

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





#### Early Intervention Programs, 2008



# RA SE

#### Recovery After an Initial Schizophrenia Episode

A Research Project of the NIMH





#### **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



#### **Coordinated Specialty Care**





#### **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

Kane et al., Am J Psychiatry, 2016; Rosenheck et al., Schiz Bull, 2016



#### Timing is Important

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



et al., Schiz Bull, 2016

Kane et al., Am J Psychiatry, 2016; Rosenheck et al., Schiz Bull, 2016

## **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.



#### Specialized Treatment Early in Psychosis Program

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.

Hospitalized during 6 months before enrollment Hospitalized during 1 year after enrollment Vocationally engaged at enrollment □ Vocationally engaged 1 year after enrollment 100 \* 44/48 49/60 46/57 80 34/48 25/37 26/37 Percentage of patients 60 25/57 40 14/60 20 0 STEP STFP Usual Usual treatment treatment Hospitalization Work/School



#### Specialized Treatment Early in Psychosis Program

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#### **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?
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National Alliance on Mental Illness











### 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. 2029 \$50M in 2016
- H.R. 34 21<sup>St</sup> Century Cures
  Act, 2017-2027









## Medicaid Policy Guidance



http://www.medicaid.gov/federal-policyguidance/federal-policy-guidance.html

#### Federal Policy Guidance



"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."



## Bringing CSC to Scale

#### Dates and First Episode Psychosis (FEP) Milestones

6	
Jul. 2009	NIMH clinical trials for FEP commence
Dec. 2013	NIMH implementation study completed
Jan. 2014	P.L. 113-76: \$22.8M set-aside for FEP
Apr. 2014	NIMH/SAMHSA FEP guidance to states
May 2014	SAMHSA technical support to states begins
Dec. 2014	P.L. 113-483: \$22.8M set-aside for FEP
Oct. 2015	NIMH clinical trials for FEP completed
Oct. 2015	CMS coverage of FEP intervention services
Dec. 2015	P.L. 114-113: \$50.5M set-aside for FEP
Dec. 2016	P.L. 114-255: 21 <sup>st</sup> Century Cures Act
May 2017	P.L. 115-31: \$53.3M set-aside for FEP
Mar. 2018	P.L. 115-141: \$68.5M set aside for FEP
Mar. 2019	P.L. 115-245: \$68.5M set aside for FEP

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

#### **Cumulative Number of States with Early Psychosis Intervention Plans**



#### Early Intervention Programs, 2008



#### Early Intervention Programs, 2018



#### **RAISE Research Questions**

#### Is early intervention feasible?

#### Is early intervention effective?

#### Are evidence-based services scalable?



### A Decade of Progress



#### Looking Ahead

## Connecting the U.S. early psychosis community





## Learning Health Care



- Provide CSC services
- Measure results
- Improve services
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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 o ~75% community clinics  $\circ$  ~2,300 currently enrolled ○ ~5,000 target enrollment ○ ~20,000 assessments/year



#### **EPINET Practice Opportunities**





## **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





#### https://www.nami.org/Learn-More/Research/Advancing-Discovery-Summit-Series

#### **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.



NIH	National Institute of Mental Health	Transformi and treatm	Transforming the understanding and treatment of mental illnesses.						
ff	MENTAL HEALTH	INFORMATION	OUT	REACH	RESE/	ARCH	FUN	DING	
Opportunitie	es & Announcements	Funding Strategy fo	r Grants	Application	Process	Managin	g Grants	Clinical Re	
Home > Funding > Grant Writing & Approval Process > Concept Clearances									

#### 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.



NAMHC Concept Clearance; May 29, 2019

#### **EPINET Partners**



National Institute of Mental Health

### 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.



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