Position Statement 12: Evidence-Based Healthcare

Policy

Mental Health America (MHA) is dedicated to accelerating the application of scientific and practical knowledge to help in the recovery of people with mental health and substance use conditions. This focus on evidence-based healthcare spans the development, exposition, evaluation, replication, translation, dissemination and implementation of knowledge about mental health and substance use disorders and their prevention and treatment and includes all forms of knowledge, from randomized, double-blind, placebo-controlled clinical trials and large epidemiological studies through clinical practice, outcome monitoring and insights and outcomes reported by people in treatment (e.g., patient registries[1]).

Effective access to reliable and persuasive evidence in an understandable format is vital to the development of informed decision-making partnerships between providers of healthcare services and people in recovery. Evidence-based healthcare should balance scientific knowledge, clinical expertise and experience, the goals, values and experiences of people in treatment and their families and friends, and systematically and objectively measured person-centered outcomes, to inform healthcare delivery and decision-making. To ensure this balance, processes for collecting, evaluating and translating relevant evidence and for applying such findings to practice and policy should be transparent and respectful of the perspectives and values of people in recovery. This will take work, and MHA pledges to aid in translating and disseminating the needed information and to seek partnerships to that end.[2]

A stronger focus on evidence presents an opportunity to improve the quality of mental health and substance use disorder care, to empower people in recovery and their families and friends to seek and demand continually improving care and services, to ensure that their care is effective, and to move toward more person-centered and person-reported, recovery-oriented outcomes.

Some controversy exists about the application of evidence-based practices. At the crux of the controversy is the concern that policymakers and insurance administrators may use lack of expensive randomized clinical trial evidence as a rationale for denying reimbursement for other desirable services in order to contain cost. Such policies do not reflect the reality of a clinical trial enterprise that is in crisis[3] and risk stifling the growth and use of effective "best," "emerging" or "promising" (hereinafter "promising") practices, particularly peer-to-peer services.

While cost is an inevitable consideration in reimbursement decisions, it is of paramount importance to honor the needs of people in treatment for expedited access to a variety of treatments when evidence-based treatments are not tolerated or prove ineffective or insufficient. Of particular concern to people in recovery and their families and friends is that many of the current evidence-based practices cited in this position statement reflect the approaches of earlier eras, and focusing on these practices to the exclusion of others could impede further

innovation – particularly for promising peer-delivered and recovery-oriented services that lack the profit potential to make randomized trials economically feasible.

MHA urges that all manufacturers' and patent owners' experimental and observational evidence about potential treatments be fully disclosed to people seeking treatment to make that access fully informed. This is of greatest importance with promising practices that are not yet established as evidence-based.

MHA recommends:

- funding and providing incentives for implementation of a comprehensive information technology infrastructure covering all behavioral healthcare.

- ensuring that people in recovery are integrated throughout the development of an evidence-based behavioral healthcare system, from formulating the research questions to translating the evidence into practice.

- funding and pursuing the necessary studies to use electronic health record data to develop a learning behavioral healthcare system, capable of translating practice-based evidence into improvements in clinical and psychosocial treatment and quality of life outcomes.

- focusing quality assurance on person-centered and person-reported, recovery-oriented outcomes.

- advocating training and quality improvement initiatives to promote promising and evidence-based practices.

- ensuring that health plan documents, including all notifications to individuals about benefits, medical necessity guidelines, and practice guidelines, contain the full array of evidence-based treatments and do not preclude promising practices, with appropriate justification, in order to provide optimal care for the individual.

- encouraging health plans and health care systems to provide decision-making aids for individuals and providers to help in planning treatment, and which integrate the latest available evidence. Ensuring that people in recovery play a role in determining what tools would be most useful.

- funding new research to maintain innovation and turn promising practices into evidence-based practices.

- ensuring cultural humility and linguistic competence as an essential element of evidence-based healthcare.

- advocating and assisting in dissemination of information through partnerships with people in recovery at all stages of the research and evaluation process.

Background

Clinical Studies. Regulatory standards and traditional academic research regard double-blind, placebo-controlled randomized trials as the gold standard for making causal inferences.[4] Such trials are valuable and appropriate in getting to firm scientific conclusions about efficacy and safety, but MHA believes that we must employ a broader range of methods if we are to address the range of challenges encountered in treating mental health and substance use conditions. Promising practices should be tested by practice-based evidence (described below) and by larger and longer trials, and should not be neglected simply because a more studied treatment alternative exists. More affordable and less ethically-challenging kinds of clinical studies, like controlled, randomized and cross-over open-label and observational studies should be used to study clinical interventions and human interactions and assess more subjective outcomes, using diverse populations of study participants from a variety of settings.[5]

Outcome Measurement
Outcome measurement is essential to make any system of care accountable. Although the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the states have worked for many years on the development and refinement of standard outcome measures to define improvements in the symptoms, functioning and quality of life of people in treatment, this remains a work in progress. In 1996, the MHSIP (Mental Health Statistics Improvement Program) Mental Health Report Card was issued,[6] which was co-authored by advocates and consumers and provides an excellent blueprint for the evaluation of treatment programs over time. Some states, like Ohio, have been willing to dedicate resources to collect and analyze data over time showing changing evaluations of Access, Quality & Appropriateness, Treatment Planning, General Satisfaction, Quality of Life – Outcomes, Functioning, and Social Connectedness. Ohio's 2014 report candidly showed a significant decline in evaluation of outcomes in 2013, which prompted the state to focus more attention on the quality of its programs.[7] The Ohio report is a good introduction to the MHSIP Report Card methodology, which should be updated to better document more recovery measures and more detailed information on seclusion and restraint avoidance but is already proving quite helpful as a tool to reform state systems.

The National Behavioral Health Quality Framework is the focus of current definitional work, building on the MHSIP measures for definition of mental health outcomes.[8] SAMHSA behavioral health barometers already measure the prevalence of youth and adult substance use and mental health issues by state,[9] and the inclusion of mental health and substance use outcome measures in the national framework should lead to more treatment data becoming available.

The hope is that standard definitions and measures can be developed and refined over time that will facilitate epidemiological studies of electronic health data across the country, assessing and improving treatment, provider and system efficiency and effectiveness.[10] Critically, the standard measures must then be refined over time to measure what people in treatment care about in improving their symptoms, functioning and quality of life. Thus, MHA devoutly hopes, people in treatment and their providers will be able to collect and use a variety of systematically-measured outcomes to better understand and better participate in shared decision making among

treatment alternatives. As outcome data are accumulated and analyzed, it will become more and more feasible to use the data in evaluating and modifying treatment and monitoring and improving provider services and systems of care.

In addition, MHA hopes for the development of specific person-centered and person-reported outcome measures that facilitate measurement-based care for the individual, determined by the individual's goals. Providers should work with individuals to plan short and long-term recovery goals, and care should then be planned in service of these ultimate goals. Progress toward these goals should be consistently measured and inform care, making care "measurement-based." In this way, the health care system and the individual can be most effectively aligned in meaningfully working toward recovery and care can be tailored specific to the individual's needs.

Learning Health Care System
The "learning health care system" approach was eloquently outlined in the Institute of Medicine's 2012 report, "Best Care at Lower Cost."[11] In a learning health care system, rather than relying solely on translated evidence from clinical trials into practice, the health care system also generates and disseminates evidence in real-time. The learning health care system features consistent outcome measurement, payments that are capitated, and incentives based on performance. When a particular provider consistently achieves notable outcomes, the system investigates what this provider or the individuals they work with are doing differently. The system then adds this new bit of information to its decision-making aids that individuals and providers use together in planning care, so that the evidence is immediately useful in treatment. In this way, learning health care systems deemphasize fidelity to evidence-based practice, and instead foster personalization, learning, and experimentation, while maintaining a focus on outcomes.

Patient Centered Outcomes Research
Patient Centered Outcomes Research is a new term that has been used to describe naturalistic clinical trials that compare treatments and focus on long-term as well as short-term outcomes of importance to people in recovery. In 2010 the Affordable Care Act authorized the development of an independent, non-profit organization to drive the development, synthesis and use of this research. The Patient Centered Outcomes Research Institute (PCORI)[12] is tasked with helping patients, clinicians, purchasers and policy makers make better informed health care decisions. PCORI research is intended to be responsive to the values and interests of people in recovery and to provide them and their caregivers with reliable, evidence-based information for the health care choices they face.[13]

The U.S. Governmental Accounting Office (GAO) reported in March of 2015 that PCORI is fulfilling its mandate and detailed the extensive organizational development that PCORI has achieved.[14] Despite criticism that PCORI has moved too slowly,[15] it seems to MHA that the extensive preliminary work was necessary and the direction is good. In addition, PCORI has begun to fund behavioral health research. From 2012 to 2015, PCORI funded 43 projects (9.5% of the total number of projects) on studies related to mental health and substance use disorders, for a total of over 100 million dollars (9.1% of its total funding awards, details available on their

website).[16] Of these, over a third of the total monies awarded went directly to pragmatic clinical trials or studies that compared two treatments. Other funded studies examined new approaches to patient-centered treatments and research. Many other research areas have been funded as well. With PCORI's support, scientists are testing new methods for improving shared decision making, evaluating ways to provide culturally-specific interventions to a variety of populations, and comparing mental and behavioral health based on healthcare system factors such as funding agency or restrictions on healthcare funding.

While PCORI presently focuses on integrating individuals with lived experience into the planning and execution of research, MHA hopes that PCORI can begin to focus on creating standardized person-centered and person-reported, recovery-oriented outcomes for use across its funded research, and which will influence research and practice in general as well, as explained in the "Outcome Measurement" section above.

Practice-based Evidence
Just as the development of the standard MHSIP outcome measures is already revolutionizing the evaluation of state mental health systems, electronic health records documenting practice decisions and outcomes will constitute an important new evidence base to improve treatment. Once standard outcome metrics are universally documented in clinical practice and the data is aggregated from across health care systems, it will become possible to know what range of treatments are most likely to be effective for an individual. We will be much better able to understand what works best with a range of identified risks, ranked in order of probability, within a degree of certainty that will increase over time. Informed partnerships between people in treatment and their providers should always be based on a mutual agreement to systematically and objectively assess symptom status, functioning, quality of life, and other outcomes of importance to the individual and to document treatments and outcomes to support informed decision-making and to use for population health studies. New technology may be useful for capturing outcomes of treatment on a regular and timely basis, e.g. using mobile phone applications or wearable sensors.[17] If outcomes can be associated with treatment changes over time, protocols can be developed to avoid some of the guessing and trial and error that still characterize mental health and substance abuse treatment.

Systematic Monitoring by the Person in Treatment
When people monitor their health, functioning, and quality of life—and other outcomes of importance to them—they develop important sources of information to use to improve those outcomes, and also contribute to the practice-based knowledge base that we are developing. This will only work if the monitoring is reliable, systematic and user-friendly. Results of the monitoring then can be incorporated into data bases such as electronic health records and patient registries. Although they do not meet current evidentiary standards for development of new drugs and devices, patient registries are routinely used to gather information about existing treatments and forward our understanding of personalized medicine.[18] Self-monitoring is being used as a way to track adverse events of vaccines,[19] providing important safety signals for known treatments, and all forms of systematic self-monitoring hold promise as an empowering way for people to develop their own knowledge sources to share with providers.[20] Mood, thought, and behavior tracking are also components of treatment with cognitive-behavioral

therapy, so tracking can serve both treatment and research goals. In order to increase the capacity to use these newer forms of evidence, people in recovery and their providers should consider recording and sharing these data when appropriate, after assuring that privacy and security protections are in place. Use of registries, electronic health records, and other sources of "big data" promise new perspectives to understand the effectiveness of treatments in real-world settings.

Longitudinal Studies
In addition, investments should be made in longitudinal research that demonstrates the comparative effectiveness of treatments in real-world settings over time reflecting the breadth of experience and the diversity of people in treatment. Such studies are a critical adjunct to clinical trials, which are usually very short. Several long-term studies have provided important information about mental health and substance use conditions. The Epidemiological Catchment Area study, the National Comorbidity Survey and its replication, the National Epidemiologic Survey on Alcohol and Related Conditions, and the National Alcohol Epidemiological Survey are a few of the long-term surveys that have evaluated mental and behavioral health conditions over time.[21] While these studies have helped us understand the factors that contribute to the development of mental and behavioral health conditions, the ways these conditions evolve over time and, to some extent, the effectiveness of certain types of treatments, they face many challenges as study participants drop out or die, funding dries up, or researchers age out or find other priorities. These studies have helped us understand not only these conditions themselves, but the limitations of our ability to diagnose and treat them. However, these studies were not designed with a focus on recovery and as such were designed to focus on symptoms and treatment rather than other outcomes of importance to people in recovery. Moving forward, longitudinal studies should include person-centered and person-reported, recovery-oriented outcomes to the greatest extent possible.

National Registry of Evidence-Based Programs and Practices
MHA supports efforts like the National Registry of Evidence-Based Programs and Practices (NREPP) to create a centralized clearinghouse for evidenced-based practices with transparent criteria for evaluating and approving such practices. It is vital that such a clearinghouse use flexible criteria for what constitutes acceptable evidence, including randomized clinical trials, quasi-experimental studies and observational studies. It is also vital that the evaluation criteria be driven by the goal of recovery for persons affected by mental illnesses and addictions. However, the existing registry is not user-friendly and is too cumbersome for use by most people in recovery. The MHA survey of Complementary and Integrative Treatments for Mental Illness is a far better tool for that purpose and incorporates organizational principles that would be helpful as a template.[22]

Other registries of evidence-based practices that have different focuses and information include:

- The Washington State Institute for Public Policy: http://www.wsipp.wa.gov/BenefitCost

- Pew-MacArthur Results-First
  Initiative: http://www.pewtrusts.org/~/media/assets/2014/11/evidencebasedpolicymaking aguideforeffectivegovernment.pdf?la=en

- Blueprints for Healthy Youth Development: http://www.blueprintsprograms.com/

- Child Trends: http://www.childtrends.org/

- Coalition 4 Evidence-Based Policy:
  http://toptierevidence.org/ http://evidencebasedprograms.org/

Synthesis and Dissemination

Prominent reports from the Surgeon General,[23] the President's New Freedom Commission on Mental Health[24] and the Institute of Medicine[25] all underscore the importance of narrowing the gap between research and implementation of evidence-based practices. Consequently, government agencies, private-sector health plans, academic research centers and other stakeholders are dedicating enormous resources to evaluating current science and practice, disseminating information about promising practices, and guiding the implementation and replication of such evidence-based approaches to healthcare. Ideally in the future, evidence produced from any source would be condensed and transmitted quickly as decision-making support for individuals and providers to use in setting goals and planning care.[26] Individuals and providers should, to the greatest extent possible, not have to seek out evidence; rather, it should be synthesized and made available at the point of care in a way that facilitates planning and decision-making between those on the care team.

Until such decision-making supports are available and as evidence generated and evaluated from all sources must be synthesized and published in simplified language so that people seeking recovery and their friends and families can use the information in their healthcare decision-making.[27] A good example is available in the efforts of the Cochrane Collaboration, an organization which creates systematic reviews of treatments, including comparative effectiveness reviews. All Cochrane reviews include a plain language summary to make this evidence easy to use by the general public, and reviewers include people in recovery and family members who are educated in evidence development.[28] PCORI has made a similar commitment. To be considered for funding, all PCORI proposals must include a detailed plan for dissemination of the results.

The Substance Use Challenge

Substance use conditions are a particularly neglected area of scientific study, with the persistence of punitive sanctions for relapses under current law enforcement and drug court procedures and overreliance on Alcoholics Anonymous. A 2012 report by the National Center on Addiction and Substance Abuse at Columbia University found that:

> "the gap between the evidence regarding what works in interventions for risky substance use and in the treatment and management of addiction versus on-the-ground practice is wide, and nothing short of a significant overhaul in current approaches is required to bring practice in line with the evidence and with the standard of care for other public health and

medical conditions…. Given the prevalence of addiction in society and the extensive evidence regarding how to identify, intervene and treat it, continued failure to do so signals widespread system failure in health care service delivery, financing, professional education and quality assurance. It also raises the question of whether the low levels of care that addiction patients usually do receive constitutes a form of medical malpractice…. The vast majority of people in need of addiction treatment do not receive anything that approximates evidence-based care."[29]

The recent article in the Atlantic Monthly entitled "The Irrationality of Alcoholics Anonymous"[30] gives the details. AA can be very helpful to many people drawn to it, but:

A meticulous analysis of treatments, published more than a decade ago in *The Handbook of Alcoholism Treatment Approaches* but still considered one of the most comprehensive comparisons, ranks AA 38th out of 48 methods. At the top of the list are brief interventions by a medical professional; motivational enhancement, a form of counseling that aims to help people see the need to change; and acamprosate, a drug that eases cravings.

Limitations of Research
The boundaries of scientific research are constantly being stretched, revealing new understandings and options for treating many chronic illnesses, including mental health and substance use disorders. Yet even as emerging science gives us information about how and why mental illnesses and addictions affect individuals, and about new sources of information such as genetic biomarkers that may better guide treatment choices, it also reveals the absence of universally effective treatments and practices. Even a very good medicine will rarely be effective in more than half of the people who take it, and new treatments are frequently approved after clinical trials that show that they are effective for only a small proportion of study participants, without comparing them to other drugs that may be more effective.[31] Newer studies often erode old findings, due in part to the bias toward publication of positive results and in part to the absence of full disclosure by drug companies that protect proprietary studies.[32] The result is that negative findings often show up only after an intervention or service has come into common practice. In particular, pharmaceutical use by the general population commonly reveals a lack of real-world effectiveness and side effects that were not adequately evaluated in the preapproval clinical trials. For example, the common drug company practice of excluding potential trial participants who show a high placebo response and the use of washout periods that eliminate people who are unresponsive to the drug may exaggerate the relative effectiveness of the drug.[33] In addition, the unique cultural perspectives and outcomes relevant to diverse populations need to be incorporated at all levels of evidence development and implementation. This cultural humility and linguistic competency is an essential element of evidence-based healthcare. MHA recommends ongoing, real-world surveillance of evidence-based practices to better understand their effectiveness over time and how they may be improved.

Evidence-Based Practices[34]

SAMHSA, the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, has undertaken a comprehensive effort to recognize evidence-based practices for the prevention and treatment of mental health conditions and maintains a website that allows broad access: http://www.samhsa.gov/ebp-web-guide In addition, SAMHSA has prepared eleven toolkits[35] that detail ten evidence-based practices and one promising practice. MHA hopes that, in the future, SAMHSA will be able to produce additional toolkits on a broader array of evidence-based and promising practices, including a focus on prevention and early intervention. The existing toolkits are available online and are summarized below:

- *Assertive Community Treatment (ACT or PACT)* refers to a now widely-adopted and -accepted program to provide a full-range of services within a community setting to people who have severe mental illnesses such as schizophrenia, bipolar disorder, depression or schizoaffective disorder. The primary goal of this treatment is "recovery through community treatment and habilitation." A multi-disciplinary team provides assistance in a number of areas including daily activities, family life, health, medication support, housing assistance, financial management, entitlements, substance abuse treatment and counseling. The key to its success is a high staff to consumer ratio (at least one to 10 consumers), provision of services where they are needed (in the community), uninterrupted care as someone from the team is always available, a non-coercive and recovery-oriented approach, and time-unlimited support.

- *Supported Employment* is a program that aids people in recovery in finding competitive jobs (defined as at least minimum wage jobs open to the general public) that are well suited to their interests and abilities. Supported employment is based upon six principles which include: (1) eligibility is based on choice (no one is excluded), (2) employment is integrated with treatment, (3) competitive employment is the goal, (4) job search starts soon after a person expresses interest in working (there are no prerequisites such as training classes or intermediate work experience), (5) follow-along supports are continuous, and (6) Job-seeker preferences are important. Employment specialists work alongside people in recovery to ensure that these six principles are met.

- *Integrated Treatment for Co-occurring Disorders* is a treatment model in which the same treatment team provides both mental health and substance abuse treatment for people with "dual disorders" (simultaneously occurring substance abuse and mental illness). Integrated treatment improves chances for meaningful recovery. Within this model, people in recovery receive case management, outreach and other much-needed services such as housing and supported employment. Counseling services are tailored to those who have dual disorders and include assessment, motivational treatment and substance abuse counseling. Family members are also educated about the mental illness and substance abuse, and are given support as well. Those with dual disorders are in a high-risk group and vulnerable to a host of corollary problems such as relapse, troubled finances, homelessness and health crises, which is why integrated treatment is so critical to successful outcomes.[36]

- *Family Psychoeducation* is a practice that forges partnerships between people in recovery and their families and treatment teams, who come together to support recovery. Families are given information about mental health and substance use conditions and develop coping skills. This practice has several phases. (1) The first phase involves family members in introductory sessions where they meet with a practitioner and explore the warning signs of illness, the family's reactions to symptoms and behaviors, and feeling of loss and grief, and set goals for the future. (2) The second phase is an educational workshop in which families come together to learn about the biology of the illness, normal reactions, managing stress and safety measures. (3) The final component is problem-solving sessions in which the person, family and treatment team meet every two weeks for the first few months to learn to deal with problems in a pragmatic, structured way.

- *Illness Management and Recovery* (IMR) is a psychiatric rehabilitative evidence-based practice that is designed to empower people who have serious mental illnesses to understand and manage their illness effectively. During a series of weekly sessions, mental health practitioners aid people in recovery in developing their own tailored strategies for coping with their illness, constructing their own goals for recovery and playing an integral role in decision-making about their treatment. Nine topic areas are covered in the program: (1) teaching recovery strategies, (2) practical facts about mental illness, (3) the stress-vulnerability model and treatment strategies, (4) building social support, (5) reducing relapses, (6) using medications effectively, (7) coping with stress, (8) coping with problems and symptoms, and (9) getting your needs met in the mental health system. Practitioners use a variety of techniques to accomplish these goals, such as cognitive-behavioral, educational and motivational strategies.

- *Permanent Supportive Housing* is a program to provide housing distinct from social supports for people with mental health and substance use disorders. The SAMHSA toolkit defines Permanently Supportive Housing as follows: (1) Tenants have a lease [or sublease] in their name, and, therefore, they have full rights of tenancy under landlord-tenant law, including control over their living space and protection against eviction. (2) Leases do not have any provisions that would not be found in leases held by someone who does not have a psychiatric disability. (3) Participation in services is voluntary and tenants cannot be evicted for rejecting services. Although Permanent Supportive Housing is designed for people who need support services, a person's Permanent Supportive Housing home is just that, not a treatment setting, as has been common in many residential facilities operated by mental health systems. (4) House rules, if any, are similar to those found in housing for people who do not have psychiatric disabilities and do not restrict visitors or otherwise interfere with a life in the community. (5) Housing is not time-limited, and the lease is renewable at tenants' and owners' option until abandonment or eviction. (6) Before moving into Permanent Supportive Housing, tenants are asked about their housing preferences and are offered the same range of choices as are available to others at their income level in the same housing market. As stated in (3) above, tenants have choices in the support services that they receive. (7) Housing is affordable, with tenants paying no more than 30 percent of their income

toward rent and utilities, with the balance available for discretionary spending. (8) Housing is integrated. Tenants have the opportunity to interact with neighbors who do not have psychiatric disabilities. (9) As stated in (3) above, tenants have choices in the support services that they receive. They are asked about their choices and can choose from a range of services, and different tenants receive different types of services based on their needs and preferences (10) As needs change over time, tenants can receive more intensive or less intensive support services without losing their homes. This flexibility stands in sharp contrast to the residential treatment programs and transitional housing traditionally offered by mental health systems. (11) The support services that are provided promote recovery and are designed to help tenants choose, get, and keep their housing. (12) The provision of housing and the provision of support services are distinct. In residential treatment programs, staff often provides support services and handles housing functions such as the application, move-in, rent collection, rule enforcement, and eviction. In Permanent Supportive Housing, housing and support services are handled separately to avoid all possibility of coercion.

- *Medication Treatment, Evaluation and Management (MedTEAM)* refers to systematic use of medications. Medication Treatment, Evaluation and Management is an evidence-based approach for offering medication management to people with serious mental illnesses. Four factors are involved in providing evidence-based medication management: (1) people who prescribe medications (prescribers) must know the best current evidence from systematic research; (2) prescribers must integrate that information with their own clinical expertise; (3) prescribers must be aware of consumers' experience and be able to integrate that experience into medication decisions; and (4) medication management should be based on active participation, mutual communication, and shared decision-making.

- *Treatment of Depression in Older Adults* requires different interventions than those used for younger people. MHA has identified a number of wellness activities that can contribute to Aging Well[37] and has addressed dealing with the anxiety and psychosis than can accompany cognitive aging and dementia, but has not discussed the problem of depression in older adults. This toolkit remedies this omission. The evidence-based practices discussed by SAMHSA include: (1) Cognitive behavioral therapy, (2) Behavioral therapy, (3) Problem-solving treatment, (4) Interpersonal psychotherapy, (5) Reminiscence therapy, (6) Cognitive biblio-therapy, (7) Antidepressant medications, (8) Multidisciplinary geriatric mental health outreach services, and (9) Collaborative and integrated mental and physical health care. Although partially covered by (8), MHA stresses the use of community-based, multidisciplinary mobile geriatric teams.[38]

- *Interventions for Disruptive Behavior Disorders in Children* are needed in both school and home settings. Although MHA has endorsed School-wide Positive Behavior Support in Schools (SWPBS),[39] the breadth of the problem is much greater, and both psycho-social and medication management issues are confronted directly by the toolkit. SWPBS is based on the assumption that when faculty and staff in a school actively teach and acknowledge expected behavior, the proportion of students with serious behavior

problems will be reduced and the school's overall climate will improve. Strategies such as behavioral coaching, behavioral rehearsal and role play, daily goal setting, and self-monitoring can be helpful in teaching students to manage their own behavior and emotions more effectively. The toolkit discusses oppositional defiant disorder and conduct disorder candidly and suggests the protective factors and the risk factors by developmental stage, suggesting eighteen kinds of psychosocial interventions that parents and caregivers can consider to respond to defiant behavior. It also describes the kind of medication management strategies that are recommended by clinical guidelines, given the frustrating fact that few of the medications have been clinically tested in children.

- *Consumer-operated Services* include single service providers for drop-in programs, support groups, housing, employment, training, and consultation; general recovery resource, education, and self-advocacy centers; and multiservice organizations that provide an array of services and resources. The organization must be 90% or more owned, directed and operated by people in recovery. SAMHSA's toolkit[40] advocates the FACIT (Functional Assessment of Chronic Illness Therapy) scale as the measure of fidelity, of which the most important programmatic elements are excerpted here:

ENVIRONMENT
(8) Staff treats participants with openness, directness, and sincerity. (9) Offers extensive opportunities for warm, interpersonal interactions, a sense of belonging, and socialization with other participants. (12) Belief systems: Peer principle, helper principle, empowerment, choice, recovery, acceptance and respect for diversity, spiritual growth (12) Peer principle: Relationships are based on shared experiences and values. Participants and staff characterize relationships as mutual/reciprocal. (13) Self-disclosure: Self-disclosure is almost universal. (14) Help and advice: Help and advice are offered in a friendly manner; compliance is not demanded. (15) Reciprocal helping: 67% to 100% of participants report some experience of helping other program members. (16) Personal empowerment: Virtually everyone agrees that being involved in the program has helped them make positive changes in their lives. (17) Acceptance and respect for diversity: Accepts a wide range of non-dangerous behaviors without threatening individuals' continued participation in the program. (18) Personal accountability: Program staff and leaders encourage a high level of accountability and self-reliance by program participants. (19) Group empowerment: There is a feeling of membership in the group, which offers a great opportunity to contribute not only to internal program activities and on program-specific policies and issues, but also to contribute through community activities, networking, and other relationships external to the program. (20) Choice: People have the choice to participate in a wide array of program activities with different levels/forms of participation, including the opportunity to shape these activities. (21) Recovery: The mission statement and materials describing the program include a clear statement of its hope-oriented approach. Participants can articulate this approach. (22) Spiritual growth: The expression of spiritual or religious insights is allowed within the program.

PEER SUPPORT

Mutual support, telling our stories, consciousness-raising, crisis prevention, peer mentoring and teaching (1) Formal Peer Support: Numerous peer support activities are offered to program participants on a regular basis. (2) Informal peer support: The program provides opportunity for, and supports the development of, strong mutual peer relationships. (3) Telling our stories: The program provides numerous formal and informal opportunities for sharing stories within the program and with the larger community. (4) Artistic expression: Multiple regular outlets provide opportunity for artistic expression, with a variety of media. Opportunities are individualized, enabling all who are interested to participate. (5) Consciousness-raising: People recognize themselves as valuable members of a larger community with their own unique identities, and they feel confident contributing to this community. (6) Formal crisis prevention: Multiple avenues are provided for formal crisis prevention, and these appear to be effective. (7) Informal crisis prevention: Multiple avenues are provided for informal crisis prevention, and these appear to be effective in providing regular (and sometimes face-to-face) outreach to consumer-operated service participants. (8) Peer mentoring and teaching: Virtually all participants report that there are others within the program they look up to and from whom they can receive guidance, support, and companionship. These relationships occur without regard to title or position within the program.

EDUCATION

Self-management/problem-solving strategies, formally structured activities, skills practice (1) Formal education: Numerous opportunities and educational programs are offered to participants to learn practical skills relating to personal issues, treatment, and support needs. (2) Structured curriculum: There is evidence of a formal curriculum in problem solving and self- management. Most or all participants (75-100%) have participated in classes with a structured format designed to teach self-management and problem solving. (3) Informal exchange: There is evidence of informal exchange of personal experiences to enhance individual problem-solving abilities. (4) Receiving informal support: Most participants (80-100%) report they have received informal support in self-management or problem-solving assistance. (5) Providing informal support: Most participants (80-100%) report they have provided informal support in self-management or problem-solving assistance. (6) Formal skills practice: Most participants (75-100%) are involved in some formal skills training that could lead to some kind of employment. (7) Job readiness activities: Most participants (75-100%) are involved in job readiness activities that could lead to some kind of employment.

ADVOCACY

Self-advocacy, peer advocacy, outreach (1) Formal self-advocacy activities: Most participants (75-100%) have participated in informal training activities related to self-advocacy or informal opportunities leading to peer-to-peer learning about self-advocacy. (2) Outreach to participants: All participants are informed by the program through multiple channels, e.g., Internet, newsletters, conferences. Advocacy content is regular and strong. (3) Peer advocacy: Most participants are involved in providing peer advocacy. All members consider themselves peer advocates.

- SAMHSA's toolkit discusses the evidence base for consumer-provided services: "The Consumer-Operated Services Program (COSP) Multisite Research Initiative (1998-2006), funded by SAMHSA, is the largest and most rigorous study of consumer-operated services programs conducted to date. It looked at several models of peer-operated services around the country to determine whether consumer-operated services are effective as an adjunct to traditional mental health services in improving the outcomes of adults with serious mental illness. This study found that consumer-operated services are effective, pointing specifically to the following: (1) An overall increase in well-being among study participants and a greater average increase in well-being among those who used consumer-operated services the most; (2) A significant effect on well-being for users of drop-in type services; (3) An increase in most measures of empowerment correlated with the extent to which consumers used consumer-operated services."

- A 2006 study by Corrigan similarly found positive correlations between participation in consumer operated services and core factors associated with recovery and empowerment such as personal confidence and hope; willingness to ask for help; goal and success oriented; self-esteem/self-efficacy; sense of personal power; autonomy; optimism and control over the future.[41] But more study will be required to validate other promising peer-to-peer programs. MHA is currently developing a nationwide peer-to-peer certification program to meet this need.

- *Supported Education* has emerged as promising practice in psychosocial rehabilitation for people with serious mental illnesses. Core services include: (1) Career planning including vocational assessment, career exploration, (2) Educational Goal Plan development, course selection, instruction, support, and counseling; (3) Academic survival skills including information about college and training programs, disability rights and resources, tutoring and mentoring services, time and stress management, and social supports; (4) Direct assistance including help with enrollment, financial aid, education debt, and contingency funds; and (5) Outreach including contact with campus resources, mental health treatment team members, and other agencies such as vocational rehabilitation Supported education programs and research have not been subjected to the rigorous, consistent and repeated methodology of supported employment. However, effective outcomes and significant findings in program attendance, enrollment in postsecondary education, self-esteem, peer support and reduced healthcare costs make supported education a promising practice for the treatment and rehabilitation of adults with serious mental illness.[42]

- *Mental Health Promotion* has been shown to increase social connectedness. It builds social capital, promotes community well-being, overcomes social isolation, increases social connectedness and addresses social exclusion. Evidence-based practices include: (1) community building and regeneration programs, (2) school-based programs for mental health and well-being, (3) structured opportunities for civic participation, (4) workplace mental health promotion, (5) social support, such as home-visiting and parenting programs, (6) volunteering, (7) community arts programs, (8) physical activity/exercise, and (9) media and social marketing campaigns that challenge

stigma.[43] SAMHSA has discussed but not yet developed toolkits for promotion or prevention, but MHA Position Statement 17[44] and the other position statements cited therein provide a good start to inventory the kinds of practices that can make a difference, such as Positive Behavior Support in schools, mental health education, wellness activities and early intervention.

Opportunities & Challenges

A stronger focus on using evidence in clinical decision making, followed up with a comprehensive and systematic assessment of person-centered outcomes, presents an **opportunity** to improve the quality of mental health and substance use disorder care, to empower people in recovery and their families and friends to demand and receive continually improving care, and to ensure consistently better and more meaningful outcomes. In addition, there is an opportunity to redeploy resources to programs, practices, and treatment regimens that are outcome-driven and to incorporate the recovery paradigm into mental health and substance use services and supports.

There are several challenges to the effective realization of evidence-based healthcare:

Need to Encourage Promising Practices
As the private and public markets rush to embrace anything labeled "evidence-based," one concern is that policymakers and administrators will focus on evidence-based practices at the expense of innovation. Of highest concern is the potential that reliance on narrowly defined evidence-based practices to the exclusion of promising or innovative treatments or programs will preclude the development of a rigorous evidence base for a broader range of options, or stop new treatments from being developed.

Need to Encourage Precision Medicine Research
A new challenge is posed by precision medicine research. To achieve the goal of tailoring treatments to individuals, people in treatment and providers will have to collect and share data on genetics and epigenetics, the microbiome (the collection of microorganisms in or on the body), lifestyle, specific experiences, and diet with one another and with researchers who can help determine the factors that predispose people to develop mental health and substance use disorders and that influence the course of the disorders. This will require new ways to make use of precision medicine, such as adapting proven treatments, compromising fidelity to evidence-based protocols in the interest of more precisely focused treatment that can respond better to the individual and best guide her or him on the path to recovery.

Need for Recovery Focus
People in recovery and their families and friends are particularly concerned that many evidence-based practices were developed and evaluated prior to general acceptance of the recovery model embraced by MHA and the recovery movement and therefore have little real-world relevance to their quest for a full life in the community. It should be noted that SAMHSA's announced development of toolkits for peer-to-peer programs, supported employment and supportive housing go far to address this concern, and SAMHSA has emphasized the recovery

paradigm in the toolkits that it has published. However, the existing research base is sometimes ill-fitted to address the values represented by the recovery movement, including individualized care, holistic care and peer support. Clinical research designs – particularly the "gold standard" of large, long-term, randomized, double-blind, active-placebo-controlled trials – often do not effectively measure important outcomes, such as functioning and quality of life, employment, relationships, and the real-life impact of side effects and drug interactions. Characteristics of the individual (age, gender, ethnicity, co-occurring disorders, etc.) are inventoried, but trials are often designed and conducted in such a way as to preclude conclusions specific to subgroups.

Need for Patient Centered Outcomes Research and PCORI
An essential step in the development of evidence-based treatments for mental health and substance use conditions is Patient Centered Outcomes Research that will look at the most important functional and quality of life outcomes in addition to the standardized scales documenting reduction of symptoms that are the staple of most clinical research. More recent practical trials like the CATIE and STAR*D trials[45] have been designed to improve the collection of a broader variety of outcomes, refocusing research on what works in large representative populations in real-life settings, but it will take time to build this more relevant body of evidence. PCORI's focus on engagement of people in research and treatment and its requirement for strong "patient engagement plans" in funded research empowers people who have the conditions under study to help design research that is in line with their goals and is consistent with the recovery model. MHA hopes that PCORI will assist in facilitating the generation and use of this evidence, continuing to make behavioral health a focus of research. MHA engagement with PCORI remains a key opportunity to promote recovery as a model for patient-centered healthcare, as well as providing guidance for better dissemination of research to people seeking treatment, families, friends, advocates, providers, payers, and policy makers.

Need for Alliance with People in Treatment and Public Interest Research and Reviews
People in recovery and their families and friends should be recognized as allies of researchers and should be trained to be full members of research teams. PCORI requires that applicants for research grants have a detailed plan for including people in recovery as research team members and offers the chance for website visitors to suggest research questions of importance.[46] The non-profit Cochrane Collaboration[47] involves people in recovery as part of peer review, and the related coalition of Consumers United for Evidence-Based Healthcare[48] offers various opportunities for people in recovery to partner with researchers. These organizations are already active in evaluating mental health and substance use treatments and are cited throughout MHA's position statements whenever possible.

Need for Better Access to User-friendly Information
MHA and other advocates, researchers and governments need to contribute more to the translation, summarization, and dissemination of evidence-based information, in simple language, for use by people in crisis and people in recovery in helping to determine their preferred course of treatment. The SAMHSA toolkits recognizing eleven evidence-based or promising practices are a great step in advancing this needed effort, and MHA commends SAMHSA for its efforts. MHA has contributed a thorough review of complementary and integrative treatments for mental illness,[49] and its website continues to summarize other

treatments. MHA Position Statement 35, Aging Well, summarizes the evidence on psychosocial and drug treatment for dementia and the anxiety and psychosis that sometimes accompany it.[50] The difficulty to come is the synthesis of additional information and the updating that will be required as more patient centered outcome research becomes available.

Need for a Representative Cross-section of Age, Gender, Sexual Orientation, Disability, Race and Ethnicity, and Income in Clinical Research
A related concern is the dearth of research focused on differences in response to treatment by people of different age, gender, sexual orientation, disability, race and ethnicity, and income. Evaluations of existing scientific evidence by the Agency for Healthcare Research and Quality (AHRQ) and other entities demonstrate the limitations of clinical trials in terms of adequate participation by the entire population across age, gender, and racial and ethnic categories. Children and elders are admittedly harder to study, but greater efforts must be made in order to avoid off-label uses of drugs on untested populations by gathering more evidence, including practice-based evidence. And the lack of focus on subgroups makes it impossible to assess differences in subgroup responses. This may have the unintended consequence of exacerbating health care disparities.

Funding Barriers
Funding for the National Institutes of Health (NIH) has declined 14% in the nine years between 2006 and 2014, but a 2015 Research Letter compiled by researchers at Johns Hopkins concluded that the decline in NIH-sponsored clinical trials was more precipitous. The number of newly registered trials doubled from 9,321 in 2006 to 18,400 in 2014. The number of industry funded trials increased by 1965 (43%). Concurrently, the number of NIH-funded trials decreased by 328 (24%).[51] This is important because clinical trials that are funded by the manufacturers who make the treatments being studied have a conflict of interest that may lead to biased conclusions about treatment efficacy or safety.

Policy and Program Barriers
Policy and program barriers to implementation of evidence-based practices in the mental health and substance use disorder care systems are a reality in every community. Such barriers include organizational structure, limitations on financing, unique state regulation and licensing issues, the lack of clear guidelines and models for implementation, workforce shortages and lack of sufficient training resources, technology deficits and resistance to change.

Initiative is Essential to Recovery
It is essential that advocates and people in recovery champion effective treatments and question ineffective treatments in order to prevail against the many sources of institutional inertia and misaligned financial incentives. This will require an understanding of existing evidence, a willingness to stay abreast of new developments, and a commitment to advocating for systematic and objective outcome assessment at all levels. It will also require support from provider organizations and peers in encouraging people in recovery to speak up and participate actively in their treatment and teaching them when and how to do so. Advance directives can be an important tool if properly used, especially in indicating treatments that should be avoided.[52]

Call to Action

MHA recommends:

- Funding and providing incentives for implementation of a comprehensive information technology infrastructure covering all behavioral healthcare. Very few of the initiatives described in this position statement are possible without computer systems that can track and report outcomes. The federal government has begun funding some initiatives through its Meaningful Use of Electronic Health Records program, but this has not extended to behavioral health. Whenever possible, people in recovery and their clinicians should be incented to collect data in digital formats that can be compiled and used as resources for managing individual care and for building a more robust evidence base.[53]

- Ensuring that people in recovery are integrated throughout the development of an evidence-based behavioral healthcare system, from formulating the research questions to translating the evidence into practice.

- Funding the necessary studies to use electronic health record data to develop a learning behavioral healthcare system, capable of translating practice-based evidence into improvements in clinical and psychosocial treatment and quality of life outcomes.

- Focusing quality assurance on person-centered and person-reported, recovery-oriented outcomes. Presently much quality measurement focuses on process measures, not outcomes, and most outcomes that are measured are narrowly clinical in nature. A focus on fidelity and process fails to ask whether the processes are working. Advocates should promote quality measurement (or at least reporting requirements) of outcomes that track more closely what individuals care about most at every opportunity, such as functional and quality of life outcomes, and that progress in these measures should be use to direct care. Eventually, advocates should urge that the behavioral healthcare system move toward outcomes based on progress toward an individual's goals.

- Advocating training and quality improvement initiatives to promote promising and evidence-based practices. Providers have to undergo ongoing training and quality improvement as part of professional licensure and membership in many healthcare systems, and advocates should ensure that promising practices are emphasized. People in recovery should play a role in determining required provider training.

- Ensuring that health plan documents, including all notifications to individuals about benefits, medical necessity guidelines, and practice guidelines, contain the full array of evidence-based treatments and do not preclude promising practices, with appropriate justification, in order to provide optimal care for the individual.

- Encouraging health plans and health care systems to provide decision-making aids for individuals and providers to help in planning treatment, and which integrate the latest

available evidence. Ensuring that people in recovery play a role in determining what tools would be most useful.

- Ensuring that reimbursement and coverage policies reflect the need for individualized care and maintain flexibility to respond to individual needs and to test promising practices when established treatments are ineffective or produce intolerable adverse effects.

- Funding new research to maintain innovation and turn promising practices into evidence-based practices. Encourage the consideration of low-cost alternatives to randomized control trials in generating evidence, and in compiling evidence-based practices. Continue to fund the Precision Medicine Initiative and ensure that it is applied to behavioral health.

- Ensuring cultural humility and linguistic competence as an essential element of evidence-based healthcare.[54] The unique cultural perspectives and outcomes relevant to diverse populations should be incorporated at all levels of evidence development, synthesis and publication. Mental health and substance use research has too often excluded diverse populations, which has created an even wider gap between research and practice for people of color.[55] Similar issues arise in the application of research findings to different groups based on disability, age, sex, gender identity and sexual orientation. Cultural humility as well as cultural competence must be integrated into all evidence-based practices at all stages of implementation. Research should be designed and developed by and with input and participation from members of specific cultural and ethnic populations. Practices should be adapted as necessary to the cultural and linguistic groups being served. Clinical trials and other studies should be designed to detect subgroup effects so that outcomes of evidence-based practices can be evaluated in terms of culture-specific and culturally-relevant outcomes. Fidelity to the original evidence-based practice should be secondary to cultural humility and the measurement of patient-centered outcomes.

- Advocating and assisting in dissemination of information through partnership with people in recovery at all stages of the research and evaluation process. The process to evaluate evidence and develop evidence-based programs, interventions, treatments and policies should be open to the public and include all stakeholders in the decision-making process. People in recovery and their families should have active and meaningful roles on review, evaluation and governing bodies that make decisions about the application of evidence in practice and policy. In addition, clear and complete research findings should be disclosed to people considering a treatment as a matter of course, and tools and practices should be developed to aid people in treatment in using such information in their dialogue with their caregivers (e.g., Common Ground[56]). MHA and its affiliates advocate plain language summaries of clinical research and broad dissemination of research findings, in order to allow all stakeholders to evaluate all relevant data, in a user-friendly format, to make informed decisions about treatments on an ongoing basis.[57] The federal government and the states should collect and disseminate MHSIP

Report Card information for all states and territories and spend the public funds that will be required to develop the full analytical potential of sustained and robust electronic health record analysis.

Effective Period

This policy was Approved by the Mental Health America Board of Directors on March 5, 2016. It will remain in effect for five (5) Years and is reviewed as required by the Mental Health America Public Policy Committee.

Expiration: December 31, 2021

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