National First Episode Psychosis Evaluation

Evaluation Protocol

Background and Purpose

The National First Episode Psychosis (FEP) Evaluation is funded through the federal community mental health block grant and required by the Substance Abuse and Mental Health Services Administration (SAMHSA) for all state's receiving block grant funds. Ten percent of all community mental health block grant funds are to be used for First Episode Psychosis programming. The purpose of the First Episode Psychosis evaluation is to describe characteristics of participants who are receiving First Episode Psychosis services and track their treatment experience and outcomes over time. As a block grant recipient, OhioMHAS is required to conduct an evaluation in conjunction with the contracted national evaluators housed at WESTAT, Inc., and provide local process and client-level data to assist with both state, local and national evaluation efforts. The goal is to collect process and outcomes data on all eligible and consenting participants receiving services within all local program sites, with the assistance of the local grantee's clinical and administrative staff. OhioMHAS' role is to facilitate and analyze the local data collection for the FEP evaluation.

The First Episode Psychosis evaluation is designed to:

- Describe how grantees are implementing and expanding FEP across Ohio.
- Examine what approaches and mechanisms are related to successful implementation and expansion.
- Describe the individual characteristics of youth and families receiving services in FEP sites throughout Ohio.
- Track how youth outcomes and experiences change over time.

Setting

All recruitment and data collection will take place where participant enrolls in FEP services. This will typically occur at a primary mental health service provider, where the majority of the treatment and support services will be delivered.

Measurement Instruments

All participating organizations will be expected to collect:

- *At Baseline*: gender, age, race, marital status, number of children, insurance type, approximate date of onset of psychosis, diagnosis.

- *Every six months while in treatment and at discharge*: services used, antipsychotic medication usage (type and dosage), employment and/or school attendance status, housing status, substance use (including tobacco and cigarettes), inpatient psychiatric hospitalizations, emergency room visits for psychiatric reasons, criminal justice involvement, the Colorado Symptom Index, the Social and Role Dysfunction in Psychosis and Schizophrenia scale, Lehman Quality of Life (1-item), suicide attempts in past 6 months, insight into illness. Instrument are attached.

Recruitment

No formal recruitment will be necessary. Participation in the study as well as the risks/benefits of will be presented to each potential subject at enrollment into the program.

Data Collection

Interviews will occur at time of enrollment into FEP programing, every 6 months thereafter, and at clinical discharge. Interviews with participants should take approximately 30 minutes to complete. Surveys will be administered via hard copy form and entered into a secure, password protected data portal managed by OhioMHAS.

Data Management and Analysis Plan

Roles and responsibilities: Data will be collected by clinicians from the local sites using paper forms and entered into a data portal managed by OhioMHAS. Paper forms will be shredded once entered. That data will be transmitted to the National Evaluation via the secure SAMHSA federal portal online system.

Data generated by the project: The FEP Evaluation will be using quantitative surveys that will be anonymized using study ID numbers. Data will be collected using a hard copy of the instrument, then entered into the OhioMHAS data portal manually.

Period of data retention: All data will be destroyed locally, from both the local sites and OhioMHAS after submission to OhioMHAS. Once submitted to the National FEP data portal, data will be destroyed within 3 years of the end of the project. The project will end in September 2020.

Data format and dissemination:

The Bureau of Research and Evaluation at the Ohio Department of Mental Health and Addiction Services will be solely responsible for analysis and dissemination. The primary dissemination vehicles are the Quarterly and annual progress reports, though there may be other dissemination efforts as well. Only aggregated information will be disseminated and caution will be taken to avoid disseminating small numbers with demographic information that might be used to deduce the identity of individual respondents.

Data storage, safety and preservation of access:

The security of data entered and managed on the OhioMHAS Portal will be assured. Only authorized users, which include clinicians, the PI from the Bureau of Research and Evaluation will have access. To enter the restricted sections of the site, users must successfully login with their credentials. The participating organizations are responsible for entering, reviewing, and modifying performance data. All sections of the data portal are considered confidential, and is therefore password-protected. The PI for the evaluation will have access to system components or data and is authorized for such access. Access to system information is controlled by creating/removing accounts, assigning rights to accounts, granting access through physical access controls, and granting permission for access, transport or storage of information.

Data Preparation and Analysis: Data prep and analysis will be handled entirely by the PI/evaluator for at the Bureau of Research and Evaluation at OhioMHAS.

Incentives

There are no incentives for individuals to participate in the study.

Risks/Benefits to Participants and Precautions to be Taken

Potential Risks

Potential risks for participating in this study will include the potential for psychological distress due to the nature of the information being shared. Potential participants will be informed about the nature of the questions to be asked before assent for participation in the study is secured. Moreover, participants will be under no obligation to answer any question put forth nor will responses be linked in any way to participant identity in any record. If participants feel distressed by taking the survey, they may discuss this with their mental health clinician.

Benefits

Potential societal benefits outweigh the minimal risk to participants in that information gathered will aid both local and national First Episode Psychosis quality improvement. The data collected will work to better serve participants experiencing their first psychotic episode, with the hope of creating better outcomes for Ohio citizens that are newly diagnosed with Schizophrenia.

Privacy/Confidentiality

All data collected will be de-identified using participant ID numbers rather than name. There may be data included that could lead to potential identification, however, such as date of birth, gender, ethnicity, services received, etc., given the small sample size per site. That said, only clinicians and the evaluator will have access to individual-level data. Everyone else will have only de-identified aggregated data.

Consent and Assent

The evaluation will use active informed consent procedures that informs the participants of the purpose of the evaluation, describes what their participation entails, and addresses how privacy will be maintained as described above. In addition, providers will be provided with sample consent forms as recommendations or templates for providers to use when they collect the data. The participant consent, youth assent, and parental permission forms in this document will be shared with the participating provider organizations. The PI will train all providers to include specific language in their consent and assent forms to describe the data collection activities and information that can be accessed through the client's records and in order to reduce administration time. OhioMHAS plans to provide training to the participating organizations on the data collection process, including the procedures for introducing the interview, the confidentiality information, and the consent/assent/parental permission forms.

Respondents will be informed that their participation is voluntary, and that they have the right to discontinue participation at any time without impacting services they receive, and of the risks and benefits of participation. Informed consent will be obtained using a consent form by the clinician, counselor, or other staff designated by the service provider who administers this tool. Informed consent will be obtained from anyone ages 18 and older. Informed assent will be obtained from participating older children and adolescents (age 11–17 years). For all children under the age of 18, although permission will be sought from the parents or caregivers, the child's assent decides whether the child will participate in the study or not. Written informed consent or assent will be obtained from children and families at the point of entry into services and before the collection of evaluation data. Grantees are instructed to determine whether updates to consents are required at each data collection point, as the legal custody of a child may change, a child may become old enough to participate in a youth interview, a youth may become an emancipated minor or age up into adult status.