Expansion of First Episode Psychosis Treatment in the U.S.

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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

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Schizophrenia Facts

- ~2.5 million U.S. citizens are affected
- Typical onset between ages 16-30
- Symptoms include altered perceptions, thinking, and disorganized behavior
- Unemployment, homelessness, and incarceration are common
- People with schizophrenia die 8-10 years earlier than other people

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Treatment Delays are Common

- The time between the onset of psychotic symptoms and initiation of treatment is typically 1-3 years in the U.S.
- Lengthy treatment delays are associated with negative outcomes
  - Poorer response to antipsychotic medications
  - Poorer symptomatic and functional outcomes

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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

Recommended FEP Practices

- Research-supported interventions
  - Low-dose antipsychotic medications
  - Cognitive and behavioral psychotherapy
  - Family education and support
  - Educational and vocational rehabilitation
- Team-based, person-centered care
- Collaborative decision-making
- Assertive outreach to community

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Transforming the understanding and treatment of mental illnesses.

http://www.nimh.nih.gov/RAISE

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Home > Health & Education > Mental Health Information > Schizophrenia

Recovery After an Initial Schizophrenia Episode (RAISE)

- **Home**
- Patients and Families
- State Health Administrators/Clinics
- RAISE Questions and Answers
- Published Articles
- RAISE In The News
- Contact Us / Press
- Glossary

What is RAISE?

In 2008, the National Institute of Mental Health (NIMH) launched the *Recovery After an Initial Schizophrenia Episode (RAISE)* project. RAISE is a large-scale research initiative that began with two studies examining different aspects of coordinated specialty care (CSC) treatments for people who were experiencing first episode psychosis. One study focused on whether or not the treatment worked. The other project studied the best way for clinics to start using the treatment program. Read more.

What is Psychosis?

Science News About Schizophrenia

- Disorders Share Same Gene Pathways
  January 29, 2015
- Medications May Not Meet Guidelines
  December 12, 2014
- Medical Risks Rise Early in Psychosis
  October 8, 2014

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NIMH RAISE Research Teams

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

The Feinstein Institute
for Medical Research
North Shore-Long Island Jewish Health System

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

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Coordinated Specialty Care (CSC)

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CSC Roles and Functions

Role	Services Provided	Credentials
Team Leadership	Outreach to community providers, clients, and family members; coordinate services among team members; provide ongoing supervision	Licensed clinician; management skills
Pharmacotherapy; Coordination with Primary Care	Medication management; coordination with primary medical care to address health issues	Licensed M.D., NP, or RN
Psychotherapy	Individual and group psychotherapy (CBT and behavioral skills training)	Licensed clinician
Family Therapy	Psychoeducation, relapse prevention counseling, and crisis intervention services	Licensed clinician
Care Management	Care management functions provided in clinic and community settings	Licensed clinician
Supported Employment and Education	Supported employment and supported education; ongoing coaching and support following job or school placement	BA; IPS training and experience

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RAISE Early Treatment Program Clinical Trial

- Cluster RCT
- Coordinated Specialty Care (CSC) versus TAU for FEP
- 34 Community clinics
- 21 States
- 404 participants with FEP
  - Mean age 23 years
  - Median Duration of Untreated Psychosis 74 weeks

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The American Journal of Psychiatry

Comprehensive Versus Usual Community Care for First-Episode Psychosis: 2-Year Outcomes From the NIMH RAISE Early Treatment Program

John M. Kane, M.D., Delbert G. Robinson, M.D., Nina R. Schooler, Ph.D., Kim T. Mueser, Ph.D., David L. Penn, Ph.D., Robert A. Rosenheck, M.D., Jean Addington, Ph.D., Mary F. Brunette, M.D., Christoph U. Correll, M.D., Sue E. Estroff, Ph.D., Patricia Marcy, B.S.N., James Robinson, M.Ed., Piper S. Meyer-Kalos, Ph.D., L.P., Jennifer D. Gottlieb, Ph.D., Shirley M. Glynn, Ph.D., David W. Lynde, M.S.W., Ronny Pipes, M.A., L.P.C.-S., Benji T. Kurian, M.D., M.P.H., Alexander L. Miller, M.D., Susan T. Azrin, Ph.D., Amy B. Goldstein, Ph.D., Joanne B. Severe, M.S., Haiqun Lin, M.D., Ph.D., Kyaw J. Sint, M.P.H., Majnu John, Ph.D., Robert K. Heinssen, Ph.D., A.B.P.P.

Objective: The primary aim of this study was to compare the impact of NAVIGATE, a comprehensive, multidisciplinary, team-based treatment approach for first-episode psychosis designed for implementation in the U.S. health care system, with community care on quality of life.

Method: Thirty-four clinics in 21 states were randomly assigned to NAVIGATE or community care. Diagnosis, duration of untreated psychosis, and clinical outcomes were assessed via live, two-way video by remote, centralized raters masked to study design and treatment. Participants (mean age, 23) with schizophrenia and related disorders and ≤6 months of antipsychotic treatment (N=404) were enrolled and followed for ≥2 years. The primary outcome was the total score of the Heinrichs-Carpenter Quality of Life Scale, a measure that includes sense of purpose, motivation, emotional and social interactions, role functioning, and engagement in regular activities.

Results: The 223 recipients of NAVIGATE remained in treatment longer, experienced greater improvement in quality of life and psychopathology, and experienced greater involvement in work and school compared with 181 participants in community care. The median duration of untreated psychosis was 74 weeks. NAVIGATE participants with duration of untreated psychosis of <74 weeks had greater improvement in quality of life and psychopathology compared with those with longer duration of untreated psychosis and those in community care. Rates of hospitalization were relatively low compared with other first-episode psychosis clinical trials and did not differ between groups.

Conclusions: Comprehensive care for first-episode psychosis can be implemented in U.S. community clinics and improves functional and clinical outcomes. Effects are more pronounced for those with shorter duration of untreated psychosis.

Am J Psychiatry 2016; 173:362–372; doi: 10.1176/appi.ajp.2015.15050632

RAISE Findings

- After 2 years, Coordinated Specialty Care was superior to usual community care on:
  - Quality of life
  - Symptom improvement
  - Involvement in work or school
  - Cost-effectiveness
- CSC worked better for patients with shorter duration of untreated psychosis

Kane, Robinson, Schooler, et al., 2016

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Psychiatric Services

Implementing Coordinated Specialty Care for Early Psychosis: The RAISE Connection Program

Lisa B. Dixon, M.D., M.P.H., Howard H. Goldman, M.D., Ph.D., Melanie E. Bennett, Ph.D., Yuanjia Wang, Ph.D., Karen A. McNamara, M.S.W., Ph.D., Sapna J. Mendon, M.S.W., Amy B. Goldstein, Ph.D., Chien-Wen J. Choi, M.S., Rufina J. Lee, M.S.W., Ph.D., Jeffrey A. Lieberman, M.D., Susan M. Essock, Ph.D.

Objective: The RAISE (Recovery After an Initial Schizophrenia Episode) Connection Program Implementation and Evaluation Study developed tools necessary to implement and disseminate an innovative team-based intervention designed to promote engagement and treatment participation, foster recovery, and minimize disability among individuals experiencing early psychosis. This article describes the treatment model and reports on service utilization and outcomes. It was hypothesized that individuals' symptoms and functioning would improve over time.

Methods: A total of 65 individuals in RAISE Connection Program treatment across two sites (Baltimore and New York City) were enrolled and received services for up to two years. Primary outcomes, including social and occupational functioning and symptoms, were evaluated. Trajectories for individuals' outcomes over time were examined with linear and quadratic mixed-effects models with repeated measures.

Results: Measures of occupational and social functioning improved significantly over time, symptoms declined, and rates of remission improved. Visits were most frequent during the first three months, with a mean±SD of 23.2±11.5 unduplicated staff encounters per quarter. Such encounters decreased to 8.8±5.2 in the final quarter of year 2.

Conclusions: The overall project was successful in that the treatment program was delivered and tools useful to other clinical settings were produced. The strengths of this study lie in the demonstrated feasibility of delivering the coordinated specialty care model and the associated high rates of engagement among individuals who are typically difficult to engage in treatment. Notwithstanding the lack of a built-in comparison group, participant outcomes were promising, with improvements comparable to those seen with other successful interventions.

Psychiatric Services 2015; 66:691–698; doi: 10.1176/appi.ps.201400281

Psychiatric
Services

First-Episode Services for Psychotic Disorders in the U.S. Public Sector: A Pragmatic Randomized Controlled Trial

Vinod H. Srihari, M.D., Cenk Tek, M.D., Suat Kucukgoncu, M.D., Vivek H. Phutane, M.D., Nicholas J. K. Breitborde, Ph.D., Jessica Pollard, Ph.D., Banu Ozkan, M.D., John Saksa, Psy.D., Barbara C. Walsh, Ph.D., Scott W. Woods, M.D.

Objective: This study sought to determine the effectiveness of a comprehensive first-episode service, the clinic for Specialized Treatment Early in Psychosis (STEP), in an urban U.S. community mental health center by comparing it with usual treatment.

Methods: This pragmatic randomized controlled trial enrolled 120 patients with first-episode psychosis within five years of illness onset and 12 weeks of antipsychotic exposure. Referrals were mostly from inpatient psychiatric units, and enrollees were randomly allocated to STEP or usual treatment. Main outcomes included hospital utilization (primary); the ability to work or attend age-appropriate schooling—or to actively seek these opportunities (vocational engagement); and general functioning. Analysis was by modified intent to treat (excluding only three who withdrew consent) for hospitalization; for other outcomes, only data for completers were analyzed.

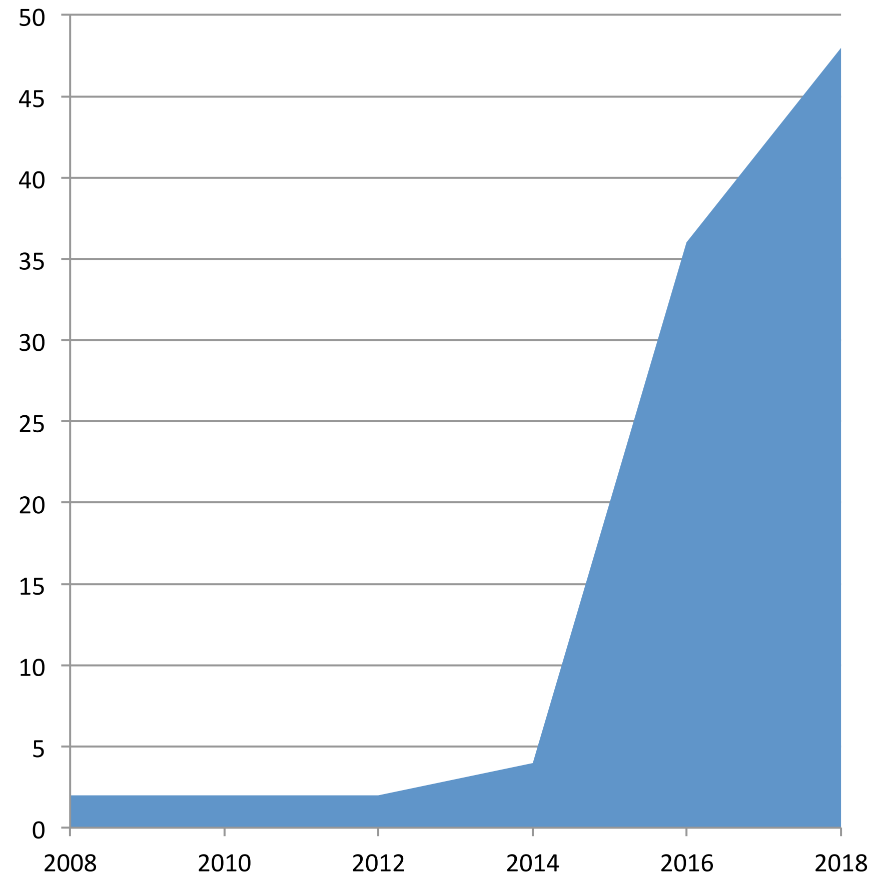
Results: After one year, STEP participants had less inpatient utilization compared with those in usual treatment: no psychiatric hospitalizations, 77% versus 56% (risk ratio [RR]=1.38, 95% confidence interval [CI]=1.08–1.58); mean hospitalizations, .33±.70 versus .68±.92 (p=.02); and mean bed-days, 5.34±13.53 versus 11.51±15.04 (p=.05). For every five patients allocated to STEP versus usual treatment, one additional patient avoided hospitalization over the first year (number needed to treat=5; CI=2.7–26.5). STEP participants also demonstrated better vocational engagement (91.7% versus 66.7%; RR=1.40, CI=1.18–1.48) and showed salutary trends in global functioning measures.

Conclusions: This trial demonstrated the feasibility and effectiveness of a U.S. public-sector model of early intervention for psychotic illnesses. Such services can also support translational research and are a relevant model for other serious mental illnesses.

Psychiatric Services 2015; 66:705–712; doi: 10.1176/appi.ps.201400236

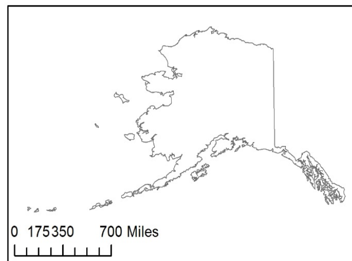
New Federal Funding Accelerates Implementation of Evidence-Based Care for First Episode Psychosis

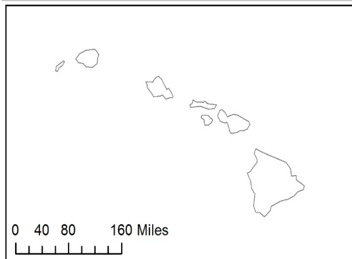
Dates and Milestones
July, 2009 RAISE studies begin
December, 2013 RAISE feasibility study completed
January, 2014 H.R. 3547 ($25M set-aside for FEP)
April, 2014 NIMH/SAMHSA provide guidance to states
December, 2014 H.R. 88 ($25M set-aside for FEP)
October, 2015 RAISE clinical trial completed
October, 2015 CMS coverage of FEP intervention services
December, 2015 H.R. 2029 ($50M set-aside for FEP)

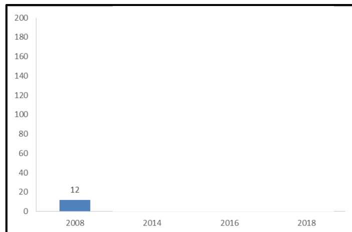


Mental Health Block Grant Plans: https://bgas.samhsa.gov/

CSC Programs before RAISE



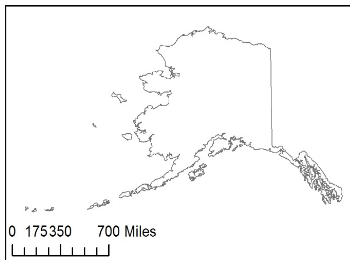


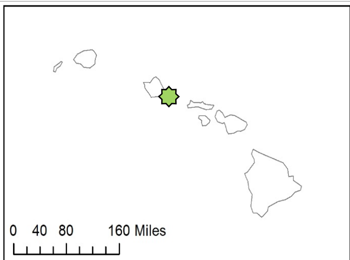


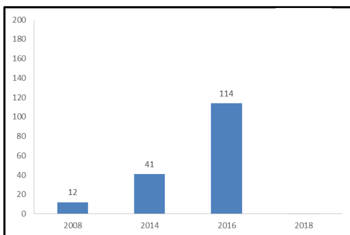
0 62.5 125 250 Miles

2008 2014 2016 2018

CSC Programs after RAISE, 2016







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2008 2014 2016 2018

Looking beyond RAISE

Can we create a national early psychosis learning community in the United States?

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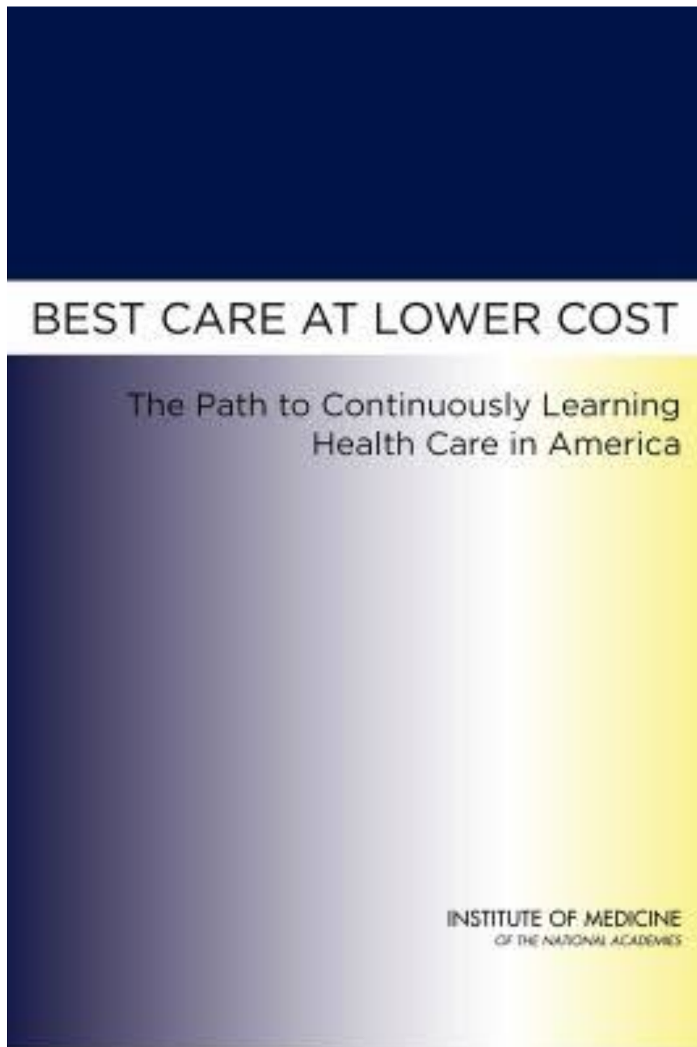
Learning Health Care



- Culture of continuous learning
- Standardized measures, data sharing, big data analytics
- Outcomes stakeholders value
- Feedback loops for ongoing system improvement
- Practice-based research
- Clinical data driving scientific discovery

Better population-level outcomes

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Early Psychosis Intervention Network (EPINET)

A national learning healthcare network of early psychosis clinics

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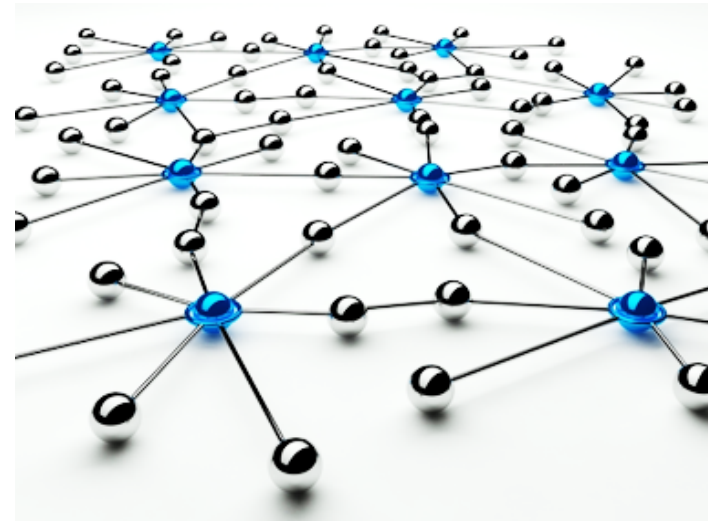
EPINET Goals

- 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

EPINET Tasks

- Establish common data elements

- Standardize clinical data collection

Evaluation of First Episode Psychosis Treatment Provided Under the Mental Health Block Grant 10% Set Aside

Harmonizing Clinical Data Collection in Community-Based Treatment Programs for First Episode Psychosis, Sep 7-8, 2017

- Develop healthcare informatics

The NIMH Data Archive

EPINET Timeline

	2016				2017				2018				2019				2020			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Phenx Early Psychosis Common Data Elements																				
SAMHSA-NIMH-Westat Fidelity Evaluation Study																				
NIMH Healthcare Informatics Platform																				
EPINET-Alpha Phase																				
EPINET-Beta Phase																				

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Clinical High Risk for Psychosis

Implementing Early Intervention Services for Clinical High Risk for Psychosis in U.S. Community Settings:

What Do We Know and What Do We Need to Know?

NIMH/SAMHSA meeting, July 27-28, 2017

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Clinical High Risk for Psychosis

CHR interventions with sufficient evidence for implementation in community settings:

- Individual family therapy
- Cognitive-behavioral therapy for psychosis
- NIMH and SAMHSA: How to facilitate at federal level?

Screening and diagnosis of CHR in community settings:

- Accurate diagnosis of CHR is possible but requires adequate training
- NIMH-funded studies underway

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  - Joanne Severe
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