Connecting Research and Policy in Early Psychosis Treatment

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Disclosures

- I have no personal financial relationships with commercial interests relevant to this presentation

- The views expressed are my own, and do not necessarily represent those of the NIH, NIMH, or the Federal Government
Scientific Discovery ≠ Uptake

17 year odyssey from discovery to practice
Research and Policy Disconnect

Scientific decision making

1. Publish results
2. Identify problem
3. Analyze data
4. Conduct study
5. Organize study
6. Develop hypothesis

Policy decision making

1. Identify problem
2. Assign resources
3. Assess reaction
4. Propose new initiative
5. Build support
6. Make political judgment
7. Support initiative
8. Build network
9. Implement action
10. Monitor outcomes

Ross Brownson et al., 2006, American Journal of Preventive Medicine
Hybrid Decision Making Model

1. Identify the public health problem
2. Agree on key research and policy questions
3. Conduct study
4. Agree on study design, dependent variables
5. Maintain support and accountability
6. Use data to inform policy decisions

High Impact Research
The “Recovery After an Initial Schizophrenia Episode” initiative seeks to fundamentally alter the trajectory and prognosis of schizophrenia through coordinated and aggressive treatment in the earliest stages of illness.
Step 1
Identify the public health problem
Established Schizophrenia

• ~2.5 million adults in U.S. are affected
• Onset typically in late adolescence, early 20s
• High morbidity and mortality
  – Multiple episodes of psychosis over the lifetime
  – High unemployment, homelessness, incarceration
  – Shortened lifespan (suicide, medical co-morbidities)
• Economic cost of $62.7 billion in 2002
  – Direct health care costs of $22.7 billion
Early Intervention Matters

- Rapid remission of positive symptoms
- Lower rates of psychiatric re-hospitalization
- Decreased substance use
- Improved social and vocational functioning
- Increased quality of life

Ryan

Coordinated Specialty Care Model

Client

- Medication/Primary Care
- Psychotherapy
- Family Education and Support
- Supported Employment and Education
- Case Management
Step 2

Agree on key research and policy questions
Disability in Schizophrenia

Can coordinated specialty care, offered early on, improve long term outcomes for schizophrenia in the US?
Step 3

Agree on study design and dependent variables
NIMH RAISE Projects

- Comparative effectiveness trial
  - John Kane
  - Nina Schooler
  - Delbert Robinson

- Implementation study
  - Lisa Dixon
  - Susan Essock
  - Howard Goldman
### Policy Makers’ Interests

<table>
<thead>
<tr>
<th>U.S. Federal Stakeholders</th>
<th>Dependent Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance Abuse and Mental Health Services Administration (SAMHSA)</td>
<td>Recovery, functioning, quality of life</td>
</tr>
<tr>
<td>National Institute of Drug Abuse (NIDA)</td>
<td>Substance abuse, tobacco dependence</td>
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<tr>
<td>Centers for Medicare and Medicaid Services (CMS)</td>
<td>Psychiatric relapse, re-hospitalization, cost of medical and specialty care</td>
</tr>
<tr>
<td>Social Security Administration (SSA)</td>
<td>School completion, early vocational milestones, competitive employment</td>
</tr>
</tbody>
</table>
Brokering Agreement on Measures

“The Social Security Administration figures its annual budget in terms of U.S. dollars, not Quality Adjusted Life Years.”
Step 4
Conduct study
Phase-specific specialty care for First Episode Psychosis vs. TAU
Representative patients (N=404) and community clinics (N=34)
Focus on clinical and functional recovery, cost of care, societal benefits
RAISE Implementation Study

**State Officials as Research Partners**
- NYS Office of Mental Health
- MD Mental Hygiene Administration

**“Turn Key” Solutions for State Administrators**
- Training and supervising existing staff
- Assertive outreach and client engagement
Step 5
Maintain stakeholder support, promote accountability
Time is Relative
Instill productive urgency
Early Data from Clinical Trial

Median duration of untreated psychosis is 74 weeks in community clinic settings
Addington et al., 2015, Psychiatric Services

Only 61% of FEP patients receive medications in line with PORT recommendations
Robinson et al., 2014, American Journal of Psychiatry

<5% of FEP patients with cardio-metabolic risk factors receive appropriate medical care
Correll et al., 2014, JAMA Psychiatry
Engineer accountability
NIMH Engagement Activities

2008 - 2010
NIMH Engagement Activities

2008 2009 2010 2011 2012 2013 2014
Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2

SSA
SAMHSA
CMS/CMMI
NIDA
ASPE

Center for Medicare & Medicaid Innovation

2011 - 2012
NIMH Engagement Activities

SAMHSA

CMS/CMMI

SSA

NIDA

ASPE

2011 - 2012

Sandy Hook Elementary School Shooting
NIMH Engagement Activities

SAMHSA

CMS/CMMI

SSA

NIDA

ASPE

Post-Sandy Hook
Interest in Early SMI

2013 - 2014
NIMH Engagement Activities

2013 - 2014
Step 6

Use data to inform policy decisions
Early Actions from Implementation Study

- **RAISE → OnTrackNY**
  - NYS Office of Mental Health
  - 4 new clinics for FEP
  - June 2013

- **RAISE → Maryland Early Intervention Program**
  - MD Mental Hygiene Administration
  - 4 new clinics for FEP/CHR
  - October 2013

- In both cases, state officials accepted feasibility data before articles were accepted for publication!
Phase-specific specialty care for First Episode Psychosis vs. TAU
- Representative patients (N=404) and community clinics (N=34)
- Focus on clinical and functional recovery, cost of care, societal benefits
Impact of Coordinated Specialty Care

- CSC participants remain in treatment longer
- CSC improves outcomes over 24 months
  - overall quality of life
  - measures of symptoms
  - interpersonal relations
  - involvement in work or school
- Participants with shorter duration of untreated psychosis derive substantially more benefit from CSC

Kane et al., in press, *American Journal of Psychiatry*
Do the right things, at the right time.
Congressional Action

Consolidated Appropriations Act of 2014

2008 2009 2010 2011 2012 2013 2014
Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2

2013 - 2014

U.S. Congress

2013 - 2014
January 17, 2014

- Increased Community Mental Health Block Grant (CMHBG) program by $24.8M
- Funds allocated for first episode psychosis (FEP) programs
- NIMH and SAMHSA to develop guidance for States regarding effective programs for FEP
Coordinated Specialty Care for First Episode Psychosis - Resources

- Evidence-based Treatments for First Episode Psychosis: Components of Coordinated Specialty Care
- RAISE Coordinated Specialty Care for First Episode Psychosis Manuals
- RAISE Early Treatment Program Manuals and Program Resources
- OnTrackNY Manuals & Program Resources
- Voices of Recovery Video Series

Corey – Another Door Opens

Supported Employment and Education (SEE) Manual

This manual teaches the principles of Supported Employment and Education and provides strategies and skills for the SEE specialist for engagement, assessment, addressing illness-related challenges to work and school, disability benefits, the prob and cons of disclosure, conducting a school and/or job search, providing follow-along support, several useful forms and handouts are provided for each aspect of providing SEE.
Innovators and Early Adopters, 2013
Early Majority, 2015

32 States
~120 Clinics
Early Services S-Curve

States with CSC Plans

How do we sustain momentum?
Beyond RAISE: Creating an early psychosis learning community in the United States
Early Psychosis Intervention Network (EPINET)
Strategic Objective 4 – Learning Healthcare Systems

FY2015

- Practice-based research model
- Common data elements, data sharing, big data analytics
- Feedback loops for ongoing system improvement
- Culture of continuous learning
- Clinical data drive scientific discovery
EPINET Goals

- Establish a national learning healthcare network among early psychosis clinics
- Standardize measures of clinical characteristics, interventions, and early psychosis outcomes
- Adopt a unified informatics approach to study variations in treatment quality, clinical impact, and value
- Cultivate a culture of collaborative research participation in academic and community early psychosis clinics
How can EPINET improve treatment?

- Fidelity to CSC model
- Monitor key outcomes
- Continuous quality improvement
- Evaluate rare events with statistical power
- Rapid piloting or fielding of new approaches

http://nhqnet.ahrq.gov/snaps11/dashboard.jsp?menuId=4&level=0&state=FL
Who has a stake in EPINET?

- 8,000 Clients
- 5,000 Relatives
- 500 Clinicians
- 50 State MHPDs
- SAMHSA
- NIMH
- CMS
EPIC-CAL??

(Early Psychosis Intervention Consortium of California)
Take Home Messages

• Scientists and policymakers often travel in “parallel universes”
• Bridging this gap requires active engagement to find common interests, shared goals, and meaningful outcome measures
• Time matters – convey “productive urgency” to scientists; help policy makers see beyond immediate needs
• Recognize that stakeholders come and go, so talk to everyone, all the time.
• Big data may help us to improve the quality of care and drive scientific discoveries

¹ Brownson et al., 2006, *American Journal of Preventive Medicine*
For more information

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Thank you!