Science Improves Care for Early Serious Mental Illness: Advances and Opportunities

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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
Systems Change

- NAMI accelerates innovation in health care, education and justice systems
- Successful systems provide improved access and better health outcomes
Learning Health Care

- Provide best care
- Measure results
- Improve services
- Examine variation
- Launch new research
Schizophrenia

- Altered perceptions, thinking, behavior
- Typical onset between ages 16-30
- ~1-2 million Americans are affected
- Unemployment, homelessness, and incarceration are common
- People with schizophrenia die nearly 30 years earlier than other people
Limitations of Typical Care

- 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
Early Intervention Matters

- Rapid remission of positive symptoms
- Fewer relapses
- Less hospitalization
- Better functioning
- Increased quality of life

Correll et al., *JAMA Psychiatry*, 2018
Early Intervention Programs, 2008

Mental Health Block Grant Plans: https://bgas.samhsa.gov/
RAISE
Recovery After an Initial Schizophrenia Episode
A Research Project of the NIMH

2008  2013  2018
RAISE Research Questions

- Is early intervention feasible?
- Is early intervention effective?
- Are evidence-based services scalable?
RAISE Studies

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

- RAISE Connection Program
  - Lisa Dixon
  - Jeffrey Lieberman
  - Susan Essock
  - Howard Goldman
Principles of Early Intervention

- Assertive outreach and engagement
- Youth-oriented, team-based treatment
- Multi-modal evidenced-based interventions
- Personalized, collaborative care plans

Azrin et al., *Psychiatric Annals*, 2015
Coordinated Specialty Care

Person with Psychosis

- Psychiatric Assessment Medication
- Case Management
- Cognitive and Behavioral Psychotherapy
- Supported Employment and Education
- Family Education and Support
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

Timing is Important

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

**Additional RAISE Findings**

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

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

The STEP public-sector model supports the feasibility and effectiveness of CSC.

Srihari et al., *Psychiatric Services*, 2015
Murphy et al., *Journal of Mental Health Policy Economics*, 2018
Specialized Treatment Early in Psychosis Program

After 1 year, Specialized Treatment Early in Psychosis was superior to usual care on:

- Symptomatic improvement
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Srihari et al., *Psychiatric Services*, 2015
Murphy et al., *Journal of Mental Health Policy Economics*, 2018
OnTrackNY Program

- A statewide CSC program for recent onset psychosis
- 325 individuals ages 16–30 were followed for 1 year
- Assertive outreach, evidence-based interventions, and continuous feedback to CSC teams

Nossel et al., *Psychiatric Services*, 2018
RAISE Research Questions

✔ Is early intervention feasible?
✔ Is early intervention effective?
☐ Are evidence-based services scalable?
Federal Funding 2014-2017

New Funding for First Episode Psychosis Treatment Programs

- H.R. 3547 – $25M in 2014
- H.R. 88 – $25M in 2015
- H.R. 34 – 21\textsuperscript{st} Century Cures Act, 2017-2027
“RAISE-ETP, RAISE-IES, and STEP demonstrate convincingly (1) the feasibility of first episode psychosis specialty care programs in U.S. community mental health settings; (2) that young people with psychosis and their family members accept these services; and (3) that CSC results in better clinical and functional outcomes than typical treatment.”
### Dates and First Episode Psychosis (FEP) Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>Jul. 2009</td>
<td>NIMH clinical trials for FEP commence</td>
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<tr>
<td>Dec. 2013</td>
<td>NIMH implementation study completed</td>
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<td>Apr. 2014</td>
<td>NIMH/SAMHSA FEP guidance to states</td>
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<tr>
<td>May 2014</td>
<td>SAMHSA technical support to states begins</td>
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<tr>
<td>Oct. 2015</td>
<td>NIMH clinical trials for FEP completed</td>
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<tr>
<td>Oct. 2015</td>
<td>CMS coverage of FEP intervention services</td>
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<tr>
<td>Dec. 2015</td>
<td>P.L. 114-113: $50.5M set-aside for FEP</td>
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<tr>
<td>May 2017</td>
<td>P.L. 115-31: $53.3M set-aside for FEP</td>
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<tr>
<td>Mar. 2018</td>
<td>P.L. 115-141: $68.5M set aside for FEP</td>
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<tr>
<td>Mar. 2019</td>
<td>P.L. 115-245: $68.5M set aside for FEP</td>
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### Cumulative Number of States with Early Psychosis Intervention Plans

Mental Health Block Grant Plans: [https://bgas.samhsa.gov/](https://bgas.samhsa.gov/)
Early Intervention Programs, 2008

August 2008 – 12 programs

NIH National Institute of Mental Health
RAISE Research Questions

✔ Is early intervention feasible?
✔ Is early intervention effective?
✔ Are evidence-based services scalable?
A Decade of Progress

2008
- 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

NIH National Institute of Mental Health
Looking Ahead

Connecting the U.S. early psychosis community
Learning Health Care

- Provide CSC services
- Measure results
- Improve services
- Examine variation
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Early Psychosis Intervention Network (EPINET)
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

NAMHC Concept Clearance; February 6, 2015
Anticipated 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
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
Advancing Discovery Summit Series

2019 Summit
On April 8–9, 2019 NAMI, the Stanley Center for Psychiatric Research at Broad Institute, The National Institute of Mental Health (NIMH), and The Foundation for the National Institutes of Health (FNIH) convened a meeting of public and potential private partners to discuss the development of the Accelerating Medicines Partnership (AMP) program for Schizophrenia (SCZ). This potential partnership, although still in the early stages of consideration, represents immense opportunity for investment and coordinated research on the root causes, progression, and treatment of schizophrenia.
Accelerating Treatment Development Research in Clinical High Risk for Psychosis

Goal:

This concept proposes to establish a network of academic and community sites that can rapidly recruit well-characterized cohorts of help-seeking individuals who meet criteria for “clinical high risk” (CHR) for psychosis. The multi-site network will conduct collaborative studies to test and validate biological measures and prediction algorithms to support experimental medicine trials involving CHR participants.
EPINET Partners

Early Psychosis Researchers

Early Psychosis Clinicians

Persons with Psychosis and Family Members
Summary

1. Early intervention improves clinical outcomes among people with first episode psychosis (FEP).
2. Coordinated Specialty Care is a feasible and effective approach to early intervention in FEP.
3. The Early Psychosis Intervention Network will test learning health care principles of science-driven, continuously improving care in early psychosis.
Acknowledgements

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Thank You!

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