Comparative Effectiveness:
New Initiatives from AHRQ

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Spotted at the Comedy Central rally in DC:

Changes in the era of health care reform

Payment system reform

Medical homes

Accountable care organizations

Many other new changes

Comparative effectiveness

Comparative effectiveness

What comparative effectiveness is:

What comparative effectiveness is not:

Comparative effectiveness

What comparative effectiveness is:

- Head-to-head evaluation of real therapeutic choices
- Aimed at providing clinically relevant data

What comparative effectiveness is not:

- Cost-effectiveness analysis
- Aimed at denying care to patients

What does the new emphasis on comparative effectiveness mean?

Increased role for AHRQ

More research to generate clinical CE data

- DEcIDE network, other efforts

New areas of emphasis for CE

- Translating CE into clinical practice
- Expanding CE beyond traditional clinical studies

Tools for improving medication use

Changing prescribing habits/patterns

Creating incentives through payment policy

Tools for improving medication use

Changing prescribing habits/patterns

- Academic detailing

Creating incentives through payment policy

- Prior authorization and other reimbursement policy tools

Key questions for an intervention or policy

Is it effective?

Is it cost-effective?

Can it be implemented sustainably?

A tale of two approaches

- Academic detailing
  - Evidence of effectiveness and cost-effectiveness
  - Limited implementation
- Prior authorization/payment policy
  - Widespread implementation
  - Limited evidence of effectiveness or cost-effectiveness

Turning comparative effectiveness into practice

New AHRQ program:

Innovative Adaptation and Dissemination of AHRQ Comparative Effectiveness Research Products

iADAPT

iADAPT background

AHRQ supported comparative effectiveness

Original research

Evidence summaries

Clinician guides, patient education materials

BUT:

Not having an impact on health care system or medical practice

Goals of iADAPT

Stimulate the development of approaches to increase the use and application of comparative effectiveness findings

- identify the right settings and stakeholders
- explore different methods of adaptation
- disseminate evidence to improve care
- evaluate the interventions implemented

iADAPT-funded projects

Informatics interventions

Adaptation of consumer guides

Interventions in nursing home settings

Outreach to vulnerable populations

Our project: Academic detailing

A National Academic Detailing Resource to Adapt and Disseminate CER Findings (NaRCAD)

What is academic detailing?

What will be provided by this new national resource?

Academic detailing

- Pharmaco-epistemology
  - How do we know what we know about drugs?
- Educating physicians
  - Understanding effective learning
- Academic detailing
  - History and research
  - Current programs
  - NaRCAD

The problem

Limited data when drugs first approved

- with limited relevance to many patients

Physician data overload

- hundreds of important drug-related papers published each month

Imbalanced information

Need for non-product-driven overviews

- delivered in a clinically relevant, user-friendly way

Clinical trials

Usually don't provide head-to-head comparative data about relevant Rx choices

A drug that achieved a surrogate outcome may not produce expected clinical benefit

e.g., Avandia (rosiglitazone) and M.I.

Unanticipated adverse effects are likely

e.g., Vioxx (rofecoxib)

Use differs in trials vs. actual practice

Efficacy vs. effectiveness

Information overload

- Dozens of biomedical journals
- Physician time constraints
- Systematic overviews
  - cover selected fields, but…
  - are lengthy, abstruse hard to wade through
  - may not be recently updated
- Some important findings not in journals
  - FDA alerts, 'Dear Doctor' letters
  - important trial data presented at clinical meetings
  - unpublished results

Information imbalance

- Trial design, promotion, CME favor use of new, costly drugs
- Needed head-to-head comparative studies often not performed
- Most drug information comes from industry
  - $30 billion per year on promotion
  - 2/3rds of continuing medical education is industry-funded

    NB: this is in the process of changing

Industry-generated information

- A dominant source of drug information
  - often ***only*** available source for new products
- Main purpose is to increase sales, so promotes positives not negatives
- Selective about which comparisons are presented

- Clinical trial: Drug A vs. Drug B for reducing blood sugar levels in diabetes
- After 6 months of therapy, Drug A was better than Drug B
- After 12-48 months, no difference between the 2 drugs
- What was the message delivered to doctors by the industry?

- After 6 months of therapy, Drug A was significantly better than Drug B

Does promotion work?

- Yes!
- Clear evidence that sales reps and samples change prescribing
- Social science literature shows the persuasive effects of relationships, gifts
  - symbolic power of even small gifts
  - reciprocal obligation
- Marketing promotes costliest products

The rationale for academic detailing

- FDA has limited data when drugs are first approved
  - with limited relevance to many patients
- physician data overload
  - hundreds of important drug-related papers are published each month
- imbalanced communication
  - manufacturers provide much of the information
- the need for non-product-driven overviews
  - delivered in a relevant, user-friendly way

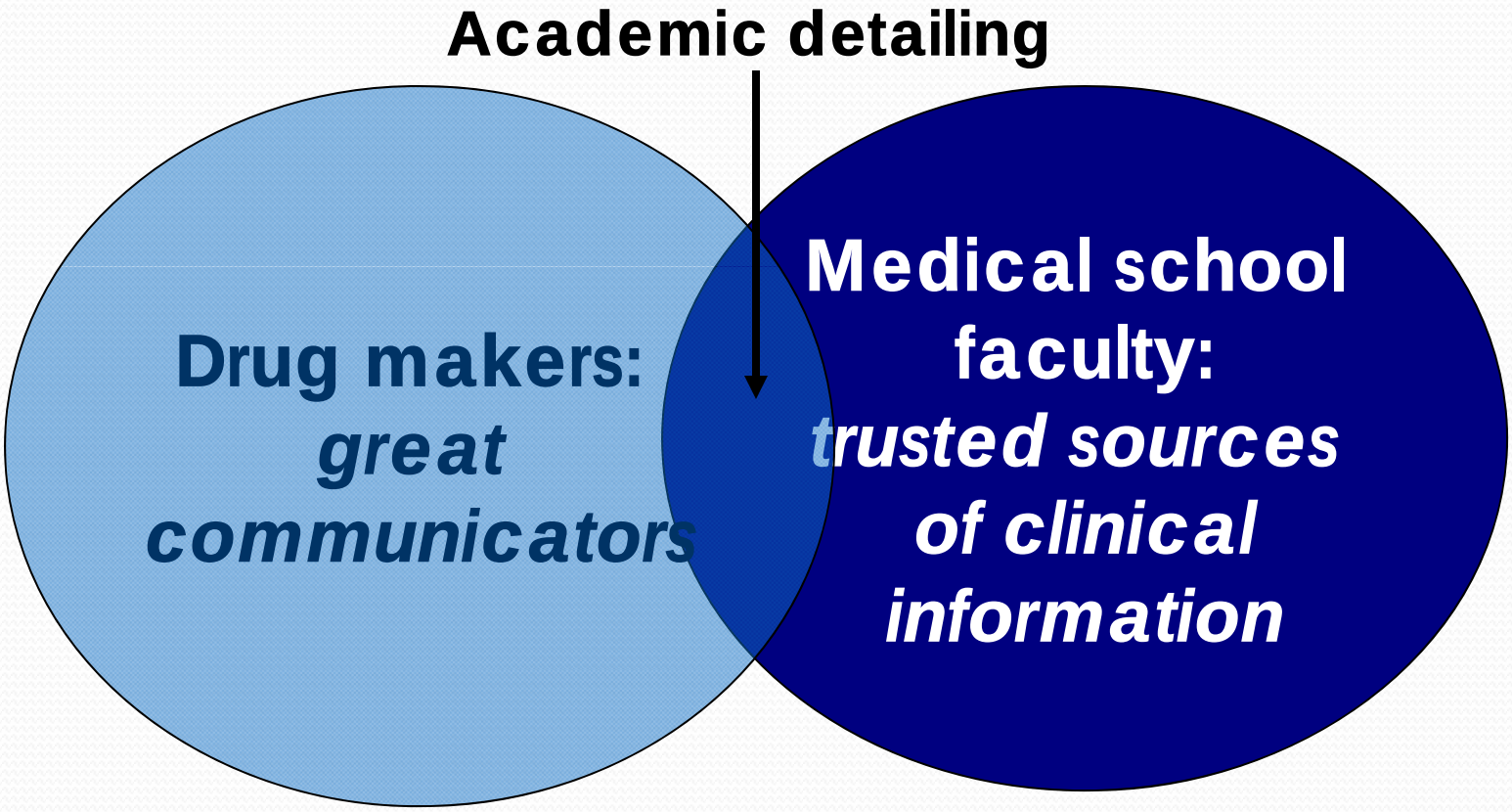
The goal of academic detailing

to close the gap
between the best available evidence
and actual prescribing practice,
so that each prescription is based
only on the most current and accurate
evidence about efficacy, safety,
and cost-effectiveness.

Two different worlds

- **Academia:**
  - MD comes to us
  - Didactic
  - Content ornate, not clinically relevant
  - Visually boring
  - No idea of MD's perspective
  - Evaluation: minimal
  - Goal: ????
- **Drug industry:**
  - Go to MD
  - Interactive
  - Content is simple, straightforward, relevant
  - Excellent graphics
  - MD-specific data informs discussion
  - Outcome evaluated, drives salary
  - Goal: behavior change

The rationale for academic detailing



Academic detailing

- Synthesizes up-to-date evidence about ***comparative*** efficacy, safety, and cost-effectiveness of commonly used drugs
- Content independently created by independent clinical experts and practitioners
- Academic detailers provide information interactively, in physicians' own offices
- A time-efficient way to keep up with new findings

The content of academic detailing

- Well trained clinicians (pharm, RN, MD) visit prescribers in their offices and offer a **service** that provides **independent, unbiased, non-commercial, non-product-driven, evidence-based** information about the **comparative** benefit, safety, and cost-effectiveness of drugs used for common clinical problems.

The method of academic detailing

- Information is provided **interactively**
  - generally in the doctor's **own office**
- This enables the educator to
  - **understand** where the MD is coming from in terms of knowledge, attitudes, behavior
  - **modify** the presentation appropriately
  - keep the prescriber **engaged**
- The visit ends with specific practice-change recommendations.
- Over time, the relationship becomes more trusted and useful.

What academic detailing **is not**

- memos or brochures provided through the mail
- lectures delivered in the doctor's office
- about policing
- primarily about cost reduction
- "counter-detailing"
  - effective drugs should be used
  - effective drugs will be cost effective

The history of academic detailing

- Developed in early 1980's
  - "un-ads" for physicians with clinical background and specific prescribing recommendations
  - patient educational materials
- Effective from the start
  - 92% MD acceptance rate from 'cold calls' to physicians
  - Significant 14% reduction in inappropriate prescribing

    Avorn & Soumerai, NEJM 1983

Current status of the evidence

- A mass of AD literature has developed in last 25 years
- A large systematic review in 2007 combined 69 studies and confirmed efficacy of AD
  - O'Brien MA, Rogers S, et al. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane, Database of Systematic Reviews 2007, Issue 4
- Effectiveness varies with quality of execution
  - like brain surgery

Is it cost-effective?

- Economic analysis of the original 1983 research which coined the term 'academic detailing' found that for each $1 spent on their academic detailing program $2 was saved in Medicaid drug expenditures.[1]
- When evaluating global primary care clinical practice changes in a large British study of academic detailing, cost effectiveness was still demonstrated even where only modest overall effect sizes were observed.[2]
- Independent economic study of an Australian DATIS service-oriented academic detailing program showed that between $5 and $6.50 of direct health expenditure was saved for each $1 spent delivering the program.[3]

1. Soumerai SB, Avorn J. Economic and policy analysis of university-based drug "detailing". Med Care 1986;24(4):313-31.

2. Mason J, Freemantle N, Nazareth I, Eccles M, Haines A, Drummond M. When is it cost-effective to change the behavior of health professionals? JAMA 2001;286(23):2988-92.

3. Coopers & Lybrand Consultants. Drug and Therapeutics Information Service - Update of the economic evaluation of the NSAID project. In: May FW, Rowett D, eds. *DATIS progress report to the Department of Health and Family Services October to March 1995-96. Canberra: Australian Commonwealth Department of Health and Family Services 1996.* .

Program objectives

- Optimize therapy for patients
  - Safety, efficacy, and cost of therapeutic options
- Provide evidence-based resources
- Facilitate good therapeutic decision-making by physicians
- Establish a viable, sustainable educational model
- Lower costs by providing better medicine
- Provide a ***service*** to prescribers

- *Emphasis on quality of care, not just cost*

Existing programs

- Multiple states
  - PA, DC, MA
    - Independent Drug Information Service (iDiS)
  - ME, SC, VT, others
- Different funding models
  - CDC chronic disease prevention funds
  - User fee on private sector detailers
  - Lottery funds

Establishing a program

- Needs assessment
  - Patient populations affected
  - Clinicians for likely outreach
  - Clarity about goals of program
    - What academic detailing is and is not
- Establish a source of funding
- Develop a management structure
- Identify clinical areas to be targeted

Developing the intervention

- Training personnel
  - Social marketing techniques
  - Specific topic content
- Developing materials
  - Must be based on solid clinical evidence
  - Literature summaries
  - Un-advertisements
  - Patient-directed materials

Getting in the field

- Access clinicians
  - Harder than it seems
  - Problem of “no detailers” policies
- Being part of a larger effort can help
  - Massachusetts: collaboration with CDC

Assess program effects

- Are we meeting the prescriber's needs?
- Qualitative
  - Experiences of providers
  - Process measures of success getting into offices
- Quantitative: think carefully about metrics
  - Often suggest less medications, or less costly medications

  But sometimes:
  - Suggest more medications or increased awareness, testing, treatment

NaRCAD: 5 components

- Establish a network of interested programs
- Provide training in the techniques and content of AD
- Adapt CE materials into effective AD tools
- Evaluate outcomes of AD programs
- Communicate findings and lessons to promote improved AD practice over time

Establish a network of interested programs

- Identify organizations that could benefit from AD
  - Medicaid programs
  - State coverage programs
  - Community health organizations
  - Private insurers
- Provide input and advice on establishing programs
  - Funding sources, establishing collaborations
  - Identifying clinicians
  - Understanding goals of program

Provide training in the techniques and content of academic detailing

- Host multiple training sessions
  - Education in principles of social marketing and persuasive communication
  - Role play with clinicians to master techniques
- Cost of developing sessions covered by AHRQ
  - Will be offered 4-6 times in next 3 years
  - Can train new or existing detailers
  - Also relevant for pharmacists, managers

Adapt comparative effectiveness materials into effective academic detailing tools

- Rigorous clinical content is the baseline
- Develop materials for doctors and patients
  - Concise
  - Visually engaging
  - Designed for detailers to use
- Examples: **www.rxfacts.org**

Evaluate outcomes of academic detailing programs

- Qualitative evaluation of implementation processes
- Surveys and interviews with detailers and physicians
- Quantitative evaluation of prescribing patterns
- Repeated evaluations over time

Communicate findings and lessons

- Build on the network of programs
- Foster discussion of different approaches
- Provide feedback on what works
- Develop new innovations and elements for improved academic detailing

The future of academic detailing: NaRCAD

- Opportunities to establish new AD programs
  - subsidized by iADAPT support for NaRCAD:
    - establishing programs
    - developing materials
    - training detailers
    - evaluating outcomes
    - network collaboration to improve quality and identify best practices

Remember the evidence: Effectiveness depends on implementing high-quality academic detailing

Changing gears

So far: Efforts to translate existing comparative effectiveness findings into practice

Next: Comparative effectiveness studies in different settings

Expanding comparative effectiveness beyond traditional clinical studies

- Comparative effectiveness of delivery systems
  - Public and private sector try new ways to deliver care
  - Many ideas theoretical, or with limited impact
  - Need for rigorous evaluation of which approaches are most effective
    - Both evaluation and demonstration projects

Comparative effectiveness delivery system grants (AHRQ)

Comprehensive care for mentally ill adults

Primary care practice transformation

Coordinated care programs

Medical home in pediatric practice

Physician quality reporting and patient outcomes

Impact of Medicaid policy on cardiovascular drug use and outcomes

Medicaid policy for cardiovascular drugs

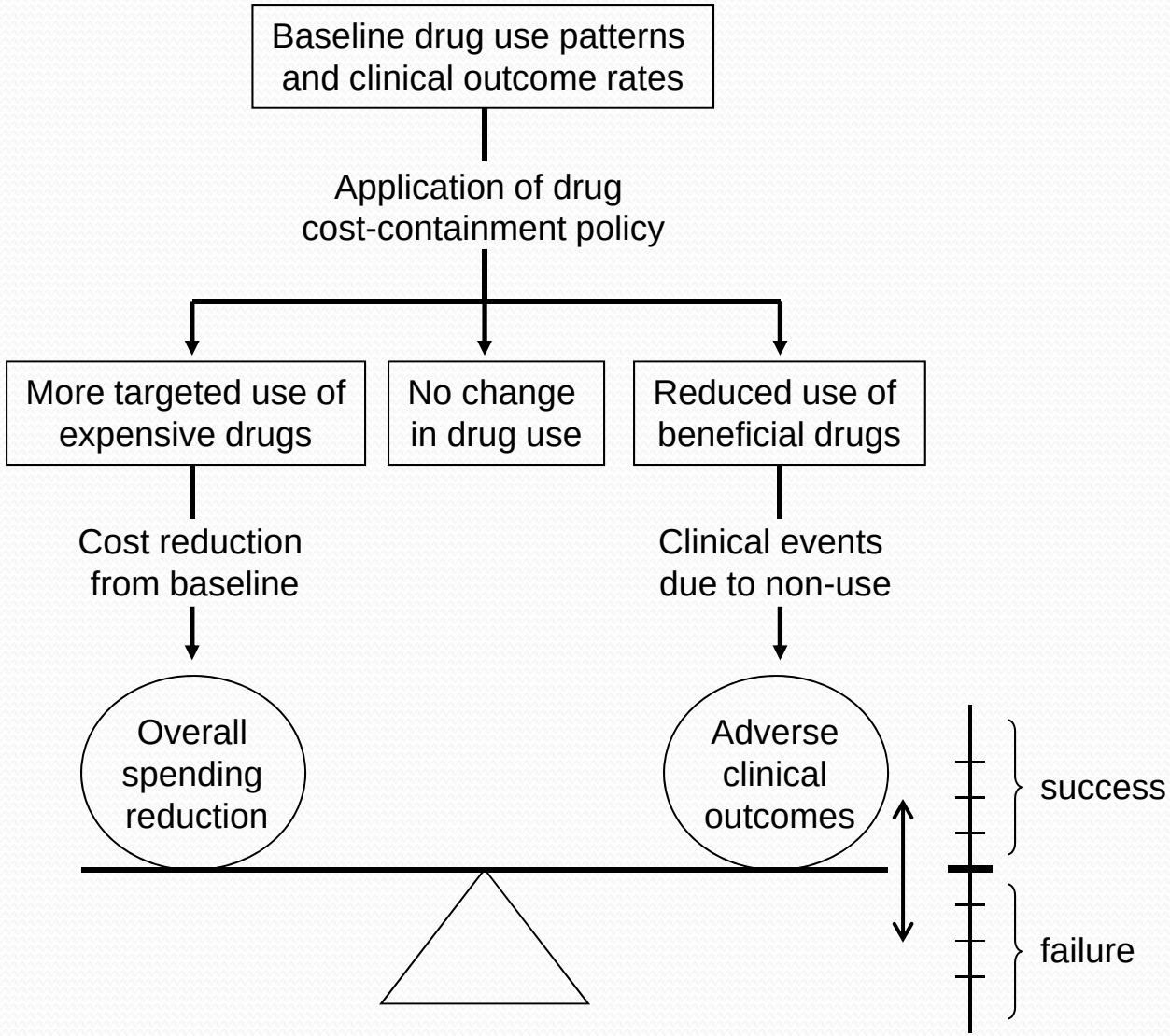
Conceptual overview

Brief review of prior studies

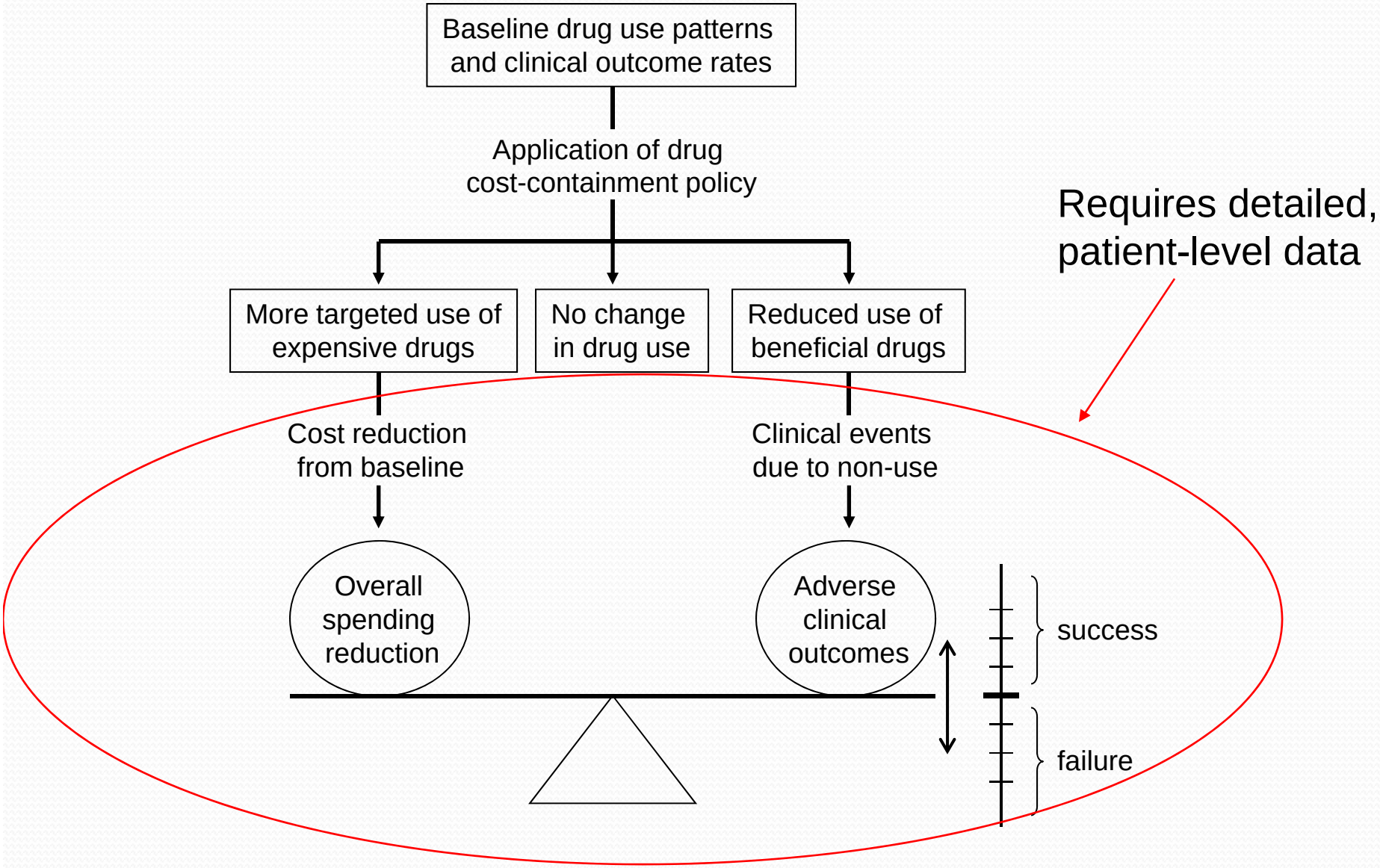
New research plan

Input from Medicaid stakeholders

The policy-maker's challenge



The policy-maker's challenge



Prior studies of Medicaid policy

Focused on prior authorization

Gathered data on policies from Medicaid programs and websites

Two case studies:

- Coxibs/NSAIDs
- ARBs/ACE-Is

Data analysis

CMS drug use data

Prescriptions and units dispensed and dollars paid by Medicaid for all medications, by calendar quarter, aggregated by state

Units converted to defined daily doses (DDDs) for coxibs and ACE/ARBs

Main outcome measures:

- DDD
- Spending

Models of policy impact

- Interrupted time-series analysis
  - Evaluate level of drug use and spending before/after prior authorization implementation
  - States with no program serve as controls
  - Two types of effects, controlling for secular trends:
    - Level effect: Immediate change in outcome
    - Slope effect: Change in trend over time

Coxibs: the clinical scenario

Compared to non-selective NSAIDs

- Similar efficacy
- Much more expensive
- Clinical benefit for properly selected patients
  - well defined risk factors

Widely variable use across states

Goal for policymakers

- Target coxibs to high-risk patients
- Avoid overuse in others

Prior authorization programs

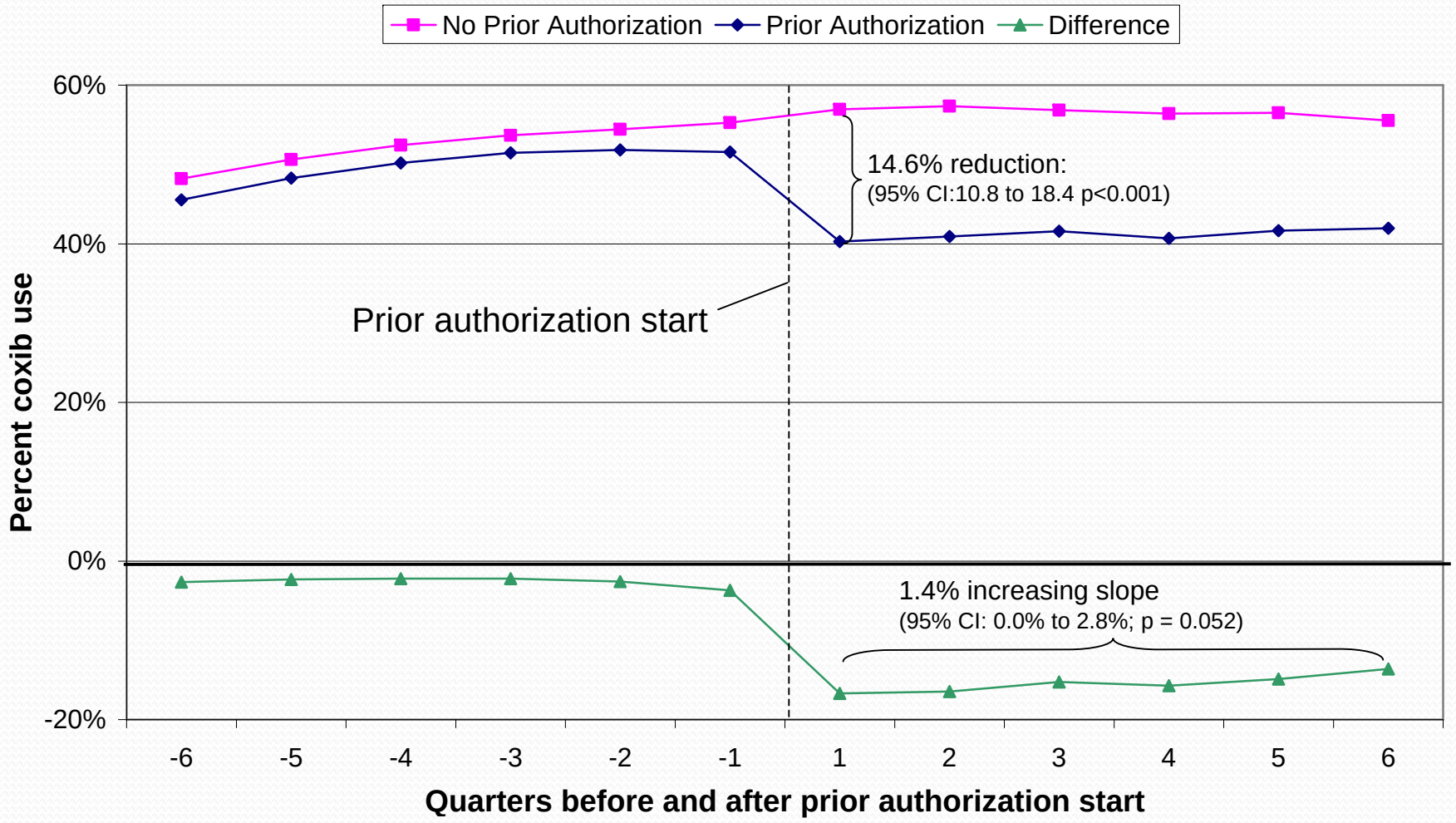
8 states implemented immediately

22 states implemented between 2000 and early 2003

20 states provided control data

- 6 states with programs scheduled to begin after study period

Proportion of NSAID defined daily doses accounted for by coxibs before and after implementation of a prior authorization program



Fischer et al, *NEJM*, 2004

Coxib prior auth - summary

36 states had prior authorization programs for coxibs at end of study

Implementation of program associated with one-time decrease in coxib use of 14.6%, slow increase subsequently

No difference in impact by adherence to clinical evidence

Renin-angiotension axis blockers: ACE –I vs. ARB

Important component of HTN therapy

Both classes effective at blocking RAA

ACE-I can cause cough or angioedema

- Rate of ACE-I intolerance ~10% (5%-20%)

ARBs much more expensive than ACE-I

- ACE-I: Many generics, $8-$15 per month
- ARB: All brand-name, $46-$58 per month

ARB prior authorization: key variables

Prior trials of ACE inhibitors

Preferred drug lists (PDL)

- Preferred drugs in class can be prescribed without prior authorization
- Other drugs in the class require prior authorization

Prior authorization programs

19 states with prior authorization for ARBs implemented and 3+ quarters of post-intervention data

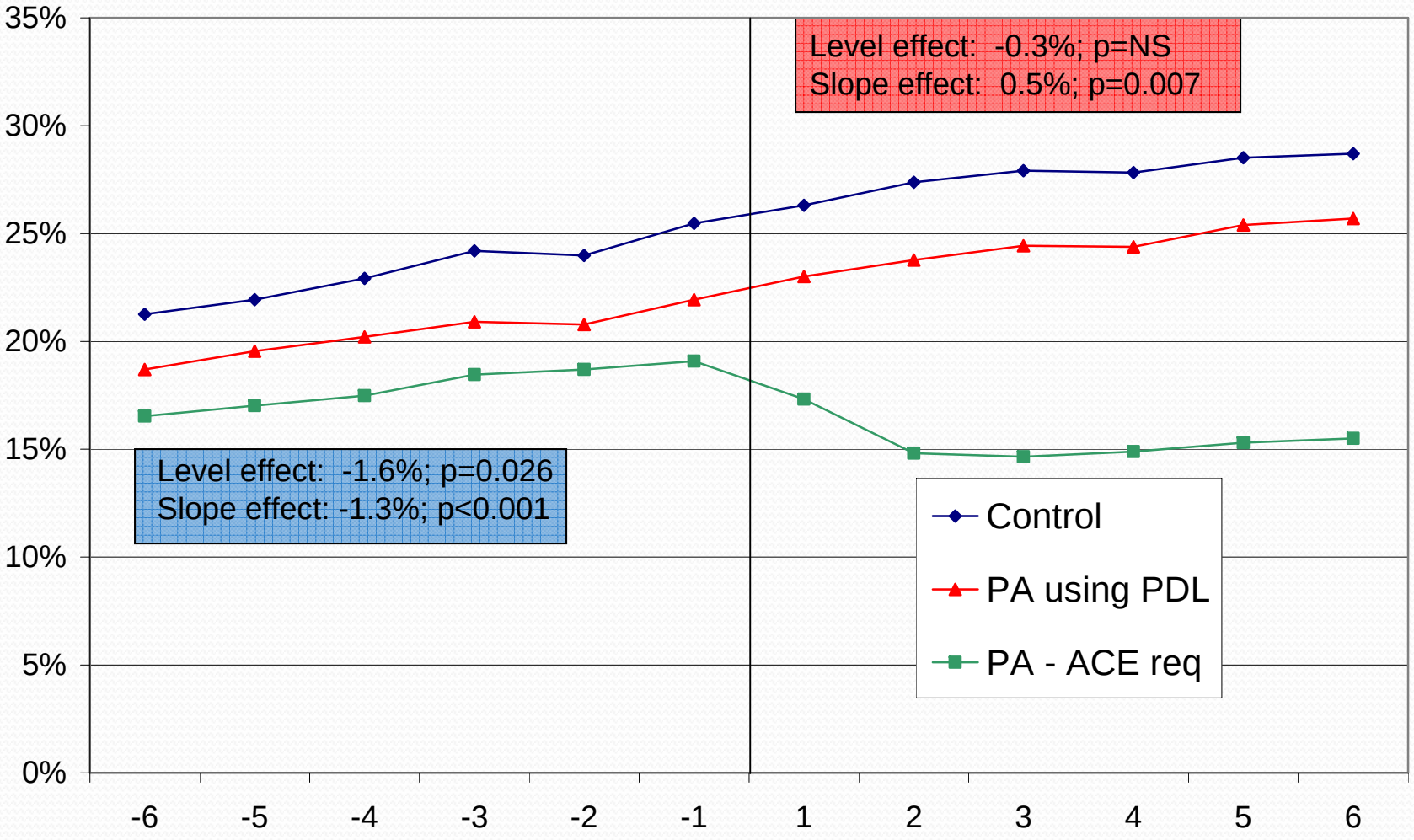
- 15 using PDL only
- 4 with requirement for ACE-I trial

18 states with no prior authorization for ARBs

- Control states

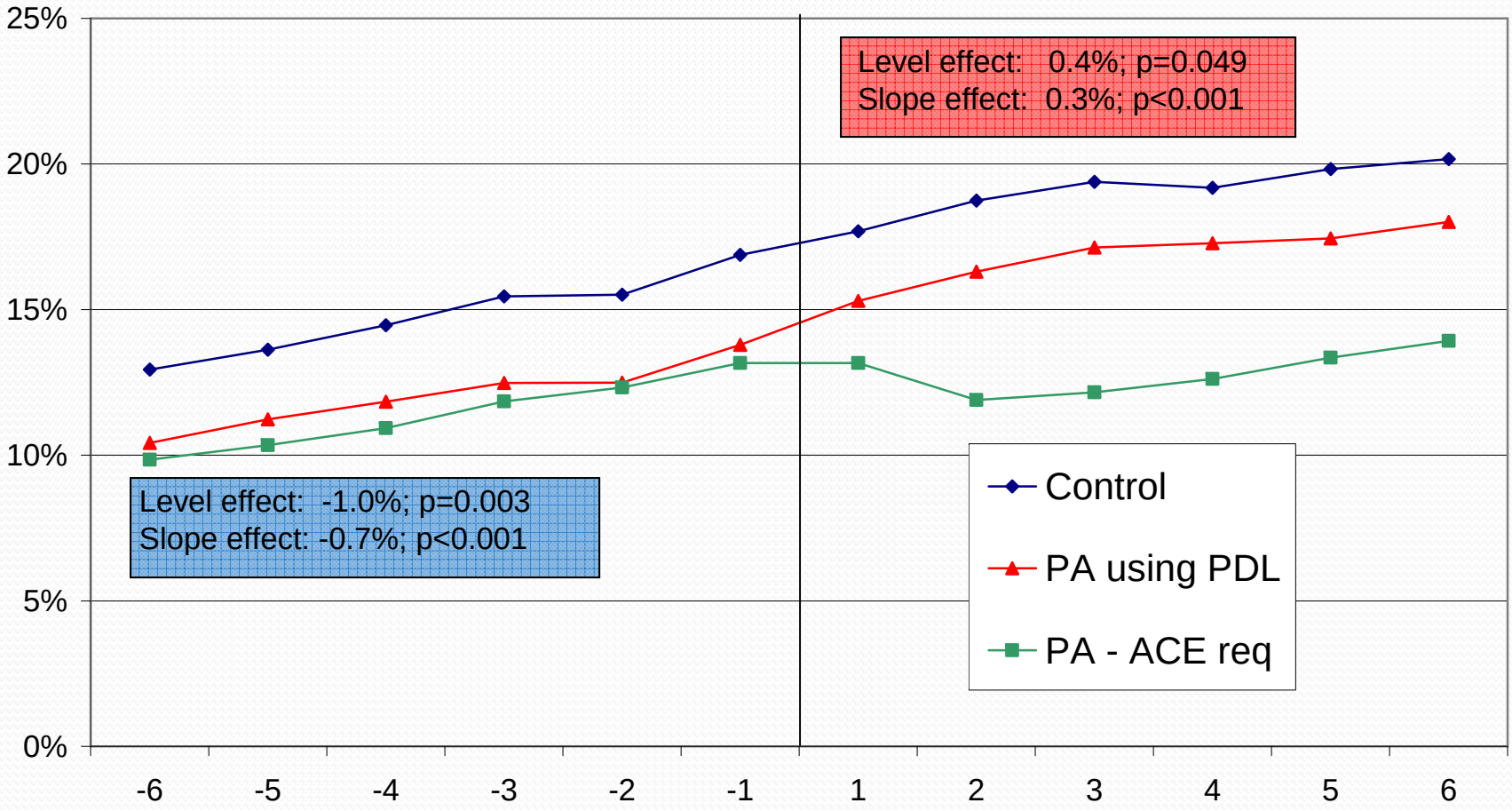
13 states with prior authorization for ARBs scheduled or recently implemented but inadequate post-implementation data

ARB DDDs as a proportion of RAA-blocker DDD's before and after prior authorization



Fischer et al, *Health Affairs*, 2007

ARB spending as a proportion of anti-hypertensive spending before and after prior authorization



Fischer et al, *Health Affairs*, 2007

ARBs- summary

32 states had prior authorization programs for ARBs at end of study

Implementation of program with only PDL ***increased*** ARB use and spending

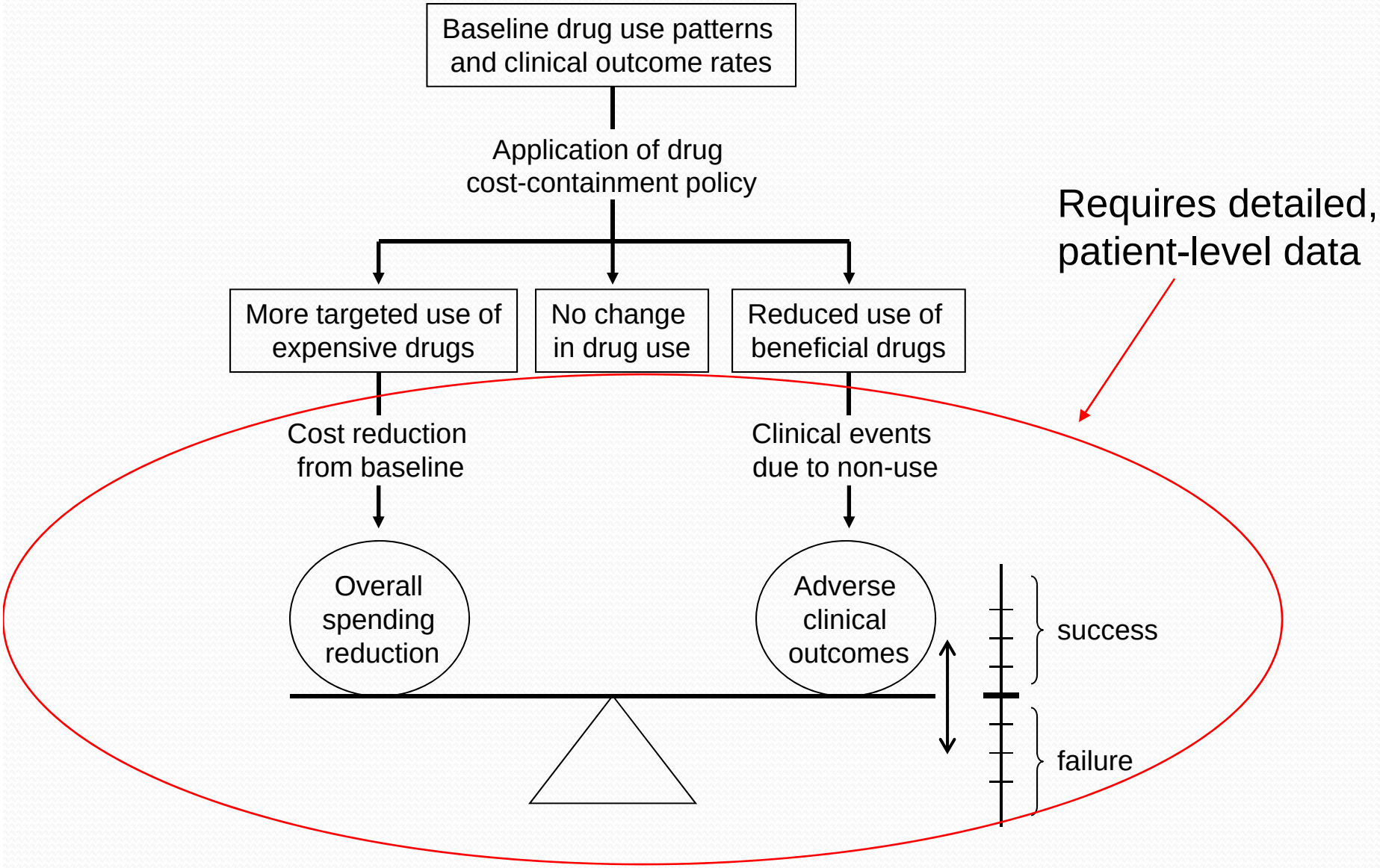
Policies requiring ACE-I trial reduced ARB use and spending by a small amount

Limitations of aggregate analyses

Cannot distinguish between reductions in overuse and reductions in clinically beneficial use

Cannot assess the impact of policy on clinical outcomes

The policy-maker's challenge



New comparative effectiveness study

Focus on cardiovascular medications

- anti-hypertensives
- anti-diabetics
- anti-platelets
- statins

Clinical area with opportunities for better care that can cost less

- thiazide diuretics
- rosiglitazone
- ezetimibe

Medication reimbursement policy approaches

Clinical guidance: Requires specific diagnosis, test result, or other clinical factor for approval

e.g. coxibs and GI risk factors; biologics

Therapeutic algorithm: Recommended treatment sequence, must be implemented in order

e.g. stepped therapy approaches

Economic preference: Choosing a preferred medication without more complex criteria

e.g. PDL's, generic drug requirements

Evaluate drug use outcomes

Patient-level data (MAX)

- Changes in overall drug use
- Changes in new starts
- Switching of regimens

- Changes in patients with strong indications
- Changes in patients without indications

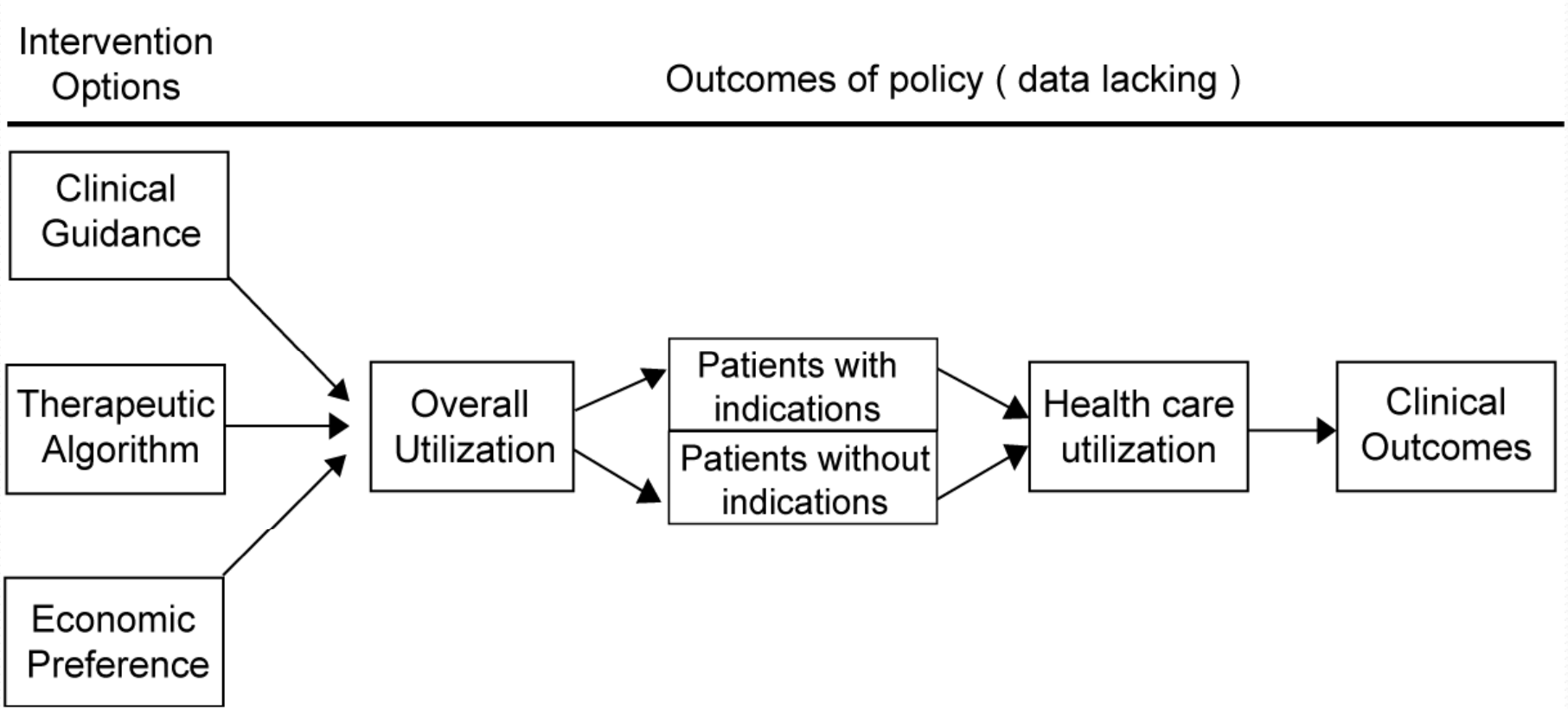
Evaluate clinical outcomes

Patient-level data (MAX)

- Clinical outcomes in overall population
  - MI
  - Vascular intervention
  - Kidney failure
  - Diabetes complications

- Clinical outcomes in patients at high risk
  - Multiple comorbidity
  - Switching/stopping of therapy

Structure of new study



Input from Medicaid stakeholders

Review and discussion of policy approaches

- Are the lists complete and accurate?
- Are the classifications reasonable?

Input on choice of drug use and clinical endpoints

- Are the right metrics being measured?

Review of preliminary results and feedback

- Are we providing the right data?

To learn more:

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