Pharm 532 Methods of Pharmaceutical Policy Analysis

Policy Cycle

Tom Hazlet, Pharm.D., Dr.P.H.
Pharmaceutical Outcomes Research & Policy Program
Department of Pharmacy
*thazlet@u.washington.edu* 206.616.2732

1

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

2

A Basic Policy Analysis Process
from Patton & Sawicki Basic Methods of Policy Analysis and Planning, 2nd Edition,1993
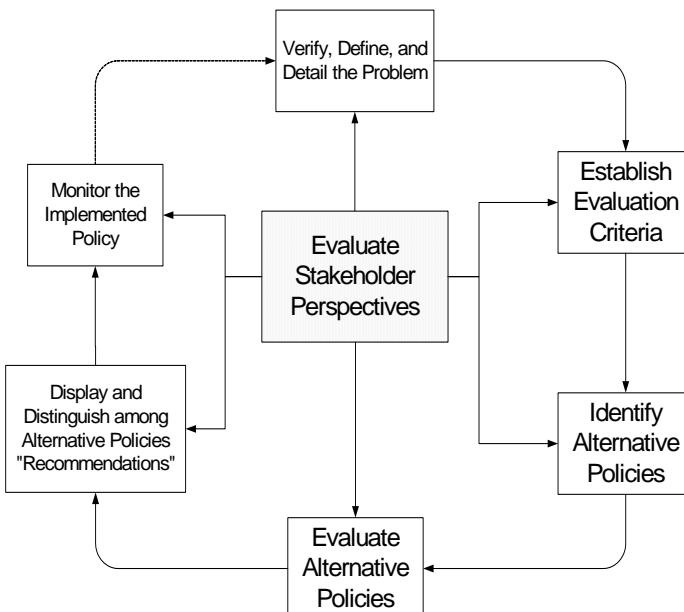
3

Policy Analysis Cycle

Bardach Eightfold Path	Patton & Sawacki
define the problem	verify, define and detail problem
assemble some evidence	establish evaluation criteria
construct the alternatives	identify alternative policies
select the criteria	evaluate alternative policies
project the outcomes	display & distinguish among alternatives
confront the tradeoffs	monitor and evaluate implemented policy
decide	
tell your story	

4

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

5

Evaluation Criteria

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

6

Evaluation Criteria 2 …

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

7

Evaluation Criteria 2a

- t
- e
- p
- a

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]

8

Evaluation Criteria 2b

● technical feasibility

● economic and financial possibility

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

9

Evaluation Criteria 2c

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?

10

Evaluation Criteria 2d

● tech

● eco

● polit

● adm

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

12

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 <gross> 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

		Evaluation Criteria			
Alternatives					
	Do nothing				

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

17

Monitoring 2

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

18

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

19

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

Cook TC and Campbell DT. Quasi-Experimentation: Design and Analysis Issues for Field Settings. Houghton-Mifflin, Boston, 1979.

20

Analysis Cycle Round 2

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

25
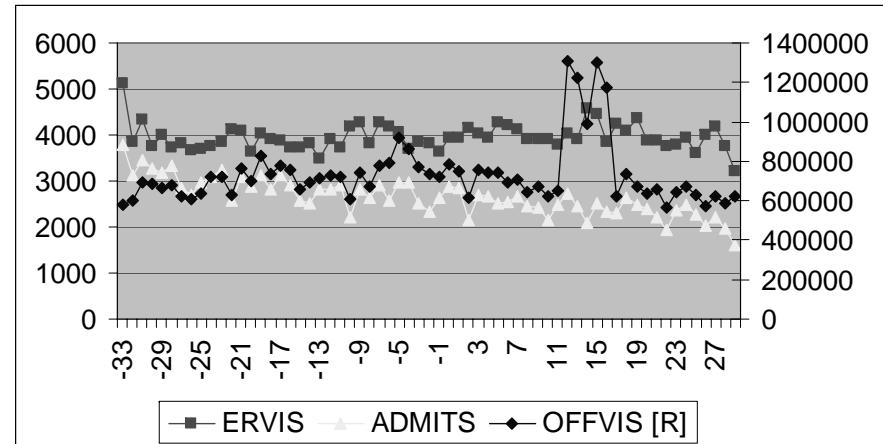
26

Measurement Issues 4

- ● "Policy" vs. "clinical" models

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

Quasi-experimental drug policy analysis		Randomized clinical trials	
Model	Analytic comparison	Model	Analytic comparison
Policy model	Time trends after policy start vs. trends before the policy	Intention-to-treat-Analysis	Drug A vs. drug B as assigned by the randomization procedure
Clinical model	Time trends after actual switching vs. trends in non-switchers	As-treated-Analysis	Drug A vs. drug B according to actual treatment

Schneeweiss et al Health Policy 2001:55;97

27

Measurement Issues 5

- ● Biases
  - ○ Policy Model
    - ● Net effect
    - ● Misbehavior → underestimation
  - ○ Clinical Model
    - ● Selection bias
    - ● Survivor cohort
    - ● Reverse causation

28

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

Your boss	Shareholders	Government
Senior executives	Alliance partners	Trades associations
Your coworkers	Suppliers	The press
Your team	Lenders	Interest groups
Customers	Analysts	The public
Prospective customers	Future recruits	The community
Your family		

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.

Keep Satisfied	Manage Closely
Monitor (Minimum Effort)	Keep Infomred
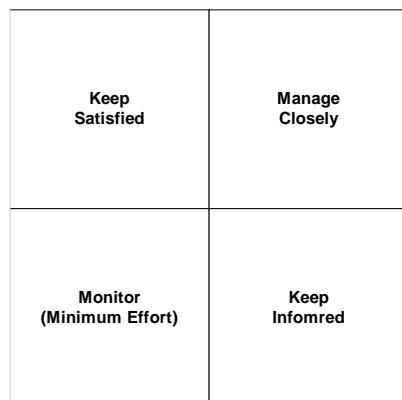
Understanding your key stakeholders

- 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

33

Alternatives 2

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

34

Questions

35