Pharm 532 Methods of Pharmaceutical Policy Analysis

Policy Cycle

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Outline

- basic policy analysis cycle
  - verifying, defining and detailing the problem
  - establishing evaluation criteria
  - identifying stakeholder perspectives
  - identifying alternatives
  - evaluating alternatives
  - display and distinguish among alternative policies
  - monitor implemented policy

A Basic Policy Analysis Process

Policy Analysis Cycle

<table>
<thead>
<tr>
<th>Bardach Eightfold Path</th>
<th>Patton &amp; Sawicki</th>
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</thead>
<tbody>
<tr>
<td>define the problem</td>
<td>verify, define and detail problem</td>
</tr>
<tr>
<td>assemble some evidence</td>
<td>establish evaluation criteria</td>
</tr>
<tr>
<td>construct the alternatives</td>
<td>identify alternative policies</td>
</tr>
<tr>
<td>select the criteria</td>
<td>evaluate alternative policies</td>
</tr>
<tr>
<td>project the outcomes</td>
<td>display &amp; distinguish among alternatives</td>
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<tr>
<td>confront the tradeoffs</td>
<td>monitor and evaluate implemented policy</td>
</tr>
<tr>
<td>decide</td>
<td>tell your story</td>
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</table>
Problem Definition

- describe the problem
- delineate the boundaries of the problem
- develop a fact base
- describe goals and objectives for resolving the problem; metrics
- identify the policy envelope
- costs and benefits of resolving the problem

Evaluation Criteria

- free market model
  - costs & benefits
    - standing
    - externalities
    - elasticity
    - marginal analysis
    - equity

Evaluation Criteria 2 ...

- technical feasibility
- economic and financial possibility
- political viability
- administrative operability

Evaluation Criteria 2a

- technical feasibility
- economic and financial possibility
- political viability
- administrative operability
technical feasibility

- A criterion for evaluating alternatives; measures whether the alternative actually produces the desired result -- meeting the major objectives.
  - To what degree does the proposed action accomplish the objectives set forth?
  - Can changes in the real world be traced back to the program, or they are the result of other factors (sometimes called “secular trends”)?
  - Is the impact direct (it addresses the stated objective) or indirect (creates an impact not associated with the program)?
  - Will change (if any) be short term (for 1-2 years) or long term (>2 years)? [discount rate]

Evaluation Criteria 2b

- technical feasibility
- economic and financial possibility

Measures the cost of the alternative(s) and the benefits it (they) will produce

Evaluation Criteria 2c

- technical feasibility
- economic and financial possibility
- political viability
- administrative operability

political viability

- Measures whether the alternative is acceptable or can be made acceptable to relevant groups.
  - Proposed policy changes must survive the political test: if a policy will not be supported by decision makers, officials or voters, it has little chance of being adopted or implemented.
  - What alternatives are available?
  - What will be acceptable to various groups?
  - What concessions will have to be made to gain support for each option?
  - Do you have trade-offs in order to secure agreement on an alternative?
Evaluation Criteria 2d

- technical feasibility
- economic and financial possibility
- political viability
- administrative operability

administrative operability

- Measures how possible the alternative will be to implement.
  - Is the existing administrative system (e.g., the FDA or Department of Health and Human Services) capable of delivering the policy or program?
    - How much control does the administrative system have?
    - What other groups/individuals must be relied upon.
    - Are you aware of administrative bottlenecks in the existing system?
    - Are there organizational limitations?
    - Specifically, will the administrative system have the authority to implement the policy? That is, have you crafted the statutes/regulations correctly?
    - Is there institutional commitment? That is, is the administrative system willing to back your program?
    - Does the existing (or proposed) administrative system have the capability to implement you program?

Identifying Alternatives

- researched analysis & experimentation
- no-action analysis
- quick surveys
- literature review
- comparison of real-world experiences
- passive collection and classification
- development of typologies
- brainstorming
- comparison with ideal

Evaluating Alternatives; Projecting the Outcomes

- Forecasting
  - extrapolation
  - modeling
  - intuitive forecasting
- Evaluation methods
  - discounting
  - efficiency
    - net present value
    - benefit-cost ratio
    - internal rate of return
  - sensitivity analysis
  - allocation formulae
Project the Outcomes - 2

- Is <gloss> modeling possible?
  - magnitude estimates?
- worst case / best case for sensitivity analysis
  - minimum acceptable performance given costs
  - likelihood estimates
  - collateral consequences of success / failure

Selecting Among Alternatives

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
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<tbody>
<tr>
<td>Alternatives</td>
</tr>
<tr>
<td>Do nothing</td>
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</tbody>
</table>

Stakeholders

Groups, individuals, and businesses, etc. – folks that will be impacted by your proposal

- who will support or oppose your proposal?
- how you will assess the degree of political influence of each stakeholder group?
- how you will assess the position of the stakeholders?

Monitoring

- Ex-ante policy analysis
- policy maintenance
- policy monitoring
- ex-post policy evaluation
Monitoring 2

- Before-after comparisons
- with / without comparisons
- actual / planned performance
- experimental (controlled) models
- quasi-experimental models
- cost-oriented approaches

Monitoring 3

Soumerai SB et al.
A critical analysis of studies of state drug reimbursement policies: research in need of discipline
_The Milbank Quarterly_ 1993;71(2):217

Monitoring 4

- Strength of research design
  - randomized controlled trial ("experimental")
  - quasi-experimental
    - well-controlled (time series with comparison group)
    - partially-controlled
      - time series without comparison
      - pre-post without comparison
      - post only (cross-sectional)
    - inadequately controlled

Menu

- Measurement issues
- Stakeholders
- Alternatives
- Assessment of Best Alternative(s)

Measurement Issues

- Administrative data (& Faust)
- Hypotheses: … didn’t hurt anyone
  - Cost saving (silo)
  - Cost saving (overall)
  - Non-cost Outcomes
  - Unintended consequences

Measurement Issues 2

- Observational vs. experimental studies
  - What makes for “experimental” studies?
  - Policy analysis and experiments
    - Informed consent
    - Law
    - Ethics
    - Why/why not studies to inform formulary decisions
      - Selective introduction

Measurement Issues 3

- “sufficient data” before and after intervention
- No co-interventions
**Measurement Issues 4**

- "Policy" vs. "clinical" models

Different names for similar concepts in quasi-experimental drug policy research and randomized efficacy research.

<table>
<thead>
<tr>
<th>Quasi-experimental drug policy analysis</th>
<th>Randomized clinical trials</th>
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<tr>
<td>Policy model</td>
<td>Intention-to-treat-Analysis</td>
</tr>
<tr>
<td>Time trends after policy start vs. trends before the policy</td>
<td>Drug A vs. drug B as assigned by the randomization procedure</td>
</tr>
<tr>
<td>Clinical model</td>
<td>As-treated-Analysis</td>
</tr>
<tr>
<td>Time trends after actual switching vs. trends in non-switchers</td>
<td>Drug A vs. drug B according to actual treatment</td>
</tr>
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</table>

Schneeweiss et al Health Policy 2001:55;97

**Measurement Issues 5**

- Biases
  - Policy Model
    - Net effect
    - Misbehavior → underestimation when non-compliance [sic., non-adherence] is high
      - Necessary to separate high and low adherence
  - Clinical Model
    - Selection bias
    - Survivor cohort
    - Reverse causation

Schneeweiss et al., policy model

DCS = differential cost sharing
Stakeholders -- Analysis

The benefits of using a stakeholder-based approach are that:

- You can use the opinions of the most powerful stakeholders to shape your projects at an early stage.
- Gaining support from powerful stakeholders can help you to win more resources.
- By communicating with stakeholders early and frequently, you can ensure that they fully understand what you are doing and understand the benefits of your policy.
- You can anticipate what people's reaction to your project may be, and build into your plan the actions that will win people's support.

Adapted from http://www.mindtools.com/pages/article/newPPM_07.htm

Identifying Your Stakeholders

<table>
<thead>
<tr>
<th>Your boss</th>
<th>Shareholders</th>
<th>Government</th>
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<tbody>
<tr>
<td>Senior executives</td>
<td>Alliance partners</td>
<td>Trades associations</td>
</tr>
<tr>
<td>Your coworkers</td>
<td>Suppliers</td>
<td>The press</td>
</tr>
<tr>
<td>Your team</td>
<td>Lenders</td>
<td>Interest groups</td>
</tr>
<tr>
<td>Customers</td>
<td>Analysts</td>
<td>The public</td>
</tr>
<tr>
<td>Prospective customers</td>
<td>Future recruits</td>
<td></td>
</tr>
<tr>
<td>Your family</td>
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Prioritize Your Stakeholders

- **High power, interested people**: these are the people you must fully engage and make the greatest efforts to satisfy.
- **High power, less interested people**: put enough work in with these people to keep them satisfied, but not so much that they become bored with your message.
- **Low power, interested people**: keep these people adequately informed, and talk to them to ensure that no major issues are arising. These people can often be very helpful with the detail of your project.
- **Low power, less interested people**: again, monitor these people, but do not bore them with excessive communication.

Understanding your key stakeholders

- What financial or emotional interest do they have in the outcome of your work?
- What motivates them most of all?
- What information do they want from you?
- What is their current opinion of your proposed policy? Is it based on good information?
- Who influences their opinions generally? Do some of these influencers therefore become important stakeholders in their own right?
- If they are not likely to be positive, what will win them around to support your project?
- If you don't think you will be able to win them around, how will you manage their opposition?
- Who else might be influenced by their opinions? Do these people become stakeholders in their own right?
Alternatives

- ... there's always “do nothing”*
  - Consider projecting the “do nothing” alternative into the future as a basis for comparison

- Basics vs. variants
  - Regulatory, subsidy, tax (dis-)incentive

- Funding if someone has to do something

*recall Bardach's admonition

Alternatives 2

- Alternatives are not necessarily mutually exclusive
  - May facilitate or mitigate some problem with basic policy
  - ... “with 3 you get egg roll”