Decision analysis as a formal analytic framework was developed over 70 years ago **for the making of decisions under conditions of uncertainty**
- Was initially applied in other areas of interest
  - Risk portfolio theory
  - Natural resource exploration

Decision modeling: 1940s

- Questions for Royal Air Force (RAF) to rescue for pilots lost in the North Sea
  - Given last known position and accuracy
  - Given water temperature
  - Given weather
- At what altitude should search planes fly?
  - Fly higher:
    - Cover more ground but might miss the pilot
  - Fly lower:
    - More accurate search, but search smaller amount of sea and increasing probability of enemy fire.
    - Longer you search: decreasing probability of finding pilot alive



Decision modeling

- Consider a range of possible choices, each choice with a range of possible outcomes
- Problem is to understand the expected value of the outcome given various choices
- The purpose of a decision model is to estimate the effects of choices in a decision making context

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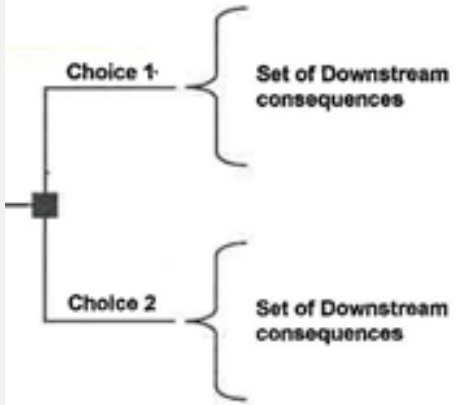


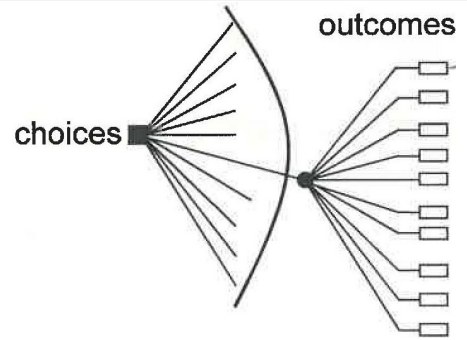
Sometimes this is easy:

consequences of making a bet in a casino in a game of known odds

Sometimes it's hard:

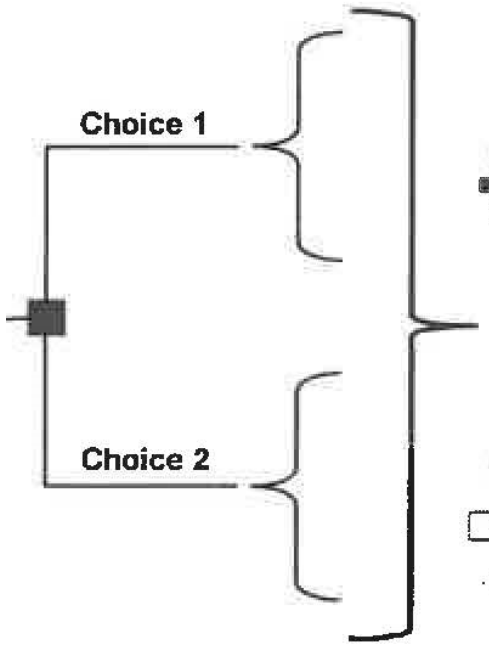
Predicting the life expectancy of earlier treatment in HIV disease (say starting HAART at a CD4 of 300 instead of 200)

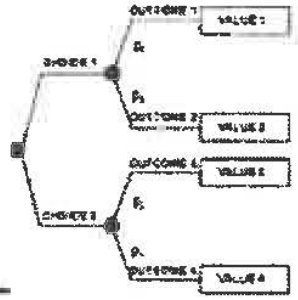
We often use ***models*** to help us with these predictions



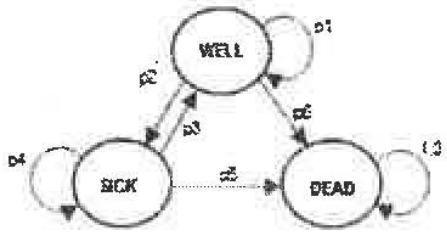
Decision modeling

- There are many types of modeling methods on can use to estimate downstream events:

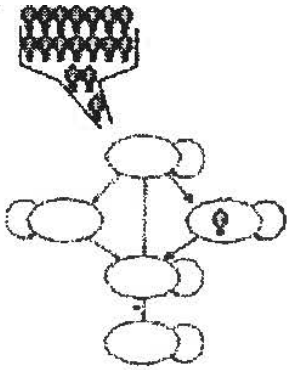




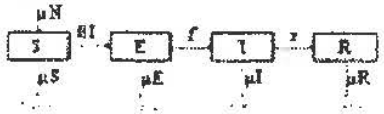
Decision Trees



State Transition (Markov) Models



Individual Microsimulation



Dynamic Transmission Models

Agent-Based Models

Decision modeling

- Step 1: Frame the question
- Step 2: Structure process
- Step 3: Estimate the probabilities
- Step 4: Estimate the costs
- Step 5: Analysis
- Step 6: Test assumptions
- Step 7: Interpret results

Framing: conceptualize the problem

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- Feature of healthcare delivery system
- Scope and structure
  - E.g. Affordability to implement a prevention program to increase screening rate, early detection, initiate timeliness treatment, and decrease mortality
- **Payer perspective** of the analysis
  - Public health provider/program who will pay for interventions

Inclusion	Exclusion
Provider's costs (direct costs) Intervention cost Staff cost Supplies	**Patient's costs** (Societal costs) Transportation cost Opportunity cost

Framing: conceptualize the problem

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- Target population
  - Size and characteristics of affected population (hypothetical population)
    - Estimates of eligible population (age, gender, stage, comorbidity, insurance status)
  - Data source (Budget holder, relevant epidemiologic studies, socioeconomic factors, or statistics)
    - e.g. Program for uninsured aged 50-75 Hispanic in greater Houston area
    - We can estimate the hypothetical target population (7,000,000*0.4*0.2*0.3)

Characteristics	Data
Total population	7,000,000
Hispanic	40%
Age 50 to 75	20%
Uninsured	30%

Possible source: US Cancer Statistics Working Group, U.S. Census Bureau

Framing: conceptualize the problem

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- Time horizon is a short period (Usually 3 years or 5 years)
  - **No inflation or discounting (unlike in most CEA/CUA)**
  - No cost offset by long-term effect
    - Treatment costs are usually skewed (Usually initial costs is highest)
- Outcomes
  - **No utility (Cost only)**
  - May not capture non-monetary benefit ex) reputation, goodwill
- Interventions or strategies (usual care vs. intensive care)
  - E.g. ‘outreach, ’education,’ ‘reminder’

Framing: conceptualize the problem

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	BIA
Information	Affordability
Purpose	Financial impact of new intervention
Time horizon	Short-period
Perspective	Payer
Outcomes	Excluded
Discounting	No
Results	Total and incremental annual costs

Budget impact analysis example

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BIA Example

- Routine/usual cancer care
  - Patients visit (Asymptomatic/Symptomatic) - Screening – Diagnostic procedure - Treatment
- Intensive cancer prevention program by adding promotional elements significantly increased early detection and timeliness treatment
  - 'outreach' to population at risk of specific cancer
  - 'education' to inform how to receive screening and why it is important
  - 'reminder' by sending letters to receive screening
- Intensive program was cost-effective, and now Public Health Officers are interested in implementing this program

Framing : conceptualize problem

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Intensive intervention
(Outreach, education, reminder, enrollment support,,,)

Usual care

Visit
- Symptomatic/asymptomatic

Screening
- Primary/Secondary

Diagnosis
- Diagnostic procedure

Biopsy
- Pathology

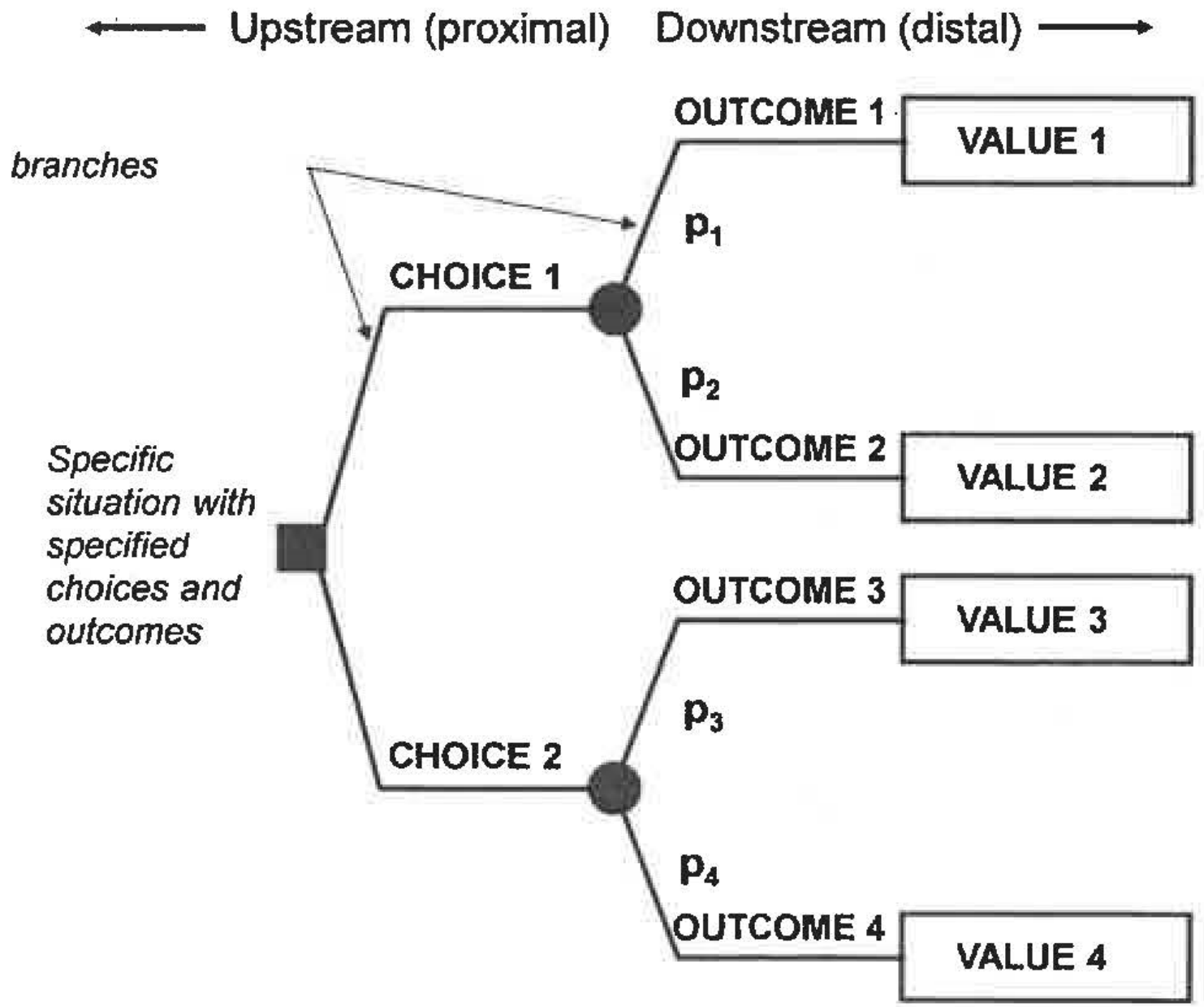
Treatment
- Chemo
- Surgery

Structure process

- Model is designed based on the scenario (clinical process, natural history of cancer)
- TreeAge, Excel
- Simple tree-model
  - Static model contains a simple calculation by simple changes with well known probabilities given others constant
- Markov model
  - Dynamic model is required for a complex scenario with sensitivity analysis to **capture uncertainty**

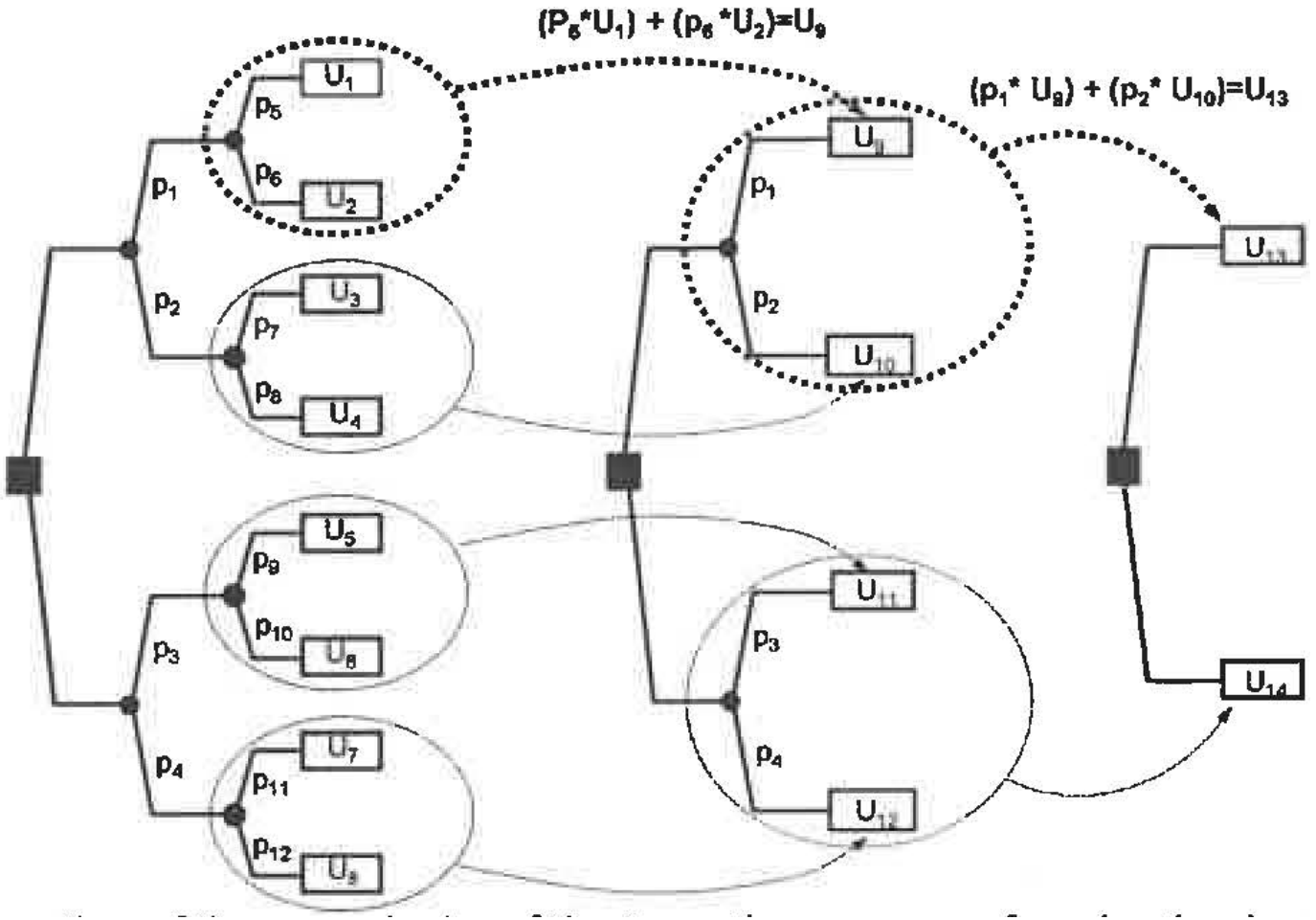
Structure

- Basic component of tree model
- We design a model to downstream based on the scenario (clinical process)
- The model rolls back (upstream) values to compare choice 1 and choice 2



Structure

- The process of evaluation is straightforward in the tree model
- Starting at the right hand side of the tree, replace each chance node with its expected value, until the only branch left are the decision nodes



Structure

- How complex should I model be?
  - Simple model may miss clinically or policy important attributes
    - May be easy to design and run
    - May get wrong answer
    - May have no clinical credence with content experts
    - Make it difficult to test robustness in assumptions
  - Complex model
    - Difficult to develop and run
    - May require data so specific it is unavailable
    - May be difficult to understand by non-quantitative people
    - But accurately reflect the clinical conditions or situation a decision

Structure

- Cancer prevention in usual care
  - Visit healthcare provider to receive screening with/without symptom
  - Receive screening
    - Positive? Negative?
      - If negative, receive another screening after 3 years
      - If positive, receive diagnostic procedure
        - Positive? Negative?

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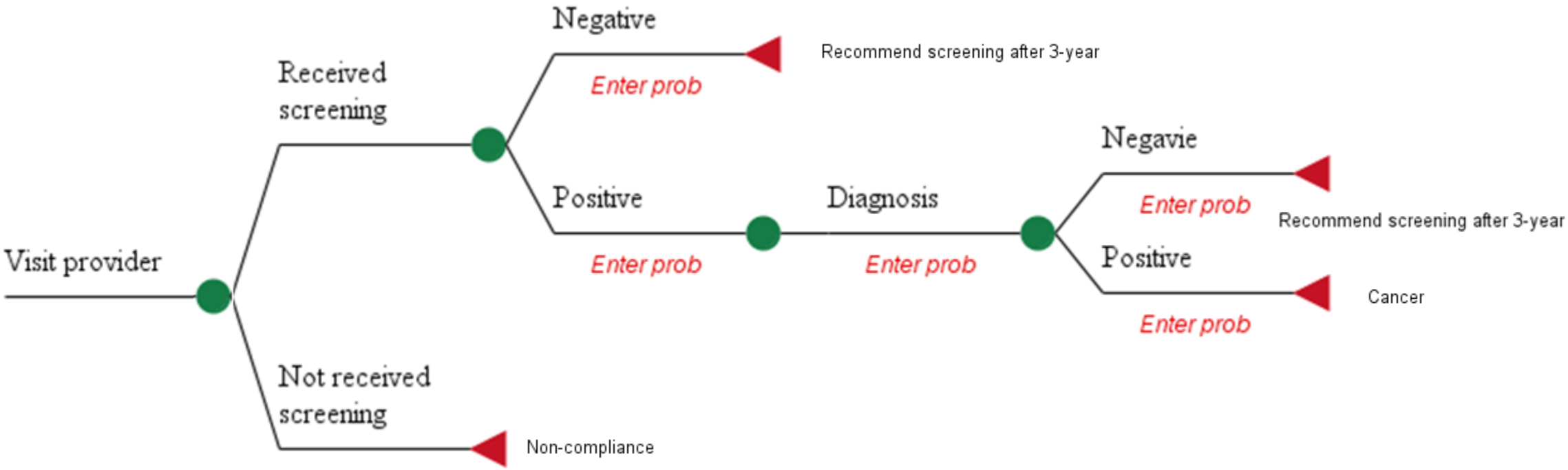
Structure

❖Clinical process in usual care



Structure

- Clinical process in intensive care
  - Outreach to the public fair or healthcare providers. Provide gift card and transportation costs if they agree to participate in the program
  - Educate participants using flip-chart about how to receive screening
  - Receive screening?
    - If not, send a reminder letter or calls
      - Positive? Negative?
        - If negative, receive another screening after 3 years
        - If positive, receive diagnostic procedure

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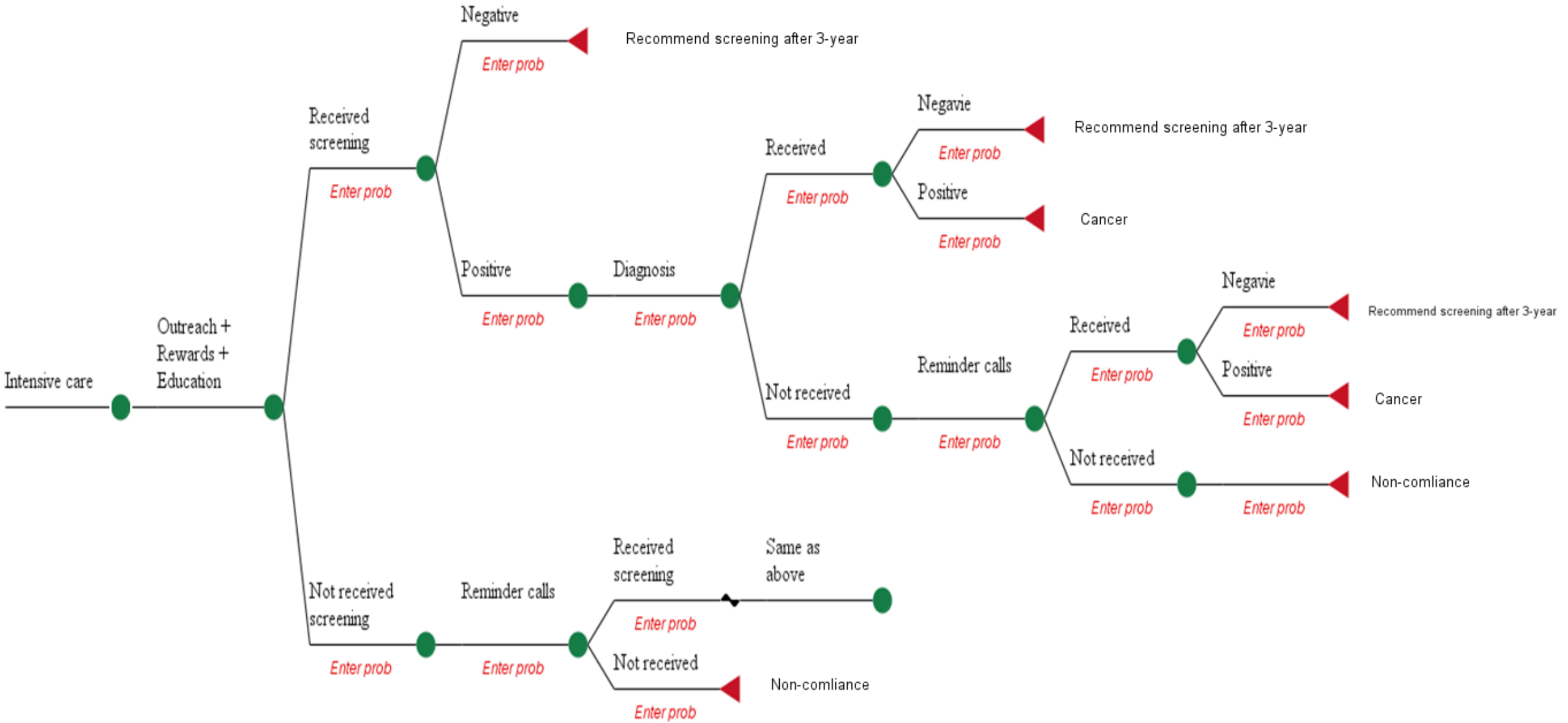
Intensive care
Outreach + Rewards + Education
Received screening
Enter prob
Negative
Enter prob
Recommend screening after 3-year
Positive
Enter prob
Diagnosis
Enter prob
Received
Enter prob
Negavie
Enter prob
Recommend screening after 3-year
Positive
Enter prob
Cancer
Not received
Enter prob
Reminder calls
Enter prob
Received
Enter prob
Negavie
Enter prob
Recommend screening after 3-year
Positive
Enter prob
Cancer
Not received
Enter prob
Enter prob
Non-comliance
Not received screening
Enter prob
Reminder calls
Enter prob
Received screening
Enter prob
Same as above
Not received
Enter prob
Non-comliance

Estimate the probabilities/costs

- Data sources
  - **Literature**
  - **Clinical data** (screening rate, detection rate, stage, vital)
    - EHR
  - **Clinical trials** (survival, treatment, surveillance)
    - Pharmaceutical companies - ClinicalTrial.gov, Clinical Data Interchange Standard Consortium (CDISC)
  - **Patient-recorded data** (screening adherence)
    - Smart health, digital health, mobile health
  - **Social/demographic determinant data** (hypothetical population)
  - **Claim data** (cost of provided procedures, health services)
    - Insurance company, Medicare, Medicaid
  - **Administrative data**
    - Invoice/bills, labor costs ((salary + fringe benefit –vacation)*productivity rate)

Estimate the probabilities/costs

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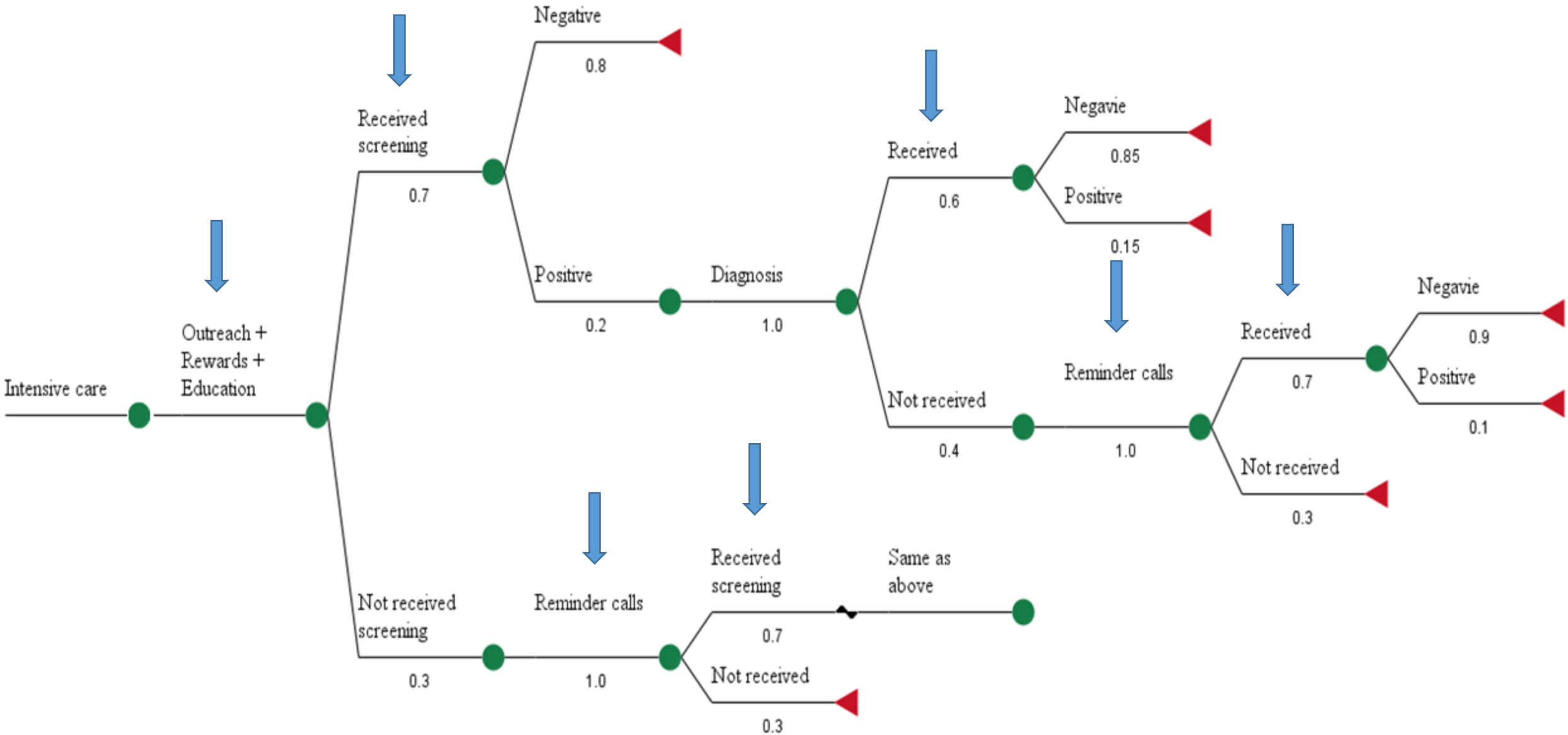
Probabilities
Screening rates
Positive/negative rate
Diagnosis rate
Normal/abnormal
Detection rate

Cost elements
Outreach (transportation, recruiter, rewards)
Education (flip charts, educator)
Reminder (letter stamp, calls, caller)
Electricity
Physician charges (screening, diagnosis)
Facility charges (Utility)
Administrative (manager)


Intensive care
Outreach + Rewards + Education
Received screening
0.7
Negative
0.8
Positive
0.2
Diagnosis
1.0
Received
0.6
Negavie
0.85
Positive
0.15
Not received
0.4
Reminder calls
1.0
Received
0.7
Negavie
0.9
Positive
0.1
Not received
0.3
Not received screening
0.3
Reminder calls
1.0
Received screening
0.7
Same as above
Not received
0.3

Evaluate the tree

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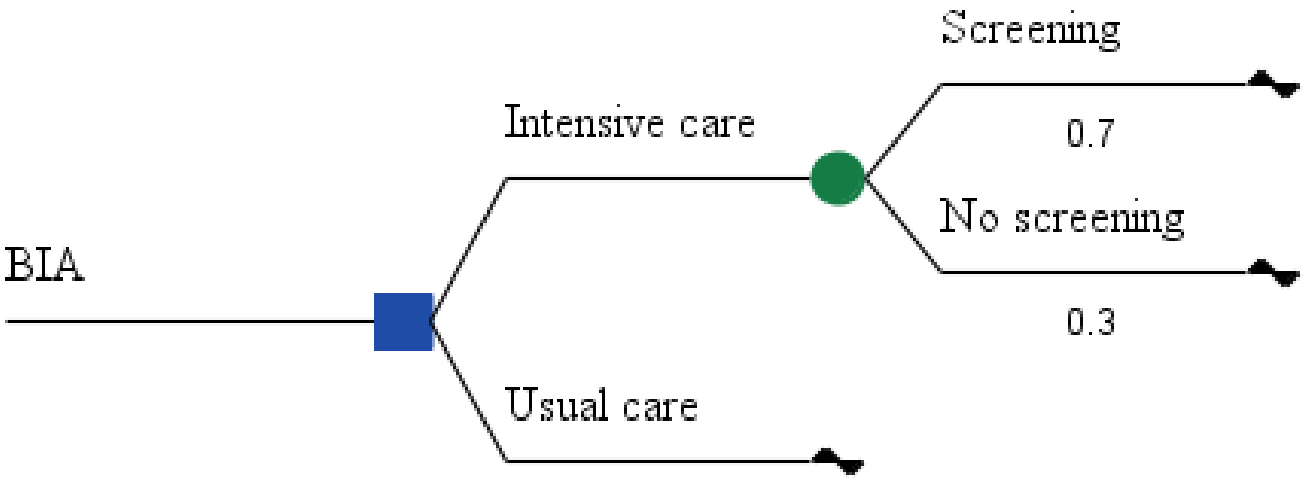
- Average out/roll back



- This result will show the total and incremental costs of program implementation for intensive care vs. usual care.

Reporting

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- **<u>Budget of status quo vs. intervention for hypothetic population over 3 years</u>**
  - Comprehensive budget
  - Incremental and cumulative budget for each year, average, and per person

Test assumption (Sensitivity analysis)

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- Test the robustness of your results
  - **Each parameter input into your model has ranges of uncertainty** (Different data sources)
  - **Cost of intervention may have a variation by physician, provider, or geographical location**

- **Key parameters (cost drivers) with high sensitivity to budget** (Which parameter is influential to the budget?)
  - **Cost may be varied by geographic location or insurer**
  - Improve the reliability and relevance for decision-making
  - Improve the understanding of applicability for other health system settings

Test assumption (Sensitivity analysis)

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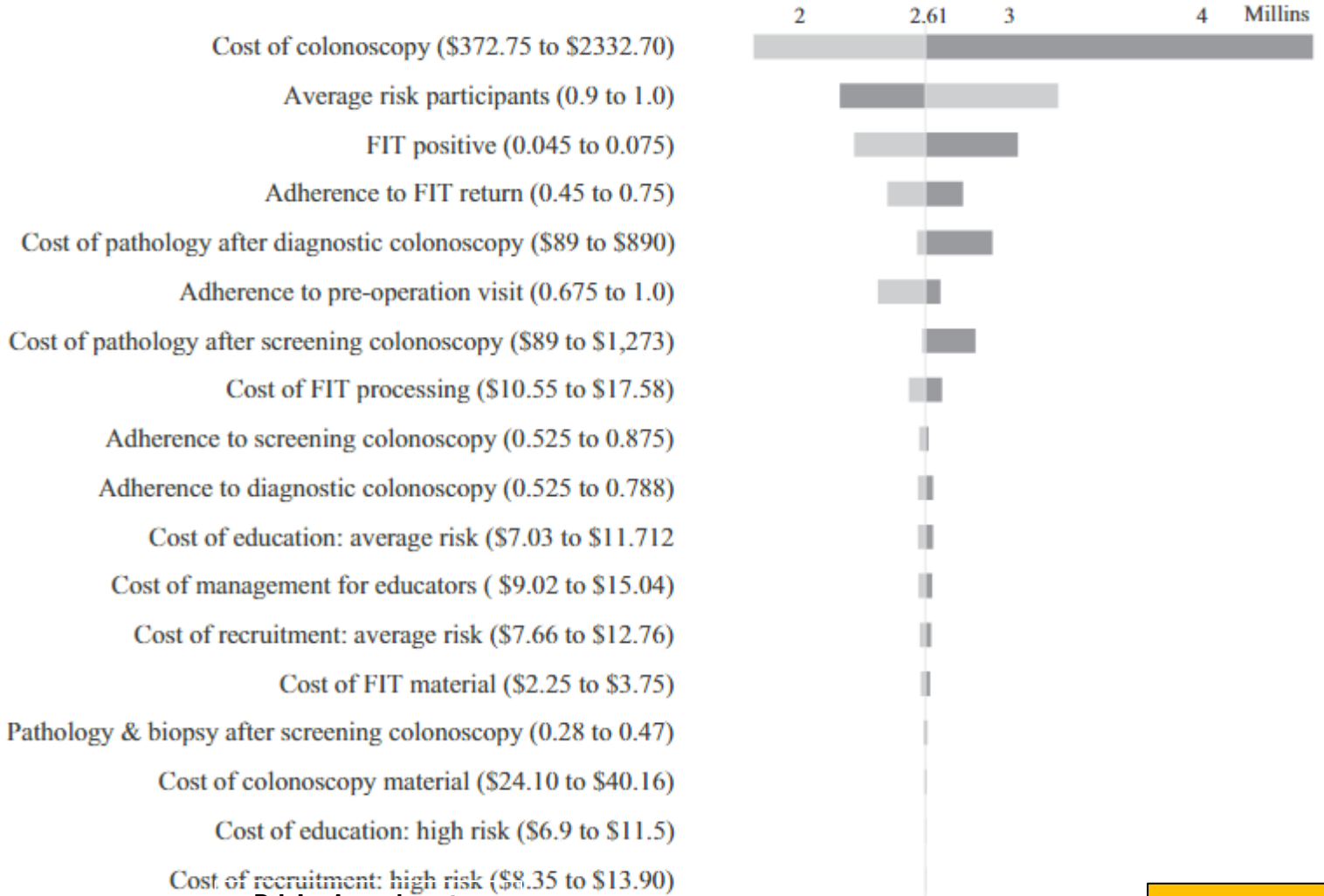
- Change assumptions in t changes
  - Ex) ±25% of parameter, l
- One-way
  - Change one at time
  - Easy, used to understand
- Multiple-way (Tornado
  - Change multiple assump
- Scenario analysis
  - Basic vs. worst vs. best
  - Ex) Adherence rate of int



Test assumption (Validation)

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- Determine face validity through **agreement with relevant decision makers on the computing framework, aspects included, and how they are addressed** (e.g., access restrictions and time horizon)

- **Verification of the cost calculator or model implementation**, including all formulas

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

- The aim of the CHEERS statement is to provide recommendations, in the form of a checklist, to optimize reporting of health economic evaluations
- Primary audiences for the CHEERS statement are researchers reporting economic evaluations and the editors and peer reviewers evaluating their publication potential
- Clearly state the study question and its importance to decision makers

Don Husereau, Michael Drummond, Stavros Petrou, Chris Carswell, David Moher, Dan Greenberg, Federico Augustovski, Andrew H Briggs, Josephine Mauskopf, Elizabeth Loder. RESEARCH METHODS & REPORTING - Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ* 2013;346 :f1049

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.
Introduction		
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Methods		
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.
Measurement of effectiveness	11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.
	11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.
Estimating resources and costs	13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.
	13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Results		
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.
Characterising uncertainty	20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).
	20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.

Consolidated Health Economic Evaluation Reporting Standards (CHEERS)

Discussion		
Study findings, limitations, generalizability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.
Other		
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.

Budget Impact Analysis

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The University of Texas
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School of Public Health

Question?

Reference:

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