Predicting the population health effects of changing tobacco exposures:

Statistical models for regulatory compliance

NASEM ENDS Workshop

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Goal of Statistical Models:

Predict population health effects of alternative tobacco products (ATPs) in the absence of sufficient empirical data

Relevant to FSPTCA:

Must demonstrate that a reduction in morbidity or mortality is reasonably likely

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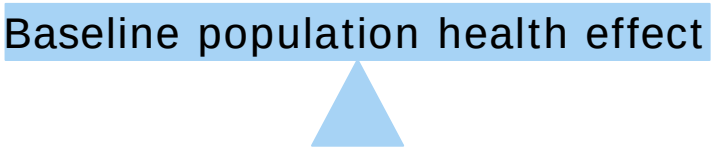
WEIGHING RISKS AND BENEFITS

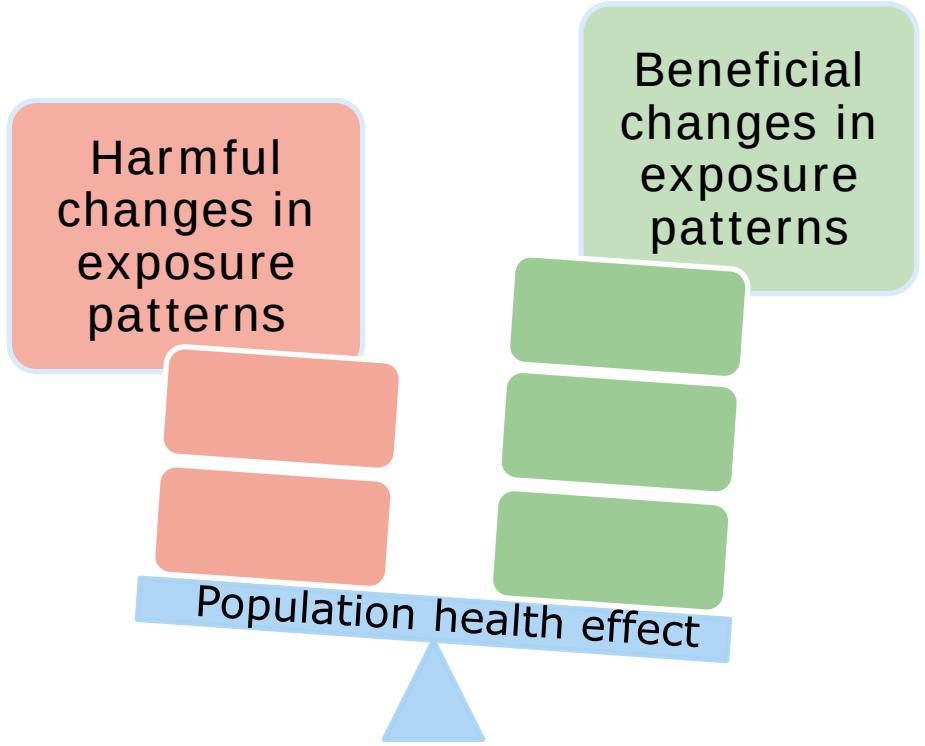
Base case

- Cigarettes only

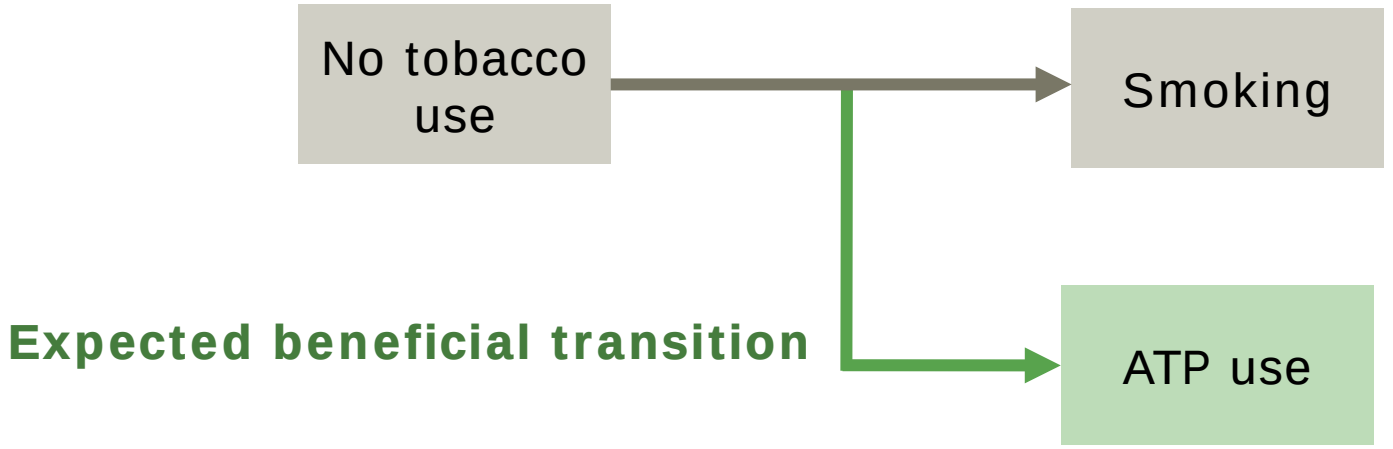


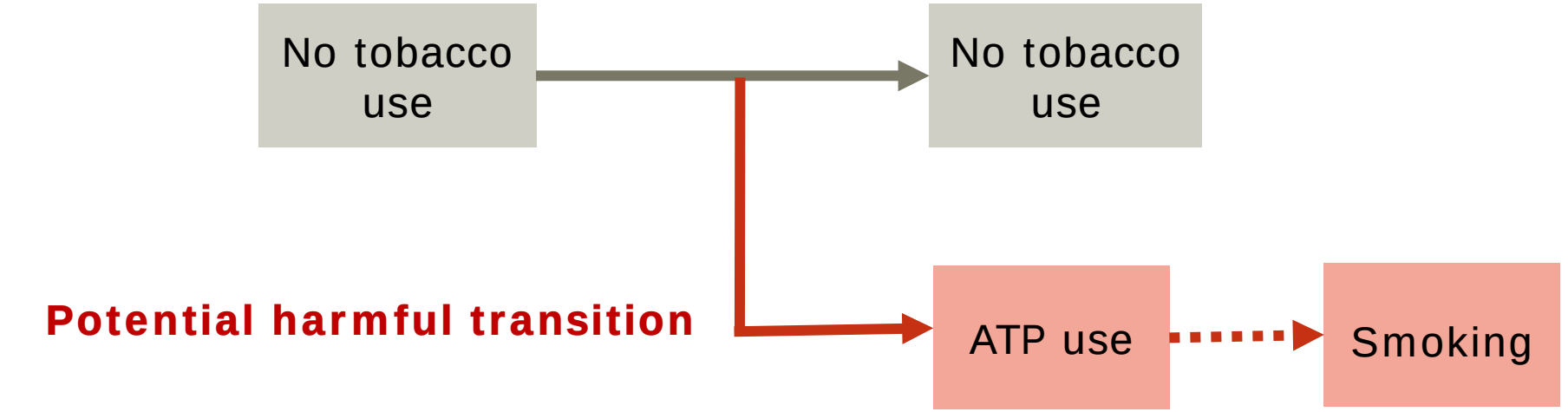
Counterfactual

- Cigarettes and ATP



INTRODUCTION OF AN ATP TO 'NEVER TOBACCO USERS'





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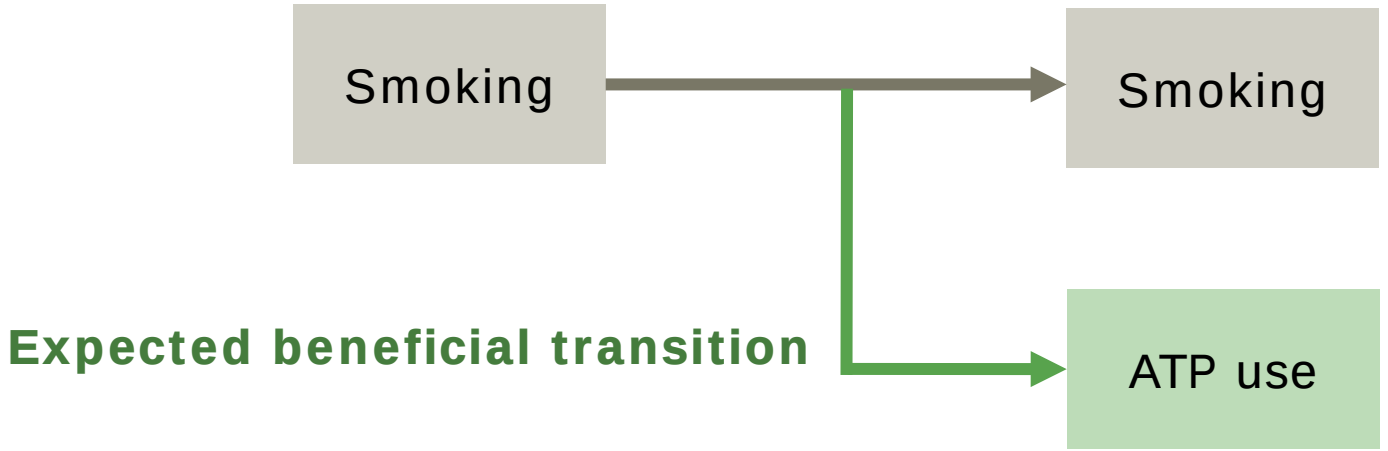
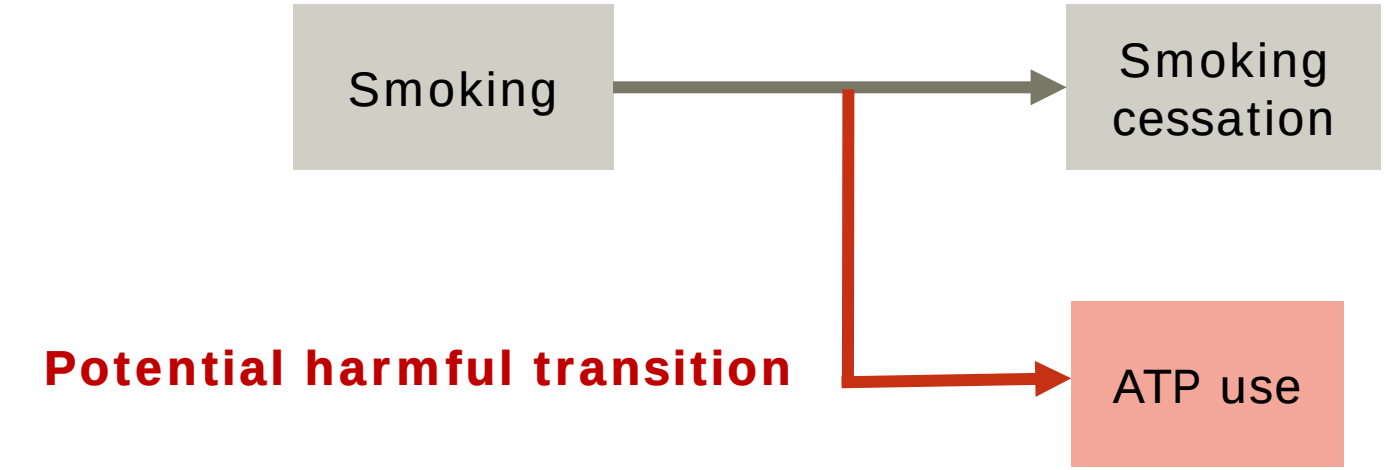
INTRODUCTION OF AN ATP TO CURRENT SMOKERS





Following a hypothetical birth cohort over time: Data requirements

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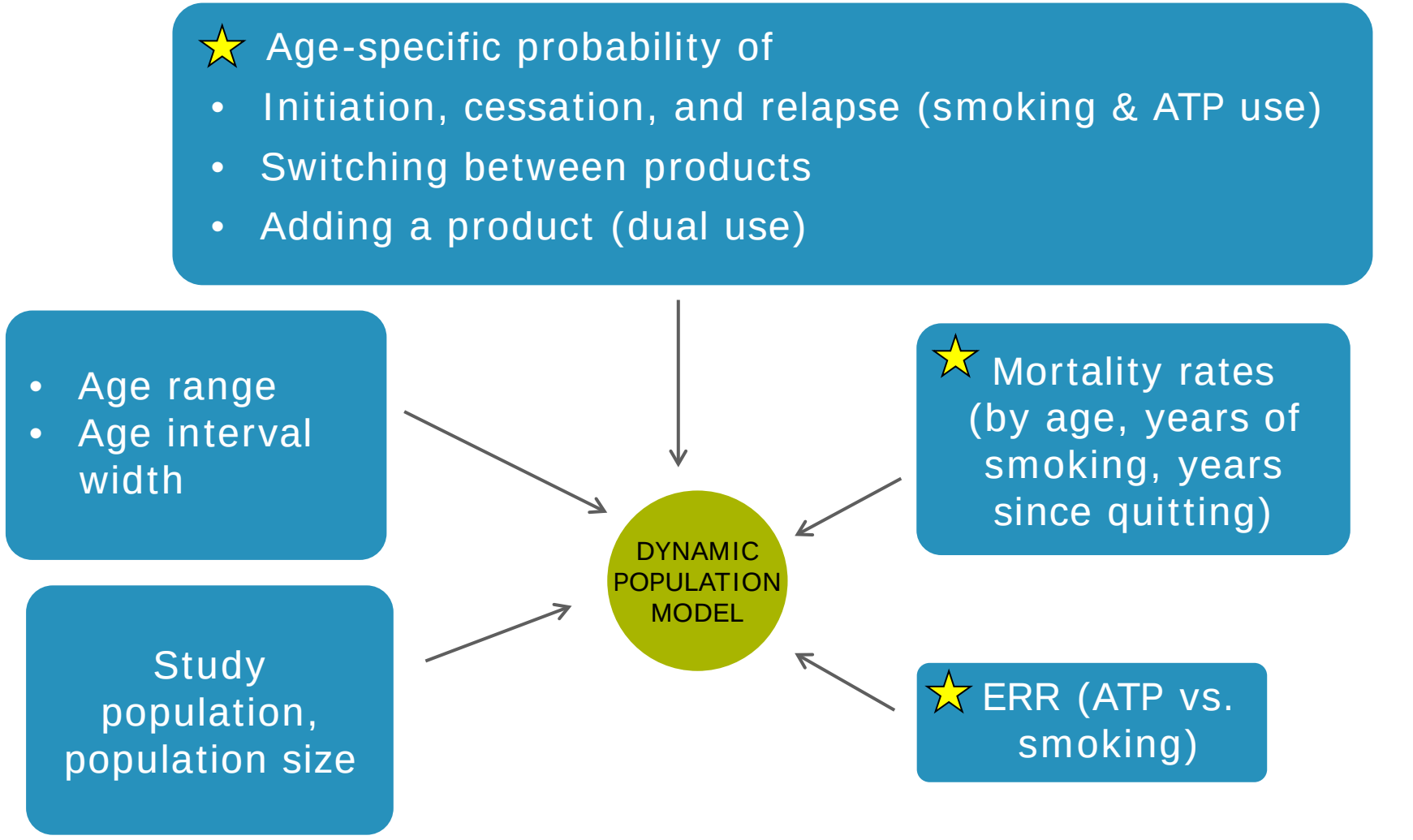

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Illustrative Example

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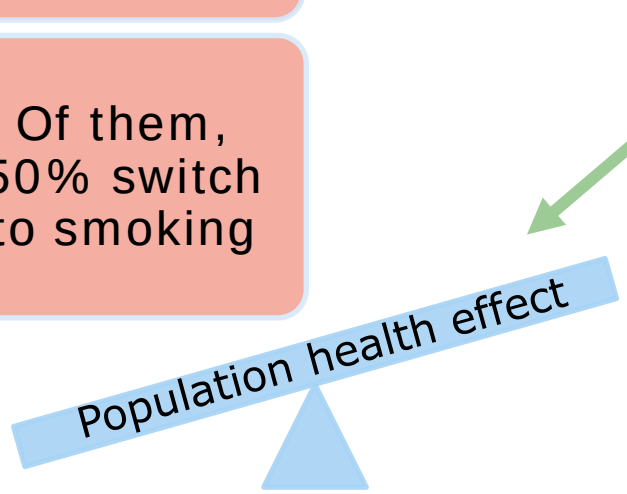
ILLUSTRATIVE EXAMPLE

3% of base case never tobacco users initiate ATP

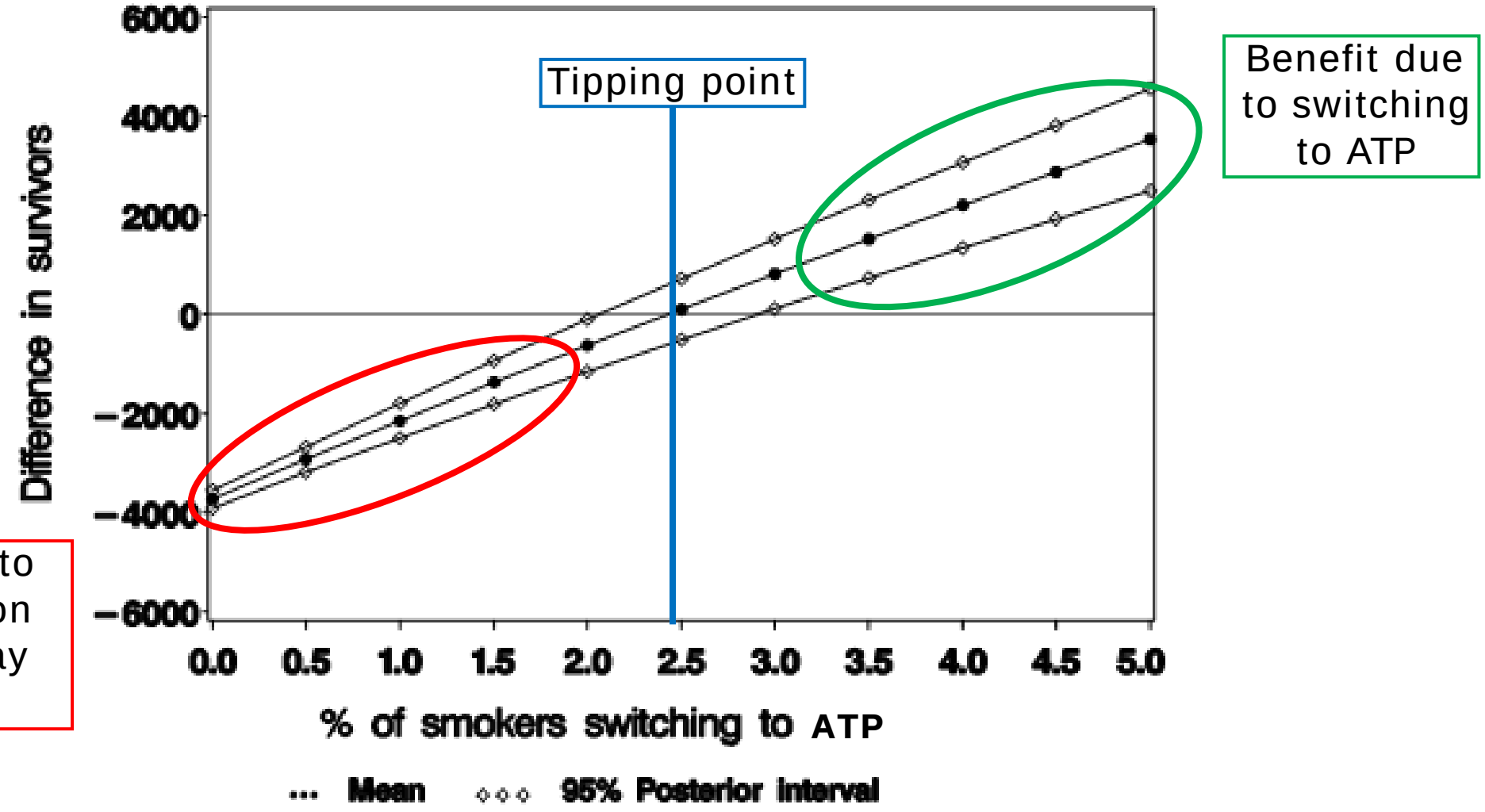
Of them, 50% switch to smoking

Some base case continuing smokers switch to ATP



- How many are needed to offset harm?
- Is this realistic?

ILLUSTRATIVE EXAMPLE: RESULTS FOR AGE 68-72



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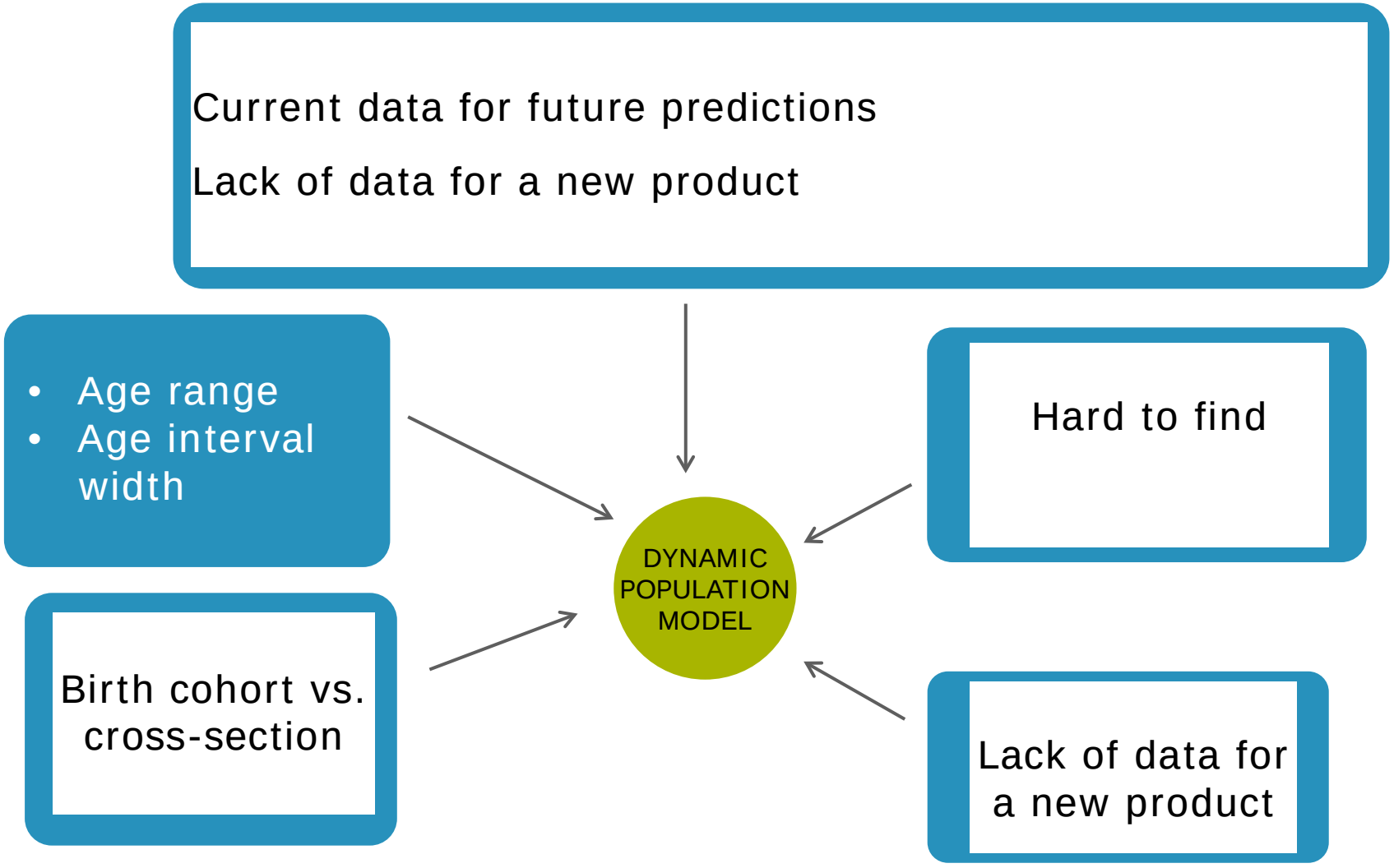
Challenges


Current data for future predictions
Lack of data for a new product
Age range
Age interval width
Hard to find
DYNAMIC POPULATION MODEL
Birth cohort vs. cross-section
Lack of data for a new product

BIRTH COHORT  VS. CROSS-SECTION 

Same age, followed until all cohort members have died

- Relatively few input values
  - ➔ Assumptions clearly defined
- Complete follow-up
  - ➔ Exposure histories known
  - ➔ All deaths accounted for

Mixed ages, followed over a pre-determined time interval

- Many input values
  - o Many birth cohorts, new members
  - o Two time variables, age and year
  - ➔Assumptions difficult to assess
- Shorter, incomplete follow-up
  - o Partial exposure histories
  - o Tobacco-related mortality missed?

BIRTH COHORT  VS. CROSS-SECTION 

- Flexible
  - o Tipping point analyses
  - o Easy expansion to >2 products
- Limitations
  - o No direct predictions for cross-sectional populations
  - o However, does provide evidence of the effects of introducing a MRTP to a cross-sectional population

- Less flexible
  - o No direct estimates of tipping points
  - o More difficult to expand
- Other limitations
  - o In theory, direct predictions are possible for the modeled cross-sectional population; but
  - o Validity and generalizability?
  - o Tipping points?

See: Bachand, A.M. and Sulsky, S.I., *Predicting the population health effects of changing tobacco exposures: statistical models for regulatory compliance*. Recent Advances in Tobacco Science, 2016. **42**:p. 9-22

THANK YOU

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CONTACT INFORMATION

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The dynamic population modeler described here was developed independently of the sponsors.

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