JUDITH A. SHINOOGLE
AWARD LECTURE:
MENTAL HEALTH POLICY
AND FDA WARNINGS

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UMBC
Employment supports for those with serious mental illness...

- Schizophrenia, bipolar, disability, Medicaid/Medicare, serious functional impairment. 4.1% of US population (SAMHSA, 2013)
- Employment rates only about 15% (Bond and Drake, 2014; Salkever et al. 2007, 2014)
- Two thirds of persons with SMI have employment as a goal (Bond and Drake, 2014; Frounfelker et al. 2011; Ramsay et al. 2011; Watkins et al. 2011)
- Evidence-based (Kinoshita, 2013; Steinwachs et al., 2014)
- Benefits of working: financial (societal and individual), self-esteem, social integration
Study Maryland Medicaid implementation of evidence-based supported employment implementation that dates back to 2002

Source Data: administrative records from 2001 to 2010, Department of Labor and Licensing, federal earning reports, BHA administrative and outcomes and Authorization records

Questions being addressed...
- Uptake, population characteristics?
- Earnings? (DLLR and federal earnings reports)
- Correlates to fidelity?
- Functioning?
- Utilization of other Medicaid services?
- Costs?
MEDICAL COSTS FOR OUR SMI SAMPLE IN FY2004...

- Medicare_payments: 12%
- SMH_Inpatient: 8%
- SMH_Outpatient: 5%
- SMH_Emergency: 1%
- Somatic_all_other: 12%
- Somatic_Home care: 17%
- Somatic_Inpatient: 17%
- Somatic_Long_term care: 7%
- Dental: 0%
- Supported_Employ: 0%

n= 25,204
Total= $522,078,340
REReducing Asthma Morbidity...

- 823,000 Marylanders diagnosed
- 11,474 Hospitalizations
- 39,834 Emergency room visits
- 67 Deaths

Prevalence of asthma among adults—
- Baltimore City 18.6%
- Maryland 13.9%

$99 million

Source: Maryland Asthma Control Program, August, 2011; figures pertain to 2009
Target population: Medicaid children in Baltimore City with Asthma

Intervention:
- Pest, dust, allergen (e.g., tobacco smoke) abatement
- Mold removal/leak repair
- Heating/cooling system repairs, weather proofing
- Medication counseling

Design: 240 interventions, matched controls from Medicaid system

Evaluation: Do cost savings in Medicaid and energy use offset intervention within 12 months?
- Secondary outcomes: missed work and school days
Antipsychotics (clozapine, Zyprexa), Antidepressants (Prozac), Stimulants (Ritalin)...

“Return on investment” of 10 to 1 (Cremieux et al, 2007).

$234 billion in 2008 up from $40 billion in 1990. 10¢ of every health care $ (not including professional fees) (Hartman et al, 2010).

Kantor et al, 2015: 60% of adults use at least 1 Rx.
THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) MATTERS...

- Principal gate-keeper with exceptional power and reputation (Carpenter, 2010; Szalados, 2007; Babiarz & Pisano, 2008)


- Problems: sample size, indications.
  - Vioxx/Bextra ($3 billion in sales pulled from market)
  - Antidepressants (SSRIs)- Warning on suicidality in youths issued October (Weissert & Weissert, 2006)

- FDA Admendments Act (P.L. 110-85), 2007-2012
Libby et al, 2007: antidepressants → suicidality

Starner et al, 2008: Avandia (diabetes medication) → cardiovascular
NEWS MATTERS...AND FOR HEALTH INFORMATION

- Agenda setting (McCombs, 2005; Iyengar & Kinder, 1987)
- Meta-analysis (Grilli et al, 2002)
- Smoking rates (Clegg et al, 2008)
- Suicide copy-cat (Ishii, 1991; Hagihara et al, 2007)
- “Mixed” quality coverage includes warning dissemination (Barry and Busch, 2010; Shih et al, 2008; Comis, 2015; Speers et al, 2004)
CAN I PUT IT ALL TOGETHER IN A TESTABLE MODEL?

- 4 warnings
  - Antidepressants (SSRIs) $\rightarrow$ suicidality (2003)
  - Rosiglitazone (diabetes) $\rightarrow$ heart attack (2007)
  - Chantix (smoking) $\rightarrow$ suicidality, aggression, anxiety, etc. (2009)
  - Leukotriene Inhibitors (asthma and allergies) $\rightarrow$ agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, suicidality and tremor

- Model: Use-Drug = $f\{\text{lagged(Warning-News)}\}$
METHODS

- Get time series from published literature or from Maryland Medicaid data
- Select major news content from news source databases using searches for drugs that treat condition (e.g., depression or asthma) and use term “safety” or “efficacy”
- Count and code those articles for:
  - Orientation (heightening concern or not)
  - Front page
  - FDA and/or Warning mention
  - Length
  - Media type (broadcast vs. print)
  - Valence
  - Quality (Schwitzer)
### Early Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coef.</th>
<th>$p$</th>
<th>$R^2$</th>
<th>$df$</th>
<th>article count</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of new child dep. where PCP RX’d an antidep.</td>
<td>-0.22</td>
<td>&lt;0.001</td>
<td>0.31</td>
<td>49</td>
<td>587</td>
<td></td>
</tr>
<tr>
<td>Rosiglitazone Claims Per Million Members (diabetes)</td>
<td>-2.4</td>
<td>0.14</td>
<td>0.14</td>
<td>17</td>
<td>97</td>
<td>n.s., revise with Medicaid data</td>
</tr>
<tr>
<td>Chantix RX count (smoke)</td>
<td>-13</td>
<td>0.039</td>
<td>0.09</td>
<td>46</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Montelukast RX count (asthma)</td>
<td>-175</td>
<td>0.09</td>
<td>0.37</td>
<td>46</td>
<td>105</td>
<td>Trend, Seasonal adjustment</td>
</tr>
</tbody>
</table>

Basic model: 2 month lag of news coverage articles that heighten concern
NEXT STEPS...

- Form of models...
  - Lag structure (autocorrelation)
  - Diminishing effects with time

- Test other variables beside direct reporting on articles that heighten concern (e.g., front page placement, length, valence)

- Granger causality...

- Limitations
  - Errors of omission (e.g., DTC, drug approval issues, physician letters)
  - Selected warnings...
POLICY IMPLICATIONS...

- Health education, health communication
- Managing risk of complex situations which impact many
  - Risk communication by the FDA and other agencies with similar, limited policing authority
- Optimizing and leveraging journalism
  - Foundation of democracy (Overholser & Jamieson, 2005)
  - Media is a key source of information for most of us
FOR MORE INFORMATION...

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>50% of payments for these services for youth <18 years old are made by Medicaid

Source: Maryland Asthma Control Program, August, 2011; figures pertain to 2009