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Improving Behavioral Health Services for Individuals with SMI in Rural and Remote Communities

Increasing the Availability of Evidence-Based Practices in Rural and Remote Communities for Individuals with SMI

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Increasing the Availability of Evidence-Based Practices in Rural and Remote Communities for Individuals with SMI

The term "evidence-based practice (EBP)" refers to a behavioral health service or intervention that integrates the best research evidence with clinical expertise, cultural competence, and person-centered care in order to produce positive outcomes for individuals experiencing mental illness. However, EBPs are often developed within an urban context and do not fully capture the unique needs of rural communities inherent in their geography, resources, and culture. Given the discrepancies between urban and rural environments when implementing EBPs, best practices in rural and remote communities are often created through modifications to account for sparser geographic regions, a limited workforce, funding constraints, and cultural needs. Many rural states develop creative adaptations to best utilize their available resources to provide the most effective care possible.

Adapting EBPs for Rural and Remote Communities

As policymakers look to craft legislation and develop standards that ensure the highest quality of services in rural communities for adults with SMI, and providers look to implement programs of high quality that achieve maximal outcomes, they must creatively tailor evidence-based practices (EBPs) for delivery in a rural context. When EBPs are tailored to fit rural needs, it may be more important for funders and providers to measure the outcomes of services than rely on the monitoring of fidelity using instruments that were developed and tested in urban and suburban settings.

Rural mental health experts on our Expert Panel expressed a need for more research on implementing adaptations of EBPs for addressing SMI in rural communities and the associated challenges. Implementation efforts are most effective when addressing the specific needs and interests of providers (Systematic Review of EBPs for SMI in Rural America), and to this end, policymakers should carefully listen to and consider the unique barriers for rural providers, as well as the distinctive beneficial elements that rural communities provide. For example, rural experts commented that individuals in rural areas may have extended family, religious, and other cultural support systems that may not be as strong in more urban environments.

Key Lessons for Policymakers:

- Conduct effectiveness research across states and rural providers to understand and test the adaptations that are made to EBPs to accommodate for rural challenges.
- Work with CMS to develop reimbursement rates for modified EBPs that allow the services to be sustainable in rural and remote areas.
- Incorporate education and training opportunities on the use and benefits of clozapine and long-acting injectable medications into psychiatry residency training programs, as illustrated with the University of North Dakota's residency program's clozapine clinic, to increase prescribers' comfort level with these medications, including how providers working in rural areas can use these important medications in treating adults with complex cases of SMI.

Key Lessons for Providers:

- Collaborate with primary care providers and other community organizations to provide support services and adapt EBPs to the needs of rural and remote communities.
- To increase clozapine utilization, psychiatrists can collaborate with rural community centers (e.g., CMHCs, FQHCs, RHCs, and primary care) to administer regularly scheduled blood draws and ensure safe monitoring.

While many providers report consistently applying practice-relevant scientific evidence in treatment, fewer report regularly adhering to multistep and team-based EBPs due to organizational barriers, such as insufficient resources and staffing, time, and supports (Lee, 2015). Rural providers have also reported a sense of isolation from colleagues, limiting the ability to discuss research – a challenge to effectively supporting an exchange of information supporting tailored delivery of EBPs.

In analyzing EBPs for SMI in rural areas, findings show that adaptations occur but often are not documented. This limits the ability for other providers to replicate modifications and achieve the same results as the original EBP (Weaver, et al., 2015). Partnerships between researchers and rural practitioners can lead to developing locally relevant and user-friendly resources for those practitioners to improve their ability to provide evidence-based services. Rural considerations should be included when conducting research and creating policies on effective mental health interventions, as rural communities offering culturally relevant care can increase use of services (Trawver et al., 2020). In addition, if practices are adapted without careful tracking of outcomes, it cannot be known or shown whether the changes resulted in outcomes similar to those demonstrated using the EBP in non-rural areas. States can invest in data infrastructure to support rural providers in tailoring EBPs and measuring the impact of these modified practices in their communities.

Individual Placement and Support (IPS) is an EBP of supported employment that has been successfully implemented in rural settings. While there are significant barriers to implementing this practice in rural communities, results from 15 states demonstrate effective strategies for tailoring implementation of IPS for rural communities. Challenges in implementing the EBP have included limited public transportation, stigma related to mental health, internet connectivity, and employment opportunities. Strategies have differed by location, but common elements have been using natural supports for transportation, providing computer access for job applicants, developing relationships with local employers, and hiring IPS workers with local knowledge and cultural competence. In a region with no buses, a creative transportation solution involved a client who wanted to be an Uber driver providing transportation for other clients. The Expert Panel noted that the lack of anonymity in rural areas poses challenges of bias against clients, but helps to strengthen relationships. While there are benefits of close-knit communities and regional knowledge, IPS providers must address the barriers of stigma and an unwillingness to relocate to work. While implementing IPS in rural communities has unique challenges, this EBP has been successfully tailored to effectively provide supported employment in rural areas (Al-Abdulmunem, et al., 2021).

ACT is an EBP for adults with SMI that utilizes well-developed fidelity measures that have been demonstrated in multiple settings to enhance client recovery and minimize psychiatric hospitalizations. In 2008, SAMHSA published an ACT EBP toolkit that provides information for policymakers, providers, and families on implementing ACT programs. The ACT toolkit includes information about ACT team composition and roles and recommends a standardized fidelity measure (SAMHSA, 2008). According to SAMHSA's Northwest MHTTC, ACT is a "trans-disciplinary team approach providing intensive outreach-oriented services to individuals with severe and persistent mental illnesses and co-occurring disorders. Utilizing a client-centered approach, team members are responsible for addressing the needs of consumers and carry low caseloads to allow for individualized care and frequent contacts (1:10 staffing ratio). Ideally, services are available 24/7 and are directed to consumer needs with most treatment services delivered in the community" (Northwest, MHTTC, 2021).

While ACT has been widely implemented by states across the country, Expert Panel members highlighted ACT as an example of an EBP that is very difficult to provide with exact fidelity in many rural areas. Specifically, because of the relatively low population density in rural areas, in order to serve clients with the required 1 to 10 staffing ratio in rural areas, ACT teams might need to cover an area of hundreds of miles. In addition, states have found it hard to recruit the full multidisciplinary workforce needed to staff an ACT team 24/7 in rural areas. In the preliminary responses to NRI's 2020 State Profiles survey, 9 of 14 states discussed modifying ACT when discussing their SMHA's support and implementation of EBPs to better serve their rural communities. Adjustments to staff-to-client ratio requirements were highlighted by three states (Alabama, Mississippi, and Utah). Program flexibility and utilization of other community resources were indicated by four states (South Dakota, Texas, Virginia, and

Wisconsin). Kentucky reported that it uses more flexible billing processes to fund ACT, and West Virginia said it adjusts age requirements to increase access.

Spotlight on Mississippi's Intensive Community Outreach and Recovery Teams

Mississippi developed Intensive Community Outreach and Recovery (ICORT) teams to address the workforce challenges associated with complying with ACT standards in rural regions, while still providing comprehensive services for individuals with SMI in need of intensive support. ICORT has fewer staffing requirements and higher staff-to-client ratios than ACT, and it has its own fidelity scale and review process tailored to ICORT to ensure desired outcomes. ICORT has standards for operation that the Department of Mental Health monitors, and the state reports that teams have seen very successful outcomes since their inception. Outcome measures for ICORT are modeled after ACT measures, including number of admissions and discharges, number of individuals admitted to ICORT on outpatient commitment, and others. In addition, ICORT tracks the length of stay at hospitals and crisis centers for individuals served by the ICORT team (Hutchins, J., personal communication, December 3, 2020).

Training and technical assistance are particularly important to successfully achieve fidelity for the ICORT program and advocate for its expansion. Mississippi has been measuring the outcomes of the ICORT program and has demonstrated it is an effective alternative to ACT in rural areas. The Department of Mental Health's data on ICORT outcomes has been important in demonstrating to legislators that ICORT teams are caring for individuals in their districts who were previously not being served, a showing that has increased support for the program. On March 30, 2021, Mississippi's Medicaid authority released guidance stating that ICORT is an ACT team, and should be billed to Medicaid as such, effective April 1, 2021.

Spotlight on South Carolina's Intensive Community Teams

Similar to Mississippi, South Carolina has implemented Intensive Community Teams (ICT) as an alternative to ACT. This was done to overcome the barriers associated with maintaining fidelity to the ACT model, including meeting the staff-to-client ratio requirements. For ICTs, the ideal staff-to-client ratio is 1 to 25, with a maximum ratio of 1 to 35. This modification allows the program to maintain its fidelity in rural contexts. ICTs service every county across the state, and clients can move fluidly across levels of care, allowing the services to be customizable to each individual. In addition to ICT, clients can receive services at each of South Carolina's mental health centers and clinics. Since services are sometimes not as developed in all centers, such as where all types of providers on site may not be on-site every day, there are modifications that can be made for rural areas. For example, psychiatrists can utilize telehealth to service a smaller, rural center.

Like Mississippi and South Carolina, North Dakota adapted the ACT model to work within the resources the state had available, and those states are now formally able to provide ACT. Psychiatrists are part of the team, addressing a workforce barrier the states had once faced with challenges finding a psychologist and licensed addiction counselors (McLean, A., personal communication, January 12, 2021). In rural East Texas, ACT was also not a possibility due to personnel shortages. However, they have increased the availability of intensive case management services for individuals with higher acuity, which requires fewer staff resources but still an effective intervention (Dudley, R. personal communication, January 22, 2021). However, New Mexico had an opportunity to incentivize implementation of ACT with a 20% bonus payment, but providers were too under-resourced to afford the start-up costs to create the ACT teams (Lindstrom, W., personal communication, October 21, 2021). This challenge demonstrates that even with financial support, EBPs like ACT often need to be modified to make them available in rural settings.

More research is needed on adaptations to EBPs in rural settings to demonstrate whether desired outcomes are achievable with modifications, and programs should be monitored to measure the same outcomes to see if the tailored version results in similar outcomes in rural environments (McLean, A., personal communication, January 12, 2021). It is a top priority for rural and remote communities to have access to evidence-based treatment, as currently there is a lack of access to affordable, high-quality care in rural communities (Dudley, R., personal communication, January 22, 2021).

It is a recurring theme among rural providers that their priority must be assuring the provision of basic mental health services, including counseling and access to medication, rather than a strict adherence to EBPs (Expert Panel, personal communication, October 21, 2020). EBPs are important to consider, but often needs are so acute and resources are so diminished that rural and remote communities build their practices so that they work within their constraints (Expert Panel, October 21, 2021). While providing EBPs with fidelity is seen as the ultimate goal, most EBPs have been developed in an urban or suburban context, and adhering to fidelity is often not possible within a rural context, so that outcomes from EBPs tailored to rural situations are viewed as more relevant measurements. In addition, our Expert Panel members suggested that EBPs are often best achieved in co-located care sites, particularly in a consultative context in which mental health professionals consult with primary care providers, police, and first responders to provide services (Expert Panel, October 21, 2021).

Even within rural communities, there is wide variation in the level of services available. In South Dakota, implementing fidelity monitoring was extremely difficult, as the largest city in South Dakota has 250,000 residents, which is the lowest population considered metropolitan under federal guidelines. Though it is clear EBPs often need to be tailored for rural communities, providers still must determine what types of adaptations are needed for a specific community. For example, South Dakota is paying for training and the up-front costs for providers to become certified in the Functional Family Therapy (FFT) model, but an in-person team with full fidelity is likely not possible. The state uses quality monitoring of its own design in collaboration with the FFT model to support adherence but adaptability in a rural environment (Wolfgang, T., personal communication, October 21, 2021). Similarly, in Alaska, there are different levels of rurality even within the state, with most communities averaging 5,000 to 7,000 residents. Since Alaska struggles to have enough staff available to each community to meet the needs of residents, the provision of many EBPs with full fidelity to the model is not a realistic goal (McLaughlin, J., personal communication, October 21, 2021).

While there are cases in which EBPs can be applied with fidelity in rural areas, there are many situations where they cannot, and adaptions are needed to the EBP itself or to its implementation. For example, Wellness Recovery Action Plan (WRAP) is an example of an EBP which has worked in rural settings. However, there are times that fidelity is broken to provide services virtually, which are modifications that providers are willing to make to ensure that people receive the support they need.

Adapting EBPs and their implementation for Rural and Remote Communities Key Lessons:

- Allow for flexibility, permitting rural providers to use their knowledge of their community to modify EBPs or their implementation to better assure coverage of the population.
- Conduct research across states and rural providers to understand and document the adaptations that are made to EBPs or their implementation to accommodate rural challenges. This research will allow other providers to replicate the modifications, and for scientific studies on outcomes and effectiveness to be conducted. Rural communities should collect data in order to assess adaptations and outcomes, but national efforts to study adaptations will help improve the research-base and understanding of which EBP modifications are effective, and can help to develop educational and training materials to further the field.

Clozapine & Long-Acting Injectables

First- and second-generation atypical antipsychotics, such as clozapine and long-acting injectables (LAIs), are increasingly being used in the United States for individuals with SMI who are not responding to or adherent to oral antipsychotic medications. The U.S. Food and Drug Administration (FDA) approved clozapine for domestic use in 1990 for treatment-resistant schizophrenia. Since the FDA's approval, a growing body of evidence-based literature supports clozapine as being the "gold standard" treatment for refractory schizophrenia and other similar conditions, showing superiority to other antipsychotics, higher patient-level satisfaction and treatment adherence, and lower mortality rates as suicidal behaviors decrease. Although there is a strong body of literature supporting clozapine's efficacy, the antipsychotic is often underutilized in the United States when compared to other countries. According to the Treatment Advocacy Center, the utilization rates for clozapine in the United States and Malaysia tie at 4 percent. That compares to rates in Australia and China, which are 35 percent and 30 percent, respectively.

One barrier potentially causing clozapine's underutilization in the U.S. is the risk of rare but serious and life-threatening conditions, including myocarditis, cardiomyopathy, seizures, and severe neutropenia (a reduction in a specific type of white blood cell that can lead to serious infections). Studies show that the risk of severe neutropenia occurs in less than 1 percent of the clozapine population and typically occurs within the first 18 weeks of a patient starting clozapine. Given the risk of severe clozapine-related neutropenia, the FDA mandates regular blood count monitoring for all patients prescribed clozapine to reduce the risk of an absolute neutrophil count (ANC) of less than 500/µL.

The FDA monitors clozapine treatment and ANC through a centralized "shared-system" called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. This point of access system requires: 1) prescribers and pharmacies to certify before prescribing or dispensing clozapine; and 2) patients to be registered and monitored for severe neutropenia. Prescribers, pharmacists, and patients must all be enrolled in the REMS program before clozapine treatment can be initiated. Weekly ANC monitoring is required for the first six months of treatment. Patients transition to biweekly ANC monitoring after six months, and then monthly after the first year if the ANC threshold is maintained throughout the first year.

Despite the travel time for bloodwork monitoring, the Treatment Advocacy Center reports that statewide clozapine utilization rate is similar for urban and rural settings. Several states that are majority rural, such as Colorado, Maine, North Dakota, South Dakota, Vermont, and Washington, had some of the highest clozapine utilization rates in America, with South Dakota having the highest utilization rate of 15.6 percent among Medicaid recipients (Torrey, 2016).

Although a few rural states have shown success in clozapine utilization, some rural adults with treatment-resistant schizophrenia still face barriers to accessing clozapine. The main barrier cited by numerous studies is adherence to weekly blood monitoring for the first six months of treatment. Factors interplaying with the weekly blood draw adherence include: coordinating with healthcare facilitators, clinics, and laboratories; transportation to and from the site administering the blood draws; and relying on the patient to adhere to the weekly blood work schedule. Some of these barriers can be eliminated by coordinating with CMHCs, FQHCs, RHCs, and primary care to administer the blood draws and to monitor for severe side effects, according to Robert O. Cotes, MD, Associate Professor at Emory University School of Medicine and a national clinical expert on clozapine (Cotes, R., personal communication, November 6, 2020). Dr. Cotes says those care settings have the capacity to co-manage patients, along with telepsychiatry services, to mitigate some of the common side effects associated with clozapine, such as constipation, fatigue, low libido, sedation, sialorrhea, and weight gain.

Emerging technologies, such as Point-of Care (POC) testing devices, are a promising solution to ease the burden of weekly blood draws. Currently, there is only one FDA-approved POC testing devices for clozapine monitoring, the Athelas One, which monitors ANC and white blood count (WBC). A finger prick blood sample is put on a test strip, the test strip is inserted into the Athelas device, and the test results are transferred within minutes to a patient's smartphone. The Athelas device is also integrated with the clozapine REMS centralized platform allowing the transmission of real-time ANC and WBC analysis to the patient's psychiatrist and pharmacist. Another device, the MyCare Insight device, manufactured by Saladax Biomedical, measures clozapine levels in an individual's blood, but has not yet received FDA approval. Saladax also manufactures the MyCare

Psychiatry Clozapine Assay Kit which measures clozapine levels in an individual's blood, but does not measure ANCs, which is required for clozapine prescribing.

The second most-cited barrier to clozapine is prescribers' lack of knowledge and experience prescribing and monitoring clozapine. To address this barrier, residency programs are incorporating clozapine education opportunities to increase residents' comfort level in prescribing and managing clozapine. To illustrate this point, the University of North Dakota (UND) School of Medicine started a clozapine clinic within their psychiatry residency program. According to Andrew McLean, M.D., M.P.H., Chair of the University's, Department of Psychiatry and Behavioral Science, UND leaders were interested in developing a clozapine education program by "growing their own" clozapine clinic (McLean, A., personal communication, January 12, 2021). Medical residents are provided the real-world clinical experience of prescribing clozapine, including monitoring titration rates, and monitoring medical complications commonly associated with clozapine. Dr. McLean further added that UND's clozapine clinic accepts in-person and telehealth referrals from community providers across the state, offering initial consultation, treatment, and ongoing monitoring to support patients on clozapine. In addition, clozapine clinic medical residents review medical records as part of their case vignette training to determine prospective candidates who may benefit from clozapine but have yet to be referred to the clinic for potential consultation. These training efforts ensure that UMD graduating psychiatrists have a foundational training in clozapine while also optimizing treatment options for North Dakotans with refractory schizophrenia.

First- and second-generation Long-Acting Injectable (LAIs) antipsychotics has been shown to be an effective treatment option for patients with schizophrenia and schizoaffective disorders who are nonadherent to medication regimens, patients experiencing a first episode psychosis, and as a first-line treatment for severely ill patients. Since being introduced in the late 1960s, emerging research reports significant benefits related to LAIs, including a reduction in psychiatric rehospitalization and disease progression, prevention of relapse, improvements in psychiatric symptoms, and adherence to treatment (Brissos, et al., 2014). A limited number of studies demonstrate LAIs' effectiveness in rural communities (Camacho, et al., 2008).

LAIs are underutilized by prescribers due to lack of familiarity, concerns over medical safety, and challenges with patients accessing injections. Prescribers may be unfamiliar or hesitant due to lack of training or knowledge. For example, there are various FDA-approved LAI formulations that differ in dosing intervals (e.g., biweekly, monthly, every six to eight weeks, quarterly, biannually) requiring slow dose titration, refrigeration, or a three-hour observation time post-injection. In addition, some LAIs are gradually initiated in conjunction with oral antipsychotics. Safety issues include the inability to withdraw the medication after administration due to its long half-life and delayed release; monitoring for rare adverse side effects such as post-injection syndrome (occurs less than 1 percent of the time), and extrapyramidal symptoms including acute dystonic reactions, Parkinsonism, and akathisia. Promising research by Misawa and colleagues (2016) found that LAIs had adverse effects similar to those of oral antipsychotics; LAIs are just as safe as oral antipsychotics (Misawa, et al., 2016).

Barriers to accessing LAIs include the burden of traveling to and from the injection clinic, pain or skin irritation at the injection site, and the negative perception and stigma of being perceived as nonadherent to oral antipsychotics. Another barrier unique to rural and remote communities is that many rural pharmacies are reluctant to carry several doses of LAIs due to the cost, according to Leon Ravin, M.D., Psychiatric Medical Director, Division of Public and Behavioral Health, State of Nevada. Dr. Ravin shares that some LAIs can cost upward to $1,500 per injection, hindering rural pharmacies from keeping these expensive medications in stock. The current practice for rural pharmacies is to order LAIs from an urban pharmacy that has the medication in stock. In contrast, most rural hospitals have the financial capacity to absorb the expensive cost of LAIs. Moreover, pharmaceutical companies sometimes provide a few complimentary injectable samples a year to hospitals as a marketing strategy. One approach Dr. Ravin recommends for increasing patient access to LAIs is providing financial assistance to rural pharmacies to ensure adequate stockage of LAIs (Ravin., L., personal communication, November 19, 2021).

The administration of LAIs will continue to evolve with future psychopharmacology and technical advancements. For example, scientific advancements may include injectable formulations having longer extended-release time; nasal formulations and transdermal patches providing prolonged-release dosing, particularly benefiting patients adverse to needles; and long-acting

pump or implant devices administering antipsychotics analogous to insulin pumps currently available for diabetes management. At this time, asenapine is the only FDA-approved transdermal patch for schizophrenia that is applied daily.

The research findings illustrate clozapine's and LAIs' effectiveness in treating adults with complex cases of SMI. To ensure rural adults with SMI have access to these treatment options, community providers, patients, and families must work together in becoming familiar with these medications to understand the benefits and risks as well as ensure safety monitoring. To further encourage and support clinical utilization of clozapine and LAIs, the SAMHSA-funded initiative, SMI Adviser, has launched a Long-Acting Injectable Center of Excellence and a Clozapine Center of Excellence. The Centers of Excellence offer technical assistance to support prescribers, virtual learning collaboratives and forums to engage with colleagues, CEU trainings, on-demand consultation with national experts, and vetted clinical resources.

Clozapine and Long-Acting Injectables Key Lessons:

- Clozapine and Long-Acting Injectable (LAI) medications are evidence-based treatment options for refractory schizophrenia and other similar complex mental health conditions. However, clozapine and LAIs are often underutilized by prescribers due to lack of residency training in prescribing and monitoring for medical complications. Incorporating clozapine and LAI educational opportunities within psychiatry residency programs will increase competency in these treatment modalities.
- Higher clozapine utilization can be achieved by psychiatrists collaborating with rural community providers located at CMHCs, FQHCs, RHCs, and primary care practices to administer the regularly scheduled blood draws and ensure safety monitoring—thereby enabling rural residents with SMI to receive high-quality mental health care.

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