Improving Prescribing Quality and Controlling Costs: What Works and What's New?

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The lay of the land

- Prescriptions should be effective, safe, and affordable
- But:
  - We know that drug use is not optimal
  - Adverse drug events and errors common
  - Effective medications underused
  - Patients have trouble affording their meds
    - and programs have trouble paying for them…

Addressing the challenges

- What interventions can improve cost, effectiveness, and safety of prescribing?
  - Changing the incentives
  - Improving prescribing processes
  - Educating providers

Addressing the challenges

- What interventions can improve cost, effectiveness, and safety of prescribing?
  - Changing the incentives
    - Reimbursement policy
  - Improving prescribing processes
    - Electronic prescribing
  - Educating providers
    - Academic detailing

Today's agenda

- Reimbursement policy
  - Prior authorization and related policies
  - Evidence to date and new approaches
- Electronic prescribing
  - Promise, proofs, and pitfalls
- Academic detailing
  - How the technique was developed
  - Update on current programs

Prior authorization

- Conceptual framework and definitions
- Use of prior authorization in Medicaid
- Research studies of policy and impact
- Implications
  - Future policy development
  - Future research

Prior authorization - concept

- Sub-optimal prescribing is frequent
- For selected patients, the more expensive drug is the best option
- For many patients, a less expensive drug, or no drug at all, is adequate
- Can policy address the problems?

Defining prior authorization

- Definition: Requirement for clinical or system use information prior to providing coverage for a prescription
- Related policies:
  - Preferred drug list
  - Stepped therapy

  } Included in analyses
  - Drug rebates

Prior authorization in Medicaid

- Selected case studies
  - Cox-2 inhibitors
  - Angiotensin receptor blockers
  - Biologic anti-rheumatic drugs
  - Anti-depressants
  - Anti-psychotics

Gathering data on prior authorization programs

- Contacted all state Medicaid agencies
- Collected prior authorization forms and manuals
- Downloaded information from state Medicaid web sites

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

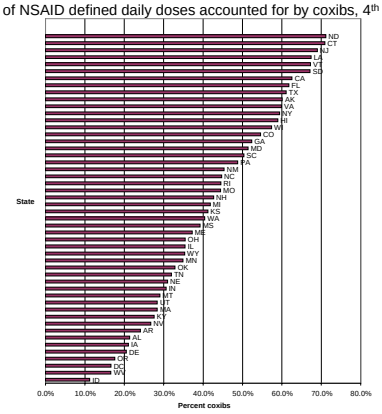
Models of policy impact

- 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

Percentage of NSAID defined daily doses accounted for by coxibs, 4th quarter, 2003



Components of coxib prior authorization

- Clinical risk factors for GI toxicity from non-selective NSAIDs: 5 factors
- Prior trials of non-selective NSAIDs
  - Caused GI toxicity
  - “Failure” for less well-defined reasons

Categorization of programs

- Narrowly evidence-based
  - 4 or 5 of the clinical risk factors for GI toxicity
  - Prior trial of non-selective NSAIDs with documented GI toxicity
- Broadly evidence-based
  - 3 or fewer of the clinical risk factors for GI toxicity
  - "Failure" of non-selective NSAIDs for unclear reasons, or no trial required

Prior authorization programs

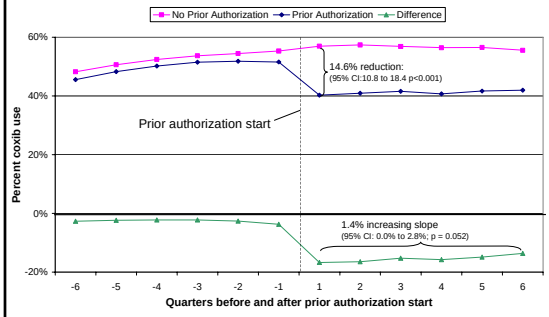
- 8 states implemented immediately
- 22 states implemented between 2000 and early 2003
  - 9 narrowly evidence based
  - 13 broadly evidence based
- 20 states provided control data
  - 6 states with programs scheduled to begin after study period

Table 2: Criteria included in coxib prior authorization policies (Total = 35 states)

Criterion	Number of states (%)
Inclusion of individual risk factors for gastrointestinal toxicity	
old age	24 (69%)
history of peptic ulcer disease	25 (71%)
history of upper gastrointestinal bleeding	28 (80%)
concurrent use of warfarin	25 (71%)
concurrent use of systemic glucocorticoids	23 (66%)
Number of risk factors included in program criteria	
none	5 (14%)
any one	2 (6%)
any two	2 (6%)
any three	3 (9%)
any four	4 (11%)
five	18 (51%)
Prior use of non-selective NSAIDs	33
caused gastrointestinal symptoms or events	17 (49%)
failed due to poor clinical effect or unspecified reasons	11 (31%)
either gastrointestinal toxicity or failure	5 (14%)

Fischer et al, *Med Care*, 2006

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

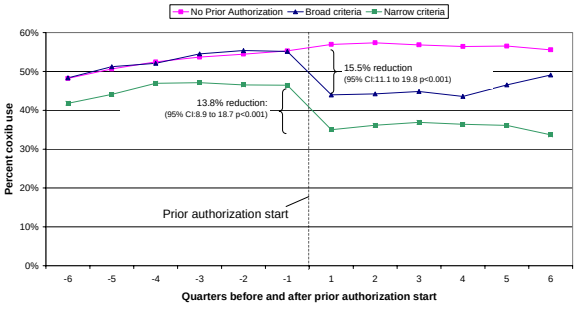


Fischer et al, *NEJM*, 2004

Secondary analysis

- Narrowly vs. broadly evidence-based prior authorization criteria

Proportion of NSAID defined daily doses accounted for by coxibs before and after implementation of a prior authorization program, stratified by association of prior authorization criteria with evidence-based patient selection guidelines



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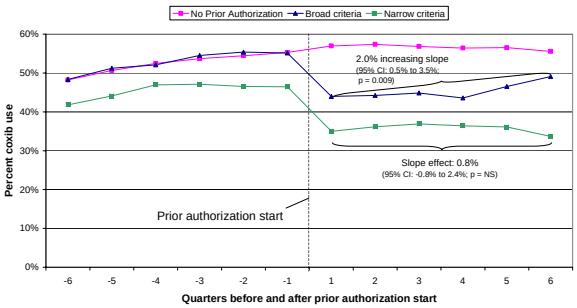


Fischer et al, *NEJM*, 2004

Economic impact

- National implication: Over 17 million NSAID prescriptions = $167 million/yr

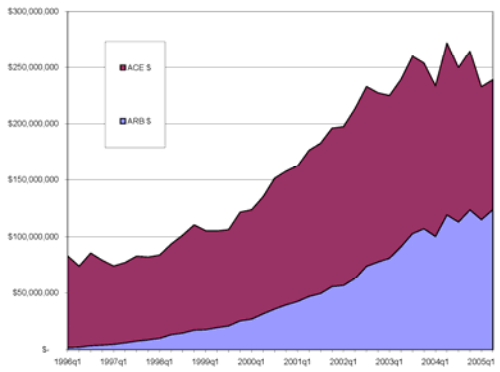
Coxib prior auth - summary

- Rapid increase in coxib utilization
- 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

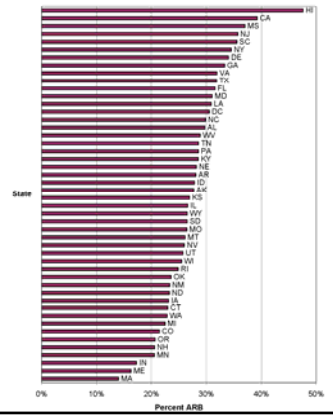
Renin-angiotension axis blockers: ACE –I vs. ARB

- 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

Medicaid spending on ACE-I and ARBs



ARB prescriptions as a proportion of all RAA blockers, 2004



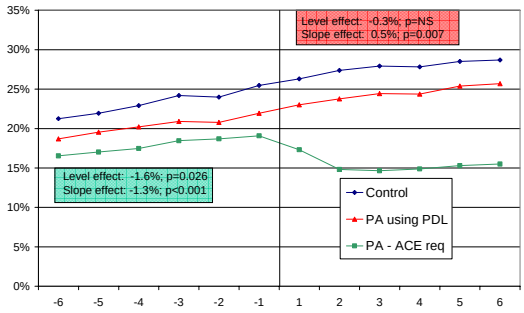
ARB prior authorization: key variables

- 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

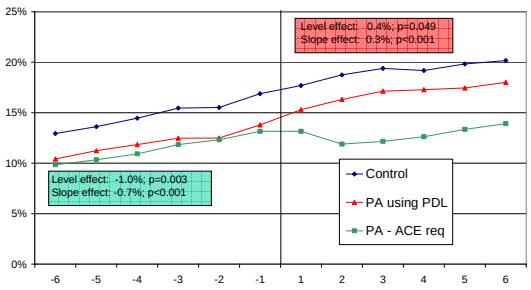
- 19 states with prior authorization for ARBs implemented and 3+ quarters of post-intervention data
  - 15 using PDL only
  - 4 with requirement for ACE-I trial
- 18 states with no prior authorization for ARBs
  - Control states
- 13 states with prior authorization for ARBs scheduled or recently implemented 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

- Rapid increase in ARB utilization
- 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

Challenges of policy analyses

- Discretionary aspects of state drug reimbursement policies not known
- State rebate arrangements not public
- Aggregate data: limited to medications with relatively simple substitutions
- Qualitative analyses: can give insight for policy development

Biologic DMARDs: clinical scenario

- Disease Modifying Anti-Rheumatic Drugs
- Widely used for RA, other diseases
- Much more expensive than alternative drugs (methotrexate, hydroxychloroquine)
- Potentially significant toxicities

Characteristics of Prior Authorization (PA) for DMARDs

States with PA programs for DMARDs	32 (100%)
Programs with detailed clinical criteria	20 (63%)
Programs with clear approval criteria	14 (44%)
Programs requiring prescription from a rheumatologist	6 (19%)
PPD required before prescribing	2 (6%)
Specific DMARDs requiring PAs	
abatacept	17 (53%)
adalimumab	16 (50%)
anakinra	22 (69%)
etanercept	17 (53%)
infliximab	26 (81%)
rituximab	13 (41%)

Fischer et al, *Arthritis Care & Research*, 2008

Biologic DMARDs results

- Quantitative analyses limited
- Programs implemented at times of high use and spending
- Trends in quantitative date suggest:
  - Initial blunting of growth in use and growth in spending
  - Effect attenuates over time

Psychiatric medications

- Much more challenging to evaluate
  - Vulnerable populations
  - Multidrug therapy common
- Case studies of policy responses to new drug safety data
  - Anti-depressants in children
  - Anti-psychotics in the elderly
- Different methods, looking for changes over time

Anti-psychotics in the elderly: clinical scenario

- Behavioral issues in dementia patients
  - Difficult to manage
  - Most medications ineffective and/or unsafe
- Increasing use of APMs
  - especially atypicals
- 2005-6: evidence emerges that APMs increase mortality risk in the elderly
- FDA black box warning in 2005

Table 1. Common characteristics of Medicaid programs with prior authorization (PA) policies regarding APMs, August 2005

Program attributes	As of August 2005	As of June 2006
	N (%)	
Number of programs available for evaluation	**22**	**26**
Require PA for one or more atypical antipsychotic medication*	21 (95)	25 (96)
Require PA for one or more conventional APMs*	8 (36)	8 (31)
Change prior authorization policies since April 2005*	TBD	12 (46)
Changed prior authorization policy to reflect April 2005* FDA advisory	0 (0)	0 (0)
PA requirements waived for atypical APMs based on the following criteria:		
Prescription written by physicians with the "appropriate specialty" (i.e., psychiatrists)	4 (19)	4 (16)
Patient is elderly (age 65+)	1 (5)	1 (4)
Patient is in a long-term care setting	1 (5)	1 (4)
PA required for one or more atypical APMs if patient is age < 18	5 (24)	5 (20)

Polinski et al, *Health Affairs*, 2007

APMs requiring authorization

Require PA for:

Abilify (aripiprazole)	7	(33)
Abilify Oral Solution	6	(29)
Clozaril (clozapine)	13	(62)
Generic clozapine	5	(23)
Fazaclo (clozapine)	13	(62)
Geodon (ziprasidone)	4	(19)
Geodon IM	7	(33)
Risperdal (risperidone)	5	(23)
Risperdal Consta	9	(43)
Risperdal M-tab	8	(38)
Seroquel (quetiapine)	4	(19)
Zyprexa (olanzapine)	11	(52)
Zyprexa IM	7	(33)
Zyprexa Zydis	9	(43)

Anti-depressants in children: clinical scenario

- Increasing recognition of mental illness in pediatric patients
- Use of SSRIs more widespread
  - Best evidence for fluoxetine
- New evidence that SSRIs may ***increase*** the risk of suicide in pediatric patients with depression
- FDA black box warning in 2004

Table 1: Antidepressants promoted or discouraged for children in Medicaid prior authorization policies, for specific scenarios

Prescribing provision	States with policy that mentions children (N=8)		States with policy but no mention of children (N=22)	
Fluoxetine can be prescribed for children with minimal or no restriction	7	88%	21	95%
Fluoxetine is promoted or required as the first-choice anti-depressant for children	2	25%	0	
Non-fluoxetine SSRIs can be prescribed for children with minimal or no restriction				
Paroxetine	4	50%	20	91%
Sertraline	4	50%	17	77%
Citalopram	5	63%	15	68%

Fischer et al, *Psychiatric Services*, 2008

Psychiatric medications - findings

- Significant heterogeneity across states
  - Agents requiring authorization
  - Clinical elements of policy
- No changes over time in response to new safety data
- Drug utilization data not analyzed

Implications of qualitative findings

- Heterogeneity is a common finding
  - Potential problem
    - Suggests a poor evidence base
    - Can infer confusion for prescribers
  - Also an opportunity
    - State programs as policy laboratory
- No evidence of response to new data
  - Should there be?
  - What structure would allow for this?

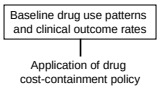
Implications of quantitative findings

- Prior authorization programs can play a role in containing drug costs
- Effect not consistently associated with clinical grounding of criteria
- Merely selecting a preferred agent in high-cost drug class does not appear effective; may even increase use of class as a whole
- Requiring “stepped therapy” more effective

Overall policy context

- Value-based insurance design
  - Removing barriers to use of highly effective medications as a cost-saving strategy
  - Prior authorization and PDL's implicitly use this approach
- Individual patient data: measure policy impact on patient-level drug use outcomes and clinical outcomes
- Can future research answer the policy-maker's question?

The policy-maker's challenge



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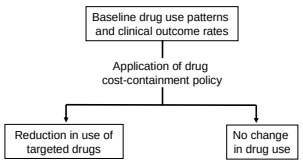

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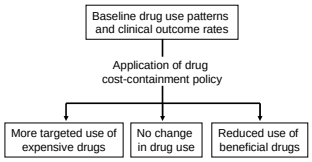

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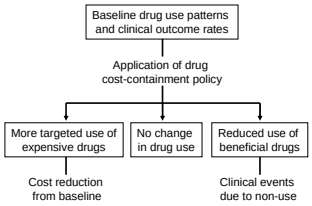

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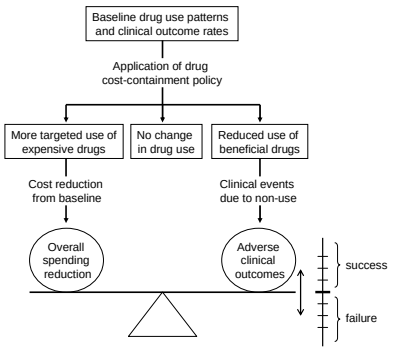

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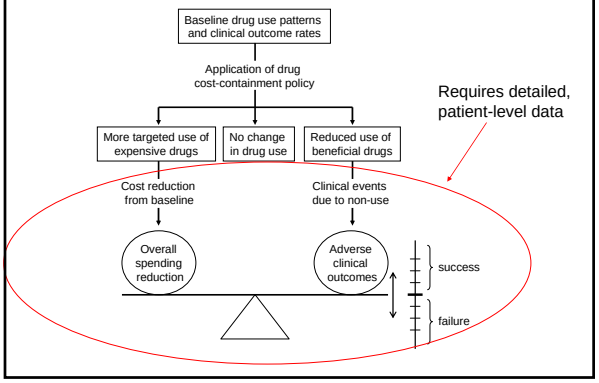


Reimbursement policy

- One critical tool for shaping drug use
  - Can be effective in changing drug use
  - More research needed to measure clinical impact
- Occurs after the prescribing decision
- How do we move up the pathway to improve prescribing?
  - Process: electronic prescribing
  - Prescribers: academic detailing

E-prescribing: overview

- Promise of e-prescribing
  - Multiple areas of medication use
- Evidence to date
  - Quantitative
  - Qualitative
- Remaining barriers
- New opportunities

Promise, proof, and pitfalls: areas of focus

- Safety
- Efficiency
- Medication costs

E-prescribing: key points

- E-prescribing has the potential to improve patient safety and increase the quality and efficiency of prescribing
- Evidence that these gains can be achieved in outpatient setting with current systems still being developed
- Barriers to full adoption must be addressed aggressively

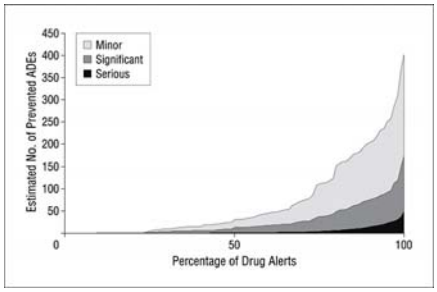
Increasing safety - promise

- Address legibility problems
- Better information at point of prescribing
  - ⇨ 25% fewer ADEs (CITL, 2003)
  - – Avoid allergic reactions
  - – Avoid drug-drug interactions
  - – Use medications more safely
    - Doses, frequency, age

Increasing safety - proof

- Quantitative data from inpatient setting (Bates, JAMA 1998; Bates, J Am Med Inform Assoc 1999; Raschke, JAMA 1998)
  - Improved antibiotic management
    - Evans, N Engl J Med 1998
  - Safer prescribing for the elderly
    - Peterson, Arch Intern Med 2005
  - Guiding use of high-risk medications
    - Fischer, Drug Safety 2004
- Outpatient setting
  - Qualitative data
  - Projections based on alerts accepted

Cumulative number of serious, significant, and minor adverse drug events (ADEs) prevented by safety alerts



Weingart, S. N. et al. Arch Intern Med 2009;169:1465-1473.

ARCHIVES OF INTERNAL MEDICINE

Increasing safety - pitfalls

- Limited quantitative outpatient data
- E-prescribing alone may not reduce errors (Ghandi J Gen Int Med 2005)
- >90% of alerts overridden by prescribers (Isaac, Arch Int Med 2009; Weingart, Arch Int Med 2003; LaPane, J Gen Int Med 2008)
- Possibility of new errors
  - Selecting wrong patient/drug
  - Doses/formulations not in system

Increasing safety – challenges

- Defining true safety gains
  - vs. efficiency
- Improving alert acceptance (Shah, J Am Med Inform Assoc 2006)
- Data infrastructure to support safety
  - Connectivity to other systems
  - Link to EMRs
  - How to input additional clinical data

Increasing efficiency - promise

- 1 billion callbacks per year (HHS 2004)
  - Patients: time, adherence
  - Pharmacists: time, distraction
  - Prescribers: time, workflow
- Inefficient processes throughout the system (Flynn, Am J Hlth Syst Pharm 1999)

Increasing efficiency - proof

- Qualitative data on efficiency: surveys and focus groups
  - Avoiding lost prescriptions
  - Reduced calls for offices/pharmacies
  - Ability to group prescribing tasks

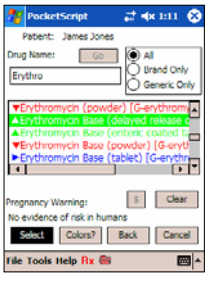
Increasing efficiency – pitfalls and challenges

- No quantitative data
  - RoI to providers not clear
- Connectivity and reliability problems
- Inability to transmit to PBMs
- Inability to e-prescribe schedule II meds

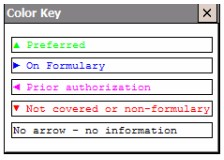
Controlling costs - promise

- Large potential savings from prescribing less expensive medications
  - Generic substitution (Haas, Ann Int Med 2005)
  - Therapeutic substitution (Fischer JAMA 2004)
- Improved adherence for patients started on medications with lower copayment (Shrank, Arch Int Med 2006)

Formulary decision support (FDS)



- Drugs color-coded to indicate formulary status
- Reminder only, prescriber chooses medication
- 3 copayment tiers



Medication use by tier

		Baseline	Intervention Period E-Rx Only		Intervention Period All Rx	
			N (%)	Change (95% CI)	N (%)	Change (95% CI)
Tier 1	**Intervention**	**54.8%**	**61.4%**	**6.6% (5.9%, 7.3%)**	58.5%	3.7% (3.2%, 4.1%)
	Control	**53.2%**	**55.8%**	**2.6% (2.5%, 2.7%)**	55.8%	2.6% (2.5%, 2.7%)
Tier 2	Intervention	35.8%	30.6%	-5.2% (-5.9%, -4.5%)	32.3%	-3.4% (-3.8%, -3.0%)
	Control	36.4%	33.7%	-2.7% (-2.8%, -2.6%)	33.7%	-2.7% (-2.8%, -2.6%)
Tier 3	Intervention	9.4%	8.0%	-1.4% (-1.8%, -1.0%)	9.2%	-0.2% (-0.5%, 0.0%)
	Control	10.4%	10.6%	0.2% (0.1%, 0.2%)	10.6%	0.2% (0.1%, 0.2%)

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Tier 2	Intervention	35.8%	30.6%	-5.2% (-5.9%, -4.5%)	32.3%	-3.4% (-3.8%, -3.0%)
	Control	36.4%	33.7%	-2.7% (-2.8%, -2.6%)	33.7%	-2.7% (-2.8%, -2.6%)
Tier 3	Intervention	9.4%	8.0%	-1.4% (-1.8%, -1.0%)	9.2%	-0.2% (-0.5%, 0.0%)
	Control	10.4%	10.6%	0.2% (0.1%, 0.2%)	10.6%	0.2% (0.1%, 0.2%)

Model results

Change in predicted probability of co-payment tier when e-prescribing vs. non-e-prescribing (95% CI)*

Tier 1: + 3.3% (2.7, 4.0)

Tier 2: - 1.9% (-2.5, -1.3)

Tier 3: - 1.5% (-1.8, -1.1)

*Controlling for secular trends and baseline differences between intervention and control physicians

Fischer et al, *Archives of Internal Medicine*, 2008

Projected cost impact

- $3.32 per prescription per patient-month
- For 100,000 insured patients, savings of $3.98 million per year
  - Range from $1M - $8M depending on assumptions

Fischer et al, *Archives of Internal Medicine*, 2008

Controlling costs – pitfalls and challenges

- Data need to be current and accurate to affect decisions
- Prescribing changes only seen when actually using e-prescribing
- Study results in pilot program setting
  - Infrastructure not there yet

Major barriers to e-prescribing

- Adoption remains slow (Gans, Health Aff 2005; Fischer, J Gen Int Med 2008)
- Adoption barriers
  - Cost, learning curve
  - Usability/reliability
  - Data security concerns
- CMS incentives have begun to increase adoption despite these reservations

E-prescribing: new opportunities

- E-prescribing of controlled substances
  - Better tracking
  - Avoiding tampering
- Taking advantage of medication history
  - Enhancing adherence
- Meaningful clinical decision support
  - Pay-for-performance environment

Overcoming barriers to realize gains

- Make e-prescribing positive for practices
  - Smaller practices, support, interoperability
- Demonstrate patient preference
- Ensure reliability and security

E-prescribing summary

- E-prescribing has the potential to improve patient safety and increase the quality and efficiency of prescribing
- Evidence that these gains can be achieved in outpatient setting with current systems still being developed
- Barriers to full adoption must be addressed aggressively
  - Make it easy to use
  - Meet the needs of patients and clinicians

Improving prescribing at the origin

- Reimbursement policy can target selected medications
- E-prescribing can try to improve processes, offer decision support
- Ultimately, prescriptions originate with physicians
  - Improving MD decision-making may be the most potent intervention

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

The “telephone” problem

- Excellent basic and translational research
- Frequently irrelevant drug review
- Lack of head-to-head studies
- Inadequate post-marketing safety surveillance
- Distorted communication of data
- Minimal prescriber accountability
- → **Irrational prescribing, resulting in:**
  - **suboptimal outcomes for patients**
  - **unaffordable costs**

An informational vacuum

- In medical school
  - We do a poor job preparing students to manage drug information in the real world
- The house officer years
  - free lunches / infomercials
  - 'product placements' in teaching hospitals
- After training
  - few sources of non-commercial information
  - industry dominates CME / blurring of boundaries
  - no requirements for continuing pharmacologic competency
- Little comparative data is available to adequately weigh Rx alternatives

A bizarre marketplace

- Person choosing product isn't the consumer
- Consumer can't choose among products
- MDs don't know what drugs cost
- We don't know our patients' drug coverage
- Some consumers are insulated against cost
- Data needed to 'comparison shop' don't exist
- Manufacturer-dominated information flow
  - generic manufacturers lack both $$ and rationale
  - passivity of gov't and most other payors
  - not a major goal for academia

>>>>>>>>>> market failure.

FDA lesions make things worse

- Anti-regulatory trends:
  - ***"Government is not the solution to our problem; government <u>is</u> the problem."***
    - President Ronald Reagan, 1st Inaugural Address
  - user fees have helped change FDA orientation
  - the power of lobbying and $$ to shape policy
  - loosening of FDA limits on promotion

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

Limitations of pre-approval data

- The randomized controlled trial is the "gold standard" FDA uses for determining efficacy, BUT…
- how do the label and the ads relate to the patients seen in routine practice?

The trials that FDA evaluates…

- are funded and conducted by the drug's manufacturer
- are generally designed to speed approval
- may last a short time, even for a drug to be taken for a lifetime
- often compare a new drug to a placebo
- are assessed by FDA reviewers whose salaries come from industry "user fees"

Drug approvals are based on:

- volunteer patients, usually healthier
- under-representation of important groups
  - especially the elderly
- small samples
- selected clinicians, settings
- protocolized care: compliance, monitoring
- short duration
- surrogate endpoints
- *compared to what?*

as a result…….

- This usually doesn't provide head-to-head comparative data about relevant prescribing choices.
  - example: hypertension Rx; ALLHAT
- A drug that achieved a surrogate outcome may not produce the expected clinical benefit.
  - example: Avandia (rosiglitazone) and M.I.
- Unanticipated adverse effects are likely.
  - example: Vioxx (rofecoxib)
- Use differs in actual practice vs. trials
  - by doctors
  - by patients

No requirement that new drugs tested against standard of care

- The law states that a drug must be judged "effective" if it works better than placebo.
- FDA has no budget to conduct its own trials.
  - It must depend on studies conducted by the company that makes the drug.
  - NIH generally does not fund such studies either.
- This may be changing:
  - Comparative effectiveness research

FDA faces major challenges

- severely understaffed
- has had no systematic way to follow up on problems once a drug is marketed
- may require years to get important new risk information into label and ads
- has had little clout to force manufacturers to follow up on adverse effect signals

» Source: Institute of Medicine, 2006; Government Accountability Office, 2006; FDA Science Board, 2007

Drinking from a fire hose

- To stay abreast of all important new drug developments, a primary care doctor would have to regularly scan dozens of journals.
- Systematic overviews (Cochrane, DERP) cover selected fields, but…
  - are lengthy and hard to wade through
  - may not be recently updated
- Some important findings are not in journals
  - FDA alerts, 'Dear Doctor' letters
  - important trial data presented at clinical meetings

Limitations of promotional materials

- Industry-generated marketing messages are a dominant source of drug information.
  - often the ***only*** available source for new products
- Their main purpose is to increase sales.
- Industry sales reps can be a problematic source of drug education
  - most have little or no real scientific training
  - most are on commission
  - messages often skewed to favor the product they're selling

Does promotion work? Yes!

- There is clear evidence that sales reps and samples change prescribing
  - otherwise industry wouldn't spend >$30 billion per year doing it
- A large social science literature shows the persuasive effects of relationships, gifts
  - the symbolic power of even small presents
- Marketing promotes only the costliest products

Modeling evidence-based practice

- DOPE database of ~250,000 anonymized patients with data on all filled Rxs and all Dxs and medical encounters
- Identified all treated hypertensives
- Developed algorithm to 'replace' all meds with guideline-driven Rx, based on Dxs
- Estimated savings projected nationally: $1.2 billion
  - **Ref: Fischer MA, Avorn J, JAMA 2004**

What we need:
evidence-based,
non-product-driven
research and ***communication***
about drugs

This is a ***public good,***
not a marketplace solution

The goal of academic detailing

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

The logic of academic detailing

- Med school faculty have a solid grasp of the evidence about drug benefits and risks
  - ***but we're often terrible communicators.***
- Drug makers are superb communicators
  - ***but do so only to increase product sales.***
- Can the ***content*** of the former be communicated to prescribers through a ***'delivery system'*** based on the latter?

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 content of academic detailing

- Well trained clinicians (pharm, RN, MD) visit prescribers in their offices and offer a **service** that provides **non-commercial, non-product-driven, evidence-based** information about the **comparative** benefit, risk, 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 formulary compliance
- about cost reduction primarily

The first academic detailing “un-ads”

As used in the original New England Journal of Medicine randomized controlled trial
- Avorn & Soumerai, NEJM, 1983

- The reverse side of each page contained concise clinical background and specific prescribing recommendations
  – with references
- Can be accessed at:
  www. **PowerfulMedicines.org**

Patient education materials

- In focus groups, many physicians said they would be more willing to change their prescribing if they had an easier way of explaining to the patients why the change was necessary.
- So created what might be the first “direct-to-consumer unadvertisements”

Initial results of the first study

- 92% MD acceptance rate from ‘cold calls’ to physicians
- Significant 14% reduction in inappropriate prescribing
  – Avorn & Soumerai, NEJM 1983
- Benefit-cost analysis based on actual expenditures: saved $2 for every dollar spent
  – Soumerai & Avorn, Medical Care 1987

Where we are now

- Academic detailing programs operating in Canada, Europe, Australia, developing world
  - public payment for drugs a spur to public action
  - programs funded by government, but controlled by profession
- HMO uptake in U.S.
  - rising drug costs drive payors to action
- State-funded programs in PA, MA, NY, SC, DC, New England
- 2008: Sen. Kohl introduces bill to create a federally funded national academic detailing program

Status of the evidence

- A cottage industry of literature has developed in last 25 years
- Cochrane Collaborative exhaustive review in 2007 confirmed efficacy
- Effectiveness varies with quality of execution
  - like brain surgery
  - it's not a pill

The Pennsylvania program

- State pays > $3 billion / year in publicly funded drug benefits
  - constrained budgets, public health mission
  - → motivation to improve prescribing
- The non-profit "Independent Drug Information Service" began visiting doctors in October '05
  - *Wall Street Journal,* March 2006
  - *"The Daily Show,"* May 2006
  - *N.Y. Times,* September 2006
- www.**RxFacts.org**

Clinical topics

- coxibs/NSAIDs
- G.I. acid Sx (PPIs, H_2 blockers)
- anti-platelet drugs (clopidogrel, aspirin)
- hypertension
- cholesterol
- diabetes
- depression
- COPD

Materials

- materials prepared by Harvard Medical School clinical faculty members
- evidence documents
  - review and assess all recent literature
- "un-advertisements"
- patient scenarios
- physician reference cards
- patient education materials
  - help facilitate behavior change
- All materials available at www.**RxFacts.org**

How is it working?

- Physician reaction: surveys
  - Overwhelmingly positive
    - Information is useful: 4.6/5.0
    - Would like continued detailing: 4.6/5.0
- Drug use impact: 6 month claims data
  - $286,000 reduction in PPI spending
    - $572,000 if changes persisted for a year
    - Most savings in high-volume prescribers
  - Considers only savings to PACE program
    - does not include savings to Medicaid, state employees, other insurers

Implications of stratification

- Program is most cost-effective if targeted at high-volume prescribers
- They are easy to identify from paid claims data
- Economies of scale are possible if other payors can help defray costs
  - "free rider" issue

Drivers of change

- Growing awareness of need to use medications appropriately
- Escalating drug costs
- Heightened concern over side effects
- Rising skepticism by MDs, patients
- Greater sophistication in data accessibility, informatics

"How can we possibly afford this?!"

- The U.S. already spends more per capita on drugs than any other nation.
- Much of that is wasted.
- Government (federal, state, VA) is footing a big part of the bill.
  - e.g., Medicaid spent $1 billion a year on Vioxx
  - similar argument for Avandia, Zyprexa, etc.
- Providing evidence-based drug information probably saves more than it costs.

Academic detailing

- Effective educational tool
- Changing the knowledge base for prescribing
- Increasing number of programs
- Interest at the NIH level
  - Link to comparative effectiveness
  - Recent grant announcement from AHRQ

Where are we now?

"***May you live in interesting times***"

-Chinese proverb (curse)

A time of opportunities

- Policy
  - Recognition of need for innovation
  - Medicaid programs in the lead
- E-prescribing
  - Adoption is increasing
  - Can it deliver on its promise?
- Academic detailing
  - Rethinking models of learning

What lies ahead

"The lion and the lamb shall lie down together, but the lamb won't get much sleep."

-- Woody Allen