Effect of Drug Utilization Controls and Coverage on Quality, Cost and Outcomes among Patients with Mental Illness

Stephen B. Soumerai, ScD
Professor of Ambulatory Care and Prevention
Harvard Medical School and Harvard Pilgrim Health Care

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Social Security, Medicare, and Medicaid Spending as a Percent of GDP

Source: GAO analysis based on data from the Office of the Chief Actuary, Social Security Administration, Office of the Actuary, Centers for Medicare and Medicaid Services, and the Congressional Budget Office.
U.S. Prescription Drug Expenditures

U.S. Rx Drug $ as Proportion of Health Expenditures

Source: Data from the Centers for Medicare & Medicaid Services, Office of the Actuary
Average Monthly Expenditures for Income Level of $5,000-$9,999

2002 BLS, Consumer Expenditure Survey, Table 2
Pharmacy

It's cheaper to buy marijuana.
Examples of Research on Pharmaceutical Policies Affecting the Mentally Ill

- **Cost containment policies**
  - Drug benefit limits (caps) in Medicaid
  - Drug cost sharing
  - PDLs/Prior Authorization

- **Physician surveillance of sedative-hypnotic prescribing**

- **Medicare Part D**

- **Preliminary principles for reducing costs/maintaining quality**
Three Studies on the Effects of Drug Benefit Limits on the Quality and Outcomes of Care among Patients with Chronic Somatic and Psychiatric Illness


Support: AHRQ, NIA, NIMH
Effects of Medicaid Three-Drug Benefit Cap on Medication Use among Multiple Drug Recipients (N=860) and Other Outpatients (N=8002)

(Predominately elderly/disabled with multiple morbidities)

Largest Impact of Cap on Use of Essential Medical Therapies Among Patients With Mental Disorders/Chronic Pain + Physical Illness

% Change in Doses of Essential Drugs

- Psychosis, bipolar *
- Anxiety, sleep *
- Chronic pain *
- Diabetes
- Heart disease
- Seizure disorder
- COPD, asthma

Mean change = -34%

* significantly different from those without this co-morbidity, p<0.0001

Source: Fortess et al, JAGS, June 2001
Effects of Drug Benefit Cap on Nursing Home Admissions among Elderly and Disabled (aged 60 and Over)

Source: Soumerai et al. NEJM 1991;325:1072-7
Effects of Drug Benefit Cap on Antidepressant Use in Schizophrenia
(Similar Effects for Antipsychotics)

Effect of Drug Benefit Cap on Emergency Mental Health Services
(Similar Effects for Partial Hospitalizations)

Conclusions: Adverse Effects of Caps on Drug Coverage (12-15 states)

- Reduces use of clinically important medicines (e.g., antipsychotic agents, cardiac meds)

- Increases use of institutional services
  - nursing homes and hospitals (elderly)
  - day hospital and acute care (schizophrenic)

- May increase total health care costs
  - mental health cost offsets 17 x drug savings
  - don’t include quality of life, criminal justice costs
“Piecemeal efforts at cost containment may accomplish their narrow goals, [but] may come at the considerable price of diminished access, decreased quality…and offsetting cost increases.…”

“Vulnerable patients have sustained needs in a system of care that is in fragile equilibrium. Even slight perturbations in their support system can have direct consequences and also secondary or compensatory effects.”

NAMI Case Report (2005):

Cap studies were “instrumental in the development of the 10-point statement in which NAMI supports State strategies …”

AARP Case Report (2005):

“AARP has used findings to advocate “against restrictions on drug coverage….“ and to advocate “to provide or expand drug coverage for low-income persons in NY, MA, WI, TX, IL, and other states.”

AARP attorneys called Soumerai as a witness in a federal court trial that challenged the state’s proposal to cap TennCare drug coverage at two brand drugs and five drugs overall.
“These studies have not only provided background data supporting subsidies for low-income enrollees in the MMA, but they have contributed to more rational state policy decisions.”

Chief Medical Officer, CMS (2005)
Principles for Preferred Drug Lists

- First, measure level of inappropriate use. Can the policy selectively reduce inappropriate care, while maintaining essential treatments?

- Avoid access restrictions for:
  - Drug classes with heterogeneity in adverse effects
  - Most vulnerable populations (e.g., schizophrenia, bipolar)

- Provide multiple preferred agents/choices

- Use simple/rapid prior approval procedures

- Evaluate quality impact early and modify policies
Effects of Medicaid PA Policy on Use of Nongeneric and Generic NSAIDs: Large Savings, No Observed Adverse Effects

Decrease = 65% (95% CI, 60 to 71%)

(Similar results: ACE Inhibitors, Nitrates, and other non-psych drugs with class effects)

Three Recent Studies on the Impact of Prior Authorization/Step Therapy among Medicaid Patients with Schizophrenia or Bipolar Disorder

- Zhang et al. (IN PRESS)
- Adams et al. (IN PRESS) (for informal discussion only)

Support: AHRQ Public-Private Partnership, Eli Lilly and Company, US Centers for Disease Control and Prevention, NIMH, RWSF (HCFO)
Discontinuities in Atypical Antipsychotic (AA) Therapy following Prior Authorization & Step-therapy among Medicaid Beneficiaries with Schizophrenia

SB Soumerai, F Zhang, D Ross-Degnan, DE Ball, RF LeCates, MR Law, TE Hughes, D Chapman, AS Adams

AHRQ Public-Private Partnership
Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care; Eli Lilly and Company; US Centers for Disease Control and Prevention

Source: Soumerai et al. Health Affairs 2008;27:w185-95
Policies Promoting “Preferred” Drugs Within a Therapeutic Class

- Preferred Drug Lists (PDLs)
  - Prior authorization (PA) usually required
  - Often “fail first” requirement
- ~10 state Medicaid programs and about 1/3 of Part D Plans have PA policies for atypicals (AAs)
Background to Present Study

- Schizophrenia: high disabilities/costs
  - Without drug treatment, 80% have a recurrence in ≤1 year
  - Many patients discontinue treatment, due to administrative barriers
  - Variations in side effects and clinical response to AAs and side effects
A Longitudinal Study of Medication Nonadherence and Hospitalization Risk in Schizophrenia

- First study of the temporal relationship between nonadherence to atypical antipsychotics and hospitalization
- 1191 patients with schizophrenia in ME and NH
- Medications gaps of ≥ 30 days significantly associated with ~50% increase in schizophrenia-specific and all cause hospitalization

MaineCare Preferred Drug List for Atypical Antipsychotics (7/2003)

Preferred Step Order for Newly Treated*:

“Preferred” Atypicals: Fail first
1. Risperidone (Risperdal)
   \(\downarrow\) (If Fail)
2. Ziprasidone (Geodon) or Quetiapine (Seroquel)
   \(\downarrow\) (If Fail)

“Non-preferred” Atypicals: PA
- Olanzapine (Zyprexa) or Aripiprazole (Abilify)

* or PA can be requested to bypass step order
Time to Treatment Discontinuity Among Newly Treated during the Pre-policy and Policy Periods

Study Cohort
- Pre-Policy (N=230)
- Policy (N=224)

Comparison Cohort
- Pre-Policy (N=71)
- Policy (N=63)

Either ≥30 days w/o therapy following initiation of AA or switching/augmentation of the initiation therapy
No Effect of PA on Medicaid Pharmacy Reimbursements for Atypicals for Schizophrenia (Similar Results in Two Other States)

Source: Soumerai et al. Health Affairs 2008;27:w185-95
The Impact of Prior Authorization for Antipsychotic and Anticonvulsant Medications among Medicaid Beneficiaries with Bipolar Disorder

Y Zhang, AS Adams, D Ross-Degnan, F Zhang, SB Soumerai
Harvard Medical School, Harvard Pilgrim Health Care,
and University of Pittsburg School of Public Health

Support:
- Robert Wood Johnson Foundation’s Health Care Financing and Organization (PI: Dr. Soumerai)
- Thomas O. Pyle Fellowship at Harvard Medical School

(IN PRESS)
Bipolar Disorder

- Disabling costly illness ($45 billion/year)
- Effective medications
  - Mood stabilizer: Lithium
  - Atypical antipsychotics (AA)
  - Anticonvulsant agents (AC)
- Discontinuation of treatment increases costly acute episodes
- Variations in adverse effects/clinical response
Time to Discontinuation of Bipolar Medications among Newly Treated Before, During PA Policy

- Pre-Policy (N=1014)
- Policy (N=946)

Increased risk of discontinuation of all bipolar meds after policy

- Maine

No increased risk of discontinuation after policy

- New Hampshire
Modest Effect of PA on Expenditures for Bipolar PA Medications

$27 savings per patient (8 months PA)
Results

Conclusions

- Modest savings on Pharmacy Reimbursement ($3 average drug savings per month)
- Twofold increased risk of D/C of all bipolar meds

Research in progress

- Reduced psychiatric visits among discontinuers
- Increased ER visits among seriously ill discontinuers
- Small savings not worth the risks
“Given the rapid increase in the use of PA policies and other cost-control mechanisms in Medicaid, the relative lack of data on their risks and benefits is cause for concern. It is sobering to realize that if such policies were considered for a clinical study, the possible risks of reduced access to essential medications would likely result in a failure to obtain human-subject approval from most institutional review boards (IRBs).”

Source: Soumerai, Health Affairs 2004; 23:135-46
Four Studies on the Intended and Unintended Effects of NY Benzodiazepine Triplicate Prescription Policy in Medicaid

- Pearson et al. *Arch Int Med* 2006;166:572-9

Support: NIDA, NIA
Rationale of 1989 NY Benzodiazepine Triplicate Prescription Policy

- **Common perceptions**
  - BZs are widely overused
  - “Abuse” is significant problem

- **History of NY TPP**
  - 1978 controlled drugs, 1981 barbiturates
  - BZs added January 1989

- **Intended effects of BZ surveillance**
  - Reduce abuse and cost, hip fractures
  - MDs will maintain appropriate use
Impact of Triplicate Prescription Policy (TPP) on Monthly Benzodiazepine (BZ) Prescribing (N= 374,455)

Number of BZ Recipients Per Month

Effects of TPP on Bz use among patients living in neighborhoods with different racial compositions

Triplicate Prescription Policy
(Additional studies: approximately equal effects on appropriate use, patients with seizure, bipolar, panic disorder, and schizophrenia)

Benzodiazepine Use and Incidence of Hip Fracture among Women in Medicaid Before and After NY Regulatory Surveillance (TPP)

“Controlling benzodiazepine prescribing may not reduce hip fractures, possibly because the 2 are not causally related.”

(Yet most Medicaid drug utilization controls assume such a relationship.)

MEDICARE DRUG BENEFIT

Benefits and Consequences for the Poor and the Disabled

High Vulnerability of Dual Enrollees

- High demand for health services
  - High rates of chronic physical and mental illness
  - Use of high cost medications (e.g., atypical antipsychotics)

- Growing proportion of Medicaid and Medicare enrollees
  - <16% of population, responsible for 50% of drug costs
Who are the dually enrolled?

- Functional Limitations
- Fair/Poor Health
- <High School
- Income<$10,000
- Non-White

Source: MCBS (2003)
Administrative Barriers to Medication Use in the Medicare Drug Benefit

Jeff Parker, Florida Today
Auto Enrollment of Dually Eligible Disabled Medicaid/Medicare Patients

- Who is better or worse off with Medicare Drug Benefit?
  - Varies by state (e.g., Medicaid drug caps?)

- Several ongoing issues
  - Problems making transition/negotiating system
  - Increased cost-sharing in many states
  - PDLs reduce access?

- **Part D**
  - $1 to $2 for generics
  - $3 to $5 for brands

- **Medicaid**
  - Zero cost-sharing in 10 states
  - Range of $1-$3 in other states
    - Majority ≤$2

Source: Kaiser Commission on Medicaid and the Uninsured
Proportion with Cost-Related Non-Adherence (CRN) Before and After Part D (N=43,933)

- Non-Elderly Disabled:
  - 2004: 29.5%
  - 2005: 29.7%
  - 2006: 27.2%
  - Relative change: -8.4% (2005-2006)

- Elderly:
  - 2004: 12.6%
  - 2005: 11.3%
  - 2006: 8.6%
  - Relative change: -23.8% (2005-2006)

Source: Madden et al. JAMA 2008;299:1922-8
Can evaluation studies precede (or coincide with policy implementation?)

- Successful researcher-policymaker collaboration in BC, Canada
- Confident expansion of successful policies
- Timely abandonment of ineffective/harmful policies