Evidence-based decision making and tobacco harm reduction modeling: Opportunities and Barriers

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1. Definitions
   - Evidence-based decision making
   - Tobacco Harm Reduction (THR)
   - Individual vs. population level effects

2. THR and rationale for modeling

3. Barriers and opportunities afforded by modeling

4. Summary, discussion/questions
1. Definitions
Evidence-based decision making

- Entails “…conscientious, explicit and judicious use of current best evidence…” (David Sackett)
- Current, popular concept in various settings
  - Clinical medicine
  - Policy development
  - Program formulation & evaluation
- Aims to make decision process transparent, increase objectivity
- Promotes
  - Critical assessment of available data
  - Identification of data gaps
  - Discussion (theoretically)
Features of evidence-based decisions

- Specifies
  - Underlying assumptions
  - Sources of information

- Underlying logic can be examined

- Can assess effect of
  - Changes to assumptions
  - Application of new, different data
How else are decisions made?

- Depends on setting, context
  - Discussion/consensus
  - Majority opinion (voting)
  - Authority
  - Intuition/judgment

- These approaches have their place

- Is their place in science, medicine, or policy/program development & evaluation?
Tobacco Harm Reduction

- Construct: Reducing exposure to certain tobacco constituents leads to fewer health effects

- THR may be achieved by
  - Individuals reducing the number of cigarettes smoked
  - Cigarette design modification (e.g., low tar products)
  - Product substitution (e.g., SLT, snüüs, PREPs)
Individual vs population THR benefits

- Individual benefits of THR include, for example:
  - Reduced risk of disease
  - Reduced duration, severity of disease

- Population benefits of THR include, for example:
  - Reduced number of sick people
  - Less time sick
  - Economics: increased productivity, decreased medical care costs

- Population level benefits may outweigh individual benefits (policy implications)
Example: individual vs. population effects

Barendregt et al., 1997. *NEJM* 337:1052-1057

Individual smokers' costs > nonsmokers' costs at every age

Nonsmokers' aggregate costs > smokers' aggregate costs after about age 70

Smokers' aggregate costs > nonsmokers' aggregate costs for a while…

Individual smokers' costs > nonsmokers' costs at every age
2. THR and rationale for modeling
Some arguments used against THR

- “Reduced harm” might be misinterpreted as “safe”
- Some smokers might be dissuaded from quitting
- Some individual smokers will not benefit
  - Not all tobacco constituents reduced
  - Not all health outcomes affected
- THR products might serve as “gateways” to cigarettes
- Society “should not” tolerate tobacco use in any form
Some arguments used for THR

- Individual users have the right to choose less harmful products
- Some individual users will experience health benefits
- ETS will be reduced or removed
- THR products might assist users in quitting
- At the population level, THR likely to reduce tobacco-associated health effects
THR: Non-human evidence

- Toxicology studies measure effect of exposure in non-human species
- Product composition data compare levels of specific constituents in different products
- Generally suggest reduced harm, but
  - Not directly applicable to population-level or individual human health questions
  - Require extrapolations that might not be valid
- Can be used to formulate hypotheses re: human effects
THR: Human evidence

- Comparisons of health effects among groups of users
  - Observational epidemiological studies
  - Forced switching studies
- All generally show reduced risk
- Methodological, interpretational limitations
- PREPs have not been available long enough, widely enough to study
Rationale for THR models

- Long term epidemiological studies ideal, but not expedient
- Existing data inadequate to answer critical questions
- Modeled effects can be compared to results of epidemiological studies when data become available
- Models support decision-making in the short run
What is a model?

“a simplified representation of a system or phenomenon, as in the sciences or economics, with any hypotheses required to describe the system or explain the phenomenon, often mathematically”

(Dictionary.com Unabridged (v 1.1), Based on the Random House Unabridged Dictionary, © Random House, Inc. 2006.)
Examples of THR models

- Schematic:

- Mathematical:

\[ i_{d,\text{base}}(\alpha) = \frac{i_{d,0}(\alpha)}{\sum_c RR_d(c, \alpha)n_{c,0}(\alpha)} \]

Hoogenveen et al. 2008; Cost Effect Resource Alloc 6(1). http://www.resource-allocation.com/content/6/1/1
THR models require data

- Description of target population ✓
- Specification of products to be assessed ✓
- Specification of outcome – individual disease(s), life expectancy, healthy life expectancy, etc. ✓
- Exposure prevalence, each product
- Rates of uptake, quitting, switching, re-uptake
- Relative risk or risk difference
- Rate of risk change over time
3. Barriers and opportunities afforded by modeling
Barriers to developing THR models

- Models, by definition, are simplistic
  - Populations, risks, tobacco use states are dynamic
  - Diseases have multiple causes
  - "Health" hard to define

- Need reasonable estimates, assumptions
  - Exposure prevalence, each product
  - Rates of uptake, quitting, switching, recidivism
  - Relative risk or risk difference
  - Rate of risk change over time after changing habit

- Challenging (social) climate
Opportunities offered by THR models

- High level of scrutiny may increase rigor, quality of work
- Specification of underlying assumptions should promote healthy discussion, critical evaluation
- Modeled results can be validated against other modeling approaches, observational data
- Models can be revised as new data become available
- Pragmatic approach to evaluating products that might reduce harm to consumers
- Promotes rational, evidence-based decision-making
Evidence-based decisions entail:

“...conscientious, explicit and judicious use of current best evidence...”

(David Sackett)
Opportunities offered by THR research

- Various sectors join to generate, share and critically evaluate data
- Open the discussion
- Promote rational decision making by all sectors
  - Consumers
  - Producers
  - Policy makers
4. Summary, questions/discussion
Although there are significant scientific, social barriers,

- Individual and group-level decisions have to be made
- The process should be transparent, logical
- Existing data are inadequate support decisions
- Observational studies must be done, but may take decades
- Models can support decision making in the short run, can be modified with new data, refined assumptions
Discussion/questions?