Behavioral Health is Essential To Health

Prevention Works

Treatment is Effective

People Recover
Insights from Measures Used in the National Evaluation of the 10% Set Aside and Proposed for NIMH EPINET

May 23, 2017
The views, opinions, and content expressed in this presentation do not necessarily reflect the views, opinions, or policies of the Center for Mental Health Services (CMHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), or the U.S. Department of Health and Human Services (HHS).
Agenda

• Welcome and Introductions
  – David Shern, Ph.D., NASMHPD
  – Monique Browning, SAMHSA’s Center for Mental Health Services

• SAMHSA Mental Health Block Grant 10% Set Aside Evaluation
  – Preethy George, Ph.D., Westat
  – Shoma Ghose, Ph.D., Westat

• Using the Modified CSI, the Alexandria Experience
  – Nichole Rohrer, Psy.D. TRAILS Program, Alexandria CSB

• Establishing a National Early Psychosis Intervention Network in the United States
  – Robert K. Heinssen, Ph.D., NIMH
SAMHSA Mental Health Block
Grant 10% Set Aside Evaluation
(MHBBG 10%)

Preethy George, Ph.D.
Shoma Ghose, Ph.D.
The MHBG 10% Evaluation is a collaboration among the following three federal agencies:

- Substance Abuse and Mental Health Services Administration (SAMHSA)
- National Institute of Mental Health (NIMH)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
The Westat Evaluation Team

- Westat is the company that has been contracted to lead the evaluation.

- Westat is conducting the evaluation in collaboration with NRI and the National Association of State Mental Health Program Directors (NASMHPD).
The Westat Evaluation Team (cont.)

Principal Investigator:
Abram Rosenblatt

Senior Investigators:
Lisa Dixon
Howard Goldman

Project Manager:
Preethy George

Research Methods Group
Tamara Sale
Ted Lutterman
Kristin Neylon
Patricia Shea
David Shern
Donald Addington
Gary Bond
Robert Drake
Objectives of the MHBG 10% Evaluation

- Identify and describe CSC program services being offered nationally.
- Assess program fidelity to the NIMH-CSC model*.
- Explore local environmental and contextual factors related to how CSC programs are implemented.
- Explore how CSC programs increase access to essential services and improve client outcomes such as symptom severity, employment, education, and quality of life.

## Core Research Questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>Data Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Site Survey</td>
</tr>
<tr>
<td>1. To what extent do FEP programs increase access to mental health (MH) services?</td>
<td>✔</td>
</tr>
<tr>
<td>2. What services are being (or will be) provided as a result of the state implementation of CSC?</td>
<td>✔</td>
</tr>
<tr>
<td>3a. Does high fidelity CSC lead to earlier identification of MH (and co-occurring substance use) problems?</td>
<td>✔</td>
</tr>
<tr>
<td>3b. How well does CSC engage various demographic groups?</td>
<td>✔</td>
</tr>
<tr>
<td>4a. To what extent do individuals with FEP and their families actively participate in CSC programs?</td>
<td>✔</td>
</tr>
<tr>
<td>4b. What impact does participation in CSC services have on the individual’s functional outcomes?</td>
<td>✔</td>
</tr>
<tr>
<td>5a. To what extent are selected evaluation sites delivering CSC with high fidelity?</td>
<td>✔</td>
</tr>
<tr>
<td>5b. Do CSC programs with higher fidelity have better participant outcomes?</td>
<td>✔</td>
</tr>
</tbody>
</table>
Four Study Components

All Sites that Receive MHBG 10% Set Aside Funds for First Episode Psychosis participate in this national online survey

(approximately 248 sites)

<table>
<thead>
<tr>
<th>Data Collection Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Site Survey</td>
</tr>
</tbody>
</table>

Sites Selected to Participate in the National Evaluation

(approximately 32 sites)

<table>
<thead>
<tr>
<th>Data Collection Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Client Outcomes</td>
</tr>
<tr>
<td>3. Fidelity Assessment</td>
</tr>
<tr>
<td>4. Process Assessment</td>
</tr>
</tbody>
</table>
Timeline for Study Components

- **Year 1**
  - Q1: 9/16
  - Q2: 12/16
  - Q3: 3/17
  - Q4: 6/17

- **Year 2**
  - Q1: 9/17
  - Q2: 12/17
  - Q3: 3/18
  - Q4: 6/18

- **Year 3**
  - Q1: 9/18
  - Q2: 12/18
  - Q3: 3/19
  - Q4: 6/19

- **Client-level outcomes every 6 months**

- **OMB Approval**

- **Online Survey**

- **T1 Fidelity Assessment**

- **T2 Process Evaluation**

- **T2 Fidelity Assessment**

- **T1 Process Evaluation**

- **T1 Process Evaluation**

- **T2 Process Evaluation**
Site Selection

- 38 Study Sites

- Site selection factors:
  1. Representation from 10 HHS regions of the U.S.
  2. Program Model/Type
  3. Variation in FEP Services Implementation Status
  4. Variation in technical assistance received at start up of program
  5. Urban/Rural
Site Selection Process

1. Identify Sites Using 10% Set Aside funds for CSC
   - 248 sites

2. Sites that have begun to use funds to support CSC services (based on self report)
   - 216 sites

3. Create a short list of possible study sites based on specified criteria to ensure diversity

4. List of Possible Study Sites
   - 56 sites

5. Discussions with Sites to determine whether sites meet study inclusion criteria
Study Sites
Outcome Measures

As part of the discussions with sites, we asked sites what outcomes they are collecting from clients. Specifically we were interested in tools that assess:

1. Symptoms
2. Functioning
3. Quality of life
## Symptom Measures Used by Sites

<table>
<thead>
<tr>
<th>PhenX Tools Used by Sites</th>
<th># of Sites that Use this Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Brief Psychiatric Rating Scale (BPRS) (clinician reported)</td>
<td>8</td>
</tr>
<tr>
<td>2  Modified Colorado Symptom Index (self report)</td>
<td>1</td>
</tr>
</tbody>
</table>

| Other Tools not in the PhenX Toolkit                                                     |                                 |
|------------------------------------------------------------------------------------------|                                 |
| 3  MIRECC-GAF (Symptom Scale)                                                            | 12                               |
| 4  Clinical Global Impression (CGI)Scale                                                  | 7                                |
| 5  BASIS                                                                                  | 3                                |
| 6  Each of the following tools had at least 2 sites using them:  Dimensions of Psychopathology Symptom Rating; LOCUS; and SIPS | 2/each                           |
## Other Measures Used by Sites

<table>
<thead>
<tr>
<th>PhenX Tool</th>
<th># Sites that use this measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Social and Role Dysfunction in Psychosis and Schizophrenia</td>
<td>14</td>
</tr>
<tr>
<td><strong>Other tools</strong></td>
<td></td>
</tr>
<tr>
<td>2. Lehman Quality of Life</td>
<td>12</td>
</tr>
<tr>
<td>3. Duncan Feedback Informed Treatment Measures</td>
<td>6</td>
</tr>
<tr>
<td>4. Schizophrenia Quality of Life Scale</td>
<td>3</td>
</tr>
<tr>
<td>5. Reaching Recovery Toolkit</td>
<td>2</td>
</tr>
<tr>
<td>6. BASIS 32</td>
<td>2</td>
</tr>
</tbody>
</table>
# MHBG 10% Study Measures

## Minimum Data Set
List of items that are routinely collected by most Coordinated Specialty Care Programs

## Symptom Measures
1. Modified Colorado Symptom Index (CSI)
   2. If available, Brief Psychiatric Rating Scale (BPRS)
   3. If available, MIRECC-GAF (symptom scale)

## Quality of Life and Functioning Measures
1. Global Functioning: Social And Role Scales
2. Lehman Quality of Life Scale (global scale only)
   3. If available, MIRECC-GAF (social functioning & occupational functioning scale)
Data Collection Timeline

April 2017

Oct. 2017
Study/data collection begins

April 2018

April 2019-
(data collection ends)
Timeline for Reporting Outcome Data

April 2017

October 2017

April 2018

October 2018

April 2019

All new clients at the sites become part of the study for 12 month period

Data Collection Time 1

Data Collection Time 2

Data Collection Time 3

Data Collection Time 4
Study Outcome Measures

- **Global Functioning: Social and Roles Scale**
  - Clinician Reported
  - Excellent interrater reliability and evidence of construct/discriminant validity
  - Examines how an individual is doing in social and role domains, regardless of their symptoms

- **Lehman Quality of Life (global scale)**
  - Client Self Report
  - Quick and easy to complete
Study Outcome Measures

• Modified Colorado Symptom Index
  – Client self-report
  – Excellent ratings of reliability and validity
  – Short and easy to complete
Using the Modified Colorado Symptom Index: The Alexandria Experience

Nichole Rohrer, Psy.D.
TRAILS Program, Alexandria CSB
## Background

- Virginia has 8 programs from across the 5 major regions:
  - Alexandria
  - Fairfax-Falls Church
  - Prince William
  - Loudoun
  - Rappahannock-Rapidan
  - Western Tidewater
  - Highlands
  - Henrico

- Grants began in March 2015
- All VA sites agreed to use the Colorado Symptom Index (CSI) as an outcome measure in 2015
- Submissions to the State began in January 2016
- Data is collected quarterly
City of Alexandria

- Densely populated urban community of approximately 150,000 within 15.4 square miles
- 60% of Alexandria City Public School students are on free and reduced lunch
- Diverse community
  - Asian: 4.63%
  - Black: 29.32%
  - Hispanic: 36.00%
  - White: 27.10%
  - Native Hawaiian/Pacific Islander: 0.16%
  - Native American: 0.21%
  - Multi-racial: 2.58%
  - Native languages: 113
TRAILS Program

• Began enrolling clients in February 2015
• Includes clients with Affective Disorders
• Client demographics are similar to the City’s
• Started using the Modified Colorado in July 2015
• Submissions to the State began in January 2016
• To date we have data on 21 clients
Data Trends

- Preliminary review of site data
- Data shows slight improvement over time
- Variability in reporting
- Reports at baseline are lower than expected
- Increase in symptoms following baseline
  - Possibly related to increased insight
  - Comfort with reporting
Data Trends (Continued)

• Cognitive and anxiety symptoms appear to persist
  – Potentially impacted by situational factors
• Client report is not always consistent with other data
  – Provider report
  – Program information re: work and school
Clinical Uses

• CSI is helpful with identifying changes in symptoms
  – Increases and decreases
  – Clients may report symptoms on the CSI they do not report to the clinician
• Sites find the Distress Tolerance Index helpful
• CSI is useful as a therapeutic tool
  – Individually and with families
  – Medication
• Use during screening
Challenges

• Language
  – Understanding terminology
    • Sometimes a client will get stuck on language
    • “What do you mean by most of the time?”
    • “What is a hallucination?”
    • “What does tense mean?”
  – Non-English speaking clients
    • Currently the measure is only in English and Spanish
  – Cultural differences
    • The meaning of words can differ
Additional Observations

• Formatting and Length
• Lack of family or provider report
• Use with individuals under 18
• Client’s rapid responses
• Inability to complete form
• How the CSI presented to clients
Other Considerations

• Frequency of administration
  – Could giving it more often be helpful or more accurate?

• Does the diagnosis impact client reporting?

• What happens when the client is not able to complete the evaluation?
Conclusions

• Preliminary data shows some improvement
• CSI is clinically helpful in our work with clients and families
• Looking forward to what VA and other sites find using the CSI
QUESTIONS?
Establishing a National Early Psychosis Intervention Network in the United States

Robert K. Heinssen, Ph.D., ABPP

NASMHPD/NRI Webinar on Outcome Measurement in First Episode Programs

23 May 2017
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
Recovery After an Initial Schizophrenia Episode (RAISE)

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?
Coordinated Specialty Care

Service User

- Medication/Primary Care
- Cognitive Behavioral Psychotherapy
- Supported Employment and Education
- Family Education and Support
- Case Management
✔ Early intervention for first episode psychosis is feasible in the U.S.

✔ Coordinated specialty care is more effective than usual care.

✔ It is possible to implement research-based services in community clinics.
RAISE Findings Influenced States’ Adoption of Evidence-Based Care for First Episode Psychosis

Dates and Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>July, 2009</td>
<td>RAISE studies begin</td>
</tr>
<tr>
<td>December, 2013</td>
<td>RAISE feasibility study completed</td>
</tr>
<tr>
<td>April, 2014</td>
<td>NIMH/SAMHSA provide guidance to states</td>
</tr>
<tr>
<td>December, 2014</td>
<td>H.R. 88 ($25M set-aside for FEP)</td>
</tr>
<tr>
<td>October, 2015</td>
<td>RAISE clinical trial completed</td>
</tr>
<tr>
<td>October, 2015</td>
<td>CMS coverage of FEP intervention services</td>
</tr>
<tr>
<td>December, 2015</td>
<td>H.R. 2029 ($50M set-aside for FEP)</td>
</tr>
</tbody>
</table>

Cumulative Number of States with Early Psychosis Intervention Plans

Mental Health Block Grant Plans: https://bgas.samhsa.gov/
CSC Programs before RAISE

2008  2014  2016  2018
CSC Programs after RAISE/MHBBG

- 2008
- 2014
- 2016
- 2018
Looking beyond RAISE

Creating an early psychosis learning community in the United States
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
EPINET Tasks

- Establish common data elements
- Standardize clinical data collection
- Develop healthcare informatics

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

Welcome to the PhenX Toolkit

The PhenX (consensus measures for Phenotypes and eXposures) Toolkit is a catalog of recommended, standard measures of phenotypes and environmental exposures for use in biomedical research. PhenX measures can be used to expand a study design beyond the primary research focus. Use of PhenX measures facilitates cross-study analysis, potentially increasing the scientific impact of individual studies. The PhenX Toolkit is a Web-based resource and is available for use at no cost. More >>

Mental Health Research Collection

- Demographics
- Life Events
- Broad Psychopathology
- Impairment
- Tobacco, Alcohol, and Substance Use
- Suicide Behavior
- Post-Traumatic Stress
- Eating Disorders
- Early Psychosis

https://www.phenxtoolkit.org//
### PhenX Early Psychosis Workgroup

#### Translational Research
- Dost Öngür, MD, PhD*
- Cameron Carter, MD
- Raquel Gur, MD, PhD
- Larry Seidman, PhD
- Carol Tamminga, MD
- Akira Sawa, MD, PhD

#### Clinical Services
- Lisa Dixon, MD, MPH*
- Nev Jones, PhD
- Rachel Loewy, PhD
- Diana Perkins, MD, MPH
- Tamara Sale, MA

*Early Psychosis Workgroup Co-Chairs
PhenX Vetting Criteria

- Validity, reliability, and utility of measures
- Degree of burden on research participants, service users, investigators, and/or clinicians
- Broad applicability and general acceptance
- Ease of implementation across CSC settings

48 scientists, clinicians, service users, and CSC program administrators provided feedback!
## Selected Clinical Services Measures

<table>
<thead>
<tr>
<th>Domain</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric Diagnosis</td>
<td>Structured Clinical Interview for DSM-5 Disorders – Clinician Version</td>
</tr>
<tr>
<td>Psychopathology</td>
<td>Colorado Symptom Index*</td>
</tr>
<tr>
<td></td>
<td>Brief Psychiatric Rating Scale</td>
</tr>
<tr>
<td>Psychosocial Functioning</td>
<td>Global Functioning Scale: Social*</td>
</tr>
<tr>
<td></td>
<td>Global Functioning Scale: Role*</td>
</tr>
<tr>
<td>Family Functioning</td>
<td>Systematic Clinical Outcome Routine Evaluation Index of Family Functioning and Change (SCORE-15)</td>
</tr>
<tr>
<td>Pharmacotherapy</td>
<td>Brief Adherence Rating Scale</td>
</tr>
<tr>
<td></td>
<td>Glasgow Antipsychotic Side-Effect Scale</td>
</tr>
<tr>
<td>Shared Decision Making</td>
<td>CollaboRATE</td>
</tr>
<tr>
<td>Satisfaction with Services</td>
<td>Youth Services Survey</td>
</tr>
<tr>
<td>Recovery and Wellbeing</td>
<td>Questionnaire about the Process of Recovery Personal Wellbeing Index</td>
</tr>
</tbody>
</table>

*Required measure in the MHBG 10% Set Aside FEP Evaluation*
Gaps in Clinical Services Measures

- CSC program fidelity/program quality
- Duration of untreated psychosis
- Hospitalizations, emergency department visits, crisis intervention services
- Quality of school or work involvement
## EPINET Timeline

<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>Q</td>
<td>Q</td>
<td>Q</td>
<td>Q</td>
<td>Q</td>
</tr>
<tr>
<td>Phenx Early Psychosis Common Data Elements</td>
<td>Q 1</td>
<td>Q 2</td>
<td>Q 3</td>
<td>Q 4</td>
<td>Q</td>
</tr>
<tr>
<td>SAMHSA-NIMH-Westat Fidelity Evaluation Study</td>
<td>Q 1</td>
<td>Q 2</td>
<td>Q 3</td>
<td>Q 4</td>
<td>Q</td>
</tr>
<tr>
<td>NIMH Healthcare Informatics Platform</td>
<td>Q 1</td>
<td>Q 2</td>
<td>Q 3</td>
<td>Q 4</td>
<td>Q</td>
</tr>
<tr>
<td>EPINET-Alpha Phase</td>
<td>Q 1</td>
<td>Q 2</td>
<td>Q 3</td>
<td>Q 4</td>
<td>Q</td>
</tr>
<tr>
<td>EPINET-Beta Phase</td>
<td>Q 1</td>
<td>Q 2</td>
<td>Q 3</td>
<td>Q 4</td>
<td>Q</td>
</tr>
</tbody>
</table>

NIMH aims to solicit additional stakeholder input on CSC measurement approaches.
Acknowledgements

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

- RAISE Connection Program
  - Lisa Dixon
  - Jeffrey Lieberman
  - Susan Essock
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- **NIMH RAISE Team**
  - Susan Azrin
  - Amy Goldstein
  - Joanne Severe
  - Michaelle Scanlon

- **SAMHSA MHBG Team**
  - Paolo Delvecchio
  - Cyntrice Bellamy
  - Steven Dettwyler
Thank You!

rheinsse@mail.nih.gov
Thank you!

• Stay Tuned! Next Learning Exchange Call in June! Date TBD.
• Additional Technical Assistance Materials: https://www.nasmhpd.org/content/information-providers
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