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
Limitations of Typical Care for Schizophrenia

- Treatment is often delayed 1-3 years
- Initial medications do not always conform to treatment guidelines
- Health risks are rarely addressed
- Many persons with psychosis die within one year of initial diagnosis
RAISE
Recovery After an Initial Schizophrenia Episode
A Research Project of the NIMH
Coordinated Specialty Care (CSC)

Person with Psychosis

- Psychiatric Assessment & Medication
- Cognitive and Behavioral Psychotherapy
- Case Management
- Supported Employment & Education
- Family Education & Support
- Shared Decision Making

NIH National Institute of Mental Health
RAISE Research Questions

- Is early intervention feasible?
- Is early intervention effective?
- Are evidence-based services scalable?
RAISE Early Treatment Program

After 2 years, Coordinated Specialty Care was superior to usual community care on:

- Engagement in treatment
- Symptomatic improvement
- Involvement in work and school
- Quality of life
- Cost-effectiveness

New Funding for First Episode Psychosis Treatment Programs

- H.R. 3547 – $25M in 2014
- H.R. 88 – $25M in 2015
- H.R. 34 – 21st Century Cures Act, 2017-2027
Early Intervention Programs, 2018

August 2018 – 265 programs
RAISE Research Questions

✔ Is early intervention feasible?
✔ Is early intervention effective?
✔ Are evidence-based services scalable?
Early Psychosis Intervention Network

EPINET: Connecting the U.S. early psychosis community
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
<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
<td>Q4</td>
<td>Q1</td>
</tr>
<tr>
<td>Phenx Early Psychosis Common Data Elements</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>MHBH 10% Set-Aside Fidelity Evaluation Study</td>
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<tr>
<td>NIMH Healthcare Informatics Platform</td>
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<td></td>
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<tr>
<td>Harmonizing Clinical Data Collection in Community CSC</td>
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<td></td>
<td></td>
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<tr>
<td>EPINET-Alpha</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>EPINET-Beta</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
A collaboration among 3 federal agencies:

- Substance Abuse and Mental Health Services Administration (SAMHSA)
- National Institute of Mental Health (NIH)
- Assistant Secretary for Planning and Evaluation (Department of Health & Human Services USA)
Objectives of the MHBG 10% Evaluation

- Identify and describe Coordinated Specialty Care (CSC) program services offered nationally.
- Assess program fidelity to the NIMH CSC model.
- Explore local environments and contextual factors related to how CSC programs are implemented.
- Explore how CSC program participation is associated with improved client outcomes, e.g., symptom severity, employment, education, and quality of life.
Study Design

- **Hypothesis:** Sites with higher fidelity to the CSC model will have better client outcomes than sites with low fidelity.

- **Mixed-methods design:** Qualitative & quantitative data

- **Site Survey:** Overview of CSC programs nationally (250 sites)

- **Outcomes analysis:** Client level outcomes on symptoms, functioning and quality of life (36 sites)

- **Fidelity assessment:** Site fidelity to the CSC model (36 sites)

- **Process assessment:** Environmental context in which CSC is implemented (36 sites)

**Note:** All sites receive MHBG 10% Set Aside funds for early psychosis.
36 MHBG 10% study sites in 21 states & Puerto Rico
## Number of client interviews & percent of total enrolled at each assessment point

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 Months</th>
<th>12 Months</th>
<th>18 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Count (percent)</strong></td>
<td>780 (100%)</td>
<td>486 (62.3%)</td>
<td>325 (41.7%)</td>
<td>173 (22.2%)</td>
</tr>
</tbody>
</table>

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Participant Characteristics

- **Age:** Mean 20.6 years; 75% of clients 18-27 years
- **Gender:** 68% male, 30% female, 2% transgender or other

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Participant Insurance Type

- 48% Medicaid
- 32% Private insurance
- 4% Medicare and/or other type
- 19% uninsured
Changes over Time: School and Work

At Baseline
42% of clients were employed or in school

At Most Recent Interview
65% of clients were employed or in school

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
## Changes over Time: Symptoms, Quality of Life & Social Functioning

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline (Mean, Std. dev.)</th>
<th>Most recent interview (Mean, Std. dev.)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado Symptom Index</td>
<td>22.5 (13.1)</td>
<td>14.0 (11.6)</td>
<td>&lt;.0001***</td>
</tr>
<tr>
<td>Lehman’s QOL Score</td>
<td>4.1 (1.5)</td>
<td>5.0 (1.3)</td>
<td>&lt;.0001***</td>
</tr>
<tr>
<td>Social Scale</td>
<td>5.0 (1.8)</td>
<td>6.1 (1.7)</td>
<td>&lt;.0001***</td>
</tr>
<tr>
<td>Role Scale</td>
<td>4.5 (2.3)</td>
<td>6.0 (2.2)</td>
<td>&lt;.0001***</td>
</tr>
</tbody>
</table>

- Clients showed significant improvements in severity of symptoms and had more positive feelings about their life.
- Clients were also functioning at a higher level socially and in occupational/educational roles.

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Changes over Time: Adverse Life Events & Crises

- Homelessness: 7.1% Present at Baseline, 4.6% Present at Most Recent Interview
- Psychiatric Inpatient Hospitalization: 67.4% Present at Baseline, 14.1% Present at Most Recent Interview
- ER visits: 44.9% Present at Baseline, 12.8% Present at Most Recent Interview
- Any legal issues: 17.7% Present at Baseline, 10.4% Present at Most Recent Interview
- Suicide Attempts: 7.8% Present at Baseline, 2.6% Present at Most Recent Interview

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Overall fidelity scores ranged from 119 to 150.

<table>
<thead>
<tr>
<th>Fidelity Rating</th>
<th>N (%) of sites</th>
<th>Mean item rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent (149 or above)</td>
<td>2 (6%)</td>
<td>&gt;4.5</td>
</tr>
<tr>
<td>Good (132-148)</td>
<td>25 (69%)</td>
<td>≥4.0</td>
</tr>
<tr>
<td>Fair (116-131)</td>
<td>9 (25%)</td>
<td>&gt;3.5</td>
</tr>
<tr>
<td>Poor (Below 116)</td>
<td>0 (0%)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- 77% of sites attained good to excellent fidelity.
- 23% were rated in the fair range.
- Most sites achieved excellent fidelity on most fidelity items.
Fidelity and Client Outcomes

Primary Outcome Measure
(Mean Δ between baseline and most recent interview)  r  p

<table>
<thead>
<tr>
<th>Scale</th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado Symptom Index</td>
<td>-0.29</td>
<td>0.0860</td>
</tr>
<tr>
<td>Lehman’s Quality of Life Scale</td>
<td>0.13</td>
<td>0.4742</td>
</tr>
<tr>
<td>The Global Functioning Social Scale</td>
<td>0.26</td>
<td>0.1360</td>
</tr>
<tr>
<td>The Global Functioning Role Scale</td>
<td>0.04</td>
<td>0.7516</td>
</tr>
</tbody>
</table>

- Statistically significant relationship (with alpha at .10) between site fidelity score and change in the Colorado Symptom Index severity score.

- Higher total fidelity scores associated with greater reductions in CSI scores.
# Fidelity and Client Outcomes

## Secondary Outcome Measure

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol use</td>
<td>-0.53</td>
<td>0.0010</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>0.16</td>
<td>0.3527</td>
</tr>
<tr>
<td>Marijuana use</td>
<td>-0.27</td>
<td>0.1266</td>
</tr>
<tr>
<td>Other drug use</td>
<td>0.13</td>
<td>0.4780</td>
</tr>
<tr>
<td>Homeless past 6 months</td>
<td>-0.24</td>
<td>0.1717</td>
</tr>
<tr>
<td>Psychiatric inpatient hospitalization past 6 months</td>
<td>-0.12</td>
<td>0.4940</td>
</tr>
<tr>
<td>ER visits past 6 months</td>
<td>-0.01</td>
<td>0.9451</td>
</tr>
<tr>
<td>Any legal issues past 6 months</td>
<td>0.08</td>
<td>0.6516</td>
</tr>
<tr>
<td>Suicide attempt past 6 months</td>
<td>-0.07</td>
<td>0.6911</td>
</tr>
</tbody>
</table>

Strong correlation between site’s total fidelity score and reductions in alcohol use (-.53)
State Involvement in CSC Programs

- 36 study sites
- Reps from 22 states
- Interviews to understand role of the state in administering and supporting CSC programs.

<table>
<thead>
<tr>
<th>Study Site States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
</tr>
<tr>
<td>California</td>
</tr>
<tr>
<td>Delaware</td>
</tr>
<tr>
<td>Florida</td>
</tr>
<tr>
<td>Georgia</td>
</tr>
<tr>
<td>Idaho</td>
</tr>
<tr>
<td>Indiana</td>
</tr>
<tr>
<td>Massachusetts</td>
</tr>
<tr>
<td>Maryland</td>
</tr>
<tr>
<td>Michigan</td>
</tr>
<tr>
<td>New Mexico</td>
</tr>
</tbody>
</table>
Financing and Funding for CSC Programs

- 22 of 36 sites received more than half their funds from MHBG 10% Set Aside.

- Broad consensus that the frequent and extensive staff-client contact, team meetings, and services that were not billable to insurance would not be possible without Set Aside funding.

- Administrators generally said their programs could not be sustained at fidelity without the MHBG funds.
### Staffing and Turnover

#### CSC Staff Turnover From Time 1 to Time 2

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4</td>
</tr>
<tr>
<td>Less than 25%</td>
<td>11</td>
</tr>
<tr>
<td>25% to 49%</td>
<td>14</td>
</tr>
<tr>
<td>50% or more</td>
<td>7</td>
</tr>
</tbody>
</table>

Number of Sites

From 1\textsuperscript{st} to 2\textsuperscript{nd} round of site visits, 7 sites experienced $\geq50\%$ turnover, including 2 sites that lost 70-75\% of staff.
The MHBG 10% Set Aside funds are critical to the implementation of Coordinated Specialty Care (CSC).

Despite differences across sites, programs were generally able to implement CSC with fidelity.

Clients experience improvements as they move through CSC.

Initial results suggest that fidelity to the CSC model is related to specific clinical outcomes.
A Decade of Progress

200
• 2 States
• <20 CSC Programs
• <100 Clinicians
• <500 Youth

2018
• 49 States
• 265 CSC Programs
• ~1,000 Clinicians
• ~10,000 Youth

Scientific Traction

State and Federal Investments

Early Psychosis Learning Community
Learning Health Care

- Provide CSC services
- Measure results
- Improve services
- Examine variation
- Launch new research
Scope of EPINET

- 5 Regional CSC Networks
- ~55 CSC programs in 8 states
- ~75% community clinics
- ~2,300 currently enrolled
- ~5,000 target enrollment
- ~20,000 assessments/year
EPINET Practice Opportunities

Optimized Care

Prioritize Improvements

Implement Improvements

Measure Results

Provide Care

Best Practices
1. Early intervention improves clinical outcomes among people with first episode psychosis (FEP).

2. Coordinated Specialty Care (CSC) is a feasible and effective approach to early intervention in FEP.

3. The Early Psychosis Intervention Network (EPINET) will test learning health care principles of measurement-based, science-driven, continuously improving care for early psychosis in community CSC programs nationwide.
Acknowledgements

- NIMH RAISE Team
  Susan Azrin
  Amy Goldstein
  Joanne Severe
  Michaelle Scanlon

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  Cyntrice Bellamy
  Gary Blau
  Steven Dettwyler

- The MHBG Evaluation Team
  Abram Rosenblatt
  Lisa Dixon
  Howard Goldman
  Preethy George
  Donald Addington
  Gary Bond
  Robert Drake
  Mihran Kazandjian
  Ted Lutterman
  Kristin Neylon
  Tamara Sale
  David Shern
Thank You!

Susan T. Azrin, Ph.D.
National Institute of Mental Health
E-mail  Susan.Azrin@NIH.gov
Additional Slides
RAISE Studies

- RAISE Early Treatment Program
  - John Kane
  - Nina Schooler
  - Delbert Robinson

- RAISE Connection Program
  - Lisa Dixon
  - Jeffrey Lieberman
  - Susan Essock
  - Howard Goldman
Timing is Important

Clinical improvement is greatest when CSC is delivered closer to the onset of psychosis.

Greater clinical improvement for patients with shorter DUP (Cohen’s d = 0.54)

Good science requires independent replication.
After 1 year, Specialized Treatment Early in Psychosis (STEP) was superior to usual care on:

- Symptomatic improvement
- Likelihood of hospitalization
- Number and length of inpatient episodes
- Vocational and academic engagement
- Cost-effectiveness

The STEP public-sector model supports the feasibility and effectiveness of CSC.
Statewide CSC program 325 individuals ages 16–30 followed for 1 year:

- After 6 months, education and employment rates increased from 40% to 80%.
- After 3 months, hospitalization rates decreased from 70% to 10%.
- Global functioning improved continuously over 1 year.
RAISE Research Questions

✔ Is early intervention feasible?
✔ Is early intervention effective?
☐ Are evidence-based services scalable?
Optimized medication administration contributes to better FEP outcomes and fewer side effects
Robinson et al., 2018, *American Journal of Psychiatry*

FEP specialty care improves symptoms and functioning for persons from racial and ethnic minority groups
Oluwoye et al., 2018, *Psychiatric Services*

In the RAISE clinical trial, Coordinated Specialty Care did not reduce alcohol or substance misuse
Cather et al., 2018, *Psychiatry Research*
Site Survey: Technical Assistance/Training Models

- OnTrack: 32%
- NAVIGATE: 23%
- EASA: 18%
- Other: 18%
- FIRST: 10%
- PIER: 5%
- None: 6%
Fidelity Assessment

5 items were rated at low fidelity in the majority of sites:

- Family Education and Support
- Supported Employment
- Early Intervention
- Duration of CSC Program
- Population Served

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Peer Support in CSC

25 of 36 sites reported having a Peer Support component.

Peer Roles Across CSC Study Sites (N=25)

- Client work: 25
- Team meetings: 24
- Family work: 23
- Service planning: 23
- Conduct groups: 22
- Community outreach: 20
- Psychiatric appointments: 18
- Program development: 18
- Education/ workshops: 11
- Administrative: 6

The MHBG 10% Set Aside Study: Final Report. Prepared for SAMHSA by Westat, 2019
Reported Effects of Turnover

- **Reduced enrollment**: Slowing or stopping CSC enrollment while new staff are hired.

- **Increased staff stress**: Hiring a replacement can take months, increasing stress for other team members and making it harder to provide quality care.

- **Reduced client trust**: Client may find it hard to develop rapport with a new clinician.

- **Lost investment in training**: Sites may spend as much as $70,000 training staff who leave soon after.
EPINET Research Opportunities

- Reducing duration of untreated psychosis
- Mitigating suicide risk in early psychosis
- Determining optimal dose of initial CSC
- Evaluating new pharmacologic approaches
  - First Episode Psychosis
  - Clinical High Risk for Psychosis