TCORS 2.0
University of Michigan & Georgetown University

Center for the Assessment of Tobacco Regulations [CAsToR]

The Role of Simulation Modeling in Tobacco Research and Regulation: Yesterday, Today and Tomorrow

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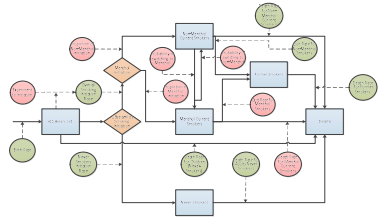

Disclosures

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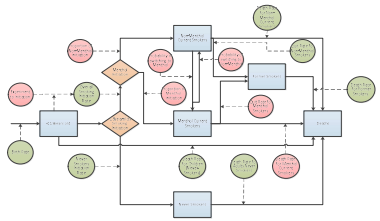
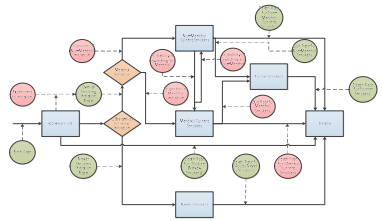
- No conflicts of interest.



Acknowledgments

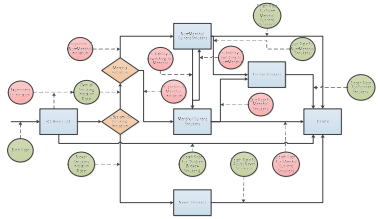
- My CAsToR colleagues
- Especially Dr. David Mendez

Why modeling?



- To address issues of interest and/or importance that involve complex dynamics (multiple variables, interactions among them, non-linear relationships, etc.)
  - *Not easily addressed without modeling*
- Often involve future outcomes
  - *Can't afford to wait to learn outcome*
- Provide input for decision-making on adopting interventions or weighing alternative interventions
  - *For businesses, public sector regulators and legislators, etc.*

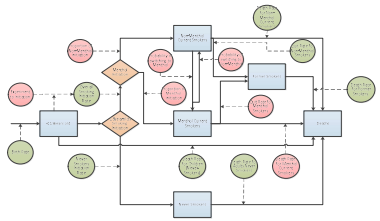
Why modeling?



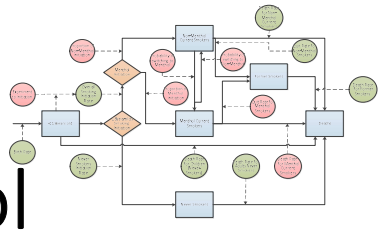
Josh Epstein (*J Artificial Societies & Social Simulation*, 2008):

- We are using a model *whenever* we try to project a future outcome.
  - *Usually implicit model, "in our heads," with unspecified assumptions, untested internal consistency, logical consequences unknown, relationship to actual data also unknown*
- Therefore, "[t]he choice…is not whether to build models; it's whether to build *explicit* ones."
- With explicit models,
  - *Assumptions described in detail*
  - *Impacts of changes in assumptions clear*
  - *Results replicable*
  - *Results data-driven*

Simulation modeling in public health

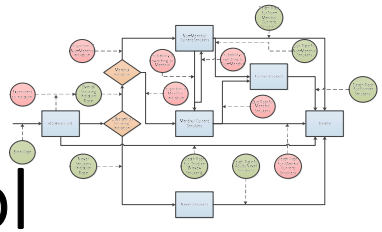


- Projecting likely course of infectious diseases
- Estimating impacts of control measures over time
- More generally, developing a national plan to be prepared to address future infectious diseases
- Understanding the evolution of a chronic disease epidemic like obesity
- Assessing cost-effectiveness of alternative approaches to reducing health effects of diseases



Simulation modeling in tobacco control

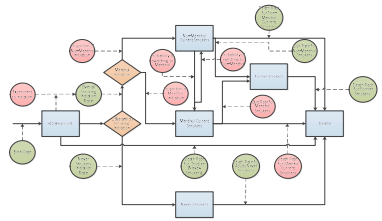
- Forecast smoking prevalence and health outcomes (for goal setting, etc.)
- Estimate future impacts of interventions, alone or in combination, on smoking prevalence and health outcomes (policies, regulations, media campaigns, increasing availability of cessation treatment, educational interventions)
- Evaluate cost-effectiveness of different interventions
- Identify potential importance of unintended intervention side effects
- Assess past trajectory of smoking and health outcomes if
  - *Existing interventions had not occurred*
  - *Non-adopted interventions had been adopted*
- Identify research gaps and establish priorities to improve data for future models



Simulation modeling in tobacco control

Special relevance: Family Smoking Prevention and Tobacco Control Act of 2009 requires FDA to use a public health standard

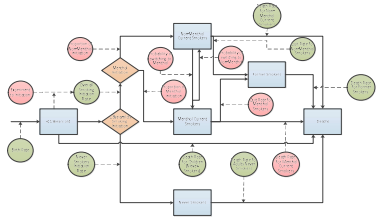
- FDA must evaluate population health impact
  - *New field of regulatory science*
  - *Differs from drug standard of individual patient safety and efficacy*
- Means that simulation modeling will be an important method for evaluating modified and novel tobacco products



Types of models used in tobacco control

- Aggregate (compartmental) models
- Individual (agent-based) models

Compartmental models

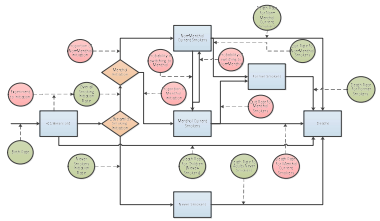


Main characteristic

- Tracks aggregate quantities describing homogeneous groups (e.g., total number of smokers in the US population)

Structure

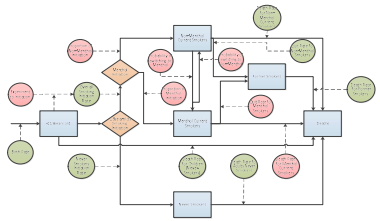
- Stocks: Aggregate quantities of interest representing homogeneous groups (e.g., number of smokers in the initial year)
- Flows: Rates of transitions among stocks (e.g., smoking initiation and cessation rates)



System dynamics models

Specific type of aggregate model characterized by complex, nonlinear interactions and feedback effects

Agent-based models



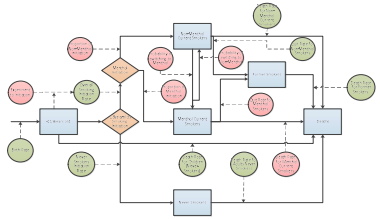
Main characteristic

- Track individuals as they interact with their environment and other individuals through social networks

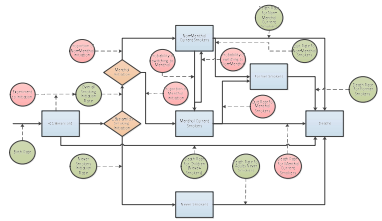
Structure

- Agents: Individuals with unique traits followed throughout the simulation
- Attributes: Individuals' traits (e.g., age, gender, SES, smoking status)
- Rules: Behavior of the agents as they interact with each other and with their environment

Choice of characteristics of groups or individuals in both types of models

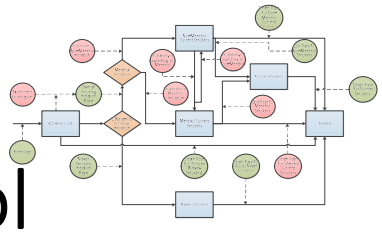


- Depends on purpose of model
- Includes characteristics that affect the link between smoking and health outcomes (e.g., age, gender, race/ethnicity, SES)
- Includes characteristics associated with smoking patterns (e.g., greater difficulty quitting smoking among low SES and menthol smokers)
- Influenced by variation in response to interventions (e.g., low SES are more price-responsive; so are adolescents and young adults)
- May be defined by availability of data (e.g., are there data characterizing differences in racial/ethnic groups' policy responses?)



Simulation models used in tobacco control

- Many models.
- Models used by CAsToR investigators
  - *SimSmoke and variations (David Levy)*
  - *Mendez-Warner UM model (David Mendez)*
  - *CISNET (Ted Holford, Rafael Meza, and others)*



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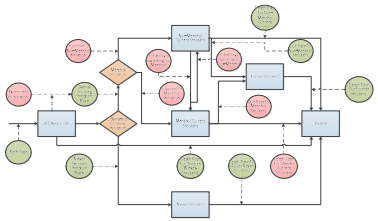
Forecast smoking prevalence and health outcomes (for goal setting, etc.)

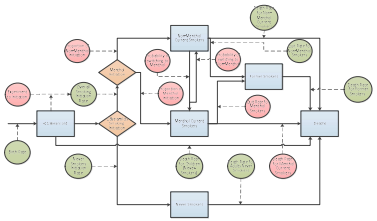


Most basic use of tobacco simulation models.

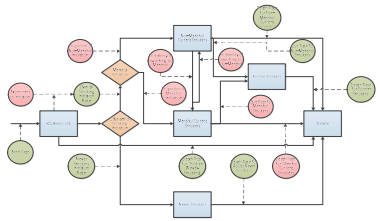
One important application: Goal setting (e.g., Healthy People goals)

- *Why 2010 prevalence goal not attainable (Mendez and Warner, AJPH 2000)*
- *How to achieve prevalence goals with aggressive tobacco control (Levy et al., AJPM 2010 [2010 goal achieved by 2013]*
- *Relevance to endgame goals; e.g., Healthy People 2030: reduce smoking prevalence to 5%*

Estimate future impacts of interventions on smoking prevalence and health outcomes

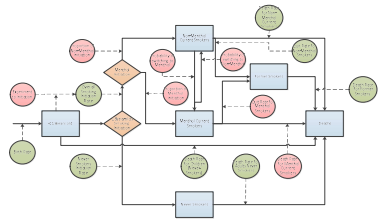


- Taxation
- Smoke-free policies
- Ad bans
- Warning labels (including GWLs)
- Media campaigns
- Youth access laws (including T-21)
- Mandated cessation treatment
- Mandated cessation treatment coverage
- Educational programs
- Mandated less hazardous cigarettes
- Combinations of policies and interventions
- Possible future FDA regulations (banning menthol; nicotine reduction)



Evaluate cost-effectiveness of different interventions

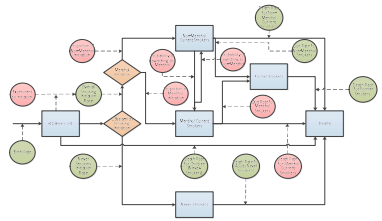
- School-based education programs
- Teen smoking cessation program
- Raising the legal age of smoking
- Smoke-free workplaces
- Comparison of C-E of smoking cessation treatment alternatives (NRT, non-nicotine pharmaceuticals, counseling, unassisted quitting)



Identify potential importance of unintended intervention side effects

Examples:

- Youth-oriented prevention policies for e-cigarettes
- Nicotine-reduction regulation



Assess past trajectory of smoking and health outcomes

If…

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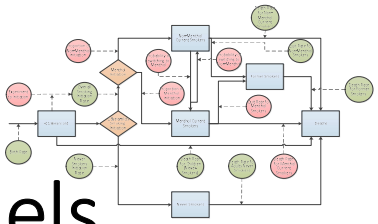
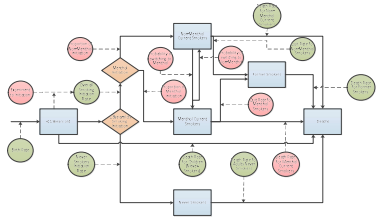
Identify research gaps and establish priorities to improve data for future models



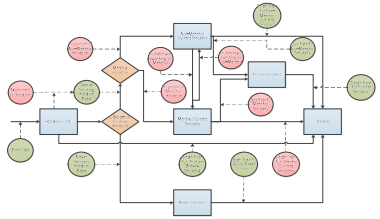
- All of above contributions can contribute to this use of models
- Use of sensitivity analysis to determine
  - *Unknown parameter values important to an analysis*
  - *Unknown parameter values not important to the analysis*
- Identifies research priorities to address the issue in question

Simulation modeling for tobacco regulatory science: Going forward
Subject matter

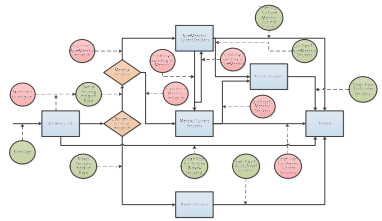


- Issues of (possible) contemporary relevance to FDA
  - *Menthol ban (Le and Mendez; Levy et al.; others)*
  - *Nicotine reduction (Tengs et al., Prev Med, 2005; Apelberg et al., NEJM, 2018; Levy et al., NTR, 2020; our TCORS project)*
  - *Other regulations on combusted products (e.g., increase pH; maximum yields of various carcinogens; etc.)*
  - *Regulation of flavors in non-combusted products*
  - *Permitting or prohibiting the marketing of various alternative products*
- Issues relevant to policymaking outside of FDA
  - *Effects of heavy taxation of combusted products and low taxation of non-combusted products*

Simulation modeling for tobacco regulatory science: Going forward
Methods



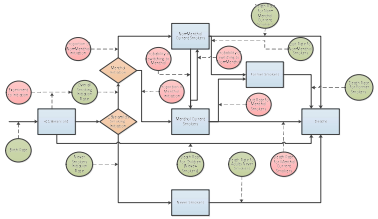
- Develop standards of good practice for modeling?
  - *Questions like: Should there be standards for base-case or status quo assumptions?*
- Is there a role for AI?
  - *Used in COVID modeling*
- Standards for educating other tobacco control researchers about modeling?



A final word

[I]n the next phase of tobacco control…models will be a key tool for designing strategies to address groups with high rates of prevalence and to hasten the end of the tobacco epidemic.

Source: Appendix 15.1, Surgeon General's report, 2014



Thanks

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